VIDEO: *NIH Update Regarding Oversight of Foreign Subawards*

DATE: *September 2023*

Megan Columbus: This summer, NIH published a federal register notice allowing comments on the proposed clarification of foreign subaward requirements. We appreciated the responses from the community and the many thoughtful comments we received. We'd like to take this opportunity to provide some background about the policy and to update you on modifications we have made based on the feedback. Thank you for joining us for this NIH update regarding oversight of foreign subawards. My name is Megan Columbus. I serve as the Director of Communications and Outreach in the NIH Office of Extramural Research, and I'll be your moderator for today's discussion. I'm very pleased to open with some words from NIH's Acting Director, Dr. Larry Tabak, after which we'll have a presentation by Dr. Mike Lauer, NIH's Deputy Director for Extramural Research, followed by a conversation where Mike and I will be joined by Michelle Bulls, the Director of the Office of Policy for Extramural Research Administration, in which we'll dive deeper into questions and comments received from the community about foreign subawards, so let's get started. Welcome, Dr. Tabak.

Lawrence A. Tabak: Thank you, Megan, and thank you to the members of the community who have provided feedback on the topic we'll be discussing today, NIH policies for overseeing foreign subawards. We thank you for your interest and your thoughts. It's important to note that our updated guidance is not actually a new policy. These new rules are meant to help our grantees deal with longstanding regulations and policy. Two of our auditors, the HHS Office of the Inspector General and the US Government Accountability Office, have called on us to take action to ensure that primary grant recipients have access to subrecipient data and records. This is about stewardship, compliance and robust conduct of research. The update to the policy guidance empowers primary recipients to obtain on a regular basis records and data from foreign subrecipients without having to worry that they will not be able to access material when needed. In a way, our response to the auditors is to remind prime recipients of their responsibilities. We understand their concerns regarding a focus on foreign subrecipients. I personally appreciate the concern, but we all take on responsibilities as recipients of federal grants. Before coming to NIH when I was a principle investigator at the University of Rochester, I engaged in several international collaborations, and it was a routine part of that work to obtain data and records from my collaborators. As I anticipate my departure from my current role, I've lately been going through all my files to consolidate things and sure enough found primary data from colleagues in France and the Netherlands from work conducted many years ago. Prime awardees have always have the duty to oversee the funds that they pass on to subawardees. We now have added specifics on how such oversight must be conducted. Both of our auditors, the OIG and the GAO, focused on foreign subgrantees for reasons articulated in their reports. Dr. Lauer and his colleagues will review those reasons in more detail during this webinar. I hope this webinar will answer any remaining questions you have about the updated guidance.

Megan Columbus: Thank you, Dr. Tabak. We greatly appreciate your contribution to our discussion. To tell us more about the background on NIH's clarification of foreign subaward requirements and to discuss recent changes, I'd now like to introduce Dr. Michael Lauer.

Michael S. Lauer: Thank you, Megan. I also want to thank Dr. Tabak for his comments. As Dr. Tabak mentioned, I am now going to discuss the OIG and GAO audits in more detail and describe the steps that we are taking to enhance our oversight of foreign subawards. We'll start with these two audits. There are two. The first on the left was one from the Office of the Inspector General. It was released in January of 2023, and it indicated that NIH as well as a prime recipient, EcoHealth Alliance, missed opportunities for proper oversight of foreign subrecipients. The audit on the right was released by the General Government Accounting Office in June of 2023, and the title really says it all: NIH Could Take Additional Actions to Manage Risks Involving Subrecipients. I'm going to talk about each of these in detail. Let me start with a backdrop of the structure of NIH awards as it applies to subrecipients. This picture is taken from the GAO report. The top row shows the funding agencies, in this case, the National Institutes of Health on the left and the US Agency for International Development or USAID on the right. Those agencies issue monies, dollars, to the prime recipients, and that's in the next row below. These prime recipients can be foreign institutions like Wuhan University, or they can be domestic institutions like EcoHealth Alliance, the University of California, and Duke University. Now in many cases, the prime recipients will issue subawards to other institutions, and those other institutions could be domestic - that's the example shown in the right where the University of California issued a subaward to a domestic institution, EcoHealth Alliance - or they could be foreign subrecipients, and those are the examples that are shown on the left. This includes Wuhan University, the Wuhan Institute of Technology, and the Academy of Military Medical Sciences. So, this is the general structure, and one of the key points is shown on the right, which is that the terms and conditions of award flow down. So, they flow from the agencies, the government agencies to the prime recipients, and then the prime recipients, in turn, will flow down the terms and conditions to the subrecipients be they domestic or foreign. Let me go into that in a little bit more detail. This is a long-standing principle. It is found in regulation, and it states that "The recipient" ... In this case, we mean the prime recipient ... "as the direct and primary recipient of NIH grant funds is accountable to the NIH for the performance of the project, the appropriate expenditure of grant funds by all parties, applicable reporting requirements. and all other obligations. The terms and conditions flow down to the subrecipients and requirements that apply to the recipient, the prime recipient, apply to the consortium recipients." As Dr. Tabak mentioned in his comments, this is really the heart of it. It's the responsibility of the prime recipient to in turn oversee the work of the subrecipient. Now the regulations go into more detail about what exactly this means. So this is a regulation that pass-through entities, and a pass-through entity in this case, would be the prime recipient, have to ensure that every subaward includes the following information at the time of the subaward. In other words, this has to be something which is included in the agreement between the prime recipient and the subrecipient, and that is there has to be a

requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary. So, the requirement that subrecipients must make records, statements, information available to prime recipients is nothing new. This is something which is present in long-standing regulation. Now one of the key obligations that all prime recipients and therefore subrecipients have is providing access to records. This is also regulation that the HHS awarding agency ... so, in this case, it would be the National Institutes of Health, Inspectors General, Comptroller General of the United States ... That's the GAO ...and the pass-through entity or any other of their authorized representatives must have the right of access to any documents, papers or other records of the nonfederal entity which are pertinent to the federal award. Now notice here in the regulation the explicit mention of the pass-through entity. The pass-through entity is the prime recipient, so that means that the prime recipient has to have access to documents, papers, and other records. Again nothing new, something that has been present in regulation for a long time. All right. So, with that background of long-standing regulations, what happened? And we're going to start with the first audit. So, in the case of the first audit, the prime recipient submitted a Research Performance Progress Report or RPPR. I'm going to use that term from this point on. The RPPR identified concerns about possible noncompliance. Now the RPPR, which as you know is typically submitted once a year, is a critical document. It is the main vehicle by which the agency is able to assess scientific progress. It is also our opportunity to assure ongoing compliance, and it is used by the agency to make decisions about whether or not to continue funding or take other actions. Other actions could include withholding support or imposing specific award conditions. It could include changes in the budget. So the RPPR is an absolutely critical document, and in this particular case, the RPPR suggested that there may have been some compliance problems. Well, there were disagreements between the agency and the prime recipient as to whether or not there were noncompliance issues, and therefore the agency decided to request from the prime recipient records in line with those long-standing regulations that I just showed you. We asked for lab notebook entries, and we asked for original electronic files. The response that we received from the prime recipient was that they didn't have the records, and furthermore, they didn't have access to them. In order to get access to them, they had to request them from a foreign subrecipient. So, they passed on the request to the foreign subrecipient at least twice, and to this day that request has not been honored, and therefore the agency's ability to get access to those records has been obstructed. The OIG in their report issued this commentary. They said, "Our oversight work has continually demonstrated that grant-awarding agencies' oversight of subrecipients, whether domestic or foreign, is challenging. This is partly due to governmentwide regulations that NIH follows that are designed to have a prime grant recipient monitor the activities of a subrecipient, rather than requiring the grant-awarding agency...to conduct active monitoring of the subrecipients." Those are just the regulations that I read to you a few minutes ago. The OIG goes on, "For foreign subrecipients, the effectiveness of the prime recipient's monitoring may depend on the level of cooperation between the recipient and the subrecipient. In certain countries in which research is performed, there may be a risk that larger political or governmental issues may

