Elyse Sullivan: All right. Let's get started. Thank you so much for joining our session on Data and Resource Sharing: Firming Foundations For Future Frontiers. My name is Elyse Sullivan, and I am your moderator for this 45-minute session. Presenting today, we have Dr. JP Kim, who is our NIH Extramural Data Sharing Policy Officer, and we have Dr. Nonye Harvey, who is a Health Science Policy Analyst within the office of Extramural Research at NIH. Our format today includes a presentation followed by some time for Q and A. So let's get started. Take it away.

JP Kim: Thank you, Elyse, appreciate it. I should note that actually, although Elyse did give me the title of Doctor, I'm actually only a recovering lawyer, or a patent lawyer, as it were. So let's get started. Next slide. Next slide, please. There we go. So presenting today, actually our director, Julia Slutsman, she was going to be here, unfortunately an unexpected conflict came up, so you will here from myself and my colleague, Nonye Harvey. We are in the office of Extramural Research. We actually are part of the Genomic Data Sharing Implementation Team in OER. And our group is actually out of the Office of the Director at NIH. Next slide, please. So today, sort of the road map of what we're going to be discussing is, as you can see, basically five bullet points, a background of NIH data sharing and resource sharing initiatives, and we're going to focus on just some select policies. We'll do a refresher on the NIH Research Tools Policy and the 2003 Data Sharing Policy. And we'll give you a good overview of the NIH Genomic Data Sharing Policy. And we'll actually touch on the evolution of Agency-Wide, that's Federal Government-Wide, Access of Federally Funded Research Results. And then finally, we'll talk about an update on the Final NIH Policy on Data Management and Sharing, which recently came out in October of 2020. Next slide, please. One of the things we should note to you, is that that policy I just mentioned about the new Data Management Sharing Policy is actually going to be talked about at length in our after hours conversation in Auditorium A. So that's today at 5 to 5:45pm Eastern Time, as it is now 3, 3:45pm Eastern Time right now, so that will be in 2 hours. All right. Next slide. So that you all know, the NIH has a very long standing commitment to an investment in data sharing. As you can see here, what we actually say in our Grant Policy Statement is "Consistent with both the NIH mission to improve public health through research and its longstanding legislative mandate to make available to the public the results of the research activities that it both supports and conducts." There are many, many initiatives in the like that actually have their foundations in data sharing and dissemination. Next slide, please. So there's actually a long history, and you're actually very much blessed by not actually having the whole list of all of the data sharing and research sharing initiatives over the years. But one of the big ones actually we went back to was the research tools policy in 1998, which actually is then followed up by 2003 with the NIH Data Sharing Policy. And various policies resulted from that, I mean, sort of came after that, including the Genome-wide Associations policy, the GWAS policy, which eventually became the GDS policy in 2014. And then as you can see finally the NIH Data Management and Sharing Policy which will be effective in 2023, that was just recently announced in October of 2020. Next slide please. So the reason we are talking about data sharing and resource sharing is because it's very important to advance research, but we actually also recognize that there are various challenges associated with this. There's actually obviously cost, and burden, or time burdens and resource burdens that requires infrastructure to do the sharing. Human resources, you need people to help basically process the requests and actually curate data and the like. There's also policy coordination among key stakeholders, agencies, funders, publishers. We've all worked on those issues. And there are of course ethical, legal and social implications and privacy issues, such as data security and informed consent and the like. We know that there's somewhat limited training out there in the community, so we're actually working on that. Fortunately, there is a growing amount of training that is being developed across agencies and funders and universities and other organizations. Sometimes there's a lack of rewards and incentives for sharing of data in this publish and perish world, but we're actually looking at that as well. There's another thing of proprietary interest, cultural shifts and institutions and investigators wanting to maintain the competitive advantage, for example, for intellectual property and the like. And I said, as a recovering patent attorney, an intellectual property attorney, I very much know what those are about and basically know that we need to balance those to advance research. And finally, compliance and enforcement especially after the award ends. What are NIH's sharing policies for those? What are their requirements? And how do they apply, and how do you do that? So there are a lot of challenges as I noted. So, Nonye, next slide, please. So some of the goals of data sharing are very important. We want to advance rigorous and reproducible research, enable validation of research results, in other words be sure that the research, the results we show are actually true. Make high-value datasets accessible so that other researchers can actually build upon that, thus the phrase, "Firming foundations." We build upon those foundations for future research. It also helps to accelerate future research direction because you