Elyse Sullivan: Welcome! Thank you, all, for joining us.

0:06

We're expecting a great turnout today, so we're going to hold just for a moment

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to give people a chance to join, and then we'll get right into it.

0:42

All right. Let's get started. Welcome to part one of the new NIH

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Data Management and Sharing Policy webinar series. Today we're focusing on understanding

0:54

the new DMS policy. I'm going to talk just for a moment about some logistics

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and some formats for today's event. Today's session will include a prerecorded discussion

1:06

with our expert panel, followed by about 30 minutes of live Q&A from our audience.

1:13

Several of you submitted questions in advance of the webinar, and we've incorporated many of those into our panel discussion.

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During the 30-minute live Q&A, we will get to as many additional questions as we can.

1:29

Some logistics to go over with you all, while the prerecorded discussion is playing, we invite you to enter any questions that you have in the

1:37

Q&A box at the bottom of your Zoom screen, so that's what we're going to be monitoring.

1:42

Our team will be compiling these questions and asking as many as we can during the live

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Q&A part of the event. You all will actually have the opportunity to upvote some of these questions.

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There's a little thumbs-up icon that'll show up next to a question, and you can go ahead and upvote any questions

2:02

that you also feel are very important, and that'll help us prioritize which questions to handle

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in the live Q&A portion. We're also offering a chat box to communicate with any ...

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with the hosts and panelists. If you have technical or logistical issues during the event, put your comment in the chat,

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and we'll be able to help you out. Our team will actually also be using the chat

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to chat out some links during the event, just some important resources that we want you to know about.

2:38

One tip, there is a small arrow next to the chat button in your Zoom webinar,

2:43

and this will allow you to toggle on and off your chat notifications. So just a tip, if you want to see those notifications or not,

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you do ... can control that. Finally, I did want to mention that the entire session will be recorded

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and will be made available following today's event, probably within about 5 to 7 business days.

3:05

We've also put together some resource slides that are available on the NIH sharing site.

3:10

This is sharing.nih.gov/about/learning, and in the chat, we're going to actually put a direct link

3:18

to that resource deck. That's just something that we also wanted you to have as part of this event.

3:26

All right. Before we introduce our main panelists for today, we have a special welcome from Dr. Lyric Jorgenson,

Dr. Jorgenson's Introduction the the DMS Webinar

3:34

the Acting Associate Director for Science Policy at NIH.

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Lyric Jorgenson: Hello, I'm Lyric Jorgenson, the Acting Associate Director for Science Policy at the National Institutes of Health.

3:47

I'd like to welcome you all to the first webinar of our two-part series, A Conversation with NIH:

3:54

Implementing the New Data Management and Sharing Policy. The webinar you're tuning into today,

4:01

Understanding the New NIH Data Management and Sharing Policy, will provide an introduction

4:06

to many of the important basics of the policy. The second webinar in our series,

4:11

taking place in September 22nd, 2022, will take a deeper dive into the nuances of the policy,

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so please make sure to tune into that one as well. Just as a brief reminder, the NIH Data Management and Sharing Policy

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was issued on October 29th, 2020, and goes into effect January 25th, 2023.

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It is important to note that the policy was developed through substantial and consistent consultation

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with the research community, tribal nations, our federal partners and many other experts and stakeholders

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engaged along the way. The 2-year delay in implementation was indeed deliberate.

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We wanted to make certain that our timeline here is ambitious but also take into consideration the need to develop additional resources for implementation

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and provide institutions with the time they need to get ready to be successful. We've been busy since 2020, taking advantage of this time

5:08

to present at dozens of meetings, seminars and other venues to get the word out to stakeholders about this policy.

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If you heard one of those previous presentations on the policy, either from me or one of my colleagues here at NIH,

5:23

you probably heard us use the phrase "culture shift." You may even be thinking, "What exactly do we mean?"

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Simply put, we want to make practices of data management and responsible data sharing the norm.

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That is, considered routine to the conduct of science itself, just as reporting out on the findings of a study.

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Through this new policy, we aim to catalyze this culture shift. The core principle embedded in the policy

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is maximizing the availability of scientific data resulting from taxpayer-funded research.

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This will be achieved in part by prospectively planning for data sharing through the submission of a data management

6:05

and sharing plan with applications for the research funding. By maximizing the availability of scientific data,

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we all can work together to enable researchers to rigorously test the validity of research findings,

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strengthen analyses through combined data sets, allow for the reuse of hard-to-generate data,

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open new and exciting frontiers of discovery and, perhaps most importantly to me,

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help foster trust in publicly- funded research activities by promoting research transparency.

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With all of that said, we must be realistic and recognize that challenges in beliefs and practices takes time.

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We realize that some researchers may already have significant experience in planning for how to share data,

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while others, well, this might be new practice. We are working to make implementation

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as smooth as possible, but we know there will be challenges. Flexibility and patience will be key

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as we move forward with implementation. If and when issues do arise,

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I want to reassure you all that NIH will work through them with you as partners in the process.

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For NIH's part, we will continue to develop additional resources based on the needs of the community,

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so keep asking for the help. Resources to be on the lookout for in the future include final supplemental information

7:27

on protecting the privacy of research participants when data are shared and final supplemental information

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on responsible management and sharing of American Indian and Alaskan Native participant data.

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I want to thank you, all, once again for joining us today for today's webinar. We look forward to continuing to work with you all,

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and I hope you find this as just one of many valuable resources, as you prepare for the NIH Data Management and Sharing Policy.

7:56

Thank you very much for your time.

Introduction of Panel and Topics

8:01

Elyse Sullivan: The January 25th policy implementation date is quickly approaching, and we know that you have a lot of questions.

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We have an expert panel here today to help you better understand the policy and what it means for you. My name is Elyse Sullivan,

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and I will be moderating today's event. Joining us from the Office of Science Policy,

8:22

we have Taunton Paine, and from the Office of Extramural Research, we have Julia Slutsman and Cindy Danielson.

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Today's discussion will cover the goals of the policy, what types of data are subject to it

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and the expectations of the policy itself. We will then move into discussing

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how to prepare DMS Plans and budgeting for related costs.

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Finally, we'll discuss the timing of when data should be shared and some factors to consider when selecting data repositories.

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We have chosen these topics based on the most common questions that we've heard from researchers,

9:01

institutional officials and other groups, and we plan to cover additional topics in part two of this webinar series,

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which is coming in September. So with that, I will turn my first question to Taunton.

What are the goals of the policy?

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Can you start by summarizing the goals of the policy for us?

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Taunton Paine: Thanks, Elyse. Dr. Jorgenson provided an excellent overview of the reasons why NIH developed this policy.

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NIH has a longstanding commitment to make results of research available, including both publications and data.

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In fact, NIH has had data sharing policies for decades that have grown incrementally over time

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to cover a substantial portion of NIH's portfolio of research. These policies have focused on setting expectations

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for sharing data from large awards, from genomic studies and for research funded by specific NIH institutes, centers or programs.

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The NIH Data Management and Sharing Policy will create a consistent minimum expectation for all research supported by the agency.

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Sharing data can help to, as Dr. Jorgenson mentioned, enable researchers to test the validity

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of research findings and foster trust in publicly-funded research activities by promoting transparency.

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Fundamentally, the goal of the policy is to increase the availability of data underlying NIH-supported research and, in so doing,

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to help advance NIH's mission to enhance health, lengthen life and reduce illness and disability.

What does this policy apply to?

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Elyse Sullivan: And can you help us understand what types of research this new policy applies to?

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Taunton Paine: The NIH Data Management and Sharing Policy applies to all research funded or conducted,

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in whole or in part, by NIH that results in the generation of scientific data.

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Let's start by looking at the definition of scientific data, which the policy defines as "the recorded factual material

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commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings,

11:04

regardless of whether the data are used to support scholarly publications." These scientific data are also what we ask

11:10

researchers to address sharing. Elyse Sullivan: All right. Well, how much ... How about some examples of scientific data?

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Taunton Paine: The exact scope of scientific data will vary depending on the context, but it will relate to the aims

11:25

and the questions of the proposed research. As very general examples, the scientific data

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for a study of HIV/AIDS might include single-cell RNA sequencing of T lymphocytes or other immune cells,

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the study of a rodent model of PTSD might include electrophysiological recordings

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and functional MRI images, and a study of cardiovascular health might include step activity from a wearable device.