impede cooperation and prime recipients will have limited ability to effectively monitor their foreign subrecipients." The OIG continues to talk about the specific case in their audit. "Although documentation indicates that WIV" ... WIV is the Wuhan Institute of Virology, they're the foreign subrecipient ... So "WIV cooperated with EcoHealth" ... EcoHealth was the prime recipient ... So they "cooperated with EcoHealth's monitoring for several years. WIV's lack of cooperation with the international community following the COVID-19 outbreak - consistent with the response from China - limited EcoHealth's ability to monitor its subrecipient, and greater transparency is needed..." So, on the basis of this, the OIG issued a series of recommendations, and this is the recommendation that we are focusing on today. They recommended that NIH "Implement enhanced monitoring, documentation, and reporting requirements for recipients with foreign subrecipients." Let me read this again, that NIH "Implement enhanced monitoring, documentation, and reporting requirements for recipients with foreign subrecipients." And NIH responded and said that we generally concur. We will "evaluate how best to consider the OIG recommendation..." We consider ongoing existing regulations. We would "also evaluate best practices across the government...", and that is something that we did indeed do with our colleagues at the Department of Health and Human Services. Now I'm going to move to the second audit. This audit was issued by the Government Accountability Office, the GAO, and it was released just a few months ago in June of 2023. The title really says it all: NIH Could Take Additional Actions to Manage Risks Involving Foreign Subrecipients. So in their audit, they asked us about the OIG audit, and this is taken from their report. "In March of 2023, NIH officials told us they did not have a timeline for implementing the HHS-OIG's recommendation." This is the recommendation that I just read you. "However, obtaining additional authority...could be a lengthy process. While NIH pursues long-term actions... it has not initiated near-term actions, which could enhance its own internal processes." They go on, "Evaluating opportunities to enhance its existing internal processes in tandem with other longer-term efforts to implement the HHS-OIG's January 2023 recommendation, would position NIH to more immediately demonstrate progress to improve its oversight of awards with foreign subrecipients." I want to comment on the word "immediately". The GAO indicated to us that there was real-time pressure here. We needed to act very quickly and furthermore, that we should take advantage of the existing authorities that we have. And so, in May of 2023, we knew that this recommendation was going to be coming from GAO. We issued an announcement in the Federal Register and also in the NIH Guide in which we talked about updated policy guidance for subawards and consortia and we said that "NIH reserves the right to request copies of the written agreement" ... The written agreement is the agreement between the prime recipient and the subrecipient ... "and relevant supporting documentation. Failure to provide requested documentation may lead to remedies and potential enforcement actions. Furthermore, NIH encourages recipients to ask potential subrecipients to submit language in their letters of support indicating their awareness of these requirements and their willingness to abide by them." Now we also issued some proposed language in which we said that in agreements between the prime recipient and the foreign subrecipient, there should be a provision "to provide copies of all lab notebooks, all data, and

all documentation that supports the research outcomes as described in the progress report. These supporting materials must be provided to the prime recipient with each scientific update no less than once every six months or more frequently." Shortly after we issued this announcement, the law firm Ropes & Gray issued this independent commentary. We did not solicit this commentary, and we did not know that this commentary was coming out. I would strongly recommend that those of you who are interested in learning more about this read their commentary and also read the audits, the OIG and the GAO audits. The commentary is fairly lengthy, but this is a key concept that the commentary raised. "Through this new requirement, NIH effectively has underscored the importance of subrecipient monitoring as an essential obligation." This is exactly what Dr. Tabak said. That the prime recipient has an essential obligation to oversee the work of subrecipients -foreign subrecipients, domestic subrecipients - and as part of that oversight, they have to have access to records. This goes beyond good stewardship and good science. This is something which is grounded in long-standing regulation. It is nothing new. Now we received extensive responses to the Federal Register Notice. We also received a number of letters and phone calls. We are aware of at least one journal article, and the commentaries were quite strong, and these were some of the key themes that we heard. One is that more time is needed, that there was more time needed for external input. That this requirement would impose excessive administrative burden and particularly on institutions that are less well-resourced, and therefore may exacerbate various inequities. There was a suggestion that we should take a risk-based approach. In other words, this policy clarification update would only apply to certain kinds of research and certain kinds of institutions or certain countries. There were allusions to NSPM-33. NSPM-33 is National Security Presidential Memo number 33, which relates to research security. A lot of questions about why the focus on foreign subrecipients. Some of the comments suggested that the explicit focus on foreign subrecipients smacks of colonialism. Why every 6 months? And it was pointed out to us that progress reports are annual. Now the language, and I'd like to remind you that the language talks about documents that support the information which is provided in the progress report. It's not all documents. It's not every last scrap of data, every last page of a laboratory notebook. It's that which informs the progress reports. So, it was pointed out to us that progress reports are annual. They don't come out every six months, and so people may not know in six months what's going to go into the progress report. And then another question was, what about digital platforms? Many researchers, and I would say we at NIH, also use sharing platforms. For example, at NIH we use SharePoint, and Teams, and Box, and there are many others. I'm just pointing these out as examples of various digital platforms that we use at NIH, I use personally in my work, and it's a way in which we can share documents with each other as well as share documents with other external collaborators. And so we are responding by making some changes to the new Guide Notice as well as to the Grants Policy Statement, and we're going to say this: "For foreign subrecipients," there needs to be "a provision requiring the foreign subrecipient to provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report, to the primary recipient with a frequency of no less than once per year, in alignment with the timing

