0:00

Elyse Sullivan: Welcome again. We'll go ahead and get started. Welcome to part two of the New Data Management

0:07

and Sharing Policy webinar series, diving deeper into the New DMS policy. My name is Elyse Sullivan

0:16

and I'll be moderating today's event. And joining us from the Office of Science Policy,

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

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The format for today's session will include a brief recap from part one of our webinar series.

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Then we'll go into a pre-recorded discussion session with our expert panel

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and then we'll have about 40 minutes of live Q&A from our audience.

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And several of you submitted questions in advance of this webinar and we've incorporated as many of those as we can into

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our pre-recorded panel discussion. And during the live Q&A portion, we're going to try

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and get to as many new questions as possible.

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So while the pre-recorded discussion is playing, we invite you to enter any questions that you had in the Q&A box

1:16

that'll be located at the bottom of your screen. So go ahead and use that Q&A box to let us know

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what questions you have. Our team will be on the backend compiling these questions

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and we'll use those questions to structure our live Q&A portion of the event,

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and you all will actually be able to help us prioritize those questions using the up-vote capability.

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So you can go ahead and give the thumbs up and up-vote any questions that are asked

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that you think would be helpful.

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We hope you don't experience any technical or logistical issues, but if you do, go ahead and let us know in that Q&A box

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and we'll try and help you out. I did want to mention that this entire session is being recorded

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and it'll be made available in about a week. We've also put together some resource slides

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to accompany today's session and these are available on the NIH sharing site at sharing.nih.gov/about/learning.

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And in the chat, we can put a direct link for folks to access those slides.

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Okay, now we're ready to dive in and let's queue up our prerecorded panel discussion,

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and it may just take one moment to load.

2:47

In today's webinar, we'll be covering additional topics that were not covered in detail in the first webinar,

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but that we know there's a lot of interest in. We'll be discussing protecting privacy

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when sharing data from human research participants, the responsible management and sharing of American Indian

3:05

and Alaska native participant data, and we'll go into the interaction of the genomic data

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sharing policy with the data management and sharing policy. We'll also discuss a number of other topics

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that we have received questions on, such as intellectual property, informed consent,

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secondary research and timelines for sharing.

Webinar 1 Recap & Policy Overview

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We're going to start with a few minutes on the DMS policy basics and a recap of the topics covered in Webinar One.

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For those who missed our first webinar, we encourage you to view the recording and take a look at the resource slides provided.

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And as we covered in Webinar One, NIH has long been committed to making the results of research available,

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and the new DMS policy really promotes the transparency and accountability in research

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by setting a minimum expectation for data sharing. This means that other policies or IC specific expectations

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may build upon this requirement, but this policy does set a consistent baseline across NIH.

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And in terms of applicability, all research funded in part or whole by NIH

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that produces scientific data is subject to the policy. And we encourage folks to check out our webpage

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on research subject to the policy for more specifics.

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As for the requirements of the policy, they're quite simple. One is that all applications subject to the DMS policy

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are required to include a DMS plan that details how data will be managed and shared,

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and two, that investigators and institutions follow through and comply with the approved plan.

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In Webinar One, we also discussed how to prepare DMS plans and budget for related costs.

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As a reminder, DMS plans should describe how the data will be managed and appropriately shared by addressing six key elements.

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And we've provided an optional format page or template that investigators may find helpful

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in structuring their plans. And we really recommend taking a look at our page on writing a DMS plan for all these details.

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Regarding costs, you are allowed to request funding to support the data management and sharing activities

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that you describe in your plan. And we would like to point folks to our page on budgeting for DMS

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for all these details on the allowable costs and where to put your budget.

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Finally, we touched on the timing of when data should be shared and factors

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to consider when selecting a data repository. To remind folks, the policy expects data

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to be shared no later than the time of publication in a peer reviewed journal

6:04

or the end of the award, whichever comes first. We also reviewed a number of resources for finding

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and selecting an appropriate data repository. These may be helpful when trying to sift

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through the various options out there. This information can all be found on our Sharing Scientific Data section of our website.

6:26

In closing, I do want to point out that we have a new DMS policy overview webpage.

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That's a really great place to start. It walks through the various steps from planning and budgeting to submission and review of plans,

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and finally implementing your DMS plan. Again, we do encourage folks to check out the Webinar One

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recording and resource slides if you have not done so yet. And with that recap, I'm going to turn to our expert panel

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to dig into some new topics today. Taunton, let's start by covering any recent developments

7:03

and resources since part one of our webinar series in August. Has anything changed since then?

7:11

Taunton Paine: Yes. There have been several developments since the last webinar that I'd like to mention.

Recent Developments & Resources

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NIH has provided several documents that relate to the data management and sharing policy

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and our intended to provide instructions or helpful guidance. These include a supplemental information

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relating to best practices for protecting privacy when sharing human research participant data,

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and another supplemental information on considerations and best practices when conducting research

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with American Indian and Alaska native participants. We also issued a notice about how NIH

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is harmonizing some aspects of the genomic data sharing policy with the data management and sharing policy,

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in particular, focusing on how plans for sharing genomic data should be communicated to NIH.

8:00

The other panelists and I will be discussing these topics in more detail in this webinar.

8:05

I do want to address one development that I'm sure many on this webinar are aware of and may have questions about.

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No doubt many of you know that on August 25th, the White House Office of Science and Technology Policy

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published a memo directing all federal agencies that support research, including NIH,

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to expedite access to results of federally funded research. NIH supports this important step

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in advancing transparency and accessibility. To be clear, the first requirement

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is for federal agencies to develop plans in response to this memo. And over the coming months,

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NIH will work expeditiously to develop and share its plans for implementing the White House directives.

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What's important to know for today's conversation is that we anticipate that the data management and sharing policy that we're discussing in these webinars

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is consistent with the directives of the memo and we do not anticipate making changes to the policy or its implementation.

9:03

Elyse Sullivan: Thanks for the update. And you mentioned that NIH just released a supplement

Protecting Privacy When Sharing Data From Human Participants

9:08

to the DMS policy on protecting privacy when sharing data from human participants.

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Can you tell us a little bit more about that and is it introducing any new rules?

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Taunton Paine: So the supplemental information on protecting research participant privacy is the direct result of public comments

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and requests from the research community for additional clarification from NIH on how to appropriately share data

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from human research participants under the DMS policy. Let me emphasize first that this supplemental information

9:41

is not intended to be a guide for compliance with any regulatory requirements, nor is it establishing binding rules for NIH awardees.

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Researchers must of course continue to follow any applicable laws, regulations and policies

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related to protecting privacy. Rather, the supplemental information provides a basic framework

10:03

to help researchers and institutions consider options for protecting privacy

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when sharing data from human research participants. It is also intended to update and replace guidance

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that was previously provided under the 2003 data sharing policy. This framework is intended to be broadly applicable

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for the range of research activities that might be conducted under the data management and sharing policy.

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So it addresses both identifiable and de-identified information. It's also meant to be considered for different data types

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and data that may have been collected in different settings. Elyse Sullivan: Thanks, Taunton.

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And can you summarize for us some of the best practices that are laid out in this resource?