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Elyse Sullivan: So now can you talk about what types of things are not scientific data? Taunton Paine: It's important understand

11:59

that the definition of scientific data explicitly excludes certain things, which means that they would not be expected to be shared.

12:06

These include data that are not necessary for or of sufficient quality to validate and replicate the research findings,

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laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers,

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plans for future research, peer reviews, communications with colleagues or any kind of physical objects, such as specimens.

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This policy also does not apply to administrative data associated with awards and does not expect sharing of software

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or code developed from a study, although NIH has issued best practices for when software and code are shared.

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Under this policy, researchers are responsible for identifying their scientific data.

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No one is in a better position to understand the scientific data generated during your research than you all.

12:54

Elyse Sullivan: Thanks, Taunton. Can you walk us through what types of NIH-funded activities

12:59

are going to be subject to this new policy? Taunton Paine: In terms of the types of activities that will be subject to the policy,

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the scope includes research funded or conducted by extramural grants, contracts, intramural research projects

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and other funding agreements, such as other transactions. The policy applies regardless of the level of funding.

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However, there are certain activities that are just excluded entirely from the scope of the policy.

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This includes research and other activities that do not generate scientific data, including training, infrastructure development

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and any non-research activities. Projects that only develop or support infrastructure resources

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and do not generate findings or scientific data, such as establishing repositories, are not subject to the policy.

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NIH will provide a list of relevant activity codes to help understand what's in and what's out of the scope of the policy.

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Elyse Sullivan: Okay, let's talk about the timing of when the policy goes into effect.

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Taunton Paine: The policy will take effect for competing grant applications that are submitted to NIH from January 25th, 2023,

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and subsequent receipt dates. Proposals for contracts that are submitted to NIH on or after January 25th, 2023,

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will also need to comply with the policy, as will NIH intramural research projects conducted on or after January 25th, 2023,

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and other funding agreements, such as other transactions, that are executed on or after January 25th, 2023,

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unless otherwise stipulated by NIH. Elyse Sullivan: Okay, so we covered policy applicability

What does the DMS Policy require?

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and the timing of the policy. Taunton, in a nutshell, what does this policy actually expect

14:47

from investigators and institutions? Taunton Paine: So the policy is straightforward

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in that it only has two basic requirements. First, it requires the submission

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of a Data Management and Sharing Plan, which will be included with each application for funding

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and will generally describe how, where and when data will be shared.

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Second, once the plan is approved by the funding NIH institute, center or office,

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the policy requires compliance with that plan, which will be achieved by making it a term and condition of award.

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Of course, plans may be updated over the course of the award, which we'll talk about more later.

Do all data need to be shared?

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Elyse Sullivan: And a common misconception that we hear is that the policy requires all data to be shared.

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Taunton, can you help clarify this? Taunton Paine: As I mentioned before, the policy only requires submission of a Data Management

15:40

and Sharing Plan and compliance with the version of the plan approved by the NIH institute, center or office funding the research.

15:47

It does not require data sharing. However, it does expect that in developing their Data Management and Sharing Plans,

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researchers will maximize appropriate sharing of scientific data. So, no, the policy does not require

16:01

or expect that all data generated during the course of a study be shared. Under the policy, researchers have the responsibility

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to determine both what constitutes their scientific data and to propose how they will maximize appropriate

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sharing of those scientific data, including identifying scientific data that will not be shared,

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and they should provide justifications for these decisions. Remember that a number of things are excluded

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from the definition of scientific data and thus are not expected to be shared, in particular,

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any data that are not necessary for or of sufficient quality to validate and replicate the research findings.

16:37

The policy emphasizes that all data should be managed but recognizes that not all data must or even can be shared.

Are there acceptable reasons for not sharing scientific data or limiting sharing of scientific data?

16:45

Elyse Sullivan: Thanks, and can you talk us through some of the factors that may limit how data can be shared?

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Taunton Paine: Yes. I want to point out that while the policy expects researchers to maximize appropriate sharing of scientific data,

16:59

it also recognizes that in order for sharing to be appropriate, there are justifiable ethical, legal and technical factors

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that may limit sharing of scientific data in some way or, in some cases, preclude sharing entirely.

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In the frequently asked questions on the sharing.nih.gov website, we provided a number of potential examples

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of these factors that would be appropriate for limiting sharing, and these include when informed consent

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will not permit or will limit the scope or extent of sharing and future research use

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or when working with previously collected biospecimens or data, existing consent prohibits

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or limits the scope of sharing and use. Relatedly, I would like to mention that NIH has recently issued a resource

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providing points to consider and sample language for informed consent in research studies with plans to store

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and share data or biospecimens for future use that may be helpful when thinking about consent in this context.

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Elyse Sullivan: Thanks, and, Taunton, we get a lot of questions about privacy and safety concerns with sharing.

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Can you speak to this? Taunton Paine: Sharing can also be limited if the privacy or safety of research participants

18:06

would be compromised or place them at greater risk of re-identification or suffering harm, and if protective measures, such as de-identification

18:14

and certificates of confidentiality, would be insufficient to mitigate these risks.

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NIH has proposed a set of considerations for protecting privacy when sharing data from research participants

18:25

to help guide researchers and institutions in making these decisions and will be expanding more on this in future resources.

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Elyse Sullivan: And what about if laws or regulations prohibit sharing? Taunton Paine: Of course, sharing must be limited

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when there are explicit federal, state, local or Tribal laws, regulations or policies

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that prohibit or limit disclosure in some way. Nothing in this policy changes the expectation

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that researchers abide by other requirements that may apply to them, For example, the common rule,

18:57

the HIPAA Privacy rule, state laws or even foreign laws that may limit sharing of some types of data.

19:05

There may also be restrictions imposed on sharing by existing or anticipated agreements

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that may be necessary to enter into in order to conduct the research, for example, with third-party funders,

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with research partners, with repositories or with HIPAA-covered entities that provide protected health information

19:22

under a data use agreement. There may also be limitations imposed through licensing limitations

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attached to materials needed to conduct the research. Last, I want to emphasize that we've clarified through

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a frequently asked question that the Small Business Innovation Research and Small Business Technology Transfer program policy directive permits

19:43

SBIR and STTR awardees to withhold applicable data for 20 years after the award date,

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as stipulated in the specific SBIR/STTR funding agreement and consistent with achieving program goals.

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Elyse Sullivan: Thanks, Taunton. So are there any other factors that we should discuss when it comes to limitations on data sharing?

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Taunton Paine: We also recognize that researchers commonly access existing data to conduct their research, for example,

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analyzing data obtained from a data repository, and although some of these primary data might reasonably fall within the definition of scientific data

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in some cases, NIH would not expect that data that are already available be shared again.

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I also want to point out that NIH recognizes and respects Tribal sovereignty and the concerns

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that American Indian and Alaskan Native communities sometimes have regarding data management and sharing,

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and NIH has also proposed additional considerations for when researchers are working with tribes

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that we'll be addressing in more detail in the future. A central tenet of these proposed considerations

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is to facilitate respectful partnership and mutually agreed upon data management and sharing practices, which may ultimately

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require limitations on sharing in some cases. Now, these are examples of factors that would clearly

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be appropriate for limiting sharing, and it's not a comprehensive list. There may be others that we encounter in practice,

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and NIH may update guidance accordingly in the future. Elyse Sullivan: Thanks.

21:13

Can you give us some examples of reasons that would not be considered justifiable reasons

21:18

to limit sharing? Taunton Paine: We've provided a few examples of factors that NIH would generally not find acceptable

21:24

for limiting sharing, and these include arguments that data are too small, that researchers anticipate data will not be widely used

21:32

or that data are not thought to have a suitable repository. Elyse Sullivan: Thank you.

What are the elements of a DMS Plan?

21:38

All right. Let's switch gears and get to talking about DMS Plans.

21:44

Cindy, can you talk to us about how to go about preparing these plans and what they should include?

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Cindy Danielson: Thanks, Elyse, definitely a great question to dig into. When the final policy was issued back in October of 2020,

21:57

NIH also put out supplemental policy information describing the elements we'd like to see

22:02

in a Data Management and Sharing Plan, or DMS Plan. This was published as an NIH guide notice,

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and we've also incorporated this information into the NIH Scientific Data Sharing website

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at sharing.nih.gov, to make it easy to find all of the relevant information in one place.