don't have to actually recreate the research that was done as opposed to validating and looking at it and moving forward based on those foundations. And it increases opportunities for citation and collaboration amongst researches. So also another aspect is to promote public trust in research. We want to foster transparency and accountability in the research. We want to demonstrate stewardship over the taxpayer funds that basically these research results are being shared. Maximizing research participants' contributions. And supporting appropriate protections of research participants' data, that's basically informed consent and the like, basically people's privacy and the like. And one other thing I'll note to you is that when we talked about demonstrating stewardship over taxpayer funds, this actually also helps us to, as I noted earlier, we wouldn't fund the same research over to find the same research results, but in fact we actually would fund, those research dollars could go to actually building upon the foundation of the research that was already done. Next slide. So now let's talk about two policies in particular, the Research Tools Policy and the 2003 Data Sharing Policy. Next slide. Although the Research Tools Policy doesn't specifically talk about data, this is actually more focused on items like transgenic mice, cell lines, reagents and the like. It actually came up "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts" that applies to both our grants and contracts and cooperative agreements. It came out in 1999. It was interesting because basically what was happening was mice, transgenic mice, were not being made very available, and there was a lot of issues with respect to controlling research through the sharing of the mice. So what happened was we can up with these principles and guidelines under what we call the Research Tools Policy. We want to ensure academic freedom and publication. In other words, you shouldn't have a funder say, it's like, "Well, we'll fund you if you don't publish on these things. We don't want you to share that information with anyone." So that is something we are very much proponents of. We want to ensure appropriate implementation of the Bayh-Dole Act. That means with respect to inventions, we want to make certain that inventions are shared, especially research tools, to move forward with research because transgenic mice, as the example, was that many people use transgenic mice in research, but if they couldn't get access to them, then the research would be impeded. And so we also will talk about minimizing administrative impediments to academic research. So that was actually, some people would say that it was too complicated to share these resources. And so what we came up with was trying to streamline things using something called the Uniform Biological Materials Transfer Agreement, or the Simple Letter Agreement, which was basically streamline the terms and such you should ask for research tools and then as a basic overarching principle was to ensure dissemination of research resources developed with NIH funds, as I said, under contracts or grants, but honestly, the Research Tools Policy also applies to the Intramural Program here at the NIH. The guidelines were basically examples and ways that you could do these dissemination of research resources arising out of NIH-funded research. So as a package, principles and guidelines were released as a Research Tools Policy. Next slide. So that was actually talking about research resources, not necessarily data, but as I said, materials and the like. So the 2003 NIH Data Sharing Policy actually came out, it was issued in February 2003, and it applied for all applications received on or after October 1st, 2003. It's actually going to be effective until January 24th, 2023, because the new DMS policy, Data Management Sharing Policy, will be effective on January 25th going forward. This one is for grants, contracts, cooperative agreements that requested 500,000 or more in direct costs in any given year. And the policy basically expected a data sharing plan. How you're going to share data or state why data sharing is not possible. And under this policy, we have expected the timely release and sharing to be no later than the acceptance for publication of the main findings from the final data set. I should note to you even though this was the 2003 policy, data sharing has actually been something that has been in the Grants Policy Statement at the NIH for many years, and resource sharing, although we explicitly came out with that in 1999, the Grants Policy did expect sharing of research resources, so these policies help to further clarify and accentuate the importance of sharing of resources and data. Next slide, please. So the Genomic Data Sharing Policy came out in 2015. It was actually an outgrowth of the GWAS Policy. Next slide. So the purpose is to as you can see, set expectations and responsibilities for investigators and institutions to ensure broad, responsible and timely sharing of genomic research data. We note institutions because basically when the NIH gives out grants, it's to institutions, although the PI, Principal Investigator, is of course named on there, it's both the investigator and the institution that must need ensure that things are complied with the terms of conditions of the award it complied with. The scope of the GDS Policy is for all NIH-funded research generating large scale human or non-human genomic data and secondary research using these data. It applies to all funding mechanisms, as I talked to you before, grants, contracts, cooperative agreements and intramural support regardless of costs, unlike the 2003 which had the 500K limit. And it was effective as of January 2015. And for the