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

Samuel, Sara; Paine, Taunton

NIH's New Data Manag Sharing Policy—How Acad 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/fi[nancial relationships]
with respect to this education[al activity.]

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Special Thanks

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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, includir

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 requiremer

Overview of the New Data Management and Shar...

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Taunton Paine
Director, Scientific Data Sharing Policy
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NIH POLICY FOR DATA MANAGEMENT & SHARING:
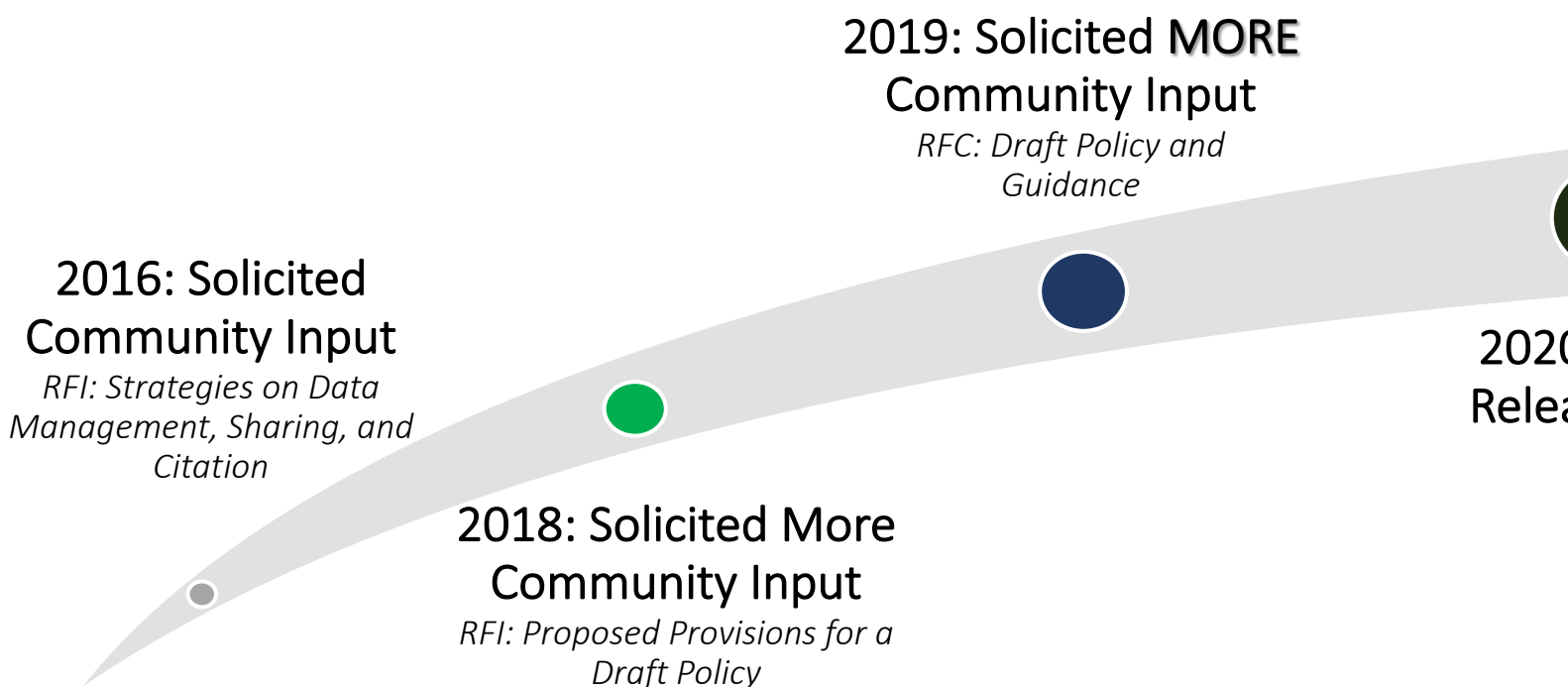## Data Stewardship Goals

- **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 r**
  - Foster transparency and acc
  - Demonstrate stewardship ov
  - Maximize research participar
  - Support appropriate protecti

- Sought public comment repeatedly

- Tribal Consultation*
  *Details provided in "NIH Tribal Consultation Report: NIH Draft Policy for Data Managem

- Intersection with other government agencies & Secretary's
  Human Research Protections

2019: Solicited MORE Community Input
RFC: Draft Policy and Guidance

2016: Solicited Community Input
RFI: Strategies on Data Management, Sharing, and Citation

2020 Relea

2018: Solicited More Community Input
RFI: Proposed Provisions for a Draft Policy

NIH Policy for Data Management a

- **Submission of Data Management & Sharing Plan for all N** *(how/where/when)*

- **Compliance with the ICO-approved Plan** *(may affect futu*

- **Effective January 25, 2023** *(replaces 2003 Data Sharing Po*

- **Supplemental info available to assist**

- **Aims to foster data stewardship**

- **Scope:** All NIH-supported research generating *scientific data*
  - **Recorded factual material** commonly accepted in the scientific co validate and replicate research findings, regardless of whether the publications
  - **Does not include** lab notebooks, preliminary analyses, peer revie

