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NIH's New Data Management and Sharing Policy—How Academic Medical Centers Can Prepare for January 2023

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NIH's New Data Management Sharing Policy—How Academic Centers Can Prepare for J

A **PRIMER** Virtual Event
**2021 Social, Behavioral, and
Educational Research Conference**
November 16



**2021 Advancing Ethical
Research Conference**
November 16-19

Taunton Paine & Sara Sa

Disclosure

*I have no relevant personal/professional/financial interests
with respect to this education*

Taunton Paine, Director, Scientific Data Sharing
Office of Science Policy, National Institutes of Health

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Sara Samuel, Informationist, University of Michigan

Presenter 1: Taunton Paine



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Presenter 2: Sara Samuel



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Science Policy
- Diane Wilson, MPP, JD, MA, Assistant Dire
Regulatory Affairs, University of Michigan M

Learning Objectives

1. Understand the specific guidelines, NIH's and to whom they apply
2. Discuss essential elements of and best p Management and Sharing Plans, including
3. Identify the resources and stakeholders v will need to be engaged for researchers t plans, along with the challenges they will opportunities that the policy's requirement

Overview of the New Management and Share

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Taunton Paine
Director, Scientific Data Sharing Policy
Office of Science Policy, National Institutes

NIH POLICY FOR DATA MANAGEMENT & SHARING: Data Stewardship Goals

- **Advance rigorous and reproducible research**

- Enable validation of research results
- Make high-value datasets accessible
- Accelerate future research directions
- Increase opportunities for citation and collaboration