Intramural Program, it was actually effective as of August of 2015. Next slide, please. So there's two-tiered access for human data. You would note that unrestricted-access are basically data that are publicly available to anyone, such as the 1000 Genomes project. And then there's controlled access where individuals, and their institutions, must obtain approval from the appropriate NIH Data Access Committees to use the data from the NIH-designated repository, which in the NIH many people know is dbGaP or the Database for Genotypes and Phenotypes here at the NIH. Next slide. There's a process for submitting data. Trying to go through this rather quickly here. Data submission, basically what happens is you want to submit data for NIH-funded research, you actually note your data use limitations in your application. You need to have the Institutional Certification provided, submit to the NIH data repository, for example, dbGaP, and you would either go to unrestricted access or controlled access. And then if you're a researcher who wants access to the data, you put in a data access request, which is co-signed by your institution, and that you agree to the terms of use of the Data Use Certification. And then basically also the PI agrees to Code of Conduct. And then the Data Access Committee will review your data access request, or DAR, and look through that and they verify the credentials and consider the potential for group harm and either basically approve or reject or ask for additional information. Next slide, please. PI and Institutional Responsibilities When Accessing Data. Basically, to be approved for access PIs submit the data request, as I noted earlier, and then in the Data Use Certification and Addendum, they agree to various terms that you'll only use the data for the approved research, not beyond that. You'll have to protect data confidentiality. Of course you have to follow applicable laws, regulations and policies for the data rules. And very important, you're not allowed even to attempt to re-identify individual participants. And you're only allowed to share the data with individuals listed in your Data Access Request, not beyond that. Report immediately any policy violations or data management issues that have happened. And of course we need annual updates to NIH on how your research is going. Next slide. So now really quickly, let's talk about the evolution of agency-wide access for federally funded research. Next slide, please. One of the things I should note to you is that the NIH has a long standing history of data sharing. And what happened was, in 2013 there was something called the Holdren Memo which came out of the White House Office of Science and Technology Policy. It was entitled, "Increasing Access to the Results of Federally Funded Research." Now, basically what happened was, it was that the whole entirety of the federal government basically sort of, shall we say, came on board. I mean, many of them had their own sharing policies, but perhaps not to the depth and extent that the NIH did, so NIH has been doing sharing policies for so many decades now. But this particular Holdren Memo came out and actually established certain things that, well, as you see here it says, "Consistent with the American COMPETES Reauthorization Act of 2010," they were also directing all federal agencies with annual R&D expenditures of 100 million or more to work towards requiring data management plans to be developed by all funded researchers. So they also wanted to see us, our agencies, actually develop plans and provide them to everyone, provide them to the White House to sort of explain how we're going to achieve what is on the goals of the memo. And it applies to both data and to peer reviewed publications. Next slide, please. One of the fantastic things about working here at NIH is that again, very much into sharing and the like. And so as you can see, the objectives of the Holdren Memo on the right side with respect to scholarly publications, much of the language you'll see in the memo actually reflected what we were already doing as part of our NIH Public Access Policy. So we actually fulfilled most of the requirements of the publications. With respect to digital data, there were a few bullets here, shall we say, that we needed to work on to continue to meet the requirements of the Holdren Memo. Next slide. So what happened is, basically, again, the memo came up in 2013, and in February of 2015, we released a plan. The plan was actually how to address the memo. Of course, as I noted earlier, publication was already addressed by the Public Access Policy, but digital and scientific data we actually needed to do a little bit more of streamlining, tweaking and the like. And so we actually needed to consider how to require data sharing, consider how to require and evaluate data managing and sharing plans consistent with the memo and the like. We talked about encouraging the use of existing repositories and standards, and we actually at the NIH, we were promoting FAIR principles, FAIR being findable, accessible, interoperable and reusable data principles. Now, note to that as you see on the bottom, the plan in 2015 was not the policy, so NIH, as I said, we already had a Public Access Policy for publications, but we needed to work on a policy for the digital data. And so NIH was going to establish priorities for data sharing. And next slide. And that brings us to my great colleague, Nonye Harvey. Dr. Harvey will talk to you about the Data Management and Sharing Policy that actually sort of outgrew or grew from the memo. We were moving in that direction, but the memo actually provided us with additional incentives for this. So I will now hand it over to my colleague, Dr. Harvey. Thank you.