Deidentifying Data

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Taunton Paine: Sure. So I want to start by mentioning that the supplemental information provides

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one set of best practices and acknowledges that there may be other strategies for implementing

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the principles and protecting privacy. The supplemental information provides

11:02

three basic best practices that are intended to be implemented together. First, NIH recommends that scientific data

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be de-identified to the greatest extent that maintains sufficient scientific utility and data

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should generally be shared only in de-identified form. We've indicated that the appropriate standard

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for de-identification by default should be meeting the standards in both the Common Rule and the HIPAA privacy rule,

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even if these rules do not technically apply to the sharing and subsequent research use of the data.

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Elyse Sullivan: And are there any examples or resources for de-identification that we can point people to?

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Taunton Paine: The supplemental information provides a few examples of relevant tools such as the National Library of Medicine's

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clinical text de-identification tool, but regarding de-identification,

11:55

the supplemental information also acknowledges that there may be cases where certain types

12:00

of potentially identifying information may not be sufficiently addressed by applying the regulatory standards for de-identification.

12:07

For example, certain types of information even when de-identified from a regulatory perspective, may increase the risk of identifiability

12:15

of research participants by allowing inferences to be made about a participant's identity

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when combined with other information. This can sometimes be a challenge for certain types of data,

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including some types of qualitative data. For example, in a focus group or interview,

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a participant might share details from their personal life that could increase the risk of re-identification

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even if it meets a regulatory definition for being de-identified. Researchers should consider the appropriateness

12:43

of modifying this type of information or sharing data only through controlled access.

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We recognize that in some cases, scientific utility may be lost if shared data are de-identified.

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So it may be appropriate to share data that meet a regulatory definition of identifiability

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when there is explicit consent to do so and if all other applicable legal and regulatory

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requirements for sharing such data are met. As another best practice, NIH recommends using agreements for sharing scientific data.

Agreements for Sharing Data

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These agreements help make clear the appropriate uses for downstream users, especially in cases where access is controlled.

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We've provided a few elements that we think are important to include in such agreements

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including actually communicating that the institution sharing the data considered the risks associated with doing

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so, generally prohibiting any attempt to reidentify or recontact participants

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or their family members and actually communicating any limitations on subsequent use.

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Elyse Sullivan: Thanks, Taunton. And does NIH provide any example agreements for folks to reference?

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Taunton Paine: Good question, and we heard a number of comments requesting that NIH provide standard agreements.

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We do provide in a supplemental information as an example the data use and transfer agreements

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developed by the Federal Demonstration partnership. And we may provide a template form in the future

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that includes these elements specifically. The last thing I'll mention as part of the best practices

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is that the supplemental information reminds institutions that they really need to understand

14:25

the federal, tribal, state and local laws that may apply to their research and may restrict disclosure

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or set requirements for sharing scientific data such as the Common Rule, HIPAA or certain state laws.

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In particular, we want to ensure that researchers understand when the data they share may be protected

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by certificates of confidentiality and that users of data protected by a certificate are aware of those protections.

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Elyse Sullivan: Thanks. And since you just mentioned certificates of confidentiality, let's take a moment to review what those are

Certificates of Confidentiality

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and how they relate to the DMS policy. Julia, could you give us a summary?

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Julia Slutsman: Certainly. The bottom line is that scientific data may be protected by a certificate of confidentiality and data

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protected by certificates can be shared in a manner consistent with those protections. So the protections offered by certificates of confidentiality

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are not a barrier to the kinds of responsible data sharing envisioned in the DMS policy.

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To give just a bit of background for those not familiar with them, certificates of confidentiality help researchers

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protect the privacy of research participants' data by prohibiting disclosure of identifiable

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sensitive information including in response to a subpoena or court orders.

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The NIH certificates of confidentiality policy applies to all biomedical, behavioral, clinical

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or other research funded wholly or in part by NIH that collects or uses identifiable

15:52

sensitive information. Certificates provide protection in perpetuity.

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NIH and other federal agencies issue certificates of confidentiality under authorities

16:02

from the Public Health Service Act and the 21st Century Cares Act. Institutions and their investigators are responsible

16:09

for determining whether the research is subject to the policy and are responsible for ensuring that no information is disclosed

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unless permitted under the terms of a certificate of confidentiality. It's important to note that there are certain specific

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situations where identifiable data protected by a certificate can be disclosed, such as when a research participant

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voluntarily discloses the information or when the disclosure is made for research purposes, or when mandatory reporting requirements

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apply to researchers. I encourage you to refer to the NIH Grants Policy website for more detailed information

16:40

about certificates of confidentiality. Elyse Sullivan: Thanks Julia. And getting back to the supplemental information

Controlled Access Data

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on protecting privacy, Taunton, you've mentioned that some data could be shared through controlled access.

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Can you talk a little bit more about what that means? Taunton Paine: Yes. The data management and sharing policy encourages

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researchers to actually consider whether scientific data should be shared through controlled access

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even if de-identified. We heard a number of questions regarding what constitutes controlled access,

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when data should be shared that way, and when data can be shared openly. The policy does not provide a definition of controlled access,

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and the exact method for controlling access may vary, but it generally consists of sharing data

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in a manner that requires review of appropriateness of requests to use data.

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Factors to consider for whether access to scientific data should be controlled include

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if there are explicit limitations on subsequent use such as for laws, informed consent or agreements,

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if data might be considered particularly sensitive due to the ability to cause individual or group harm,

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if data cannot be de-identified to the standards described in the best practices and the possibility of re-identification

18:02

cannot be sufficiently reduced, or if previously unanticipated methods or technologies

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emerge that might pose risks to participant privacy. The supplemental information also provides factors

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to consider in determining whether to share data openly, including if participants have explicitly consented

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to sharing their data that way, and if scientific data are de-identified and institutional review determines

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that sharing would pose very low risk to the research participants. Elyse Sullivan: Thanks, Taunton.

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And are there situations where researchers may need to do something different from what's described in the privacy supplement?

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Taunton Paine: Yes, definitely. We've acknowledged that the best practices and the considerations for sharing data

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that are provided in the supplemental information are just one way to protect privacy.

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In some cases, there may be laws or even NIH policies that must be followed.

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In particular, the NIH genomic data sharing policy sets expectations for the sharing of data

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such as for how investigators should de-identify human genomic data, submit data to specific controlled access repositories

19:11

and investigator responsibilities for the secondary use of these data. In those cases, we would expect researchers

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to follow those expectations. Elyse Sullivan: Thank you. Now, let's turn to the supplemental information

Responsible Management & Sharing of American Indian and Alaska Native Participant Data

19:24

on the responsible management and sharing of American Indian and Alaska native participant data.

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So Taunton, can you tell us a little bit about the purpose of this resource and how it was developed?

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Taunton Paine: Yes. So ultimately, this supplemental information is intended to assist researchers in developing

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an appropriate data management and sharing plan when conducting research with American Indian and Alaska native tribes.

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And it emphasizes respect for tribal sovereignty and trust building between researchers and tribes

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regarding data management and sharing practices. It seeks to accomplish this by providing certain considerations for researchers

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which include contextual information and related approaches that researchers should really familiarize themselves with.

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And it provides best practices for researchers to mitigate potential risks to tribes and their members such as group harm and stigmatization,

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and facilitate respectful and mutually beneficial partnerships with tribes.