requirements for the Research Performance Progress Report submission. Such access may be entirely electronic." Let me walk through this and point out what some of the key revisions are. What is, we're not saying that the subrecipients have to provide copies, but rather they have to provide access to copies. "So, the prime recipient will never come back to us and say, "We don't have access to the document that you are asking for." They will have access even if they don't have the copy as a physical piece of paper in their hands. I'd also like to point out that what we're asking for is those materials that support research outcomes in the progress report. The next point is, is that these documents are to be shared with the primary recipient. Some people have asked us about the data sharing policy and pointed out that the data sharing policy doesn't require laboratory notebooks and other types of documentation, and I point out that it's not quite correct to conflate this kind of stewardship and oversight with the data sharing policy. The data sharing policy deals with what grantees share with the public. Here what we're talking about is what subrecipients share with their own collaborators, what collaborators share with one another. So, it's what subrecipients share with the prime recipient, so the prime recipient can do a proper job of overseeing the subaward. Okay. The next key point here is a frequency of no less than once per year. This is a change. We previously stipulated once every six months. We agree with the comments that progress reports generally come out once a year, and therefore it would make sense for this kind of access to be made available at least once a year. Now it's in alignment with the timing requirements for the RPPR. There are situations where people need to submit an RPPR twice a year, and then in that case their requirement would have to be in alignment with that. And then the last sentence is critical: "Such access may be entirely electronic." If the prime recipient and the subrecipient are using an electronic platform like the ones that I mentioned before, that is absolutely fine, and that should be stipulated then in the subaward agreement. So, I hope you found this helpful, helped to understand why we have issued this updated policy guidance and clarification, and I now look forward to a conversation with my colleagues, Megan Columbus and Michelle Bulls, where we will deal with a number of the comments and questions that you sent to us. I also want to say thank you for your feedback. This has been enormously helpful to us as we move forward in answering the auditor's recommendations and assuring the prime recipients are able to oversee their subrecipients in a manner which is robust and fully consonant with the outstanding research that you all do. Thank you.

Megan Columbus: Thanks so much, Mike, for that background and perspective. I think people will find that very helpful. Now I'd like to bring Mike back, and I would like to add in Michelle Bulls, the Director of NIH's Office of Policy for Extramural Research Administration, so that we can add some more questions into the mix. From what we've heard from the comments, I'd like them to give the full perspective here. So thank you guys for joining me.

Michael S. Lauer: Great to be here.

Michelle Bulls: Thank you, Megan.

Megan Columbus: When the updated policy guidance takes effect on January 2nd, 2024, can you tell us how this will impact existing subaward agreements and new subawards after that date?

Michelle Bulls: Absolutely, Megan. The clarifying guidance does go into effect January 2nd, 2024, and we recognize that there are existing subaward agreements. NIH will provide recipients up to 60 days from the effective date to modify existing agreements where needed. And we do understand that this may take some time depending on the number of agreements that an institution has in place, so they may ask for or request an extension if needed.

Megan Columbus: Thank you so much. There have been concerns expressed that the policy unfairly singles out foreign subawardees and potentially undermines NIH's efforts towards diversity and equity, inclusion, and reaching underserved communities. Could you speak to this concern?

Michael S. Lauer: Yeah, I absolutely get that, and we've certainly seen that in a number of the comments. Why is it that foreign subrecipients are being singled out? And I think that the best way to think about this is to look at the two audits. Both audits, the OIG and the GAO, explicitly called out foreign subrecipients. The OIG, as I mentioned, included some language about unique challenges that domestic prime recipients face when dealing with foreign subrecipients. And the GAO audit actually put the word foreign subrecipients in the title and then also went on in their discussion to talk about those unique challenges. So, the reason why we're calling out foreign subrecipients is for the same reasons that the auditors called out. Now the second point of your question is also really important, and that has to do with equity and fairness issues. We understand, of course, that foreign subrecipients are diverse, and that a number of them are less of a resource than others. Nonetheless, the general principle of compliance with terms and conditions of award, and with access to materials that support a progress report, those principles apply to all. We're hoping that by making it clear that using commonly used digital platforms will help to enable everybody to be compliant with this long-standing regulatory requirement.

Megan Columbus: Yeah, so what happens if that foreign organization is subject to local laws or policies that conflict with NIH requirements for making this information available?