Nonye Harvey: Hi, Thank you, JP. Can you all hear me?

Elyse Sullivan: Yes.

Nonye Harvey: Perfect. So welcome, everyone. I am Nonye Harvey, and I am glad that you have all joined us this afternoon. And I'm very happy to present along with my colleague, JP, on NIH Data and Resource Sharing Policies. So you all heard not too long ago a little bit about the historical context of Data Sharing Policies across the agency and reinforcing NIH's long standing commitment to making data that results available and accessible for the large community. So over the next few minutes, I will give you a brief overview of the new Data Management and Sharing Policy. And I will refer to it as the DMS policy because that's just a mouthful. So this policy, like JP had eluded to, was released October 2020 and will become effective in 2023. And with this policy NIH encourages that not just data sharing, but data management practices be consistent with the FAIR data principles. And it also establishes that baseline expectation that data sharing is the default and is a fundamental component of the research process. So again, wanting to just sort of remind folks about this culture of data sharing and investigators and researchers should incorporate data sharing practices and management planning into their research process as they are thinking about their research. You've already heard about the 2003 policy, which is a current policy, from JP, and I just really wanted to use this slide to highlight a few key differences between that policy and the current DMS Policy. And when this policy becomes effective in January 2023, it will replace the current 2003 policy. So in terms of scope, the policy applies to all NIH-funded research generating scientific data regardless of funding level or funding mechanism. So this includes grants. It includes contracts, intramural research projects and other transactions. And just to make it clear that scientific data are considered to be data that are considered to be a sufficient quality to replicate and validate research findings regardless of whether that data are used for to support any scholarly publications. So any activities that are not generating scientific data are not subject to the DMS Policy, so this would be like training and infrastructure development or non-research activities. And in terms of where to share the data, NIH does encourage the scientific data to be shared within an established repository, and this should be included in the data sharing management plan. And I'll get into that because there are three supplemental information that accompanied and were released at the same time as the policy, so I'll get into those in the next few slides. The current policy, the 2003 policy, allows some flexibility with the level of detail that you can provide in the plan. With the DMS Policy, there is more specific guidance on the recommended elements to be included in the plan, so I will go over this very shortly. This is a similar slide to the previous and more detailed, and you can reference this later on. But what I do want to point out is the timeline here. So under the DMS policy, data should be made available as soon as possible and no later than at the time of associated publication or the end of the performance period, whichever one comes first. You may also wonder how long data should be made available for. This is not specified in the policy in terms of a minimum time frame, but NIH definitely encourages data to be made available as long as it's anticipated that that data will be useful to the general public, and NIH also asks investigators and researchers to consider relevant requirements and expectations from other sources that may have a minimum time frame. So for example, some journals or repositories might have the requirement or an expectations for their policy in terms of a minimum time frame for when how long data should be made available. So just wanted to point that out. So this is the first of the supplemental information accompanying the policy, but before I get into the details of this I just wanted to make it clear that the DMS Policy does not require data to be shared, but there are specifically two requirements of the policy. Okay, so the first requirement is for submission of a data management and sharing plan. So a plan that described the data, the metadata, and that will be shared and how that will be managed and preserved. And then the second requirement is compliance with the plan as approved by the funding IC. So I just wanted to pull that out from the policy and make that clear that it's the plan and the compliance of the plan are the two requirements of the policy. All right. So let's dig into the plan. So here are some recommended elements to be included in a plan, and again, there is a link there to the supplemental information where you can go and get a few additional information, but essentially, the plan is, you should provide a description of the data to be preserved and shared, a description of the tools and software needed to access and manipulate the data, and a description of the standards that will be applied to the scientific data as well as the metadata. So for example, data formats on data identifiers and that kind of thing, name of the repository to be used, how the scientific data will be findable and available, and when and how long that data will be shared and made available to the users. The plan also should include a description of any factors that may affect access, distribution or reuse of scientific data. So these could be related to, for example, informed consent, privacy and confidentiality issues. And any considerations essentially that may limit the extent to which