

Comments of The American Association of Immunologists (AAI) on the Draft NIH Policy for Data Management and Sharing and Supplemental Draft Guidance

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Comments on the Draft NIH Policy for Data Management and Sharing:

I. Purpose

The American Association of Immunologists (AAI) is the nation's largest professional society of research scientists and physicians who are dedicated to understanding the immune system through basic, translational, and/or clinical research. Founded in 1913, AAI members are scientists at all career stages and from all sectors of research – academic, government, corporate, and non-profit. The vast majority of AAI members receives NIH funding to conduct research on critically important and promising areas of immunology. These discoveries have laid the foundation for extraordinary advances in preventing and treating disease; some recent advances, such as immunotherapies to treat certain cancers, have achieved unimaginable success.

While AAI supports the principle of data sharing and agrees with the need for effective data sharing, preservation, and management, AAI is concerned about some of the details, including those related to implementation, that are described in the draft policy; these concerns are addressed in more detail below. As a preliminary matter, AAI believes it is essential for NIH to describe clearly the specific goals of the policy, including the currently perceived deficit in data sharing. Clarification of the goals will help the research community determine exactly which data should be shared, and at what point it should be shared. NIH should also explain how this policy will interact with preexisting data sharing policies. Furthermore, NIH should describe what metrics will be used to evaluate the policy, especially to determine the value added by this policy and to ensure that there are not unintended consequences. Finally, once the policy is modified as a result of comments submitted, it is crucial that NIH provide stakeholders with the opportunity to comment on the revised proposed policy.

II. Definitions

AAI believes that additional clarification of the terms “scientific data” and “preliminary analyses,” as well as definitions of what would be considered “negative data” and “unpublished data,” are needed. NIH should provide specific examples of what would and would not be covered under each. While AAI agrees that there is value in sharing some negative/unpublished results, there is minimal value in sharing uninterpretable data (for example, experiments in which critical controls failed). NIH should recognize the large variability in the quality of data, and therefore should provide clarification about exactly which data NIH seeks to be included.

III. Scope

AAI agrees with the scope specified: that the policy should apply “to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data.”

IV. Effective Date

AAI appreciates having the opportunity to comment on the draft policy. However, as stated above, AAI urges NIH to issue another request for comments after revisions are made to the draft policy. Additional policy details are needed for the community to be able to provide the most thoughtful and thorough feedback. As a result, it may be that the anticipated effective date (2022) will have to be delayed so that NIH can address these additional comments.

V. Requirements

In developing a final policy, AAI hopes that NIH will address the following questions: 1) how the data will be curated and determined to be useful; 2) how to ensure the quality and monitoring of data (including how it will be updated and/or corrected if needed); 3) how to ensure the data will be accessible; 4) how long data will need to be stored; and 5) how to ensure the needed infrastructure is available (given that established repositories may not be able to handle the volume of data that would be stored as a result of this policy). Further, in order to reduce administrative burden with this new policy, AAI requests that NIH coordinate with, clarify, and disseminate any new policies or expectations by individual Institutes, Centers, and Offices (ICO).

VI. Data Management and Sharing Plans

AAI greatly appreciates that the NIH draft policy provides significant flexibility to investigators as they develop their individual data sharing plans; by so doing, NIH recognizes the diversity of data generated and the need for limitations in sharing due to patient privacy, intellectual property protections (including those rights impacted by the date of publication), biosecurity implications or threats to public health or safety, and other relevant issues. However, to ensure that investigators are well-positioned to submit an appropriate and useful plan, NIH should clarify exactly what data needs to be shared, in what format (e.g., raw v. processed), where (which repositories would be acceptable), and when. Without some level of specificity, NIH could receive a wide range of plans, some of which may not satisfy NIH goals or result in more burden on investigators and program officers.

In addition, AAI is concerned that, as a result of this (appreciated) flexibility, there may be a significant lack of standardization within and across ICOs. If the discretion to approve a plan is given, per the draft policy, to ICO program officers, AAI encourages NIH to train, and set parameters for, program officers, in order to ensure fairness and basic consistency. Furthermore, NIH should make researchers aware of the criteria that program officers will use to evaluate the plans.

AAI also greatly appreciates that NIH will require the plan to be submitted during Just-in-Time for extramural awards; this will minimize the potential increase in administrative burden.

AAI also strongly encourages NIH to consider how to ensure the security of shared data, as well as the implications if plans were to be made publicly available. This is an area that requires additional stakeholder input following NIH's release of a draft revised policy.

VII. Compliance and Enforcement

AAI requests that NIH clarify who will be responsible for monitoring and enforcing the policy. If compliance is expected beyond the award term, clarification is also needed as to how this is to be monitored and enforced.

Comments on the Supplemental Draft Guidance on Allowable Costs:

As there are significant costs associated with data sharing and management, AAI is pleased that NIH has included guidance in this area. However, AAI is concerned that this could essentially become an unfunded mandate if additional funds are not made available for this purpose. Clarification is needed as to whether these costs can be covered by a supplement to a grant, or if they must be supported by the grant itself (especially problematic for modular grants). Before a final policy is issued, AAI encourages NIH to determine the total cost associated with this policy, including the cost to researchers and institutions for data storage and retrieval. If the policy will also be enforced after the award term has ended, AAI requests further clarification as to how costs related to long-term data retention and management will be addressed.

Comments on the Supplemental Draft Guidance on Elements of a Data Management and Sharing Plan:

AAI appreciates that NIH has provided supplemental draft guidance. However, per the comments above, AAI urges NIH to strike a balance between the need for flexibility and the need for adequate guidance to ensure fairness and basic consistency.

Other Relevant Considerations:

AAI believes that this policy, if clarified as requested above, implemented with NIH's intended flexibility, and evaluated based on agreed-upon metrics, may enhance reliability in, and the reproducibility of, research findings, and be especially helpful to scientists seeking to re-use hard-to-generate data.