NIH **NATIONAL CANCER INSTITUTE**

Your Guide to the 2023 NIH Data Management and Sharing Policy

October 13, 2022, by NCI CBIIT Staff

> Do you know how the 2023 NIH Data Management and Sharing Policy will impact your work? If you are an NCI-funded investigator, this blog is for you. We cover the key policy distinctions, implementation changes, and resources to help you navigate the policy.

Who should follow the new policy?

Many NIH-funded researchers are familiar with the current NIH Data Sharing Policy (DSP) that was implemented in 2003, which required any NIH-funded research (i.e., basic, clinical, surveys, etc.) requesting more than $500,000 direct cost per year to plan how to share data with the wider community. The soon-to-be-implemented 2023 Data Management and Sharing (DMS) Policy removes this budget threshold and will expect any NIH-funded researcher to provide a DMS Plan detailing:

- what data will be shared.

- how data will be managed and shared.

- when data will be available.

- where data will be preserved, shared, and for how long.

- what, if any, limitations are in place that prevent data sharing (e.g., prior agreements, a lack of informed consent for human data).

- how compliance with the plan will be monitored by the applicant's institution.

While the 2023 DMS policy will eventually replace the 2003 policy, it's possible that some investigators may need to follow the 2003 DSP for a while. To determine which policy expectations to follow, check the date of your grant application.

- Who should follow the 2023 DMS Policy?
    - New grant applications (Type 1) that had receipt due dates *for (or after)* January 25, 2023

- Competing (Type 2) grant applications that had receipt due dates *for (or after)* January 25, 2023

- Who should follow the 2003 DSP?
    - Awards (e.g., Type 5 noncompeting renewals) made *before* January 24, 2023

What has changed?

We've outlined the main differences between the two policies in the table below.

Changes	2003 NIH DSP (Current Policy)	2023 NIH DMS (New Policy)
Funding Threshold	≥ $500,000 direct cost per year	Any funding level that results in the generation of scientific data (excluding training and infrastructure development) View the list of NIH activity codes that are subject to the 2023 DMS Policy.
Plans	Include a data sharing plan in research proposals detailing how your data will be shared.	Develop a data management and sharing plan that addresses required elements in detail about how you will share and preserve your scientific data.
Data Sharing Timelines	At the time of publication	ASAP, no later than the time of publication, or by the end of the performance period (whichever is sooner)

The 2023 DMS Policy also aligns with other data sharing policies you may need to follow. This table compares the expectations for the 2003 NIH DSP, 2023 NIH DMS, NIH Genomic Data Sharing Policy (GDS), and Cancer Moonshot Public Access & Data Sharing Policy (PADS).

Policies	2003 NIH DSP	NIH GDS	2023 NIH DMS	PADS
Effective Date	October 1, 2003 - January 25, 2023	January 25, 2015	January 25, 2023	October 1, 2017
Applicability/ Scope	• Expires for new applications that had receipt due dates for or after January 25, 2023 • Remains effective for non-competitive renewals for previously funded awards (Type 5) or to-be-awarded applications before the effective date on or after January 25, 2023	• Effective for new applications on or after January 25, 2015, that generate large-scale genomic data or smaller-scale studies (that NIH or NCI determines should be shared because of the state of science, programmatic priorities, utility, and/or value for the research community). • Thresholds & assay types clearly defined for meeting GDS • Timelines for sharing genomic data under GDS remain the same	• Effective for new applications (Type 1) and competitive renewals (Type 2) that had receipt due dates for or after January 25, 2023 • Competitive revisions (Type 3) and administrative supplements are not subject to the policy • Not applicable for research and other activities that do not generate scientific data (see *NIH List of Activity Codes Under DMS Policy*)	• Applicable to competing grant, cooperative agreement and contract applications submitted to NCI in response to a Cancer Moonshot Research Project FOA • Applicable to NCI intramural Cancer Moonshot Research Projects generating Publications and Underlying Primary Data on or after October 1, 2017 • Remain as NCI-specific policy to be addressed in a DMS Plan if applicable
		Only one plan will be submitted with applications with receipt due date for or after January 25, 2023		
		• Applicable to extramural (grants, cooperative agreements, contracts, other transactions) research and intramural research projects • Applicable to human and non-human data		
Budget Threshold	NIH funding of >$500k direct cost/ year that generate data	No minimum budget threshold required	No minimum budget threshold required	No minimum budget threshold required
NIH Expectations of Applicants	Include a data sharing plan in applications	Include a genomic data sharing plan in application (which will be part of the 2023 DMS Plan)	• Prospectively plan how to preserve & share scientific data • Submit DMS Plans with applications (and any DMS relevant budget costs)	• Submit a public access and data sharing Plan in applications • Deposit electronic copies of publications in PubMed Central (tagging of metadata)
		Report progress in annual RPPRs for NIH Staff to review plan compliance		
Release/Sharing Timelines	Submit and share data no later than the acceptance for publication of the main findings from the final dataset	• Submit & release data through NIH-designated data repositories • Release lower-level primary data (L2/L3) by 9 months after data generation/ QC • Release summary analyses at publication, with the latest time of data sharing is the end of the project period on or after January 25, 2023	Share scientific data as soon as possible, but no later than the time of an associated publication, or the end of performance period (whichever comes first)	• Share underlying primary data as soon as possible, but no later than the time of publication • Share data simultaneously with the publication • Make publications immediately accessible through release under the CC BY 4.0 (no embargo)

