



FASEB

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for Experimental Biology

Representing Over 130,000 Researchers

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FASEB comments in response to [NOT-OD-20-013](#), “Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance”

Comments submitted electronically via [online Comment Form](#) on December 10, 2019

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments in response to NOT-OD-20-013, Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance. FASEB is comprised of 29 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 draft policy and supplemental guidance documents, we were pleased to see FASEB’s [feedback](#) in response to [NOT-OD-19-014](#), Request for Information on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research clearly incorporated. While we are still concerned about variability in terms of individual investigators’ expectations, experience, and resource needs to ensure key data from NIH funded/supported projects are consistent with the FAIR (Findable, Accessible, Interoperable, and Re-usable) data principles, the draft policy provides flexibility to develop a culture of data management and sharing within the NIH funded community.

Comments on specific aspects of the draft policy are noted below.

Purpose: This section describes the philosophy underlying the policy and is a helpful reminder that investigators are not conducting their work within a vacuum. Highlighting the need to consider data preservation and sharing as part of the research process is critical to foster culture change. We do suggest, however, that the policy more clearly define acceptable timeframes for data sharing, as “timely manner” could be widely interpreted. These could even be conveyed as ranges to preserve flexibility.

Definitions: FASEB thanks NIH for expanding the definition of “scientific data” to include negative results. Defining scientific data as all findings contributing to a line of research inquiry ensures transparency and improves the rigor and reproducibility of research findings.

Requirements: While FASEB supports the requirement of a data management and sharing plan for NIH-funded or conducted research, we are concerned about varied supplementary information requirements requested by individual NIH Institutes, Centers, and Offices (ICOs). To minimize confusion and administrative burdens, we strongly encourage trans-NIH coordination of these supplemental requests and listing ICO-specific requirements as part of centralized resources associated with the final data management and sharing policy.

Data Management and Sharing Plans: FASEB applauds the proposal to collect data management and sharing plans as part of Just-in-Time documentation for extramural awards. Requiring submission of the plan as part of the term of award rather than the initial proposal minimizes administrative burden at the proposal stage for both the applicant and peer reviewers. Shifting the review of plans to NIH staff members rather than volunteer reviewers will also make the process more uniform and streamlined. This also allows more flexibility for grantees to make real-time updates to their plans.

One area that needs to be further clarified in the final policy is whether NIH will make data management and sharing plans publicly available. To truly fulfill the FAIR data principles, plans should be made publicly available; however, we urge further engagement with the stakeholder community to determine possible unintended consequences of this strategy. Another approach may be to share limited details about the plan to increase awareness of the work, particularly if the work leads to outputs other than publications.

Compliance and Enforcement: The strategy of making the data management and sharing plan a term and condition of the grant award demonstrates NIH's commitment to fostering a culture of data sharing among investigators and institutions supported by NIH funding and support.

Supplemental Draft Guidance – Plan Elements: FASEB commends the inclusion of supplemental guidance to help investigators understand the desired elements of a data management and sharing plan. The proposed guidance offers investigators flexibility to adapt plans to their specific research needs. This, in concert with an enhanced role for NIH staff in reviewing draft plans, should help alleviate confusion regarding expectations for data management and sharing plans.

Supplemental Draft Guidance - Allowable Costs: FASEB appreciates NIH's recognition of the costs associated with data management and sharing and applauds the inclusion of the supplemental guidance defining possible allowable costs. A concern is that the guidance only addresses those costs incurred during the term of the award but does not address costs associated with long-term data retention and accessibility.

We commend NIH for its careful consideration of the comments received in response to the NOT-OD-19-014. The result is a draft policy that is adaptable to the broad range of science supported by NIH and furthers the NIH goal of building the culture of data management and sharing across the biological and biomedical research community. Once the policy is finalized, we strongly encourage extensive engagement with the scientific community to clarify agency process and expectations prior to enforcing compliance as rushed implementation can result in unforeseen challenges.