the data is shared, that should be included. And generally I think that NIH expects researchers to maximize appropriate sharing of data that's generated from the research that it funds. And finally, oversight of data management. So regarding plan compliance, who will be monitoring, whose responsibility is this, and how would that be monitored and managed? So those are key elements that we are asking NIH as recommended because included in the DMS plan. And the second supplemental information has to do with allowable costs for data management and sharing. So this is a description of what is considered a reasonable cost that could be included in the budget. And these have to do with data curation fees, or costs associated with developing a supporting documentation, costs associated preserving or sharing data through repositories and other local data management considerations that might be unique to an institution. So those are what are called reasonable costs. What's not considered a data sharing cost that should not be included in the budget, are infrastructure costs that are typically included in the institution's indirect costs, as well as any costs that are associated with routine conduct of research. So fees associated with gaining access to a repository, those will not be considered in the appropriate data sharing costs. And I just wanted to also point out that the costs must be incurred during the performance period even if the scientific data are preserved and shared beyond the award period. And finally, this is the third supplemental information to the policy is guidance on selecting a repository for any data that's resulting from NIH supporting research. So the purpose of this supplemental information is to help encourage the use of established repositories to improve FAIRness: right, the findability, accessibility, interoperability and reusability of data. So it includes repositories beyond just NIH supported repositories. And I think this allows researchers flexibility in terms of based on their data sharing needs. So whether the repositories are supported by private or public organizations, there are some specific suggestions for desirable characteristics of a repository, that are provided in the supplemental information that would help investigators identify what is an appropriate data repository. There's a reference to a list of NIH supported data repositories. And finally, just to make a note that NIH, some ICs, institutes and centers and offices, they may designate specific data repositories. And this would be based on the data type or the type of program, and these will be included in their funding opportunity announcements. So something to be aware of. All right. So there's a lot that's been going on in the implementation space. We have about a year I would say before this policy has to roll out. And there's been a lot of work, a lot of activities that have been going on over the past year to figure out exactly how to effectively implement the policy by January 2023. It's definitely not the easiest task, but this has been a collaborative effort with the Office of Science Policy and Office of Extramural Research, which is where we sit. There's been a lot of engagement with the community, the extramural community, and within NIH as well and helping understand what the policy is about, what does it mean, what are the expectations and their requirements, and what does it not apply to, what is not subject to the policy? So for example, like biospecimens, and understanding what the implementation challenges are. So there has been some workshops, like I'm sure most of you attended or participated in the NASEM workshop earlier this year. So a lot of outreach, a lot of engagement. There's a lot that needs to be done to help enhance compliance mechanisms. So building tools to help streamline compliance, automation, looking at our processes, our systems, workflows, and all of that, developing resources, those are ongoing, and how do we harmonize the NIH Data Sharing Policies? So there's the GDS policy, which you heard from JP. There are aspects of that that are going to be subsumed on this DMS policy, and our goal is to minimize burden. So wanting to harmonize with some elements that still need to be, but at the same time streamlining that so that there's efficiency in how we're implementing NIH data sharing policies. We're developing FAQs, guidance materials, exploring opportunities to strengthen incentives for data sharing. So there's a lot going on. I do want to make a plug again for the upcoming session later on today, in probably an hour or so. And in this session, our colleagues will be sharing a little bit more and focusing on the updates on the implementation of the DMS policy, some questions that have come up from the community and some considerations that we're .. . that are in play as we're thinking about rolling this out. So it's later on today at 5. You don't want to miss it. Lots of information there. And I do know it's probably the last session for this whole conference. So before I finish or I leave you all, I just wanted to share some resources to select NIH grant policy experts. You can look at this at your leisure, and here are some links to some the data sharing policies that we have to share. And I know that we've thrown a lot of policies at you. It's a lot to digest, but hopefully it was very informative for you, and I would like to thank our colleagues at the Office of Science Policy, Cheryl Smith, Ellen Wann and Taunton Paine, and also our colleague at OER, Cindy Danielson for the contributions to this presentation. So thank you all for listening. Thank you for being here, and I think we're on to Q and A.

