

Report on Research Compliance Volume 17, Number 12. November 19, 2020 NIH Data Policy Allows Time for Compliance; PIs Must Submit Plan With Funding Application

By Theresa Defino

Under NIH's new policy, data management and sharing plans (DMSPs) won't be required until January 2023, giving both institutions and principal investigators (PIs) time to comply.^[1] But, in a significant departure from the draft policy issued last year,^[2] DMSPs must accompany funding applications, rather than be submitted following a positive funding decision during the just-in-time (JIT) process.

NIH issued the new policy Oct. 29, along with three guidance documents that address the elements of a DMSP, what costs are allowable, and recommendations "to help researchers choose data repositories suitable for the preservation and sharing of data."^[3]

While stakeholders are still combing through the four documents, some shared with *RRC* their thoughts on what NIH got right and what they wish had been addressed. Nearly uniformly they expressed a hope that more details will emerge as time goes on and the compliance and effective dates—they are the same in this case—move closer.

One supporter of the plan is John Wilbanks, chief commons officer for Sage Bionetworks, a leading nonprofit research and open science organization, who advocated for having PIs submit plans at the time of application. "Overall, kudos to [the] NIH Office of Science Policy on this," he tweeted. "Not an easy thing to shepherd through to final. My complaints are far less than the sum of good stuff here."

Policy Allows Time for Compliance

But, as he reiterated to *RRC*, NIH needs to be firm about enforcement. "Time now to teach the grants offices how to implement and hold people's feet to the fire," said Wilbanks.

"I expect noncompliance," he told *RRC*, "because all policies have noncompliance, especially as they get going." But he suggested that the "vast majority of noncompliance will simply come from inertia, lack of familiarity with the requirements, etc."

The policy calls for submission of a DMSP "outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations." It also requires investigators to comply "with the awardee's plan as approved" by NIH. As initially submitted, plans will be limited to two pages in length and will later be finalized in concert with the funding institute or center (IC).

This document is only available to subscribers. Please log in or purchase access.

Purchase Login

Copyright © 2024 by Society of Corporate Compliance and Ethics (SCCE) & Health Care Compliance Association (HCCA). No claim to original US Government works. All rights reserved. Usage is governed under this website's <u>Terms of Use</u>.