22:21

Let's talk through each of these elements. First, data type, you should provide information

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about the data type or types you're proposing to generate in your project and identify which of those will be preserved and shared.

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This will not include all data generated but should focus on the scientific data underlying the proposed research findings.

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As Taunton mentioned, what exactly those data are will vary by project, so the researchers will need to define this individually

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based on the research proposal. Next, related tools, software and code,

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you should indicate what tools or software will be needed to access and manipulate your data.

23:00

Next, standards, this is where you'll describe what common data standards will be applied

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to your scientific data and metadata to enable interoperability of data sets.

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Next, data preservation, access and associated timelines, this element is where you'll indicate your plans

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to preserve data and provide access to shared data, including timelines. This includes the name of the repository

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or repositories you propose to use to archive your scientific data and metadata,

23:31

whether persistent unique identifiers will be used to facilitate findability and accessibility of shared data

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and when and for how long shared data will be available. Next, access, distribution or reuse considerations,

23:45

any factors that affect data access, distribution or reuse should be described.

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NIH expects that researchers maximize the appropriate sharing of scientific data, but as Taunton just described,

23:57

there may be certain ethical, legal and technical factors that could limit the extent of data sharing.

24:03

NIH wants to know what these are before any data have been generated so that the proposed institute or center can assess

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whether your plan appropriately considers these factors. This section is also where ...

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the research that involves the sharing of scientific data generated from human research participants,

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you should indicate whether access to such data will be controlled, that is, made available by a data repository

24:27

only after approval, and outline how privacy, rights and confidentiality

24:32

of human research participants will be protected. Finally, oversight of data management and sharing,

24:39

this is where you will indicate how compliance with your DMS Plan will be monitored and managed within your institution

24:45

and who at your institution will be responsible for this oversight. You can find more details about these elements

24:51

on the Writing a Data Management and Sharing Plan section of NIH's sharing website.

24:57

Elyse Sullivan: Thanks, Cindy. Is there a recommended format for these plans? Cindy Danielson: In terms of the format,

25:03

we recommend that DMS Plans should be two pages or less, and while we've had this detailed information

25:09

about the elements of a DMS Plan available for some time to help researchers and organizations

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begin thinking about the content of their DMS Plans, we have heard a lot of feedback that a template would be helpful,

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especially for those who have never written a plan like this before. In response to this feedback, NIH will be offering an optional format page

25:29

that applicants can use as a template to format the elements of their DMS Plans.

25:34

We have made available a preview of that format page for template which I'll bring up now.

25:40

This is currently a draft version which is undergoing OMB clearance under the Paperwork Reduction Act,

25:46

and when that process is complete, the final version of the document will be posted in a fillable format.

25:52

The goal of this format page is to help investigators address all of the elements while still providing the flexibility

25:58

to write a plan that works best for each project. You'll notice that the information here aligns with the same elements that I just described,

26:06

data type, related tools, software and code, standards, data preservation, access and associated timelines,

26:17

access, distribution or reuse considerations and oversight of data management and sharing.

26:23

We've just broken them up into a few sections to make it easier to address each aspect.

How will Plans be submitted?

26:29

Elyse Sullivan: Thanks, Cindy. So now that we know about plans and what they should include, can you tell us about when and how investigators

26:37

will submit these plans to NIH? Cindy Danielson: Great question, and we're in the process of preparing comprehensive instructions,

26:43

which will be incorporated into the next version of the NIH Application Guide this fall that will describe this in more detail.

26:51

For now, we have issued a guide notice describing implementation details for the DMS Policy,

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which summarizes the changes that will be made to the grant application forms to accommodate the new DMS Plan.

27:03

Elyse Sullivan: And, Cindy, previously, data sharing plans were included in the resource-sharing part of the application.

27:09

Is that not the case anymore? Cindy Danielson: That's right, Elyse. The Resource Sharing Plans field is not going away.

27:15

That will remain to support other policies, namely the research tools and model organism sharing policies.

27:21

We will be updating the instructions and the NIH Application Guide to clarify that separate data sharing plans and genomic data

27:29

sharing plans will no longer be attached to the Resource Sharing Plans field. For any applications that are also subject

27:36

to the genomic data sharing policy, you'll no longer submit a separate genomic data sharing plan.

27:42

This information will be addressed as part of your Data Management and Sharing Plan. So for competing applications subject to the DMS Policy,

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applicants will need to include a Data Management and Sharing Plan. This DMS Plan will be attached to the Other Plans field,

27:57

which will be a new field added to the Forms H version of the PHS 398 Research Plan Form and the PHS 398 Career

28:07

Development Award Supplemental Form. This new Other Plans field is where you will submit

28:13

a single PDF attachment containing the elements of a DMS Plan. As I just mentioned, we will be providing a recommended format

28:21

or template to help prepare this attachment. A fillable version of that format page will be made available by the fall.

Will my Plan be public, and if so, when?

28:29

Elyse Sullivan: And so can you talk to us about what NIH will do with these plans after they're submitted, and will they be made public?

28:37

Cindy Danielson: NIH did indicate in the published DMS Policy that we may make DMS Plans publicly available,

28:43

and we may do so in the future, but we do not anticipate making plans publicly available

28:49

for initial policy implementation. We did indicate in the policy that DMS Plans should not include proprietary

28:55

or private information, so we do want to remind folks about this, even if the plans aren't made public initially.

Where do I share my data?

29:02

Elyse Sullivan: Thanks, Cindy. So now I want to move on to discussing where investigators should be sharing their data.

29:09

Julia, can you talk to us about where and how to share data? Julia Slutsman: Yes.

29:14

The policy does not require the use of any specific repository, but NIH institutes and centers or specific programs

29:20

may go beyond the policy and designate specific repositories. The DMS Policy strongly encourages

29:26

the use of established repositories because depositing data in a quality repository generally improves the fairness,

29:32

and that is the findability, accessibility, interoperability and reusability of those data.

29:38

NIH provides a supplemental information guide notice titled Selecting a Repository for data

29:43

resulting from NIH-sponsored research, which outlines 12 characteristics of data repositories that researchers should be looking for

29:50

when selecting a repository through which to share their NIH-funded research data. The notice also lists additional characteristics

29:57

which apply to human data repositories. Additional information is available on the sharing.nih.gov website.

30:04

Elyse Sullivan: Thanks, and do you have any advice on how to identify the most appropriate repository

30:11

and sort of where to start in that process? Julia Slutsman: To help investigators get started, NIH maintains listings of unrestricted access

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and controlled access NIH-supported repositories, and these are available on the sharing.nih.gov website.

30:25

For example, there's a searchable table of NIH institute and center-supported repositories

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that should help you learn more about the various NIH repositories and narrow down your options.

30:35

This table can be sorted by Funding IC, Name of Repository, Keyword and even certain repository characteristics.

30:42

We also provide some useful information about non-NIH repositories, including links to common generalist repositories

30:48

and other resources to help investigators navigate the landscape of repository options on the website.

When should I share my data?

30:54

Elyse Sullivan: Thanks, Julia. I'm sure our audience will find these resources very useful.

31:00

Can we talk a little bit about timing for sharing? When should investigators share the data that they generate?

31:06

Julia Slutsman: The DMS Policy expects scientific data to be made accessible as soon as possible. Specifically, data should be shared

31:13

at the earlier of two time points, either no later than the publication date of an associated peer-reviewed publication

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or by the end date of the performance period for the award that generated the data. Now, what that means is that for scientific data

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underlying a peer-reviewed publication, those data should be shared no later than the date in which the article

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is first made available in print or electronic form. That also means that scientific data

31:36

not disseminated through a peer-reviewed publication should be shared no later than at the end of the performance period.

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For example, scientific data may underlie unpublished findings or findings documented within preprints,

31:48

conference proceedings or book chapters. Additionally, data underlying null or negative findings are important to share,

31:54

even though these key findings are not always published. In those cases, the data should be available … made available no later than the end of the performance

32:01

period of the award generating the data. Elyse, I do want to better define the end of the performance period

32:07

in two specific scenarios. First, in instances where no cost extension is granted, the recipient should share the data

32:14

by the end of the extended performance period, if such sharing has not occurred previously. Second, if a competitive renewal is submitted,

32:21

researchers should submit an updated Data Management Sharing Plan revising the data sharing timelines

32:26

as needed to address any scientific data that were not shared during the initial award period.