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The supplemental information was developed in response to tribal nations' input received through a formal tribal consultation

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on the data management and sharing policy that began in 2019 through engagement

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with the NIH Tribal Advisory Committee and tribal leaders and with input from public comments

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from a variety of stakeholders. Elyse Sullivan: Thanks Taunton. So next, can you give us an overview

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of the recommended best practices in this resource? Taunton Paine: Yes. A critical part of the supplemental information

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is promoting an understanding of the importance of tribal sovereignty among researchers

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and the unique rights sovereignty affords to tribes to create and enforce rules for research

21:09

and sharing of scientific data. Researchers must comply with any applicable requirements

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and processes set by the tribe for conducting research and sharing scientific data, such as review by tribal

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designated IRBs or research review committees. There's another critical best practice,

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which is reinforcing the importance of proactive early discussion and clear communication

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between researchers and tribal nations about data management and sharing plans that should continue throughout the research process,

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which of course is also valuable for any research, not just projects involving tribal nations.

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Establishing partnerships to engage tribes in planning for data management and sharing before research

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begins helps to ensure an opportunity to align data sharing practices with tribal laws, policies and preferences

22:01

and to consider additional protections that may be needed. In some cases, limitations on sharing scientific data

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may be needed by applicable laws, regulations, policies, and agreements

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that may govern the sharing of data. Researchers should make efforts to safeguard

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against risks to tribes and their members by planning for appropriate protections such as consideration

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of whether a tribe may include a unique population at greater risk of re-identification or stigmatization.

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There's another important consideration for researchers and tribes, which is to determine together

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while planning for data management and sharing whether data will be managed by tribal nations,

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by researchers, or by a trusted third party. As we've mentioned, the policy strongly encourages

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the use of established data repositories and NIH has provided a set of desirable characteristics

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for repositories, but the policy does not require use of a specific repository

23:01

or indicate who should oversee it. A point to consider that is not unique to research with tribes,

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but still important for this context is that researchers should ensure that consent processes

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reflect their plans for data management and sharing. There's more detail in the supplemental information

23:19

than I'm able to go over today, so I encourage you to read it if it could be relevant for your research.

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Elyse Sullivan: Thank you, Taunton. Another topic that I wanted to touch on today is the interaction between the genomic data

Genomic Data Sharing (GDS) Policy Overview

23:33

sharing policy and the new DMS policy. So Julia, can you start by giving us a brief overview

23:39

of the GDS policy for any folks who may not be familiar with it? Julia Slutsman: Sure.

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The GDS policy went into effect in 2015. It sets forth expectations for the timely and responsible

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sharing of NIH-funded research generating large scale human or non-human genomic data

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through an NIH designated repository, as well as for the use of genomic data for secondary research.

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I want to note that individual ICs may have additional expectations to those articulated in the NIH wide GDS policy.

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NIH expects applicants who apply for NIH funding for research that generates large scale genomic data

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to describe how the data will be shared in a data sharing plan. Investigators generating large scale human genomic data

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are required to submit a submission agreement called an institutional certification to NIH at just-in-time.

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Data from research subject to the GDS policy is available through NIH designated repositories,

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including both controlled access repositories and unrestricted access repositories.

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Investigators who would like to use controlled access data submit a data access request to do so.

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If NIH approves the request to access data, the GDS policy articulates a number of responsibilities

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that investigators and their institutions must uphold to safeguard and use data responsibly.

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These responsibilities, detailed information, FAQs, and guidance about the GDS policy

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are available on the sharing.nih.gov website. Finally, I do want to highlight one important distinction

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about the scope of the GDS policy, which I was just discussing, and the DMS policy.

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The GDS policy has a broader scope as it articulates expectations for sharing of genomic data and also sets forth expectations for accessing data

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covered by the policy, whereas the DMS policy does not establish expectations for access to and secondary use of scientific data.

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Elyse Sullivan: Thanks, Julia. And will the GDS policy continue to apply to research that is also subject to the DMS policy?

Interaction Between DMS and GDS Policies

25:45

Julia Slutsman: Yes. Research subject to the GDS policy as well as the DMS policy

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will need to meet the expectations of both policies. In response to input from the community,

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NIH has taken steps to harmonize requirements across both policies and reduce burden for applicants

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and grantees whose research is subject to both policies. Elyse Sullivan: Thanks. And can you talk a little bit more

26:07

about how these policies interact and what somebody should be considering if their research is subject to both policies?

26:15

Julia Slutsman: Sure. NIH recently published a guide notice describing some implementation updates to the GDS policy

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as part of the harmonization of the two policies. I want to briefly review the areas highlighted in that notice.

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First, a separate genomic data sharing plan will no longer be required for research subject to both policies once the DMS policy

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goes into effect on January 25th, 2023. Considerations for sharing genomic data subject

26:42

to the GDS policy will be described as part of the single data management and sharing plan submitted at the time of application.

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We have more detailed guidance available on the sharing.nih.gov website for helping you complete the elements of the DMS plan

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to meet specific GDS policy expectations. Second, the process for plan assessment

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by peer reviewers for research subject to both policies will also change to support harmonization.

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Under the DMS policy, data management and sharing plans are not reviewed by peer reviewers.

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This is because considerations for sharing genomic data will be communicated through the DMS plan,

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and peer reviewers will not be asked to comment on the DMS plan nor do they factor the DMS plan into the overall impact score.

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The DMS plan will be assessed by NIH program staff. The other area that I want to highlight

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is budget considerations for genomic data sharing costs. The budget should include required costs

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for genomic data management and sharing, a brief summary of the DMS plan and a description of all requested data management

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and sharing costs must be included within the budget justification attachment.

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Fourth, compliance for awards subject to the GDS policy will be handled in accordance with the compliance enforcement terms in the DMS policy.

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We do not expect that this will result in any significant change in how non-compliance is enforced.

28:13

Finally, regarding the timing of sharing data, the GDS policy expectations have not changed.

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GDS policy guidance describes some specific submission timelines for sharing data is detailed on the website.

28:27

However, it is important to note that harmonization with the DMS policy means that the end of the performance period

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is the latest possible date to submit data in compliance with the data sharing plan.

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Elyse Sullivan: Thanks, Julia. And you mentioned that a single DMS plan should be submitted.

Single DMS Plan

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Can you talk a little bit more about how folks should be incorporating considerations for genomic data?

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Julia Slutsman: Sure. As I mentioned earlier, for applications with receipt dates on or after January 25th, 2023, subject to both policies,

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a single data management and sharing plan should be submitted at the time of funding application.

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That plan must meet both GDS policy and DMS policy expectations such as

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when and where genomic data will be shared. I want to note that the GDS policy

29:17

has expectations for certain data that may not meet the definition of scientific data. To support investigators developing data management

29:24

and sharing plans, we have updated the instructions for completing DMS plans on the NIH Scientific Data Sharing website

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and we call out where to address considerations specific to data types shared under the GDS policy.

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Let me give you an example. One DMS plan element that requires additional considerations for research subject

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to both policies is the element addressing access, distribution or reuse considerations.

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Researchers using human data will need to consider the content of the informed consent as it relates to future use and subsequent data

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sharing that anticipate any potential data use limitations that may result in accordance with the criteria

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in the institutional certification. This gives applicants the opportunity to explain in their DMS plan

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if they anticipate that their criteria and the institutional certification that cannot be met and indicate what data,

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if any, can be shared and how they plan to enable data sharing to the maximum extent possible.

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For example, in certain cases, it may be appropriate to share data in a summary format.

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In some instances, the funding NIH ICO may need to determine whether to grant an exception to the data

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submission expectation under the GDS policy.

Informed Consent

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Elyse Sullivan: So Julia, informed consent has come up in a number of contexts today. Can you discuss what the DMS policy

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expects regarding informed consent and if there's any expectations of broad consent?