Elyse Sullivan: Wonderful. Thank you so much, Nonye. Thank you, JP. We've got a few questions coming in, and so I'm going to start launching them at you all. Let's see, the first question I have here is, with regards to the sharing plan and linking to a repository, for example, we have the hyperlinks are kind of a no-no in a lot of places in the application, are links going to be allowed in the data sharing plan?

JP Kim: Hi, JP here. Unfortunately, I don't know the answer to that because as you noted, basically putting links in the application tends to sort of get around certain limits and the like. So we are developing additional, as Nonye mentioned, we're developing a lot of training and educational guidance with respect to that, the plan, including FAQs, and so we'll keep that in note as something we will answer as part of that. Unfortunately, like I said, yeah, unfortunately because of the thing about the linking I think that we have to be very cautious about that.

Elyse Sullivan: Very cautious, yes.

JP Kim: Nonye, would you like to add anything? Okay, she is muted, but she said "Okay, go next."

Nonye Harvey: I'm unmuted now.

JP Kim: There you go.

Elyse Sullivan: Are there requirements for the format for collecting or storing data that will be shared in the policy or is it up to the investigator's discretion?

JP Harvey: I think that it will be actually up to the investigators discretion. Here at the NIH we don't exactly prescribe things as much as we do sort of rely on the investigators and the institutions as to how they address certain things. However, what we will be doing, again I have to emphasize and as will be talked about at 5 o'clock, is that we're developing various aspects of with respect to implementation and guidance and the like. So basically with respect to that, we do have noted, as Nonye mentioned, elements and the like. So basically, we would expect that people should be addressing those elements, but how they address that actually will probably be up to them. But again, in development and guidance that should be forthcoming.

Elyse Sullivan: Great. And a question about costs, I guess Nonye, you mentioned that the cost must be spent during the funding period. Is that true? It cannot be spent for future years of data storage, that would not be in the funding period. Is that correct?

Nonye Harvey: Right, that is correct. So the costs must be incurred during the performance period. So even if the data is shared beyond the award period it must be incurred, so that's explicit in the policy.

Elyse Sullivan: And can you give an example of what types of costs are unallowable? I know that you said that some of the routine costs are actually unallowable.

Nonye Harvey: Yeah, so any cost that is not tied to specifically research, generating research. So let me go to my cheat sheet here. It's a lot of information, but I think costs related to something like infrastructure costs that would typically go under indirects of institutions, so F&A costs or any costs that requires you ... so if you want to access data from a repository there are fees for that, that will not be considered. But any fees related to depositing the data, that is certainly allowable. It's tied directly to maintaining the repository or preparing the data, those are considered allowable costs, but indirects are a good example and data access fees, those are the two that I can think about right now. JP, I don't know if you have any other examples, but I think anything that's not related to data sharing and management on that end.