Michael S. Lauer: Yeah, that's a very interesting question, and in fact it's not only a problem that is relevant to foreign subrecipients. We've also been hearing questions regarding prime recipients here in the United States who may be subject to a wide range of state laws, and questions have been posed to us about, what about those state laws, and how do those affect NIH grants? So, I think there are three key points to keep in mind. Number one is that recipients, prime recipients as well as subrecipients, have to be compliant with terms and conditions of award. The prime recipients are responsible to the NIH, and then those terms and conditions flow down to the subrecipient, so that's the first principle. The second principle is that NIH expects that all recipients, as well as subrecipients, will follow all applicable state and local laws, so in the case of foreign subrecipients whatever the local laws, national local laws

that affect them, they are expected to follow those. And then the third principle is one that puts these together, which is that if there is a concern about whether or not local laws or rules or regulations may affect ability to be compliant with terms and conditions of award, they are supposed to consult with their general counsel. They work with their general counsel to figure things out. A really important point here is that the facts matter, so the facts that what are the specific terms and conditions of award? And what are the specifics of the laws? And often we hear cases that sound very cut-and-dry. You're not allowed to do X, or you're not allowed to do Y, but once one actually delves into the facts, it's not as clear-cut as one might think.

Megan Columbus: Yeah, thank you. We've heard concerns that low- and middle-income countries may be challenged by the resources needed to scan notebooks and such, and they're capped at 8 percent indirect cost. Will there be additional resources available in these situations?

Michelle Bulls: Thanks, Megan. Given the fact that this requirement is not new, NIH will continue to apply the eight percent indirect cost rate to foreign entities. Our goal here is to, in fact, make sure that our recipients are compliant, and in light of the OIG's recommendation, we do not see this as an additional burden but rather as something the recipient should have been doing all along, so that eight percent rate will continue to apply.

Megan Columbus: Thank you. Can you talk to us a little bit about what exactly is the prime recipient responsible for once they receive this information?

Michelle Bulls: Well, the prime recipients should continue to review all subaward documentation to confirm that the performance outcomes that are reported in the RPPR is accurate, complete, and it properly reflects the programmatic goals of the project as outlined in the RPPR. So that's the basic responsibility - is that they align the information that they received from documentation with the outcomes in the RPPR and present that to NIH as best they can.

Megan Columbus: That makes sense. NIH's data sharing policy explicitly does not require the sharing of lab notebooks. Can you then discuss the difference between the policy on oversight of foreign subawards and data sharing?

Michael S. Lauer: Yeah, I completely get that, why these two issues may be conflated. The data management sharing policy, of course, has been at the fore this year. We just started to implement it, and it may seem kind of strange that there, we explicitly go out of our way to say that lab notebooks are not in play, but now when we are issuing this clarifying policy guidance, we're saying that laboratory notebooks are in play. And so, one might think that we are contradicting ourselves. So, I think that the way to think about this is that these are two separate issues. Data sharing is about what we expect grant recipients to share with the public. This issue, where we're talking about oversight of foreign subrecipients, deals with compliance and oversight. And here, we're not talking about what is being shared with the public, but rather what collaborators are sharing with each other - so what foreign subrecipients are expected to share or give access to their own collaborators, who are the prime recipients. So

that's the reason why there seems to be this disconnect. It's not a disconnect. We're talking really about two separate items.

Megan Columbus: Yeah, I think that's a very important distinction. Can you confirm what the expectation is for the storage of the lab documentation? Is this ever going to be provided to NIH?

Michelle Bulls: Yes, so at this time, NIH expects all institutions to comply with the record-retention policy, which is that they need to retain that documentation three years after they submit the final FFR, whether it's an annual FFR or whether it's the final for the SNAP Awards. And so one of the things that we want to make sure of is that folks have this information on file and ready and available just in case, or when NIH does conduct compliance reviews. And we do plan to do that because NIH has been under the impression that recipients have been retaining and obtaining this kind of information all along. So, us being able to go out and partner with our recipients and making sure that they're complying and helping to conduct compliance reviews, will be helpful both to us and to them as we understand that audits may take place.

Megan Columbus: I think that's an important piece of information that you just imparted there, Michelle. What are the implications of this policy for NIH's foreign prime grantees?