32:31

If the competitive renewal is not successful, applicants will still have to comply with the timeline in the approved DMS Plan from the initial performance period.

32:40

There is an FAQ on the sharing.nih.gov website with more detailed information to help you understand and plan for the timing of data sharing.

How long should my data be available to the community?

32:48

Elyse Sullivan: Thanks, and for how long does NIH expect the data to be made available for once it is shared?

32:55

Julia Slutsman: Great question. The DMS Policy does not specify a required period of time for sharing data,

33:00

recognizing that the appropriate length of time will differ across scientific disciplines. Often other entities, such as data repositories and journals,

33:08

will have their own guidelines, and there may also be applicable record retention requirements that need to be considered to inform minimum timelines

33:15

for data sharing. Elyse Sullivan: Thanks. Let's shift now to talking about costs and budgeting.

What will NIH Pay for ?

33:23

What kind of things can investigators put into budget requests related to data management and sharing?

33:29

Cindy, this question is for you. Cindy Danielson: NIH recognizes that making data accessible

33:35

and reusable for other researchers may incur costs, and you are allowed to request funding to support the data management

33:41

and sharing activities described in your DMS Plan. NIH has published ...

33:46

policy information outlining categories of allowable costs associated with data management and sharing,

33:52

which was published as a Guide Notice and has been incorporated into the NIH sharing website.

33:58

You can include reasonable costs to support data management and sharing in your budget requests.

34:03

This includes funding for activities such as curating data and developing supporting documentation, for example,

34:09

formatting data according to accepted community standards, the identifying data, preparing metadata

34:16

and formatting data for a repository. And another type of allowable cost is preserving

34:21

and sharing data through repositories, and this could include costs such as data deposition fees necessary for making data available and accessible.

34:30

Other types of allowable costs include those related to local data management considerations,

34:36

such as activities necessary to manage and preserve data before they are deposited into an established repository.

34:43

Elyse Sullivan: Is there anything that folks should keep in mind not to include in these budgets?

34:48

Cindy Danielson: There are some types of costs that should not be included in your data management and sharing budget, such as general infrastructure costs

34:55

not associated with a specific project, which are typically included in indirect costs,

35:01

as well as costs associated with the routine conduct of research, such as gaining access to research data.

35:07

You'll need to make sure that costs are not double charged or inconsistently charged as both direct and indirect costs.

35:14

It's also important to note that any costs must be incurred during the performance period, even for scientific data that will be preserved

35:21

and shared beyond the award period. For example, if your DMS Plan proposes preserving

35:27

and sharing scientific data for 10 years in an established repository with a data deposition fee,

35:33

the cost for that entire 10-year period must be paid prior to the end of the period of performance,

35:39

and you can find more details about allowable costs on the Budgeting For Data Management and Sharing page of the NIH sharing website.

35:47

Elyse Sullivan: And, Cindy, can you walk us through where these data sharing costs

35:53

should be submitted in the application? Cindy Danielson: The direct cost to support the activities proposed in your DMS Plan

35:59

must be indicated as data management and sharing costs, and the location where this dollar amount

36:04

will be indicated varies depending on whether you're submitting a detailed budget or a modular budget.

36:10

For detailed budgets, the DMS costs will be broken out as a separate line item in Section F, Other Direct Costs.

36:18

You will use a blank line and enter the appropriate label of Data Management and Sharing Costs

36:23

along with the dollar amount. For modular budgets, there are no line items, so this information will be embedded

36:29

as text within the Additional Narrative Justification, which is one of the budget justification attachments.

36:37

In addition to the actual dollar amount, you'll also include a brief summary of the DMS Plan

36:42

and a description of the requested DMS costs within the Budget Justification attachment.

36:48

Instructions with more details about exactly what to include here will be available by the fall. Again, the location varies

36:55

depending on whether the applicant is submitting a detailed budget or a modular budget.

37:01

For detailed budgets, you'll include this information as part of the Budget Justification attachment

37:06

alongside justifications for other types of costs. This is an existing attachment.

37:11

The change here is that now DMS costs will also need to be justified.

37:16

For modular budgets, you will include this information as part of the Additional Narrative Justification.

37:23

I want to highlight that both the dollar amount and the brief justification will be part of the same attachment.

37:29

This is also an existing attachment which will be repurposed to support the DMS Policy.

How will Plans be evaluated? What will peer reviewers see/review?

37:36

Elyse Sullivan: Thanks, Cindy. So I want to switch gears a little here. What can you tell us about how DMS Plans will be evaluated?

37:45

Cindy Danielson: DMS Plans will be assessed for appropriateness by NIH program staff at the proposed NIH institute or center,

37:52

who will be looking at whether the plan addresses the elements outlined and the reasonableness of those responses.

37:58

This is the responsibility of program staff, not peer reviewers. The same Guide Notice

38:04

that we just issued on DMS implementation details also summarizes processes for peer review

38:10

and plan assessment by program staff. Because peer reviewers will not be reviewing DMS Plans,

38:16

they will not see the full DMS Plans or be providing comments on those plans.

38:21

Elyse Sullivan: So, Cindy, what is the role of peer review in all of this? Cindy Danielson: In terms of data management

38:26

and sharing, peer reviewers will focus only on whether the budget request for data management and sharing is reasonable.

38:33

Peer reviewers will review the budget for data management and sharing costs alongside a brief summary of the DMS Plan

38:40

and a description of DMS costs, which will provide the details and context the peer reviewers

38:46

will need to determine if the budget is reasonable for the activities proposed.

38:51

Unlike the DMS Plan attachment, this DMS budget and budget justification information

38:57

will be available to peer reviewers to provide the necessary context for their review of the budget.

39:04

Elyse Sullivan: Thank you, and, Taunton, I've got a question for you. We hear a lot of folks wondering,

How can I know what to include in a Plan before I have started my work?

39:12

"Well, how exact must my plans be if I don't ... haven't even done the research yet?"

39:17

Can you speak to this concern? Taunton Paine: So I want to point out that one of the basic motivations of this policy

39:24

is to get applicants thinking about and planning for data management and data sharing as early as possible.

39:31

We've seen a number of complications that can arise when data sharing is only addressed once research is already underway.

39:38

That's why we expect a Data Management and Sharing Plan to be submitted at the earliest moment,

39:43

that is, with the application for funding, so that potential issues can be identified and planned for.

39:49

However, we recognize that you may not know everything about the potential scientific data to be generated

39:55

when preparing your application. The expectation is that you provide in your Data Management and Sharing Plan as much information as possible

40:03

that reflects your proposed research and demonstrates that you've planned for managing and sharing your data to the best of your ability.

40:10

We've indicated that plans that simply say To Be Determined are not a sufficient level of detail.

Will the PO come to me if there is an issue I can resolve that might otherwise hold up my funding?

40:16

Elyse Sullivan: Thanks, and, Cindy, can you talk to us about what happens if NIH program staff review the plan,

40:23

but it's not acceptable? Is there an opportunity to revise? Cindy Danielson: Yes, while a DMS Plan

40:29

must be approved prior to award, we do want to give applicants the chance to provide any additional details

40:35

that NIH needs in order to approve their plan. Depending on the outcome of that programmatic assessment

40:40

of your DMS Plan that I just described, it may be necessary to communicate with NIH staff

40:46

to resolve any issues and potentially to provide a revised DMS Plan. This will occur through the standard

40:52

Just-In-Time process, and you would work with the program officer or a grants management specialist to resolve

40:58

any issues that prevent the funding institute or center from approving your plan based on the information provided.

41:05

Elyse Sullivan: And, Taunton, are there any opportunities for researchers to update plans over the course of a project?

How often should I update my Plan?

41:13

Taunton Paine: Yes, researchers can make updates to their Data Management and Sharing Plan during regular reporting intervals,

41:20

but they can also update their plan at any other time if needed in response to new developments, for example, if the research plan changes

41:27

to take a new scientific direction, if a new better option for sharing data becomes available, such as a new repository,

41:35

or if a revision to the timeline of the project becomes necessary. Changes to the Data Management and Sharing Plan

41:41

will need to be approved by the NIH institute, center or office funding the research.

41:47

Elyse Sullivan: Thanks. So it's clear that data sharing requires work, and it's an investment.

What benefits might I see from sharing my data?