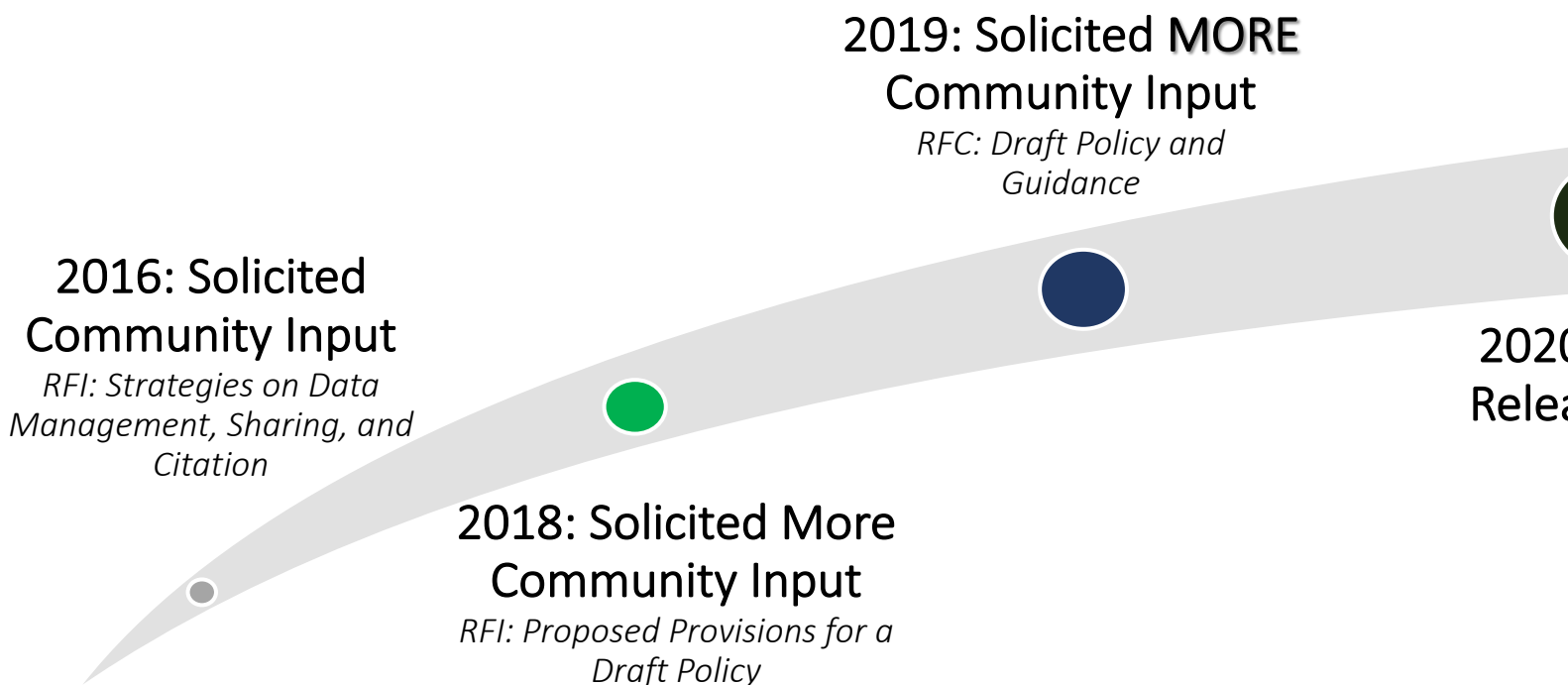


- **Promote public trust in re**

- Foster transparency and accountability
- Demonstrate stewardship over data
- Maximize research participation
- Support appropriate protection

NIH POLICY FOR DATA MANAGEMENT & SHARING: An Iterative Policy Development

- Sought public comment repeatedly
- Tribal Consultation^{*}
**Details provided in [“NIH Tribal Consultation Report: NIH Draft Policy for Data Management”](#)*
- Intersection with other government agencies & Secretary’s Human Research Protections





NIH Policy for Data Management and Sharing

- **Submission of Data Management & Sharing Plan for all N**
(how/where/when)
- **Compliance with the ICO-approved Plan** *(may affect future)*
- **Effective January 25, 2023** *(replaces 2003 Data Sharing Policy)*
- **Supplemental info available to assist**
- **Aims to foster data stewardship**

NIH POLICY FOR DATA MANAGEMENT & SHARING

Policy Details

- **Scope:** All NIH-supported research generating scientific data
 - **Recorded factual material** commonly accepted in the scientific community to validate and replicate research findings, regardless of whether they are published or unpublished publications
 - **Does not include** lab notebooks, preliminary analyses, peer review manuscripts
- **Timelines:**
 - For **when to share data**, no later than publication or end of award (for unpublished data)
 - For **how long to share data**, consider relevant requirements and expectations (e.g., repository policies, retention requirements, journal policies) for minimum time frames

NIH POLICY FOR DATA MANAGEMENT & SHARING: Additional Expectations for Plans

■ **SHARING SHOULD BE ...**

- **The default practice**

- Maximize appropriate data sharing; plans may justify exceptions (i.e., ethical, legal, technical factors)
- All scientific data should be managed; not all scientific data must be shared

- **Responsibly implemented**

- Plans should outline protection of privacy, rights, and confidentiality
- Existing laws, regulations, and policies continue to apply

- **Prospectively planned for**

- During informed consent, including communicating how data will be used
- Data submission, including whether access to data, even if de-identified



Supplemental Information to the Policy: **Repository Selection**

- **Encourages use of established repositories**
- **Helps investigators identify appropriate data repositories**
 - e.g., use of persistent unique identifiers, attached metadata, facilitates quality assurance
 - Refers to list of [NIH-supported Data Repositories](#)
- **NIH ICs may designate specific data repository(ies)**

Supplemental Information to the Policy: **Allowable Costs**



- **Reasonable costs allowed in budget**
 - Curating data/developing supporting
 - Preserving/sharing data through repo
 - Local data management consideration
- **NOT considered data sharing costs**
 - Infrastructure costs typically included
 - Costs associated with the routine con
gaining access to research data)

NIH POLICY FOR DATA MANAGEMENT & SHARING: Plan Submission and Review

Extramural Grant Awards*

Plan Submission

With application for funding in Budget Justification section

Plan Assessment

Peer reviewers only comment on (not score) budget

NIH program staff assess Plans

Plans can be updated

**Analogous requirements for contracts and intramural research*

NIH POLICY FOR DATA MANAGEMENT & SHARING Implementation Plans

What's Next?

- **Engage in outreach** to inform development of additional supplemental information (including tribal-specific considerations)
- **Develop FAQs and other resources** to aid policy implementation
- **Clarify interactions** with other NIH data sharing policies (e.g., NIH Data Sharing Policy)
- **Develop resources** to inform data management and sharing (informed by efforts such as the [2020 NASEM report on data management](#) and [2021 NASEM workshop on the culture of data management](#))
- **Develop approaches** for incentivizing good data sharing practices

NIH POLICY FOR DATA MANAGEMENT & SHARING Implementation Considerations

What's Next?