Administrative supplements and competing revisions (Type 3) do not need a DMS Plan. However, if an awarded supplemental request (including competing revisions) changes the parent award's approved data management and sharing approach, you should update the DMS Plan of the parent award.

What do I need to do?

If your research grant application had a receipt due date for (or after) January 25, 2023, you will need to follow the expectations outlined in the 2023 DMS Policy.

1. Plan for and write a data management and sharing plan according to the required plan elements.
2. Submit the data management and sharing plan with your funding proposal.
3. Revise and update your plan if necessary. Your program officer or funding contact may reach out through the standard Just-in-Time process for additional information.
4. Follow your plan. Once NCI funds the proposal, your plan becomes part of the Terms and Conditions of your award.
5. Request to update your plan if something will affect how your data is managed or shared. NCI must approve changes to your plan, so contact your program officer to discuss these updates.

6. Provide updates on your data sharing progress in your Research Performance Progress Reports (RPPR).

Read additional guidance information based on your funding mechanism.

Where can I get help?

To assist you, we've curated the following resources from NIH's data sharing website and other websites. If you still need help, add your question to the comment section below or reach out to NCI's Office of Data Sharing. If you are a grantee, you can also contact your program officer for additional information and guidance.

Resource Links

Following the policy expectations	• **Read the full 2023 NIH Data Management and Sharing Policy.** • **Find the NIH Guide notice about the 2023 policy.**
Drafting data sharing plans	• Review what you should include in a data management and sharing plan. • Check out this optional draft template for a data management and sharing plan. • Find out how to budget for data management and sharing costs. • Explore different cancer data standards and services that you could leverage. • Review cancer data science semantics basics to help you standardize your data.
Choosing a repository	• Read guidance on selecting a data repository. • Explore a list of NIH repositories. • Learn more about sharing data with repositories in the Cancer Research Data Commons. • Discover how NIH is working to make generalist repositories part of the data sharing ecosystem.
Practicing the fundamentals	• Brush up on basic tips for effective data management and sharing.

Training Webinars

NIH's Office of Extramural Research hosted a two-part series to review the changes to the policy. Watch the following videos to learn about the policy, what you need to do, and learn details about your use case:

- A Conversation with NIH: Implementing the New 2023 Data Management and Sharing (DMS) Policy, Part 1
- A Conversation with NIH: Diving Deeper into the New 2023 NIH Data Management and Sharing (DMS) Policy, Part 2

Frequently Asked Questions

Q. My work is covered by multiple policies. Do I need to do separate plans for each?
A. No, you don't. Only one plan will need to be submitted with applications having a receipt due date for (or after) January 25, 2023.

Q. Is this replacing the Genomic Data Sharing (GDS) Policy?
A. No. NCI-funded researchers generating genomic data should still follow the GDS Policy. NIH is harmonizing the GDS expectation with the new 2023 DMS Policy. To learn more about the GDS Policy and when it applies, read this short overview and implementation change.

Q. Do you have specific guidance about cancer data that we need to follow?
A. Make sure to address the recommended Plan elements outlined in the Supplemental Guidance. You should also follow other NCI policies and program-specific expectations if applicable (e.g., NCI Clinical Trial Access Policy). For example, you may have additional data sharing expectations outlined in your funding opportunity announcement (FOA) or as result of other NCI policies (e.g., Cancer Moonshot℠ Public Access and Data Sharing Policy expectations). Visit the data sharing policies page for a short overview of data sharing policies that impact NCI investigators.

Q. I'm a data scientist/bioinformatician generating secondary data. Does this apply to me?
A. Yes. The DMS Policy applies to research that generates scientific data, which can also result from secondary research. However, you will only be expected to write and follow a DMS Plan for the new secondary data generated or derived from the original data set. You may also need to include the data use limitations from the repositories or resources that you used to obtain the primary data. These expectations would be a justifiable reason for limiting sharing under the 2023 DMS Policy.

Q. I'm an early-career cancer researcher who doesn't know where to begin. What do I do?
A. Let's start you out on our data sharing "how-to" article. You'll get information on fundamental tips, expectations, and more!

[callout]**Ask your question in the comment section below!**

We'll continue to update this list of FAQs with common questions from the community.
[/callout]

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