41:53

Taunton, can you talk to us about what kind of benefits we expect to see? Taunton Paine: First off,

41:59

we all benefit from greater rigor and greater transparency in publicly funded research,

42:04

but there are several potential direct benefits for researchers who share data that I'll highlight.

42:10

First, there's a growing body of research published over the past several years suggesting that sharing data underlying published research

42:17

can actually increase the citation of those publications, particularly when data are shared through repositories.

42:25

Additionally, sharing data, especially in ways that are consistent with the FAIR principles,

42:30

that is, findable, accessible, interoperable and reusable, is another way to demonstrate your productivity

42:37

and get credit for your contributions, and there are increasing options for the citation of data sets themselves.

42:43

Importantly, sharing data can also create opportunities for future collaborations and may, in turn, provide you with access to data

42:51

and resources you might not otherwise have had. Elyse Sullivan: Thanks, and, Cindy, can you talk to us about any incentives that exist

Are there any incentives for good sharing practices?

42:59

for sharing data? Cindy Danielson: That's a great question and really comes back to one of the goals of the policy,

43:05

a cultural shift toward greater data stewardships and transparency, and one in which shared data

43:10

can help to advance rigorous and reproducible research. To make that happen, we do want to encourage

43:15

the use of data citation to incentivize data sharing, so shared data can be cited as products of award

43:22

and claimed as products of NIH funding. These data can be cited anywhere other research projects are cited,

43:29

including in the bibliography, biosketch and in the progress report. NIH will be clarifying that the information relevant

43:37

to reporting preprints and other interim research products also applies to data and will be issuing a Guide Notice

43:44

on this topic in the near future. We'll also be updating the RPPR questions

43:49

to ensure that award recipients are reporting their progress implementing their DMS Plan,

43:54

which may include citing data sets that you have generated and shared as a product of your award.

44:00

Persistent unique identifiers can help make it easier to find and access shared data sets,

44:05

and it can also help make it easier for other researchers who end up reusing those data to cite them.

44:11

Looking ahead to a future of improved data sharing, being able to track data reuse would certainly help to incentivize good data

44:18

sharing practices, so that researchers can show how the data they generated have been reused

44:23

and are accelerating future research directions. Elyse Sullivan: Thanks, and, Julia,

Do my data need a PID?

44:29

can you elaborate more about these persistent unique identifiers? Are these required,

44:35

and should they be included in data sharing plans? Julia Slutsman: So the use of persistent unique identifier

44:40

is not required but is strongly encouraged. Data Management and Sharing Plans should describe whether or not persistent unique identifiers

44:46

will be used in the data preservation, access and timelines element of the plan. After funding, unique identifiers

44:53

may also be reported in annual progress reports. Elyse Sullivan: Thanks, and, Cindy, back to you.

What might NIH do if I don't follow my Plan as I said I would?

44:59

Can you talk to us about any consequences if an investigator does not adhere to the DMS Plan?

45:07

Cindy Danielson: So first, I do want to acknowledge that we understand this will be new to many. We want to help you understand how to comply,

45:13

and with that said, NIH will be monitoring whether award recipients follow through with the plans

45:19

they proposed in their approved DMS Plan. After an award is made, the award recipient is required

45:26

to implement the approved DMS Plan, which will become a Term and Condition of Award.

45:31

They must also report on their progress, doing so in the annual RPPRs. As I mentioned earlier,

45:37

we will be updating the RPPR questions to ask for this information.

45:42

NIH staff will review this information on an annual basis to verify that the award recipient

45:48

is complying with the approved DMS Plan before issuing a non-competing award.

45:53

Failure to comply with the approved DMS Plan may result in an enforcement action, including additional special terms and conditions

46:00

or termination of the award, and it may affect future funding decisions. Elyse Sullivan: Thanks,

What if my research is also subject to other NIH data sharing policies?

46:07

and, Julia, this question is for you. We know that DMS is not the only sharing policy at NIH.

46:13

Can you walk us through what investigators should do if they're subject to multiple policies?

46:18

Julia Slutsman: The sharing.nih.gov site has a tool that researchers can use to determine which NIH-wide data sharing policies

46:25

apply to their proposals. I want to point out that applications that are subject to both DMS and GDS policies

46:32

should address the expectations and requirements of both policies within a single Data Management and Sharing Plan.

46:39

The DMS Policy establishes the foundation for NIH's data management and sharing expectations,

46:44

which NIH institutes, centers and offices and programs may choose to add to in order to meet their programmatic needs,

46:51

for instance, designating repositories for data deposition or specifying particular data collection standards.

46:57

Additionally, individual funding opportunity announcements may also include expectations related to data sharing.

47:03

The sharing website also has a searchable listing of institute and center policies to help make researchers aware

47:09

of additional expectations maintained by funding ICs. Finally, researchers and award recipients

47:15

are advised to consult with the funding NIH IC on how to comply with all applicable data

47:20

sharing policies potentially affecting their NIH-supported research project.

What should I be doing now to prepare?

47:26

Elyse Sullivan: Thank you. So kind of wrapping us up here, given all of this information, Taunton,

47:32

can you talk to us about any tips for how folks should be preparing for this new policy?

47:39

Taunton Paine: So attending this webinar is a great first step, but there's a number of other things that researchers

47:44

and institutions can be doing to prepare. First, it's a good idea to familiarize yourself

47:50

with the resources available on sharing.nih.gov, many of which have already been mentioned today.

47:57

These include further explanations of the Data Management and Sharing Policy, instructions for writing a Data Management

48:03

and Sharing Plan and information on budgets and resources for helping to identify repositories.

48:10

There's also frequently asked questions about the policy to help clarify expectations in common situations.

48:16

You could also watch for additional announcements from NIH, as this page will be updated regularly.

48:24

Second, an important step you could take is to start identifying individuals within your institution that may have relevant roles and responsibilities

48:32

that you may want to consult in developing a Data Management and Sharing Plan, such as data librarians, and to learn about

48:38

what resources might exist within your institution that could be able to assist you, such as data management and sharing platforms.

48:46

Many institutions are already preparing for implementing this policy, and your institution may have specific approaches

48:52

that you should be aware of, and they may also have additional educational and training resources.

48:58

Remember that data sharing is not new, and you may want to seek out existing sources of expertise.

49:05

Third, once you've identified relevant individuals, resources and practices at your institution,

49:10

I recommend trying to actually draft a Data Management and Sharing Plan for your research, based on the elements of a plan that NIH has provided.

49:18

The odds are good that you've been subject to a data sharing expectation in the past, either from NIH or another source,

49:24

and if so, you might consider reviewing your past data sharing practices and considering what you may need to update

49:30

in the future for the new policy. Last, there are opportunities to get involved with the community

49:36

and learn how others are planning to make this change. For example, the Federal of American Societies

49:41

for Experimental Biology has been hosting a series of competitions for developing Data Management and Sharing Plans

49:47

and demonstrating data sharing successes, and they're offering cash prizes.

49:53

Elyse Sullivan: Thanks. So this brings us to the end of our panel discussion. We hope you found this information useful,

50:00

but we also know that you probably have more questions, so we're bringing you our expert panel

50:05

live to take additional questions. Hi, all, welcome back.

Live Q&A

50:13

Thank you for that panel discussion. I did want to make a few notes. Looks like we've got a lot of great questions coming in.

50:21

Our team has been behind the scenes kind of combing through those questions

50:27

and queuing them up for us to be asked very shortly, so thank you so much.

50:32

Looks like we had a little bit of technical difficulties with our chat, and we apologize for that, and some ...

50:39

We had heard some people had some issue with screen size, so our apologies. We do want to let everybody know

50:45

that the recording of this will be made available and the links that we've been chatting out

50:51

and the resource slides that we've been showing you. So hopefully if anything was missed,

50:56

you could go back to it, and we really appreciate you joining us. So like I said, we're actually going to bring on

51:02

some additional NIH staff to help answer some of the great questions that we received during the session.

51:09

I would like to welcome Xanthia James, Cherno Barry, Casa Bagarst and Carrie Mitchell

51:16

from the Office of Extramural Research. Thank you, guys, so much for joining us,

51:21

and thank you, all, for submitting your questions through the Q&A box. We've been compiling them, and we're going to try and get through as many as possible.

51:31

All right. Let's switch to our first question.