- **Approaches and workflows** – Determine the appropriate processes by which ICs will assess Plans and monitor
- **System changes** – Enhance award management systems to support the submission, assessment, and compliance
- **Public posting of Plans** including how they will link to persistent identifiers such as DOI, and FAIR principles
- **Planning communications and guidance** to ensure NIH staff are prepared for the Policy

Elements and Common A Data Management and S

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Taunton Paine

Director, Scientific Data Sharing Policy Division
Office of Science Policy, National Institutes of Health

Info

NIH POLICY FOR DATA MANAGEMENT & SHARING: Data Management & Sharing Plan

- **Propose approach to data management & sharing**
 - Attempt to maximize appropriate sharing
 - Be consistent with FAIR (findable, accessible, interoperable, reusable)
 - Be updated throughout the award
- **Outline responsible data sharing**
 - Plans should outline protection of privacy, rights, and confidentiality
 - Existing laws, regulations, and policies continue to apply
- **Reflect applicable NIH Institute, Center, & Office expectations**
- **Address elements in 2 pages or less**

NIH POLICY FOR DATA MANAGEMENT & SHARING: Data Management & Sharing Plan

NIH recommended elements of a Plan:

1. Data type

- Identifying estimated type and amount of data to be generated (i.e. degree of data processing)
- Which data to be preserved and shared
- Accompanying metadata, other relevant data, and associated documents

2. Related tools, software, code

- Tools and software needed to access and manipulate data

3. Standards

- Standards to be applied to scientific data and metadata

NIH POLICY FOR DATA MANAGEMENT & SHARING: Data Management & Sharing Plan

NIH recommended elements of a Plan (cont.):

4. Data preservation, access, and associated timeline

- Proposed repository to be used consistent with [Supplemental Info](#)
- How data will be findable and accessible (e.g., persistent unique identifier)
- When data will be made available and for how long

5. Access, Distribution, and Reuse Considerations

- Description of factors potentially affecting data access, distribution or privacy and confidentiality protections
- Whether access to human data will be controlled

6. Oversight of data management

- Plan compliance will be monitored/ managed and by whom

Examples

1. Data Type
2. Data Preservation, Access, and Association

Example 1: Data Type

The research team will conduct approximately **20 semi-structured interviews** ... **Each interview will produce 2-3 pages** of handwritten notes in Word (.docx) format (converted from hand-written notes taken during the interview, which are promptly destroyed) and a one page analysis in **Word (.docx) format, both convertible to .pdf** for long-term storage.

In addition, the research team will **conduct analysis of the interviews in the CAQDAS program ATLAS.ti**, which will produce a **.qdp file**. ATLAS.ti is the REFI-QDA Standard for interoperability between CAQDAS programs.

The research team may come into possession of additional documents. These documents will be **digitized as .pdf files** for long-term storage.

Example 2: Data Preservation, Access Associated Timelines

Preservation

Data will be publicly shared and preserved on **Zenodo** (<https://zenodo.org/>).

Access

Zenodo is freely available to anyone. Data will be securely stored in the CERN Data Centre. Once the data is on Zenodo and published, the data set will be findable via a web search, the DOI feature, or by the assigned DOI.

Timelines

The data will be published **concurrently with publication**, but no later than the end of the experiment. Data will **be available for at least 20 years** (<https://about.zenodo.org/policies/>) and will be retained for the lifetime of the repository and the lifetime of the host laboratory CERN, or the experimental programme defined for the experiment.

Recommended practices for p

- Start early
- Know your data
- Understand applicable requirements & g
- Aim to share data in a repository
- Connect with data librarian
- Write data management and sharing cos
 - Managers, cleaning up the data, sharing
- Harmonize other documents with the Pla

How Academic Medical Centers Prepare for January

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Informationist, University of Michigan

Institutional readiness

- Identify stakeholders
- Identify local resources
- Recognize and understand challenges
- Identify opportunities
- Actions to take now

Stakeholders

- Researchers funded by NIH
 - Need to learn new policy and be able to write a Plan
- Research support staff & units (research/grant librarian)
 - Need to learn new policy to help researchers
 - Identify important things to look for in a Plan
 - Provide language to accurately describe storage
- Institutional Research Leadership
- Graduate students
 - Policy can inform how they learn to do science
- Research participants
- Taxpayers

