The Association for Research in Vision and Ophthalmology (ARVO) submitted 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["Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance"](#) on January 10, 2020.

[ARVO](#) is the largest and most respected eye and vision research organization in the world, with the mission to advance research worldwide into understanding the visual system and preventing, treating and curing its disorders. Our members include nearly 12,000 researchers from over 75 countries. These comments were initially drafted by ARVO's Advocacy and Outreach Committee (AOC) and subsequently released to membership for feedback.

Section 1: Purpose

No comments at this time.

Section 2: Definitions

No comments at this time.

Section 3: Scope

a. Other funding agencies—including many agencies in countries other than the United States—do not make data readily available to all researchers. Proposed changes to NIH's Data Management and Sharing Policy could generate a disparate impact on/unintended consequences for our members in the US and non-US alike.

b. How will this policy be harmonized with existing NIH and international policies on patient privacy, intellectual property protections, etc.? Will the proposed policy supersede or be restricted by such existing policies?

c. Would this database also house data generated from non-NIH supported research? This is especially important to consider when the data generated from large studies may be funded by non-NIH and NIH grants over different time periods. This may affect what aspects of the data can be shared on this proposed database.

Section 4: Effective Dates

No comments at this time.

Section 5: Requirements

a. There is no specific guidance in the draft policy as to what would constitute an acceptable vs. an unacceptable "Data Management and Sharing Plan". For example, while the statement, "NIH does not expect researchers to share all scientific data generated in a study" will likely reduce the administrative burden for researchers, a classification of "required", "optional", "not required" is not included in the draft policy. Will NIH provide guidance on what data will be classified as "required", "optional" and "not required"?

b. What will the protocol be in cases in which the researcher does not own the data and is contractually obligated to not release data?

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    c. How will this policy accommodate fields that do not have a consensus or an agreed upon nomenclature on data formatting?

    d. Many areas of biomedical research are lacking a consensus on the specifics of data sharing as compared to other fields where detailed standards have been developed, e.g. physics, geosciences, engineering, etc. How should data-which in our fields come in a variety of formats, complexities and sizes-be made available?

    e. Will NIH generate one database for all data resulting from NIH-supported research? If not, what is being envisioned how grantees go about setup and maintenance of such databases? Several issues consequently arise:

        o Who will assess data quality prior to and after deposition?

        o Who will curate these databases?

        o How far back in time can data still be uploaded, or will it be limitless if it meets the data standards?

        o How will the curation of these databases be adjusted as future demands on data availability (e.g., novel analytical methods) emerge?

        o How will databases be funded initially and long-term?

Section 6: Data Management and Sharing Plans

No comments at this time.

Section 7: Compliance and Enforcement

    a. How will this be funded initially and long-term?

Supplemental DRAFT Guidance: Allowable Costs for Data Management and Sharing

No comments at this time.

Supplemental DRAFT Guidance: Elements of a NIH Data Management and Sharing Plan

No comments at this time.

Other Considerations Relevant to this DRAFT Policy Proposal

- The CDC has requirements for a DMP, https://www.cdc.gov/grants/additional-requirements/ar-25.html.
- All sharing policies should apply to NIH intramural and extramural research equally.