51:36

Taunton, what ... Can you talk to us about the main differences between the new policy and the 2003 data sharing policy?

51:47

Taunton Paine: Sure, thank you. So I think the main difference between the 2003 data sharing policy and the 2020

51:53

Data Management and Sharing Policy is that the 2003 policy applied to applications

51:59

that were seeking $500,000 per year or more, while the 2020

52:05

Data Management and Sharing Policy is not limited and does not have a cost threshold in it,

52:11

so it applies much more broadly. I think the other important distinction between the two

52:17

is that the data sharing policy really only expected the submission

52:24

of a relatively simple data sharing plan and didn't have as much sort of detail in the expectations

52:31

for what we would expect people to be describing to NIH.

52:36

Elyse Sullivan: Great, thank you, and, Taunton, next question for you also.

52:41

Can you address some of the expectations around sharing qualitative data?

52:55

Taunton Paine: Yes, sure. So I think in terms of qualitative data,

53:01

so the policy does apply to studies that potentially generate qualitative data,

53:07

if the qualitative data in question meets the definition of scientific data,

53:13

which is defined in the policy as the data of sufficient quality to validate

53:23

and replicate the research findings. Qualitative data are often shared,

53:29

and there are existing repositories that can accept qualitative data,

53:35

but just as we've said for other kinds of scientific data, we've provided a number of sort of justifiable limitations

53:42

and additional considerations for sharing that would also be applicable for qualitative data.

53:49

I do want to point out, and I think this was mentioned during the webinar as well, that we have published for public comment

53:55

earlier this year a draft framework for protecting research participant privacy

54:02

while sharing data and will be finalizing that framework and discussing privacy protections in more detail

54:09

in the second webinar. Elyse Sullivan: Great, thank you. We received a few questions about sharing software,

54:18

particularly code that maybe an investigator wrote themselves.

54:23

Does that fall under what we expect to be shared? Taunton Paine: So the Data Management and Sharing Policy

54:29

does not expect researchers to attempt to maximize sharing of software or code

54:35

either that are used in the research or that are the products of research itself.

54:41

I do want to point out, however, that in the elements of a Data Management and Sharing Plan,

54:46

there is an element that relates to software or code that would be necessary to access

54:52

or to actually use the data itself, so there's an expectation that people would disclose

55:00

if there are such tools or such software or code and where they can be found

55:05

and if they will be sort of made available. I do want to also point out sort of separate from this,

55:12

the NIH recently published a set of frequently asked questions about best practices for sharing software and code

55:20

in those instances when software and code are shared. Elyse Sullivan: Thank you. All right.

55:27

We're going to get to a couple of questions about repositories and selecting the appropriate repository.

55:33

So, Julia, I'm going to have you kind of kick these off. So the first question is with regards

55:40

to generalist repositories like Figshare. If folks are already using that,

55:45

should folks be looking for other kind of more specific, discipline-specific repositories,

55:54

or is it okay to continue to use those generalist repositories? Julia Slutsman: So that's a really good question,

56:00

and the policy does not differentiate or express any preferences for which repositories investigators should use,

56:07

so it really comes down to the investigators thinking about the considerations, practical considerations

56:12

that are important in selecting a repository and for repositories that meet the kinds of criteria

56:18

that we discussed earlier. So it really comes down to where … which repositories investigators feel can best handle their data

56:26

and can best maximize its usability and FAIR principles and also, in terms of resources and budget,

56:33

which combination repositories make sense given the scope of the project.

56:39

Elyse Sullivan: Wonderful, thank you. A follow-on question, what about very large data sets,

56:45

imaging, genomic data? Some repositories may not be able to handle the size

56:51

and the file types. What should folks be thinking about? Julia Slutsman: So I think that the ecosystem for repositories

56:58

is constantly changing, and so I think for discipline-specific, for different data-specific types,

57:04

it is possible to find repositories that can handle that data and also discuss with project officers

57:10

different options for particular data types and where best to share it and make that successful.

57:16

Elyse Sullivan: Wonderful, and one of the resources that you mentioned earlier, that NIH actually has a kind of sortable,

57:23

filterable list of repositories that NIH maintains, and so if folks are looking for a place to start,

57:30

that could be a great place to look at, and there's also some lists there. So the ...

57:35

As you said, the ecosystem is large, and it's constantly changing, but we're trying to help people navigate

57:41

that as much as possible, and the lists are on the sharing website,

57:49

and maybe our trusty colleague can pop in the link to that,

57:54

in the chat for folks. All right. Another question, Julia, about some repositories.

57:59

Let's see. What if some ... What if the data that is generated

58:05

can't be shared during a repository? For example, it can't be de-identified,

58:12

but maybe it could be shared with a data use agreement and shared sort of under other auspices

58:18

that are not within a repository. Can you talk about what folks should be considering and how many years maybe the institution

58:26

must retain this data? Julia Slutsman: So the policy is really flexible in how data is most appropriately shared for given projects,

58:35

and so the Data Management Plan should discuss, given the potential limitations for a specific project,

58:41

what the best proposed plan for sharing the project might be. In terms of how long data should be shared,

58:49

that really depends on a number of considerations. If it's shared in a repository, most of the repositories may have their own best practices.

58:56

Institutions might also have their own policies with requirements for maintaining data and records,

59:01

and there might be other applicable laws and regulations, so there are a lot of different considerations that could drive how long data should be shared.

59:09

Elyse Sullivan: Thank you. Julia Slutsman: Not an easy answer for that one. Elyse Sullivan: Thank you. We're going to switch

59:16

to sort of funding and budgets. Cindy, I'm going to direct these to you. Let's see.

59:24

If expenses to maintain the infrastructure will extend beyond ...

59:29

the infrastructure for sharing data will extend beyond the project period,

59:35

how should people consider kind of putting in budget and funding requests for that type of cost?

59:41

Cindy Danielson: Sure, yeah, a good question, and as Julia just mentioned, in terms of what that timing would be, that's really flexible

59:49

and left up to what makes sense for each project, but, yes, there would certainly be cases, probably most cases,

59:57

when you would want to share data beyond the project period to ensure that the data you generated do remain useful.

1:00:03

And so in that case, all costs to support the sharing, repository fees, for example,

1:00:09

those must be incurred during the performance period, and that includes for scientific data

1:00:14

that will be preserved and shared beyond the award period. As an example, if your DMS Plan proposes to preserve

1:00:21

and share scientific data for 10 years in an established repository that does have a data deposition fee,

1:00:28

the cost for that entire 10-year period must be paid prior to the end of the period of performance,

1:00:34

and I would like to turn to our colleagues in OPERA to see if they have any additional details to add on that point.

1:00:43

Xanthia James: Hi. This is Xanthia James with OPERA. We don't have any additional comments to provide.

1:00:49

I think you covered it fairly well. Elyse Sullivan: And sort of a follow-on for you, Cindy,

1:00:56

you mentioned allowable and unallowable costs and certain things like infrastructure

1:01:02

to kind of conduct the research versus something that's very specific like a repository fee.

1:01:08

Did you want to kind of elaborate? What are those distinctions?

1:01:14

Cindy Danielson: So, yeah, and when you're thinking about an overall budget for your project, you will need to think about the different activities

1:01:21

that you'll need to do to preserve and share your data, and some of that that is really specific to your project,

1:01:27

that's most likely going to be the direct costs that you'll be including in your budget request,

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but there might be other types of costs that if your institution has resources available,

1:01:39

institutional data librarians, for example, who are helping across projects,

1:01:44

that might be funded out of your institutions and direct costs, and I know we can't answer every individual question

1:01:52

about different situations, but generally it's project-specific data management and sharing costs versus institutional overhead

1:02:00

costs that are spread across multiple projects. Hopefully that's helpful, and again, my OPERA colleagues

1:02:08

might be able to add some more specific details about how those costs could be determined.

1:02:13

Xanthia James: Yeah, so, Cynthia, I agree with what you just expressed, and I also want to add that we just want the applicants

1:02:22

to keep in mind that you just need to be ... However you want to account for those costs,

1:02:28

you just need to be consistent in how your applying direct and indirect costs throughout your budget

1:02:36

and also as it applies to your DMS costs.