JP Kim: Yeah, and also I think one additional caution is that basically, as Nonye mentioned, the indirect or overheard or F&A costs, yes, those could go to the infrastructure, and so they might be in the F&A cost, but you also have to be careful that you don't double dip?

Nonye Harvey: Yeah.

JP Kim: Yeah, if you're actually getting those costs in another grant and then you're trying to get them from this grant as well that would not be allowable. You actually have to make sure you manage that funding very carefully so it's not duplicative funding for the same thing.

Nonye Harvey: Absolutely.

Elyse Sullivan: And can you talk about how all of this data sharing is factored into review and the review criteria, and what pieces. What are reviewers looking for? What are they considering and scoring with data sharing, I think not just the DMS Policy, but any types of, any of these data sharing policies?

JP Kim: As you probably see in the DMS plan or in their FAQs currently, basically the data management and sharing plan will not actually be considered in review. The only thing that the reviewers will see is actually enough so that they can actually comment on the budget. So it is not actually part of the technical score. The only exception for that would be if we were specifically funding a data sharing or data dissemination center where of course that would actually be a part of the science, and so that's the only situation where peer reviewers would be looking for that, but otherwise, they are not actually going to be reviewing the data management plan except for the budget.

Nonye Harvey: Right. So just the program staff would be the ones that would have access and be able to view the full plan, and peer reviewers are just limited to the budget and the budget justification. And it's not factored into the score. And even with the current policy, it's not factored into the score. And I think that the GDS, under the GDS policy reviewers can see everything, right, just because it's submitted as part of the full application, and that will be different for the DMS policy where they will be limited to just the budget or the budget justification.

JP Kim: But remember, sort of as the example I had given you about a data dissemination center, but in this case, basically you will still need to have a plan that's acceptable. So basically if you don't have an acceptable plan, because it's the policy, we do talk about how the plan will be a term and condition in your notice of award. So we will need to finalize that. And the great thing about that is that after peer review, program officers actually get these, and then they will actually talk with the applicable applications with respect to if there's some issues with the plans. Okay, thank you.

Elyse Sullivan: Are there templates or other tools in the works to help out folks in how to create a good management plan and how we're going to help folks kind of work with this change?

JP Kim: Of course. The great thing about it is, there are actually templates and tools out in the community as well that are available currently, but of course, yes, the NIH is continuing to work on these things with respect to our implementation and the like. So yes, many of those are actually being explored and thought of. Nonye, would you like to add anything on that?

Nonye Harvey: No, yeah, perfectly exactly what you just said. And I think looking at the supplemental information on data elements, I think those are the core and the key recommended. So it kind of has its template of its own, but I think that, as JP mentioned, we're still trying to finalize and flesh out what an actual template that would look like, what structured elements and that kind of thing, and there'll be training for staff what to look for in training for the community at large as well. So all of those are in development, and we're hoping to get all this done and cleared by January. Lots to do, but definitely in the works. Good question though.

JP Kim: Mm-hmm.

Elyse Sullivan: Wonderful. Well, thank you all for joining us. We're about at time. Thank you, Nonye. Thank you, JP, and thank you everyone who attended for your participation and your really great questions. If you haven't gotten any of your questions answered, come to the 5 o'clock session. We'll see if there's any more questions that we can answer, and I do want to take this time to encourage everybody to give some feedback for these sessions. So accompanying every session in the auditorium description area is a link for feedback, so tell us what worked for that session. Tell us what you didn't like, and then there's also an area for overall conference feedback, so we're going to be doing this again, so we want to know what is working for you. So, again, thank you for joining us and please let us know any additional questions and any feedback you have. Thank you.

JP Kim: Thanks, everyone. We look forward to helping you.

Nonye Harvey: Thank you all.

JP Kim: Good bye.