Michelle Bulls: So, the implication is really that the policy requirement applies to domestic prime recipients who are responsible for overseeing the foreign subrecipient. But we also have to remember that this applies across the board whether domestic or foreign, if the prime is domestic or if the prime is foreign. We do expect for all recipients to retain documentation that supports information that is outlined in the RPPR that's submitted to NIH. The goal really is to align that information with the documentation that we received within the RPPR, and if we can't align that or if we have to go back and ask for additional information that's not there, that does present a challenge. So, we do expect this from every recipient no matter whether they're foreign or domestic. This happens to be a clarifying policy as recommended by the OIG - that we focus on direct prime recipients that are domestic - but it is a requirement for all.

Megan Columbus: Thank you. So, some commenters suggested that NIH should take a risk-based approach. Right? That the policy should only apply to dangerous pathogens, that kind of thing. Why didn't we go in that direction?

Michael S. Lauer: Yeah, I totally get that as well, and I see that as another example where different issues and different policies are being conflated with one another. So there, in discussion about a risk-based approach, I can think of at least two other policies that might be in play. One deals with pathogens of pandemic potential, or EPPP, and there of course has been a lot of discussion about taking a risk-based approach, totally understandably. And then another has to deal with research security, and that stems from work that is being overseen by OSTP on the implementation of NSPM-33. NSPM-33 is the National Security Presidential Memo 33 that deals with research security. This, again, this updated clarifying policy guidance, this is a different issue. This is about compliance and oversight involving all grants. And this is about

access to records involving all grants including access to records on the part of the agency, on the part of prime recipients, and on the part of subrecipients. So, again, I understand where that comment is coming from, but we're really talking about different issues.

Megan Columbus: So, what's NIH's plans? Like how are we going to make compliance easier for folks?

Michelle Bulls: So, Megan, that is a really good question, and the reason why that's important to NIH is because we want to make sure that we have a solid place and a single place where our recipients can go and obtain additional information or help them understand what the current requirements are. So OER's Division of Communication alongside with the Office of Policy for Extramural Research Administration, will develop a Web page where folks can go and understand what the requirements are for subawards, and we'll have various areas within that section which will include frequently asked questions. We will also provide a sample copy of the subaward agreement language that we expect to see, and we will also continue to add to our frequently asked question on a living basis. In other words, as additional questions come in that we might not have thought of, we are open to continuing to add to those because we want to make sure that folks understand what the requirement has been, what it is, and what we expect to see.

Megan Columbus: I'm sure that sample language will be much appreciated by teams. So, let's close with a reiteration of requirements. Can you just remind us what exactly needs to be shared when?

Michael S. Lauer: Sure, so let me start by, again, expressing our gratitude and appreciation for the extensive comments that we received. I think there was no question that because of the feedback and the conversations we've had, we are now issuing something which is more tight, more in line with regulation, and more practicable than what we had issued before. So the key point here is that subaward agreements, at the time that a subaward agreement is written and executed, there has to be a specific provision in cases where we have a domestic prime and a foreign subrecipient. And what it has to say is that the foreign subrecipient will provide access to all laboratory notebooks, data, documents that are supportive of the information that's provided in the progress report and that this access will be provided on at least a yearly basis or in line with the progress report. So, a few ... And then there's another really key point here which is that we understand, and it's perfectly acceptable for this access to be entirely electronic. So, something that the key changes that we've made from the last time, one is, is that we're focusing on access, and I think that's really important because that's actually the words that are used in the regulation is access. So, access does not mean printing lots of pieces of paper, putting them in big packages, and then mailing them off. Access could mean the use of a digital electronic platform like many of us use as part of our routine daily work. That would be perfectly fine. Second key point is that we're only looking for materials that are directly relevant and supportive of what's in the progress report. We're not looking for every last scrap of data. We're looking for what supports the information that's in the progress report. The third

is, is that we're not asking for this access to be provided every six months, but rather typically once a year because typically most progress reports come in once a year. There are exceptions where progress reports may come in more often, and then in that case, it should be in line with those progress reports. And then the final point ... I know I've said this before, but I'll say it again ... is that electronic access is absolutely fine. In fact, we here at NIH, that's how we make information accessible to one another, is we use electronic means.

Megan Columbus: Yeah, thank you. Finally, where should people go if they have questions?

Michelle Bulls: So, for business administrative questions, they should contact operagrantspolicy@nih.gov, and for programmatic questions, they'll contact Mike Lauer.

Megan Columbus: Great, thank you so much. I think this has been tremendously helpful. I appreciate you joining me and thank you all for watching.

Michael S. Lauer: Thank you, Megan.

Michelle Bulls: Thank you.