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As NIH Ponders Data Plan Requirement, Stakeholders Seek Details, Long Lead Time

By Theresa Defino

In what would be a major shift from what NIH has proposed, a leading nonprofit research and open science organization is recommending that NIH require investigators to submit a data management and sharing plan as part of their funding applications, and to be scored on the quality of the DMSP.

As proposed in a new policy NIH issued[1] in draft form in November, DMSPs wouldn't be due until an award has been approved and would be handled during the agency's "just-in-time" (JIT) process. But Sage Bionetworks of Seattle says that's not good enough.[2]

"This signals that the plan is not a valued part of the application and is, in fact, an afterthought. NIH should factor the quality of the DMSP in its funding decision process," Sage leaders argue in their comments to NIH. "We recommend that the DMSP be required as a scorable part of the application so that appropriate sharing costs can be budgeted for at the time of application, and the plan can be included as part of the review process."

Sage Bionetwork's comments are among the approximately 200 NIH has received on the draft plan, and because NIH has not yet posted any, it is not possible to know if this position has other supporters. However, other comments reviewed by *RRC,* particularly those from the Council on Governmental Relations (COGR), offered praise for the JIT requirement.[3]

Ryan Bayha, director of strategic engagement for the NIH Office of Science Policy, which issued the draft, told *RRC* in January NIH is "preparing the comments for posting to the OSP website, and should have them up within the next month." Issuing a final policy will take longer, of course.

Said Bayha: "As for next steps, NIH will consider all of the comments we've received before issuing a final policy. We cannot provide a specific time frame at this point, but we hope to have a final policy out by the end of 2020."

Judging from the comments *RRC* has reviewed, NIH will need to make a number of decisions. In addition to the timing of DMSPs, commenters have raised far-reaching questions. These include the type of data and studies that must comply, the date for compliance, where data can be deposited, how NIH will approve such plans and whether an appeal will be possible, as well as issues around cost—in particular, how long an institution would be responsible for maintaining the data.

More generally, organizations have stressed that NIH has a lot of work ahead of it—and, equally, that a lot is at stake. They urged NIH to issue guidance on a number of topic areas and, in some cases, to be more firm out of the gate.