1:02:42

Elyse Sullivan: Great. Thank you. One more question about funding,

1:02:48

will NIH be funding larger amounts of money per award

1:02:54

to account for these costs? Cindy Danielson: Sure, so we're definitely understanding

1:03:02

that this is going to be a new thing for money to think about these costs separately,

1:03:08

and we do just want to make you aware that NIH does provide many resources

1:03:14

to support data management and sharing generally. This includes in the form of repositories, tools

1:03:20

and sometimes funding opportunities to support data sharing in certain cases. NIH will continue to assess data management

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and sharing costs to determine appropriate resources as needed in the future.

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This question also makes me think of some questions that I think we've been getting about whether NIH will be raising different caps

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or thresholds and limits, and on that question, I do want to turn to OPERA to provide any insight.

1:03:49

Xanthia James: Yes, Cindy, as you mentioned, this is a new policy. We're trying to ...

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We're using this initial year to kind of work out the kinks and assess how we're going to move forward,

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so with that being said, our ... NIH is currently finalizing the strategies

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for how we're going to address additional costs

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that either may be incurred during the project period or after the project period and more ...

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We'll provide more formal guidance on that in the near future.

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Elyse Sullivan: Thank you. We have a few questions about research involving humans,

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so, Julia, I'm going to address this first question to you. DMS plans do ask about some things

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that are included in something that would be reviewed by your IRB.

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Should folks be working with their IRBs ahead of applying, ahead of creating their DMS plan?

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What would you suggest? Julia Slutsman: So that's a really good question. So NIH doesn't require that IRBs review DMS plans,

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but certainly part of the discussion [Indistinct] of the plan will include consideration

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that limitations to data sharing, and often those limitations come from informed consent or might come from IRB review,

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so as investigators develop those plans, if there's any questions about what are the appropriate applicant limitations,

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that's a good time to reach out to the IRB for clarification and just for discussion.

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And another time point to do that too is in developing informed consent forms and thinking about what might be appropriate language

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to describe future data sharing, and NIH issued in May 2022 some sample informed-consent language

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related to data sharing and future use of data that's a good resource for that, but that's another point in time that investigators

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could consider talking with IRBs as well. Elyse Sullivan: Thank you, Julia.

1:05:55

Taunton, this next question is for you. How does NIH intend to approach data-sharing requirements

1:06:01

when working with sovereign native nations? I know that you've been developing

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some additional guidance on that. Taunton Paine: Sure, so I think there's actually several relevant provisions in the policy

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and in related guidance for when researchers are actually working with tribes.

1:06:19

First, I want to sort of repeat what's in the policy and in the guidance and say that NIH respects and recognizes tribal sovereignty

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and American Indian and Alaska Native --

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the concerns that those entities sometimes have with data sharing,

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and we've indicated through an FAQ to the policy that justifiable limitations on data sharing do include

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when there are explicit tribal laws, regulations or policies that would prohibit

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or would limit disclosure of data in some way. Earlier this year, NIH actually proposed

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additional considerations for when working with tribes

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in a draft, supplemental information on responsible management and sharing of those data,

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and as was mentioned during the webinar, a central tenant of these proposed considerations

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is to facilitate respectful partnership and mutually agreed upon data management and sharing practices,

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which may ultimately require limitations on sharing in some of those cases,

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and we're actually working to finalize this document, and we plan to address these factors

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in more detail in a second webinar. Elyse Sullivan: Thanks, Taunton.

1:07:42

And another question for you, will there be additional guidance on controlled access sharing and associated data use agreements?

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Taunton Paine: Sure, so alongside that draft supplemental information that was published earlier this year,

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there's actually a second one on protecting research participant privacy

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that goes into a little bit more detail about what NIH is thinking in terms of what would constitute

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sort of best practices and operational principles for sharing human research participant data

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and does try and actually provide a set of considerations for when it would be warranted to share data

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through a controlled access mechanism and some thoughts also on the use of data-use agreements, so we'll be finalizing that later this year as well

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and also try to take that up in more detail in the second webinar too.

1:08:38

Elyse Sullivan: Thank you. Let's see. Cindy, next question is for you.

1:08:43

What about a competitive renewal? Are there any implications for what happens to data from ...

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that were under kind of the prior award period? Cindy Danielson: Sure, so, yeah, for those projects

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where you have an ongoing award, you won't be expected retroactively to satisfy this policy. When you'd come under the policy

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is when you are coming in for a competitive renewal, and in that case, we do expect you

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to propose a data management and sharing plan, and the policy is quite flexible,

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so we'd like you to think on what data you will be generating,

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and for projects that have been ongoing and generated some data and will continue to add to that,

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you might need to think through that a little differently than a completely new project, but the idea is that we're looking for proactive planning,

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and so when you're coming in for the next segment, then think about the data that you'll be generating

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and whether there are any considerations about the data

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you have already generated that you'll continue to use, so I guess it's a little hard to answer that

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because it will vary depending on the situation, but the idea is that looking ahead you'll be considering

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what data you might be appropriate to share. Elyse Sullivan: Thanks,

1:10:07

and another question for you, Cindy, what about the allowability of hyperlinks in a DMS plan?

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Can you talk a little bit about that? Cindy Danielson: Sure, so hyperlinks are not allowed per policy

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unless that they're specifically noted in a particular funding opportunity announcement or a form field instructions,

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and so that means that we will not be looking for hyperlinks, and, sorry, you should not include hyperlinks

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in your DMS plans. Where you'll more likely be telling us about what you've generated

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and where it's shared would be the RPPR. So ... Well, you shouldn't have hyperlinks in your initial DMS plan.

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Once that's been approved and you start generating and sharing data, we certainly want to hear about the progress of doing so,

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and so you can point to where shared data might be located in your progress reports,

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but due to the hyperlink policy, we do not want you to include those links in your DMS plan. Elyse Sullivan: All right. Thank you.

1:11:06

Cindy, another one for you, you've mentioned in applicability that training and fellowship

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would be excluded from this policy. Can you clarify if these folks will,

1:11:21

in fact, be generating scientific data, will they still have to propose these DMS plans, or are they not required to be submitting these plans?

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Cindy Danielson: So if you are coming in with a training or a fellowship application, you will not be submitting a DMS plan,

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and that's because the purpose of training and fellowship programs is to support training rather than research,

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and so consistent with other NIH data-sharing policies, the T's and the F's will not be subject to the DMS policy,

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training programs, support stipends, tuition fees, training-related expenses,

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travel, facilities and administrative costs and fellowship programs for stipends, tuition fees,

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training-related expenses and travel care, so these are not research-focused, and therefore they're not subject to the DMS policy,

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and, yeah, so as both the T's and the F's do not support the generation of scientific data,

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they will not be subject to this policy, and in general I've seen a number of questions

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coming in about certain specific activity codes, and NIH will continue to review the full scope of activity codes

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and will update FAQs accordingly to communicate which ones are subject to the policy and which are not,

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and we will provide more information on the sharing.nih.gov website when that is available.

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Elyse Sullivan: Thanks, Cindy. And a question, let's give this one to Taunton

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regarding the timing of sharing. So must data be shared upon the first publication,

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or is it acceptable to share data once all publications have been, I guess, submitted and approved?

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Taunton Paine: Sure, so the Data Management and Sharing Policy indicates that data should be shared

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by the time of the publication in a peer-reviewed journal. Otherwise, they can be shared

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by the end of the period of performance of the award.

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Elyse Sullivan: Great, so in this case, it would be -- The first time you publish on it, that's your time point?

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Taunton Paine: That's right. Elyse Sullivan: Great. Let's see. Cindy, a cost question for you,

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are DMS costs excluded from the 250K modular limit

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or the 500K limit for prior approval? Cindy Danielson: I'll turn this question to OPERA.

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Xanthia James: Hi. We will have to follow up with that question.

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That's a question we'll have to follow up with and will provide an answer in our FAQs on that,

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so thank you for providing that question. Elyse Sullivan: Great. Thank you.

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Next question sort of about compliance. Cindy, who is responsible for confirming

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that the PI has complied with the plan? Is it NIH, or is it the institution?

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Cindy Danielson: Sure, so in terms of compliance with the plan, what we are looking for is that what you indicated

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in your version of the plan that was approved, that you have followed through with that, and what exactly will be looked at will vary,

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but generally we're expecting that you'll put things like timelines for generating

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and depositing data in repositories, that type of thing. And so on an annual basis

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as part of the RPPR annual reporting process, we'll be asking the recipients to report on their progress

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implementing their specific DMS plan, and then the NIH staff that oversee that award

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will be looking at that information and seeing whether you did do what you said you would

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and working with you in case there are any challenges, and if anything changes over time,

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then you would have the opportunity to update your plan as appropriate. And if there's a question of who's responsible for that,

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NIH will certainly monitor your compliance, but we're also asking in your plan for you to indicate

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who at your institution will be responsible for looking at things from your side, so it really is a partnership there.

