National Institutes of Health
Office of Science Policy

AT A GLANCE

DRAFT NIH Policy for Data Management & Sharing

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Why Share Data?

- **Important for SCIENTISTS**
  - Enables validation of scientific results
  - Allows analyses to be strengthened by combining data
  - Facilitates reuse of hard-to-generate data
  - Accelerates future research
- **Important for the PUBLIC**
  - Demonstrates stewardship over taxpayer funds
  - Fosters transparency and accountability
  - Maximizes research participants' contributions

NIH has a longstanding commitment to making research results and accomplishments available to the public

Examples

NIH Data Sharing Policy (2003)

Establishes expectation that research data from large awards (≥ $500K) will be shared

NIH Public Access Policy (2008)

Ensures public access to published results of NIH –funded research

NIH Genome-Wide Association Studies Policy (2008) & NIH Genomic Data Sharing Policy (2015)

Establishes expectations for sharing large-scale genomic data

NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (2017)

Establishes expectation for the timely registration and submission of results information for all NIH-funded clinical trials

Goals of an NIH Policy for Data Management and Sharing (final yet to be developed!)

- Fosters a culture of data stewardship
- Recognizes all scientific data need to be managed; not all data may be necessary to validate and replicate findings
- Promotes effective data management and sharing consistent with FAIR principles
- Provides a flexible framework for the breadth, size, and diversity of scientific data
- Respects autonomy and privacy of research participants; allows for protection of confidential data

Current Proposal

- NIH Draft Policy proposes **researchers tell NIH how they plan to manage and share data**; includes supplemental guidance to assist with implementation (e.g., Allowable Costs & Elements of a Plan)
- **Policy is deliberately flexible** – includes consideration of factors (e.g., legal, ethical) that may limit data sharing

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Current Proposal

- **Scope**
  - All research, funded or conducted in whole or in part by NIH, that results in the generation of **scientific data.**
- **Definition**
  - **Scientific data** defined as the recorded factual material commonly accepted in the scientific community as necessary to validate and replicate research findings, regardless of whether the data are used to support scholarly publications.

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Current Proposal

- Submission of a Data Management and Sharing Plan (Plan), outlining how **scientific data** will be managed and shared
- Compliance with the approved Plan

Current Proposal

- **Plans (cont.)**
  - Plans allow applicants to propose how they intend to manage and share data, including which data will be preserved and shared
  - Respects research participants' privacy protections
    - Outlines how participants' privacy, rights, and confidentiality will be protected
    - Includes consideration of certain factors (e.g., legal, ethical) that may limit data sharing
  - Plans may be updated throughout life of the award, with approval by the funding NIH Institute, Center, or Office (ICO)

