

Report on Research Compliance Volume 19, Number 10. September 21, 2022 NIH, FDP Start 12-Month Pilot as New Data Sharing Mandate Approaches

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With just three or so months to go before NIH's data management and sharing (DMS) policy takes effect, it would be safe to say that research compliance officials are feeling nervous—and principal investigators (PIs) are, too. As of Jan. 25, most NIH award submissions will have to include a DMS plan, under a policy first announced two years ago and which replaces one in effect since 2003.

Perhaps a year into their compliance with the policy, institutions and PIs may have some real-world experience and best practices to guide them—no doubt valuable but not timely for the start of the policy.

Last month details of a soon-to-be-launched pilot on the policy were announced by Michelle Bulls, director of the NIH Office of Policy for Extramural Research Administration, which is collaborating with the Federal Demonstration Partnership (FDP).^[1]

The policy itself is fairly straightforward. Awardees must "manage and share data as described in the approved DMS plan, provide updates on data management and sharing activities in annual progress reports" and "work proactively with the appropriate program officer for approval of changes to the plan should it change during the project," as NIH said on its website.

Taunton Paine, director of the NIH Office of Science Policy's Scientific Data Sharing Policy Division, noted at the FDP meeting that the National Institute of Mental Health posted four sample DMS plans online. [2] These address:

- Clinical and/or MRI data from human research participants
- Genomic data from human research participants
- Genomic data from a non-human source
- Secondary Data Analysis

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