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Julia Slutsman: Sure. The DMS policy does not set any additional expectations for informed consent beyond what is required

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by the Common Rule, HIPAA and the GDS policy. The DMS policy does recognize the importance of informed

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consent and NIH encourages investigators to consider how to address and communicate plans for data

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sharing during the informed consent process. You also asked about broad consent, Elyse.

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The DMS policy does not expect the use of broad consent and does not set the expectation that the informed consent

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given by participants should be obtained in any particular way. The policy recognizes that limitations to data

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sharing that are based on the content of the informed consent process may be needed and when applicable,

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these should be described in the DMS plan. Additionally, three of the supplemental information notices

31:48

to the DMS policy that Taunton referred to earlier affirm certain principles and best practices

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related to honoring informed consent. First, the notice discussing selecting a data repository

32:00

for data from NIH supported research discusses the repository should have the ability to restrict access

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and use of datasets to those uses that are consistent with participants' informed consent.

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The notice related to protecting privacy when sharing human research participant data includes the principle that researchers and institutions

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develop robust consent practices. Finally, NIH has developed a resource for investigators

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which reflects input from a wide range of stakeholders and which suggests points to consider when communicating plans for sharing data and biospecimens,

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and also includes modifiable sample informed consent language.

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Elyse Sullivan: Thanks, Julia. Next, I'd like to turn our attention to proprietary considerations and intellectual property.

Proprietary Considerations & Intellectual Property

32:48

Taunton, can you talk to us a little bit about how these issues are addressed in the DMS policy?

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Taunton Paine: Sure. So I want to start by emphasizing that under the DMS policy, researchers are expected to maximize

33:02

appropriate sharing of scientific data, and scientific data are expected to be shared at the time of publication

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or by the end of the period of performance, whichever comes first. However, NIH understands that some research,

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for example, collaborations with the private sector, may introduce questions about how

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and when to share scientific data when there are intellectual property or proprietary considerations.

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And the DMS policy addresses these issues in several ways. First, research collaborators or co-funders

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may ask applicants or awardees to sign agreements that restrict how researchers share scientific data.

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NIH has indicated that award recipients are responsible for ensuring that any research partnerships

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allow for compliance with relevant NIH policies, including the DMS policy's expectations

33:56

for maximizing appropriate sharing. Data sharing expectations should be established

34:02

prior to the initiation of a partnership whenever feasible, and any limitations to sharing should be described in plans.

34:10

In other cases, providers of materials or data needed to conduct research can sometimes impose restrictions on sharing

34:17

that are not based in informed consent or participant privacy. And NIH has indicated that such agreements

34:24

may be potentially justifiable, but researchers are advised to consult with the NIH Institute, Center, or Office

34:30

funding their research to determine how to comply with applicable data sharing expectations.

34:37

In general, the policy emphasizes prospective planning and researchers should plan for how they will manage

34:43

any intellectual property arising from the research, given the timelines for sharing data provided in the policy.

34:50

If for some reason a change is required to a timeline in an approved data management and sharing plan,

34:56

researchers should consult their program officer to determine whether the data management and sharing plan should be modified.

35:03

Finally, I want to make the point that limitations on sharing that involve withholding data for general unspecified intellectual property interests

35:12

would generally not be consistent with the policy's goals of maximizing appropriate sharing.

35:18

As with all plans that propose limitations on data sharing, NIH program staff

35:23

will review the reasonableness of proposed limitations when they assess the data management and sharing plans.

35:30

Elyse Sullivan: Thanks, Taunton. And what about NIH Small Business Awards? Are there certain considerations for this type of research?

35:38

Taunton Paine: Yes. So NIH has indicated that under the small business innovation research and small business technology

35:44

transfer program policy directive, SBIR and STTR awardees may withhold applicable data

35:51

for 20 years after the award date as stipulated in the specific SBIR or STTR funding agreement

35:58

and consistent with achieving program goals. SBIR and STTR awardees may retain the rights to data

36:05

generated during the performance of an SBIR or STTR award for up to 20 years after the award date

36:12

per the program policy directive. So an acceptable data management and sharing plan can reference

36:17

and incorporate these data rights. Elyse Sullivan: Thanks. Let's dig into limitations on sharing a little bit.

Review of DMS Plans & Proposed Limitations on Sharing

36:26

So Cindy, we've described a number of situations today where researchers might propose to limit

36:31

the sharing in their data management and sharing plan. Can you talk a little bit about how these limitations

36:37

will be reviewed by NIH? Cindy Danielson: Great question. As we know that researchers and institutions are interested

36:44

in understanding how their DMS plans will be assessed and what happens if something in their DMS plan

36:49

is not found to be acceptable. I'd like to point out a recent guide notice where we provided some details on implementation

36:56

of the DMS policy. We noted here that program staff at the proposed NIH institute, center or office,

37:03

will be looking at completeness and reasonableness. That is, ensuring that the elements of a DMS plan

37:09

have been adequately addressed and assessing the reasonableness of those responses.

37:15

This includes an assessment of any proposed limitations on sharing stated in the DMS plan.

37:21

Applications selected for funding will only be funded when program staff determine that the DMS plan is complete and acceptable.

37:29

This is not a one size fits all process because the determination of whether a specific data management or sharing strategy

37:36

is acceptable depends on the context. Each DMS plan will be assessed within the context

37:42

of the proposed research project. In terms of limitations, NIH has clarified some potential examples of justifiable factors

37:51

that may limit the sharing of data in an FAQ. The specific factors that may limit sharing

37:57

will vary by project, and the goal of mentioning these upfront is to ensure that any limitations have been considered from the beginning.

38:05

The goal is to maximize appropriate sharing, so when NIH program staff are assessing a specific DMS plan,

38:12

they will be looking at whether that DMS plan appropriately considers and describes these factors.

38:19

Elyse Sullivan: Thanks, Cindy. So now let's turn to the timeline for data sharing. We covered this topic in Webinar One,

38:26

but we've received some questions. I want to elaborate about a couple of things. So Cindy, can you walk us through

Timeline for Data Sharing

38:32

what counts as publication for the purposes of the DMS policy?

38:37

Cindy Danielson: Good question, since I know that timing is on the top of everyone's minds, especially for those of you who have been thinking

38:43

about the White House memo that Taunton mentioned earlier. As a reminder, the DMS policy applies both to scientific data,

38:51

underlying peer reviewed journal articles and to scientific data underlying findings

38:56

not disseminated through peer reviewed journal articles. In all cases, scientific data should be made accessible

39:02

as soon as possible, but there are some time points for when this should happen. We've clarified these time points in an FAQ.

39:10

In terms of articles published during the award period, scientific data underlying peer review journal articles

39:16

should be made accessible no later than the time of publication. Publication is defined as the date on which the article

39:24

is first made available in print or electronic format, that is the earlier of those dates if they differ.

39:32

Elyse Sullivan: Thanks, Cindy. And we know that many researchers are taking advantage of pre-prints.

39:38

Does posting a draft of an article on a pre-print server trigger this data sharing expectation like it would with a publication?

39:46

Cindy Danielson: Only a peer reviewed journal article triggers the data sharing expectation during an award.

39:52

That means that NIH's DMS policy does not require the scientific data underlying a pre-print to be made accessible

39:59

when the pre-print is posted. However, scientific data underlying findings that are not disseminated in peer reviewed journal articles

40:08

should be shared by the end of your award, which may include data underlying pre-prints.