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Elyse Sullivan: Thank you, Cindy. So, Taunton, this next question is for you.

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Will data-sharing plans be made public, for example, in RePORTER or some other way?

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Taunton Paine: Well, I actually might defer this question to Cindy, who I think addressed it in the webinar.

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Cindy, is there anything you want to add there? Cindy Danielson: Sure, just that we are looking to learn

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the best way to do this. We would like to make these public in a way that makes the most sense

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and make sure that that helps individuals locate data

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in case they want to use that in their research, for example, and so we're going to be looking at the plans we receive

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and thinking about how that information can be made available and where would make the most sense to do that,

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so that remains open, but we're definitely interested in that. Elyse Sullivan: Thank you.

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Another question about sample plans, will there be samples available?

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See, Taunton, do you want to start? Taunton Paine: Sure, yeah, so there's a number of efforts going on that I think are pertinent to this,

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so first off, I think I mentioned during the webinar that there is actually a sort of a effort

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going on underneath FASEB that involves prizes for actually developing sample plans

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for different types of work as well as prizes related to sort of large data-sharing projects as well,

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so I would definitely encourage you to look into things like that. In terms of what NIH is doing,

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there is a number of sample plans that actually have been made publicly available,

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so on the NIMH website, for example, there are some there in terms of research

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that might fall within their category

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that would also be subject to the Data Management and Sharing Policy. I think there is an interest. It's certainly something,

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a question that we hear from time to time, so we may be providing more resources

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like that across the agency as well. Elyse Sullivan: Thank you.

1:17:55

Taunton, another question for you, what about negative data that are generated during a project that really aren't going into publication?

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Will those be up for sharing? Taunton Paine: Sure, so I think the policy was pretty clear back

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when it was published in October 2020 that NIH did want to include things like null results

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and data that underlied those as part of this policy, so if they're not published,

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it would be expected to be shared by the end of the period of performance. Elyse Sullivan: Thanks. Let's see.

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A question on consent, what if participants do not want their data shared,

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and must a participant agree to having their data kind of shared

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before participating in the research? See, Julia, would you like to take this one?

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Julia Slutsman: Sure, so this is something that really is described and indicated in the protocol and informed-consent document,

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so it should be very clear in informed-consent documents whether participation in a particular project

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involves sharing of data or does not, and often consent forms will have options

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for which critical aspects of participant [Indistinct] are required and which are not required

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[Indistinct] optional sometimes. Having data shared in the future could be optional, but it really is something

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that is specific to a particular protocol as described in informed consent.

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Elyse Sullivan: Great, thanks, and, Julia, another question, is a preprint considered published

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with regards to the sort of the time point of sharing? Julia Slutsman: So in the description of the time point, the policy describes

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that sharing through a peer-reviewed publication in whatever format that publication comes through

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would be the time point for sharing data underlying that publication.

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Elyse Sullivan: Okay, so we would say preprint, not peer-reviewed, does not kind of satisfy that time point?

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Julia Slutsman: Correct. Elyse Sullivan: Let's see. Cindy, this question is for you. What might happen

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if the DMS plan submitted might not be complete or the NIH may not deem it fully acceptable?

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Cindy Danielson: Yeah, great question, and so we do want to provide as many resources as we can now

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and point you to folks at your institution who could help you write a good DMS plan the first time,

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but we do understand this will be a learning period at first as this is a new activity you might not have done before,

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and so depending on the information you do provide in your DMS plan with your application

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when the program staff assigned to your application is assessing the content there,

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they're going to be looking at your information there to ensure that the elements of the DMS plan

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have been adequately addressed and to assess the reasonableness of those responses, and so, depending on what they find there,

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if they're missing information and they're unable to determine if that is reasonable or not,

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then you would expect NIH staff to reach out to you during the just-in-time process to ask for clarification,

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and in some cases, they might ask for a revised DMS plan and that you would work together to get your DMS plan complete

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so that it can be approved, and applications selected for funding will only be funded when program staff determine

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that the DMS plan is complete and acceptable. Elyse Sullivan: Thanks so much. All right.

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Looks like we have probably time for just one more question or a couple more questions before we wrap up.

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So there's a question about sharing data that doesn't have sort of a best practice

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or that may be useful but not necessary to sort of replicate a finding.

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Are there anything ... Taunton, can you speak to us about sort of what folks should consider

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in terms of using a repository ... open-access repository versus sort

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of keeping that data on an institutional server and making it available as needed?

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Taunton Paine: Sure, so I think there's two questions here, first about maybe whether there are best practices

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or standards for sharing data, and second data that maybe perhaps don't meet the definition of scientific data in a policy.

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So in the first case, we would, generally speaking, expect people to describe sort of anticipated standards

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that you'll be using when sharing data.

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You can indicate though that there are no sort of consensus standards within your scientific field

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for actually applying to the data that you're proposing to share,

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but again, that's for scientific data. So in a case where you have sort of other data

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that might not meet the definition of scientific data perhaps because it's not necessary to replicate

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or validate research findings, that policy would not, generally speaking, expect those to be shared

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or to be sort of addressed in plans. There's nothing that prevents you from being able to share those as well,

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and I do want to point out that there are other NIH policies, such as the NIH Genomic Data Sharing Policy,

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which may actually expect sharing of data that could have a potentially broader scope

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than the Data Management and Sharing Policy, so there may be other expectations that would expect those data to be shared,

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but this policy would not necessarily expect you to do so. Xanthia James: Hi. This is Xanthia.

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I also wanted to jump in and add that our policy also states

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that when there's a situation where it's scientific data that's not leading to the generation of a publication,

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it's expected to be shared, but we just ask that you share it by the end of the award period as opposed to data

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that is actually leading to the generation of a publication. That's expected to be shared as soon as possible

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and no later than the time of the associated publication. Taunton Paine: Right, and just to clarify,

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that's for data that meet the definition of scientific data, but there may be some cases where you have additional data types

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that might not meet that definition. Elyse Sullivan: All right. Thank you, guys.

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We've got just 4 minutes left. I hope that the questions that we did get to were useful.

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I just wanted to wrap us up by pointing out a few resources that we have to share with you all.

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So we've been shouting out links and referencing the NIH Scientific Data Sharing website.

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That's a great place to start. We have populated that with all the information that we have at this time point,

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and it's something that we will be continually updating, so for example, we're pushing new FAQs

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and updated FAQs very regularly. I believe I have a slide to show

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if whoever is controlling the slides there. That would be great. Thank you. Thank you. Thank you.

1:25:19

Let's see. We also have a dedicated inbox for questions about data sharing,

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so the sharing@nih.gov is our dedicated inbox if folks are having questions.

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We do also want to encourage folks to reach out to program officers and program staff

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if there's proposal-specific questions and utilize your institutional resources,

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for example, data librarians, data managers and folks in your sponsored programs' offices.

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Let's see. We do want to plug our webinar two, webinar number two. We're going to be diving deeper into topics,

1:26:00

so September 22nd, go ahead and register. It's a separate registration than this event,

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and we're going to be tackling some follow-on topics here. We also want to close by saying we're committed

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to keeping you folks in the loop as much as possible, so we wanted to plug some of our blogs and LISTSERVs

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and where to follow us on social media because there has been a lot of movement on this topic recently,

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and we know that we are planning on putting out some additional resources, so please do follow us and check back in to stay up-to-date.

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And with that, I wanted to plug one more event.

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We are doing a virtual NIH conference that has ... that'll be in February but also has a number

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of additional sort of preconference events, so if you're interested in this topic and others,

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please check out this useful learning opportunity. And with that, I will close by offering a sincere

1:27:05

thank you to our expert panel, our tech support, our captioners, our ASL interpreters

1:27:13

and everyone who made this a useful event. Thank you so much for tuning in, and like I said,

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we will be making the recording, the links, the slides, everything as available as we can.

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So do plan to tune in for webinar two

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when we can hopefully get to some additional topics. So thank you so much.