Local resources

- Librarians and Informationists
 - Many libraries now have data librarians
 - Identify repositories, provide info about recommended
- Information Technology
 - Identifying technical infrastructure available for s
- Data Office
 - Some campuses may have a data office which c
use agreements
- Institutional Data Repository
- Champions – committed and vocal to help v

Other resources

- Online Tutorials or MOOCs - Learn about management
- Repositories – deposit guides
- DMPTool - <https://dmptool.org/>
 - Offers institutional affiliations
 - Member institutions can provide tailored guidance

Challenges

- **Educating stakeholders**
- Gathering resources for outreach and im
- Implementing effective outreach
 - Compliance vs “good science”
- Leading and coordinating
- Changing culture
 - Think about data at the beginning of a project
- Addressing ambiguity: who owns research

Opportunities

- Recognizing data as valuable research output
 - Incentives, promotion & tenure
 - More opportunities for researchers to collaborate
- Building collaborations with different offices across campus
- Preparing institution and researchers to fulfill requirements from other funding sources
- Creating or updating an institution-wide data policy

Actions to take now

1. Start conversations

Start conversations

- Who to talk to:
 - Deans & Directors
 - Research administrators
 - Grants administrators
 - Information Technology
 - Library
 - Data Office or honest broker
- What to say:
 - The NIH recently announced a new data policy. In January 2023 will need to include a data management plan. We would like to talk more with you about this. When

Actions to take now

1. Start conversations!
2. Review institutional policies

Review institutional policies

- Check your campus faculty/researcher handbook
 - Research Data Policy
 - Institutional Data Policy
 - Data Ownership
 - Copyright Policy
- Examples:
 - Harvard University - <https://researchdatamanagement.harvard.edu/>
 - University of Wisconsin-Madison - <https://data.wisc.edu/>

Actions to take now

1. Start conversations!
2. Review institutional policies
3. Conduct a Services Gap Analysis

Conduct a Services Gap Analysis

What services do you have? What will faculty need?

- Planning for data
- Identifying data repository options
- Documenting data
- Protecting sensitive information
- Understanding funder and publisher data requirements
- Curation, documentation, and management

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Resource: Association of American Universities and Association of Public and Land-grant Universities (2021). *Guide to Accelerate Public Access to Research Data*. Washington, DC.

DOI: <https://doi.org/10.31219/osf.io/tjybn>

Actions to take now

1. Start conversations!
2. Review institutional policies
3. Conduct a Services Gap Analysis
4. Create pathways to information

Create pathways to information

- Frequently Asked Questions
- Resource list or website
 - Point to both local and outside resources (don't reinvent the wheel!)
- Workflows
 - Which service can help with each part of data

Draft: Where to find information

Data Type

Description of research and expected data [grant proposal?]

Consider ethical and legal restrictions for what you can share

Related tools, software, code

Check laboratory computers for program information used to analyze data

Will you be writing scripts or code to help process the data?

Standards

Check grant for mention of specific standards

Does your field of study have templates or standards for data collection?

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Actions to take now

1. Start conversations!
2. Review institutional policies
3. Conduct a Services Gap Analysis
4. Create pathways to information
5. Make an outreach plan & implement it

Make an outreach plan & impl

- Identify champions
- Decide on outreach approach – complian
- Decide on various methods & timelines for
 - Videos, flyers, digital signs, workshops, mee
- Write an “elevator speech” and/or presen awareness

Actions to take now

1. Start conversations!
2. Review institutional policies
3. Conduct a Services Gap Analysis
4. Create pathways to information
5. Make an outreach plan & implement it

**Do you have any resources or additional
share in the chat!**

Additional Resources

- NIH Data Management & Sharing Policy - https://grants.nih.gov/grants/policy/data_sharing/
- Selecting a Repository for Data Resulting from Research - <https://grants.nih.gov/grants/guide/grantsguide21-016.html>
- re3data (Registry of Research Data Repositories) - <https://www.re3data.org/>
- Briney KA, Coates H, Goben A (2020) Foundational Principles for Research Data Management. Research Identification Number: e56508. <https://doi.org/10.3897/rio.6.e56508>

Thank You - Quest

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