40:13

You should also keep in mind that pre-print servers may have their own requirements to share data upon pre-print posting,

40:20

and likewise, repositories storing your data may also have their own requirements for public release of data upon pre-print posting.

40:28

While these are not NIH expectations under the DMS policy, they are something that researchers

40:33

should be prepared for. Elyse Sullivan: Thank you.

40:39

And we've received a number of questions regarding the use of existing data or secondary data analysis.

Use of Existing Data & Secondary Data Analysis

40:46

Taunton, can you help clarify sharing expectations in these cases? Taunton Paine: Yes.

40:52

And there's a couple relevant scenarios to consider. A common situation is when researchers are accessing data

41:00

that have already been shared, such as through a repository. We've provided an FAQ on this

41:06

and I want to state clearly that the primary data that researchers access from repositories

41:12

or that have already been shared in some way are not expected to be shared again.

41:17

There's a number of reasons for this, including that we do not want to create duplicated records and increased storage burden unnecessarily.

41:24

However, we also recognize that there may be scientific data generated by analyzing the primary data

41:31

and the policy would generally expect researchers to maximize appropriate sharing of these data.

41:37

Researchers should be aware in those cases that repositories sometimes place restrictions on the ability

41:43

to share derived datasets and those limitations should be described in plans.

41:48

More careful consideration is required when researchers use primary data that have not been shared,

41:54

either that they maintain themselves or that they obtained from another source. Although the policy emphasizes prospective planning

42:02

for managing and sharing data generated in research, researchers should consider when the research is based

42:08

on the actual analysis of primary data that have not been shared, whether sharing their scientific data

42:15

will provide sufficient context for users. Even though it may not be expected by the policy,

42:20

in some cases, it may be possible and valuable to share primary data that were not generated under the award,

42:27

taking into account potentially limiting ethical, legal or technical factors that we've discussed before,

42:33

such as informed consent, privacy and agreements governing the use of primary data.

42:39

And when primary data are used, it's also an important best practice to appropriately cite primary data even if they aren't shared.

42:49

Elyse Sullivan: Thanks, Taunton. Okay, I've got one more question for the panel before we go to our live Q&A segment.

42:56

In the last webinar, we discussed how the DMS policy will apply to research rewards

Research Activities Subject to DMS Policy

43:02

leading to the generation of scientific data. Is there any more detail that we can share

43:07

to help folks determine if the DMS policy applies to them? Cindy Danielson: Yes, great question,

43:13

since at our last webinar we did mention that this was coming, as a reminder, the DMS policy applies to research

43:20

that results in the generation of scientific data. NIH has finalized the list of activity codes

43:26

that will be subject to the DMS policy and posted this on the sharing site in the section

43:31

about research covered under the data management and sharing policy. As an example of what is included,

43:37

you'll see many activity codes starting with R as most research projects will be subject to the DMS policy.

43:44

Also subject to the DMS policy are certain career development awards or Ks,

43:49

small business research including SBIR and STTR and research centers.

43:56

I'll also mention some examples that you won't find on the list because they support non-research projects

44:02

or research projects not generating scientific data. The DMS policy does not apply to activities such as training,

44:09

fellowships, construction, conference grants, resources and infrastructure development. This list might be helpful

44:17

if you are doing some early planning and want to understand whether your application will require submission of a data management

44:24

and sharing plan. You'll need to refer to the application guide and the specific funding opportunity announcement

44:31

that you're responding to for detailed application instructions. It's also worth noting that some NIH institutes,

44:37

centers, offices or programs may have additional data sharing expectations,

44:42

and these requirements would also be indicated in the funding opportunity announcement. But we know some of you want to see this policy applicability

44:50

at a high level even before you've identified a specific announcement. So feel free to take a look at the list now

44:56

to get an early idea of what will be needed. Elyse Sullivan: Wonderful. Thank you, panel. And now we're going to turn to our live audience

45:03

to take some additional Q&A.

45:15

Hello, welcome back. I hope you enjoyed that segment

45:21

and that you were able to hang with us through a little bit of technical difficulties. So thanks for hanging in there. My favorite part of the session

45:32

is we're going to bring in all of our panelists and some additional Q&A folks to answer your questions live.

45:39

So we had asked you to use the Q&A box, our team has been behind the scenes compiling them,

45:45

and sorting them into topics, and so we are going to try and get through as many as we can.

45:51

And then at the end, we will go through just a couple of resources on where to go for more information before we close.

45:58

So hey, Durant, can you put back up the slides, I just wanted to do a quick introduction of folks.

46:06

Actually, we can skip that part. I'll just use folks here on the screen. So you all remember our core panelists,

Live Q&A

46:14

and joining us from OER, the Office of Extramural Research,

46:19

as well, we have Kasima Garst and Carrie Mitchell, and they're going to be joining us to help answer some additional questions.

46:28

All right. A question that came up early

46:35

that got a lot of votes was regarding budget.

46:41

It was stated previously that grants are not going to get larger; additional funds

46:47

would not be available to support data management and sharing efforts. But there's been some uncertainty about this.

46:55

Taunton, can you talk to us about this question and about sort of the amount of funding

47:01

that's available for this? Taunton Paine: Sure. So I'll just say briefly, I think, you know,

47:06

there may be sort of two questions here, one about refunding generally and one kind of about budget caps.

47:12

So, you know, first, I think the agency already provides, you know, many resources to support data management

47:19

and sharing included in the form of sort of repositories and tools, sometimes things like,

47:25

you know, specific funding announcements to support data sharing for certain types of research,

47:30

we certainly plan to continue doing that. And I think I've stated pretty clearly in the past

47:36

that we will be actually assessing data management and sharing costs going forward to determine

47:41

sort of the actual appropriate level of resources that will be needed in the future.

47:46

But let me turn to my OPERA colleagues to sort of address the question about budget caps that I think might have been part of this as well.

47:59

Carrie Mitchell: Yes. So I'll just echo what Taunton just said, some of that is being looked at

48:05

as we move forward with the data sharing resource plans and looking into all of the costs that we expect to have.

48:13

We currently do not have budget caps, we are looking into that internally,

48:19

and we'll certainly send that out to the community as soon as we have more information on anything related to the cost or the budget.

48:29

Elyse Sullivan: Thank you. Turning to some of our data management and sharing plans,

48:36

that in one of the elements, element six called oversight of data management

48:41

and sharing, the question is who is expected to actually oversee this plan?

48:47

Is it sort of internal folks on the research team? Is it an external party? Taunton, do you want to start with this?

48:55

Taunton Paine: Sure, and I might turn it over to my OER colleagues afterwards to see if they want to add anything. But in the last element

49:01

of the recommended elements of the DMS plan, there's a section for sort of oversight

49:07

of data management and sharing. And in that, we've asked applicants to sort of indicate how compliance with the plans will be monitored

49:13

and managed, the frequency and oversight and by whom, such as titles and roles. The DMS policy does not set sort of specific parameters

49:22

on who this role should be within an organization. So there is, I think, some flexibility for institutions

49:28

to actually determine who should fulfill this role for their projects and who are these sort of best actually situated to do that.

49:38

I don't know if any my OER colleagues want to add anything to that. Elyse Sullivan: All right, hearing none,

49:47

I will move on. Let's see. We received a question about costs for data storage.

49:55

There is also a question about whether NIH will be developing any kind of central depository kind of like PubMed for data.

