



FASEB

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for Experimental Biology

Representing Over 130,000 Researchers

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Proposed FASEB comments in response to NOT-OD-19-014, “Request for Information (RFI) on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research”

Comments submitted electronically via [RFI website](#) on December 10, 2018

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments in response to [NOT-OD-19-014](#), RFI on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research. FASEB is comprised of 30 scientific societies, collectively representing over 130,000 biological and biomedical researchers who produce and use a wide variety of data, core data resources, and analytic tools.

In reviewing the [proposed provisions](#), we found that the cross-cutting recommendations made in our [comments](#) on NIH’s draft Strategic Plan for Data Science and the guiding principles highlighted in our 2016 [Statement on Data Management and Access](#) are also applicable to this RFI. FASEB also recognizes that this is the first of several steps in the implementation of an NIH-wide data management and sharing policy. However, one overarching concern that arose throughout our deliberations was variability in terms of individual investigators’ expectations, experience, and resource needs to ensure key data from NIH funded projects are consistent with the FAIR (Findable, Accessible, Interoperable, and Re-usable) data principles. In addition, it will be necessary for the final policy to strike a fine balance between data accessibility and administrative effort and not serve as a deterrent to those seeking to share or reuse datasets. Below we highlight specific concerns that need to be addressed before finalizing a data management and sharing policy for NIH funded research.

Definition of Scientific Data: FASEB appreciates that “Scientific Data” as defined in the proposed provisions explicitly excludes items such as laboratory notebooks, preliminary data, case report forms, draft manuscripts, and physical specimens and emphasizes the need for access to the data underlying publications. However, we encourage slight expansion of this definition to recognize the impact of negative results that may be excluded from publications. As noted in FASEB’s 2016 [recommendations](#) to enhance research reproducibility, transparency regarding experiments not yielding positive results is also critical to scientific knowledge. Thus defining scientific data as all findings, both positive and negative, contributing to a line of research inquiry ensures transparency of the underlying data, thus contributing to the rigor and reproducibility of final published work.

Breadth of Proposed Requirements for Data Management and Sharing Plans: One lesson that can be gleaned from the implementation of data management and sharing plans at other federal agencies is that an open-ended requirement for data management and sharing plans will not yield the desired result of information exchange and data re-use. Therefore FASEB recommends that NIH work with the

stakeholder community to develop a framework for data management and sharing plans that is flexible and adaptable to the breadth of research activities supported by NIH. To facilitate development of appropriate plans, we encourage NIH to develop supplemental resources and guidance for the information sought in the data management and sharing plans, including a form that balances free text with check box responses, and example forms that demonstrate plans that meet NIH's expectations for reporting versus those that would not fulfill agency requirements. We also recommend that NIH conduct a pilot implementation of the policy for a random sample of grants prior to final rollout to ensure templates and guidance documents are clear and lead to the development of appropriate data management and sharing plans.

Phased Implementation of Requirement: FASEB recognizes that the requirement for data management and sharing plans will aid NIH in its broader efforts to demonstrate proper stewardship of federal funds. We also recognize that there will be unforeseen challenges as NIH proceeds with implementation of a new data management and sharing policy. Therefore, we encourage consideration of a tiered approach for implementing any final policy to both the extramural and intramural research communities to ensure preparedness for fulfilling requirements, making course corrections, and fostering community compliance.

FASEB understand that this RFI represents the first step in a longer journey to increase access to scientific data resulting from NIH funding, and we appreciate NIH's willingness to engage the scientific community in the development of its data management and sharing policy. We encourage continuation of this active engagement, such as through RFIs, public meetings, or even a designated working group or task force, to ensure feasibility of and community support for the final plan.