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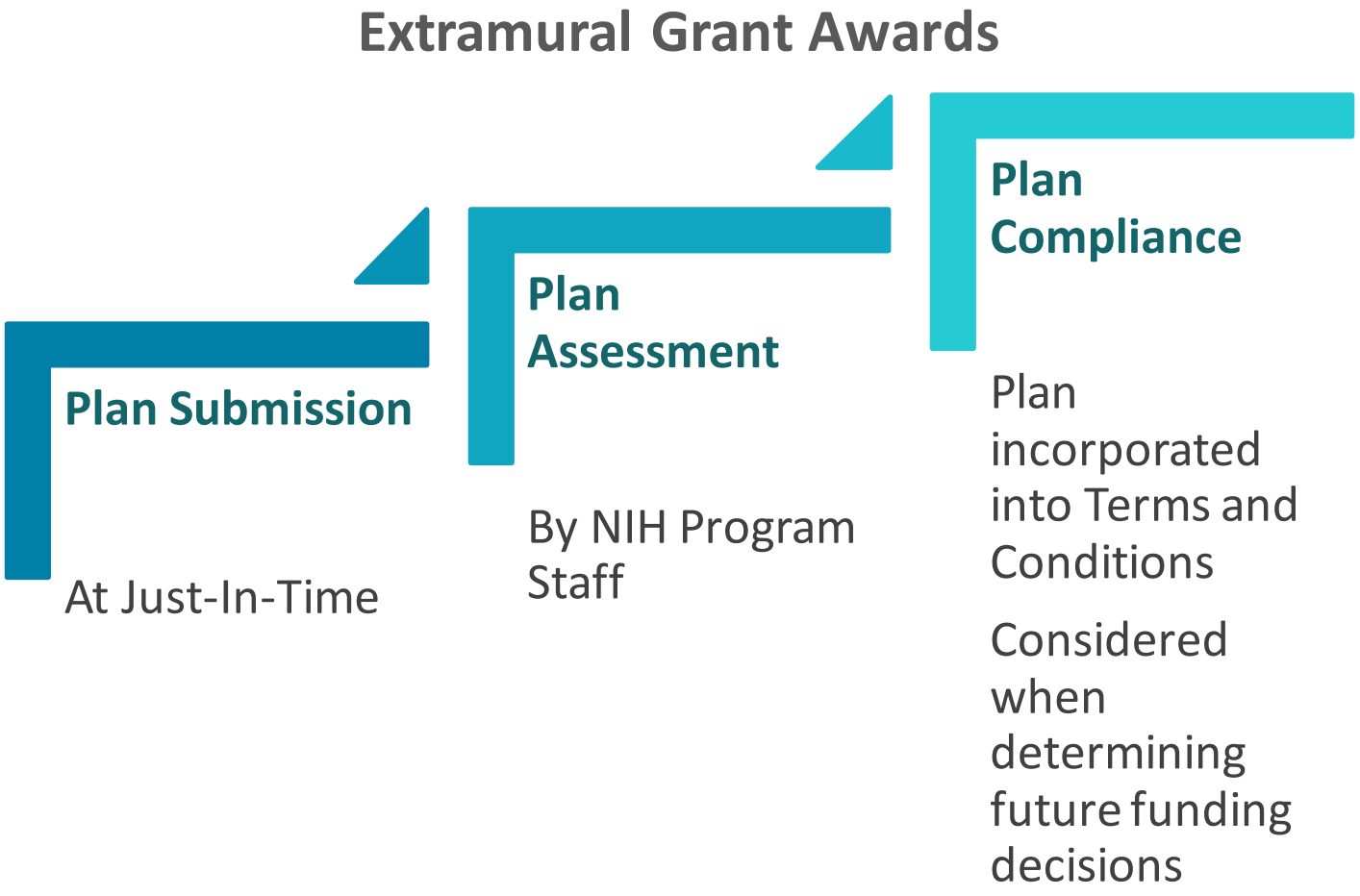
Current Proposal



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Guidance – Elements of a Plan

- **Proposed Plan Elements**
  - Data Type
  - Related Tools, Software, and/or Code
  - Standards
  - Data Preservation, Access, and Associated Timelines
  - Data Sharing Agreements, Licenses, and Other Use Limitations
  - Oversight of Data Management

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Guidance – Allowable Costs

- **Proposed: Reasonable, allowable costs included in budget requests**
  - Curating data and developing supporting documentation
  - Preserving and sharing data through established repositories
  - Local data management considerations
- **NOT considered data management and sharing costs**
  - Infrastructure costs typically included in indirect costs
  - Costs associated with the routine conduct of research (e.g., costs of gaining access to research data)

Related NIH Data Management and Sharing Activities

NIH National Institutes of Health
Office of Data Science Strategy

Home | Strategic Plan | Resources

Office of Data Science Strategy » Strategic Plan

NIH Strategic Plan for Data Science

Modernizing NIH's data management and sharing infrastructure

NIH Strategic Plan for Tribal Health Research FY 2019–2023

Engaging Tribal Nations to facilitate responsible data sharing

NIH is Seeking Public Comments!

- Comments being accepted until **January 10, 2020** and will be used to inform a final policy. Public comments will **NOT** be accepted via the webinar but must instead be sent through the link provided below.

https://osp.od.nih.gov/draft-data-sharing-and-management/

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Making Your Voice Heard

- Tips for Submitting Comments
  - Be specific
  - Provide data and/or examples
  - Include new ideas
  - Emphasize what matters to you the most!
  - Provide feedback on the draft guidance and suggest other useful guidance

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Frequently Asked Questions

- **How is a new policy going to interact with other existing, similar data sharing policies currently in effect at NIH?**
  - NIH recognizes that Institutes, Centers and Offices have promogulated data sharing policies that have filled important programmatic and scientific needs. NIH will work to ensure that there is a consistent set of agency-wide expectations upon which other policies may build.

- **Will NIH cover data preservation and sharing costs after the award period ends?**
  - NIH understands that data management and sharing activities often extend beyond the time of the award. NIH is thinking through ways to forecast long-term costs for preserving and archiving data.

- **How will the policy be evaluated? In other words, how will NIH know if the juice is worth the squeeze?**
  - NIH is thinking through ways to track data reuse. For example, encouraging the use of unique identifiers in Plans may help NIH assess the impact of shared data. NIH seeks public input in this area.

Thank You

Question & Answer

More questions? SciencePolicy@od.nih.gov