50:07

Taunton, do you want to take this one? Taunton Paine: Yeah, so as I think I mentioned earlier, you know, NIH actually already has a pretty robust ecosystem of repositories

50:15

just that are managed, you know, within the agency. This is growing over time as well,

50:23

there are some resources available on the sharing.nih.gov website to help sort of locate some of those,

50:29

I think, particularly ones that the NIH actually, you know, operates and manages,

50:34

and of course, there are many more that NIH does not. There are many, and so I don't think

50:40

there's necessarily going to be a sort of central resource, since some of these are pretty specialized resources.

50:47

But I think certainly, you know, there may be more sort of efforts in that kind of interoperability,

50:52

and sort of findability across the existing resources as well as building out capacity.

50:59

Elyse Sullivan: Thanks. We're going to turn to you a couple of questions about research with human participants.

51:07

A question here about NIH's expectations if consent was not obtained at all,

51:13

or if consent was obtained but did not include consent for sharing beyond the research team?

51:19

Taunton, we'll start with you. Taunton Paine: Sure, thanks. So I think it's important also to sort of differentiate here

51:27

between the data management and sharing policy and the genomic data sharing policy that we talked about since the GDS policy actually

51:34

has sort of fairly specific expectations for consent and what's expected to be in that,

51:39

and how it will be obtained. The data management and sharing policy, by contrast, does not sort of set specific consent expectations.

51:48

And it would not necessarily prohibit sharing of data that are obtained under a waiver of consent.

51:55

And it also doesn't set expectations for what type of consent should be obtained, but it does strongly encourage

52:01

that people will obtain actual informed consent for future research use

52:08

and sharing of their scientific data, and also really encourages, you know,

52:13

in the supplemental information that we were discussing earlier, that institutions really should actually develop

52:19

robust consent practices that actually address data sharing and to plan for consent while they're developing

52:25

their data management and sharing plans. We've also, I think, indicated in the policy

52:31

and in the frequently asked questions, that limitations in consent,

52:36

either prospectively obtained or from existing informed consent can be,

52:41

you know, potentially justifiable reasons for limiting sharing of scientific data. And last, I do want to mention,

52:48

I think we've probably mentioned it during today's webinar, and we probably mentioned it at the last one as well, but we did release a resource earlier this year

52:55

that's intended to help sort of develop informed consent as it relates to data sharing that includes things like,

53:01

you know, suggested language, and, you know, points to consider for when you're developing, you know, consent resources.

53:10

Elyse Sullivan: Thanks. All right. Next question. How can folks reconcile data sharing with confidentiality?

53:19

We know those can be at odds. So, for example, proprietary constructs

53:24

that cannot be shared with the public, or disclosure of proprietary reagents.

53:29

Taunton, we'll start with you again. Taunton Paine: Sure. So I think we've addressed

53:36

this to some extent during the webinar itself, and we talked about sort of proprietary considerations

53:42

that can emerge, you know, in certain kinds of research, I think, sort of, particularly when there are research partnerships,

53:49

or in the form of things like agreements that would be needed to obtain materials used in research that may impose limitations

53:57

on sort of subsequent use of data. In general, I think sort of any limitations, you know, would need to be disclosed in plans,

54:05

and that those plans would be, you know, assessed by an NIH program staff.

54:13

Because of the specific aspect of this question, talking about, you know, proprietary reagents,

54:19

I do want to also make you aware of the NIH research resource policy and the NIH model organism policy,

54:27

both of which are also described on the sharing.nih.gov website.

54:34

And those also apply to sort of physical objects and have certain expectations in there

54:41

related to the management of intellectual property and proprietary considerations. I do want to also sort of reinforce

54:47

that the data management sharing policy does not apply to physical objects. And so I think, you know,

54:53

it may be important to consult both of those policies as well. Elyse Sullivan: Great.

55:00

We've got a question about how the data sharing requirements apply to research data that do not meet

55:06

the Common Rule definition of human subjects, but do involve data derived from human participants.

55:13

Taunton, to you. Taunton Paine: Sure, thanks. So I think this is pretty straightforward.

55:20

You know, the policy applies to research that is subject to the Common Rule, as well as research that is not subject to the Common Rule.

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And in some cases, you know, scientific data could potentially meet the definition of identifiable private information

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and the use of it might be considered human subjects research, sort of under the Common Rule, but it would also apply in cases

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where it might not meet that definition, and might not be subject to the Common Rule. And so the supplemental information

55:47

for protecting privacy while sharing human research participant data

55:52

that we went through in some detail in the webinar, is intended to sort of address both situations,

55:59

both for data, you know, that have been sort of derived from human research participants,

56:05

but I think, you know, kind of, regardless of whether it's sort of technically subject to the Common Rule or not, so there are sort of a number of specific considerations in there

56:15

that I think would be relevant in this situation. Elyse Sullivan: Thanks. All right.

56:21

We'll stop picking on you, Taunton. The next question is regarding IRB review.

56:29

So it's not required, you know, at the submission of grant proposals, so what if the IRB doesn't agree

56:35

with what was proposed in the DMS plan? Should folks be considering modifying?

56:43

Julia, can we start with you here? Julia Slutsman: Sure. So the policy allows for the DMS plan

56:50

to be revised for a number of reasons and one of those reasons can certainly be issues raised

56:57

and determinations made by the IRB. So researchers would need to revise their DMS plan

57:02

and then discuss those revisions with program staff who would then be designated with reviewing

57:10

and approving the plan. Elyse Sullivan: Okay, thanks.

57:16

We have a similar question, Julia, we're going to hit you up again. When submitting an institutional certification

57:23

under the GDS policy, can the institutional certification be updated as a result of changes that occur

57:30

throughout the course of a research project? Julia Slutsman: So the institute certifications,

57:36

which unlike DMS plans are submitted - the institution's reasons are submitted just in time,

57:41

the DMS plans are submitted at the time of application - the institutional certification is explicitly designed to reflect institutional review.

57:47

So if there is a reason for that document to be changed,

57:53

investigators should also make sure that there's alignment between the data management and sharing plan and the content of the institutional certification,

57:59

and they should align. And so both would need to be updated as needed

58:05

if changes are made, and then reviewed by NIH staff.

58:10

Elyse Sullivan: Thank you. Another question here about human participants.

58:17

So do participants have the right to opt out of broad sharing?

58:23

And if they object to what is proposed in the consent, does that mean that they should not be recruited for the study?

58:33

Let's see. Taunton, do you want to start here? Taunton Paine: Sure, yeah. So, you know, I think we've been clear in FAQs,

58:41

you know, that the DMS policy does not require that consent be obtained in any particular way, you know, such as through broad consent.

58:48

And I think it's really important for us to actually acknowledge that research needs to include populations

58:54

that are crucial to meet scientific objectives. And that's really, I think, a concept that's, you know, behind some of the supplemental information

59:02

that we've provided as well. But, you know, we've noted that limitations on sharing stemming from informed consent

59:10

are potentially justifiable reasons for limiting sharing of data. And I want to say that very clearly, you know,

59:16

so that we all are on the same page about that. And I think the FAQ that we have about,

59:22

you know, appropriate limitations for sharing talks about both when it's sort of prospectively obtained,

59:28

and when it's, you know, for a sort of, like, actually existing consent.

59:38

Elyse Sullivan: Okay, thanks. Let's see.

59:44

We have some questions on agreements and transferring data.

59:49

So who should be involved in these agreements? Is it every individual who might be given the data?

59:56

Is it when a public paper is published.

1:00:02

Taunton, could you start with that one? Taunton Paine: Sure. And I want to sort of, you know,

1:00:08

caveat my answer by saying that I think it would be, you know, potentially fairly context specific, you know, in terms of what the transfer actually is

1:00:15

and who it's between. But in general, the points that I think

1:00:20

we've made in the supplemental information for protecting research participant privacy, where we talk about, you know,

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agreements that should cover the transfer of data.

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We don't recommend a specific individual or institutional components that would necessarily fill that role, you know,

1:00:37

but we do, I think, sort of introduce the distinction between, you know, agreements for submitting data to repositories,

1:00:46

and agreements for obtaining data from repositories, and that, you know, agreements would generally be sort

1:00:52

of warranted in both situations. So you could have, you know, certain parties would be, you know, the researcher, and the actual data repository.

1:01:06

And when data are shared between researchers, you know, I think, in that case, agreements would, I think,

1:01:11

also be sort of valuable there too. Elyse Sullivan: Okay, thanks. Let's see,

1:01:20

we have received some questions about data management and sharing plans, and the format of them.

1:01:29

Is the format page a requirement, or are other formats allowed?

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Cindy, do you want to take this one? Cindy Danielson: Sure. And so we have, NIH has published a format page,

1:01:42

which is an optional, recommended way to format the information

1:01:47

that we're looking for that the elements of a DMS plan. That is not required. So there may be other ways to represent the information

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as long as it does cover all the elements, and that will be accepted. But if you're looking for somewhere to start,

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especially for folks where this is new to you writing such a plan, then you might want to take a look at the format page,

1:02:06

it just steps you through the elements of a DMS plan to make sure that you are not forgetting anything,

1:02:12

because we do need that information so that those plans can be assessed appropriately.

1:02:19

Elyse Sullivan: Okay, thanks. We've got another question about timing.

1:02:24

When thinking about the requirement to make all data publicly available by the end of the award, how is the end of the award defined?

1:02:32

Is it the original end date? Does it include any data that are resulting in a period of no-cost extension?

1:02:39

Cindy, can we start with you? Cindy Danielson: Sure. So yes, the definition for the end of the award

1:02:46

or the performance period, that would change if you do receive a no-cost extension,

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for example, or a competitive renewal. And so it is the end of the project period.

1:02:57

In case of a no-cost extension, you know, that's your date by which if you haven't shared data already,

1:03:03

and that's another thing to keep in mind, you shouldn't be holding things back to the end of your award, data should be made accessible as soon as possible.

1:03:09

So if your data underlie results in publications, then that should be shared at the time of publication.

1:03:17

But for other things that do meet the definition of scientific data, if you have findings that have not been published,

1:03:23

then those would need to be shared no later than the end of award, and that is the specific question here,

1:03:29

what exactly is that date? And that would include any no-cost extensions there.

1:03:34

And then just to reiterate another point, and I think we didn't cover this on the first webinar as well, if you do have a competitive renewal of a project,

1:03:42

you need to, you know, look at whether you were able to complete what you anticipated in your original approved plan

1:03:50

and update that as necessary. Yeah, so I'll just end there.

1:03:56

Elyse Sullivan: Thanks, Cindy. Let's see, we have a question about

1:04:03

is de-identification required in order to share the data?

1:04:09

Taunton, do you want to talk us through this?

1:04:14

Taunton Paine: Sure. So, I think, you know, there's a couple of considerations here. So first off, you know, I want to say that,

1:04:21

as I said a number of times, you know, the Common Rule, the HIPAA Privacy Rule, these might all apply, you know, to your research

1:04:28

and might set certain expectations, and we would, you know, expect you to continue to follow them.

1:04:33

In the supplemental information for best practices, which we would sort of expect you to, you know, follow as well as those laws and regulations,

1:04:43

we've actually addressed the issue of de-identification by sort of recommending that data be de-identified

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to the greatest extent possible using the actual regulatory standard stated in the Common Rule

1:04:56

and in the HIPAA Privacy Rule. This is not not a requirement, but it is a recommendation,

1:05:01

and we do acknowledge that there may be some cases where it may be appropriate

1:05:07

to share certain kinds of information that may be, you know, potentially identifiable.

1:05:13

But I think the two sort of, you know, key considerations there that we've talked about in that supplemental information

1:05:19

in those cases are that, you know, if there's sort of actual explicit consent to do so,

1:05:26

and if you've actually complied with, you know, all sorts of other regulatory and policy

1:05:34

expectations that might be in place. Elyse Sullivan: Thank you. And there's a few questions

1:05:42

about the American Indian/Alaska native supplemental information.

1:05:47

So are these resources only applicable to tribes?

1:05:53

Or does it apply to anyone where a participant kind of selects or self-identifies

1:05:59

as an American Indian or Alaska native? Taunton Paine: So the supplemental information

1:06:06

that we talked about earlier today really focuses on, you know, sort of when you're working with,

1:06:14

you know, sovereign tribal nations, you know, but I think we had sort of acknowledged in it

1:06:20

that there may be, you know, aspects of it that I think are quite relevant

1:06:26

for when you're working with other groups and other sort of indigenous communities as well.

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And so they may not all have, like, necessarily the same expectations when it comes to things like tribal laws,

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but they may be relevant in those cases, too.

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Elyse Sullivan: All right, some really great questions here. It was mentioned that the DMS plans are not reviewed

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by the scientific review panel, but rather by NIH program officers. Does this imply that there will be a scientific score

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and then separately a review of the DMS plans? How does that work, Cindy?

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Cindy Danielson: Sure, happy to explain that. And this will be different than what happens now with resource sharing plans,

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this will be a new part of the application for these data management and sharing plans. And we did clarify this recently in a guide notice,

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it should be included in the resource deck, but I can, you know, sum up what we've said in there. And that is that the plans are assessed by NIH program staff

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but not peer reviewers. And the program staff will be looking at these plans to make sure that the elements have been adequately addressed

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and look at the reasonableness of those responses given this specific type of science that is being proposed.

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This is all within the context of the research project.

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And during peer review, the peer reviewers are not looking at the plans, they are looking at the budget that is being requested.

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And when, you know, NIH will be putting out comprehensive application instructions this fall,

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and so you'll see in there exactly what information you should be putting in the budget section. And that budget aspect of data management

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and sharing is what peer reviewers will be looking at, but the plan itself will be assessed by NIH program staff.

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Elyse Sullivan: Thank you. Let's see. We have another question here.

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Clinical trial data is often not fully de-identified. The question is, should all clinical data be shared under controlled access?

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Taunton, can we start with you? Taunton Paine: Yeah, great. So I think in the supplemental information,

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you know, for protecting privacy, we actually indicated a couple of different factors

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that researchers and institutions can consider when they are sort of determining

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whether to share data through, you know, controlled access or through unrestricted access.

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So these include, you know, if you're actually considering to share it through controlled access, whether there might be, you know, specific limitations

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that stem from things like informed consent or from laws that would need to be followed that might impose restrictions on subsequent use,

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as well as things like whether there are privacy risks or privacy concerns that really can't be mitigated by,

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you know, applying sort of relevant de-identification techniques or even things like certificates of confidentiality.

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On the other hand, we've also given people some factors to consider in terms of whether things should be made available

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through unrestricted access, which would include things like whether people have explicitly consented to doing so.

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And I think a sort of more specific consideration

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of the sort of level of risk that would actually be involved in doing so.

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Elyse Sullivan: Thanks. Let's see, another question here about DMS plans

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when the data use is already controlled by a pre-existing data use agreement,

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for example, secondary data from, you know, some large, you know,

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Ministry of Health datasets, for example.

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Taunton, we can start with you. Taunton Paine: Sure, yeah. Well, so I think, you know, in those cases,

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the policy has a number of different pieces that I think, you know, relate to this. So, first off, you know,

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the policy would not necessarily expect that researchers that are doing secondary data,

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or a secondary research that involves, you know, analysis of primary data

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that have already been shared in some way, would not be expected to share those data again,

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particularly things that are sort of made, you know, actually available through things like, you know, government repositories,

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I've seen some other questions in the chat about things like CMS data, these are not things that we would expect,

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you know, to be shared again. There's also, I think, a sort of important consideration here

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that sometimes, you know, secondary research can sort of generate things that would be considered scientific data,

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and that the policy would sort of normally expect those to be shared as well. But again, you know, in many cases,

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when you're accessing data, there can be agreements that may be necessary in order to enter into to get access to the data

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and to do the research in the first place, that may impose, you know, restrictions on how things like derived data,

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you know, can be shared. And I think the policy has been pretty clear that that's something that we would generally consider to be,

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you know, potentially justifiable as a limitation in sharing,

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but we would also expect those kinds of things to be disclosed in plans.

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Elyse Sullivan: Thank you. We've heard some concerns about researchers being scooped by sharing their data.

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You know, we definitely recognize those concerns. How does NIH plan to address this?

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Let's see. Cindy, would you like to start? Cindy Danielson: Sure. So I guess the main message is that we would really like

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to see some prospective planning, and that thinking this through at the beginning and thinking about your timelines

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for when your data will be generated when you expect to, you know, complete your analysis published ideally,

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and that we do - yes, so if you do publish your research,

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then that would occur before the end of your award. And anything that hasn't been shared at that point,

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kind of the last opportunity would be by the end of your award. And in terms of compliance, that is really the last date.

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And so we do understand, we certainly are hearing, you know, concerns about how you can make sure

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to do what you need to with your data, but we don't really have any kind of new solution now.

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I'd like to also turn to my OPERA colleagues to see if they have anything to add, you know, in terms of the compliance piece and the timing there.

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Carrie Mitchell: No, I don't have anything to add at this point. We can go to Kasima, if she has anything on her end to add, which she may not,

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but, you know, I don't have anything to add. Regarding compliance, we're going to have more information

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on how the compliance piece is going to work in the future, and we'll be communicating that out.

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Kasima Garst: Yes, and I'll also just reiterate kind of what Carrie said, too, where we definitely hear the concerns,

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and we will, you know, certainly be taking those challenges into account. And I think someone else in the Q&A

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had also mentioned something about the possibility of the utilizing no-cost extension mechanisms

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to accommodate some of those concerns. And that is something that our policy colleagues

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are looking into to make sure that we can address that as part of any compliance guidance.

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Elyse Sullivan: Thank you. So Cindy, can you talk to us about

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what accountability measures are in place for ensuring that what people say they're going to do in their plan

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actually happens, similarly, for kind of ensuring that folks

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who access the data are doing so responsibly? Cindy Danielson: Sure.

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I'll maybe take the first part of that, and in terms of subsequent access, I might turn it over to Julia for some additional thoughts.

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And in terms of accountability for making sure that award recipients do what they said they would in their approved plan,

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again, just kind of coming back to that prospective planning, that we want to make sure that you're thinking

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through the right way to do this for your particular project, and are providing those details at the beginning,

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so there can be a shared understanding between the research team as well as the NIH, you know, who's overseeing your award

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and in terms of what to expect here. So ideally, there'll be perhaps fewer surprises at the end,

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because you know how things should go. In terms of, you know, compliance,

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monitoring what is actually happening in terms of carrying out your plans,

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we will be updating the RPPR questions to ask about that progress. And this will be the chance for NIH staff

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to take a look at where you are, and if you are where you thought you would be when you put in your initial plan.

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And if there are issues at that time, then, you know, in general, working together to try and bring you back into compliance,

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if there are any issues, identifying those and dealing with those. The goal is to make sure that scientific data are useful,

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and if there are any issues impacting that, then, you know, we want to make sure that that can occur.

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And I don't know if my OPERA colleagues have anything more to add on in terms of compliance, you know, as we pointed out earlier,

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we are still coming up with those compliance monitoring processes. But in essence, we'll be asking the award recipients

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to report on what they've done at regular intervals, and, you know, making sure that that is done

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before the end of the project. Kasima Garst: Yeah, one thing I'll just add from a systems perspective,

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we are going to be updating our notice of award templates to be able to accommodate incorporation

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of the data management and sharing plans as part of the terms and conditions of Award, as well as our funding opportunity announcement

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templates to incorporate that information as well. So as Cindy and others have mentioned,

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it will be part of the terms and conditions of award regarding the plan that is approved by NIH staff.

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Elyse Sullivan: Okay, thank you. So we've just got about five minutes left. And there's a good question

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that I'm actually going to answer with my wrap-up. So the question is, is there a help desk or other resources

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if you have questions about the DMS policy? I'm going to- Durant, if you'll throw up those slides,

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I can actually walk folks through some of the resources

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that I wanted to end on. So we've mentioned extensively that we have this

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NIH scientific data sharing site. This is really going to be a great place to start

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and look for resources. We're continually adding pieces to it.

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So for example, you know, we've got this whole- this is a screenshot of the site, we've got a whole section on the data management

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and sharing policy. We've got a whole section on FAQs

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related to the data management and sharing policy. And we're adding to this, you know,

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as additional information becomes available. There is an email box sharing@nih.gov.

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And that is a great place to put some questions if you're not already finding the answer

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with the information that we've provided. We also have a learning page on our site.

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It's in the "About" section. And this is where you'll find all of the webinar resources,

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like the recordings and the resource slides and other, we think, really useful pieces of information

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for folks to kind of grab and go. So we really encourage folks to go to this learning page

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and check out what we've got.

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Similarly- oops! I meant to go back.

1:19:02

I did want to mention that on the news and events part of the sharing website, we actually have a section for latest news,

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upcoming and past events. And there is a way to sign up to get notified

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anytime a new news item or a new event is posted. So I know we heard that question,

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how do I get notified when all this new information is coming out? Go to our news and events and select

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that you'd like to be notified. So that'll send you a quick email anytime that we post anything here.

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And every time we add a resource to the website, we're trying to add a little news item

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in the newsfeed so you can - so you can see kind of what are the changes that have been made.

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In addition to this news and events page, we've got a number of blogs that we are putting out

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to keep folks in the loop, our social media channels, a number of listservs,

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if you're not already on all these listservs, please do get on them. They're a great way to stay informed.

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So, in closing, I want to sincerely thank all of our attendees for joining us.

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I want to thank all of our presenters and panelists for taking the time and answering all of these questions.

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And for our ASL interpreters, our captioners, our technical staff, thank you for making this all happen.

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And, you know, we hope that this information was useful, we encourage you to go back to our Webinar One materials

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as well, and do let us know - there's going to be a survey

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that you can take at the conclusion of this webinar. And we'd really like to know, you know, what you found useful,

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and what types of things you're still kind of looking for as we near policy implementation.

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So with that, I'll just say thank you, and we're really happy that you could join us.