- **Timelines:**
  - For **when to share data,** no later than publication or end of award unpublished data)
  - For **how long to share data,** consider relevant requirements and expectations (e.g., repository policies, retention requirements, jo policies) for minimum time frames

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 confiden

  - Existing laws, regulations, and policies continue to apply

- **Prospectively planned for**

  - During informed consent, including communicating how data v

  - Data submission, including whether access to data, even if de-i

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](#)

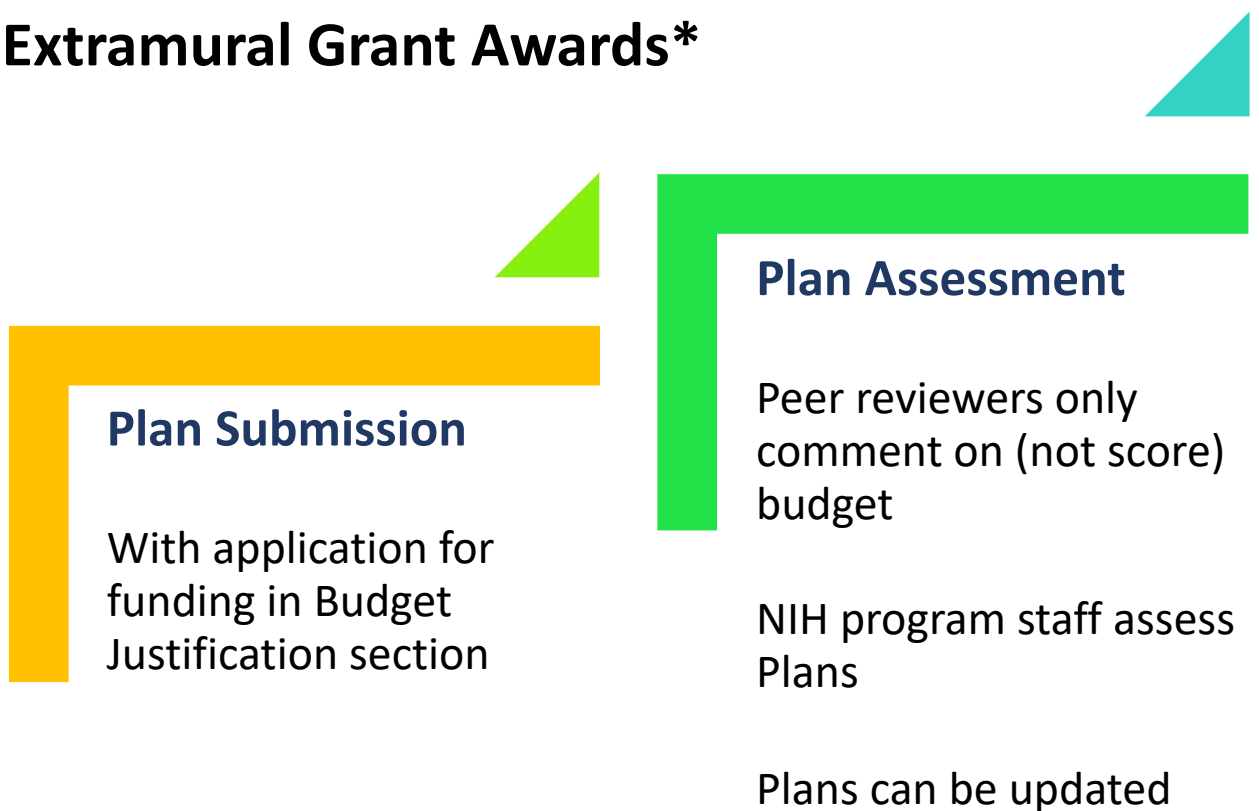- **NIH ICs may designate specific data repository(ies)**

Supplemental Information to the Policy:
Allowable Costs

- **Reasonable costs allowed in budge**
  - Curating data/developing supporting
  - Preserving/sharing data through repo
  - Local data management consideratior

- <u>**NOT**</u> **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

What's Next?

- **Engage in outreach** to inform development of additior
  supplemental information (including tribal-specific consi

- **Develop FAQs and other resources** to aid policy imp

- **Clarify interactions** with other NIH data sharing policie
  Sharing Policy)

- **Develop resources** to inform data management and s
  (informed by efforts such as the 2020 NASEM report or
  2021 NASEM workshop on the culture of data manage

- **Develop approaches** for incentivizing good data shari

What's Next?

- **Approaches and workflows** – Determine the appropr[iate]
  processes by which ICs will assess Plans and monitor

- **System changes** – Enhance award management sys[tems to]
  support the submission, assessment, and compliance [of Plans]

- **Public posting of Plans** including how they will link to
  persistent identifiers such as DOI, and FAIR principles

- **Planning communications and guidance** to ensure [that]
  NIH staff are prepared for the Policy

Elements and Common A
Data Management and S

A PRIM&R Virtual Event

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Taunton Paine
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Info

Data Management & Sharing Plan

- **Propose approach to data management & sharin**
  - Attempt to maximize appropriate sharing
  - Be consistent with FAIR (findable, accessible, interoperable,
  - Be updated throughout the award

- **Outline responsible data sharing**
  - Plans should outline protection of privacy, rights, and confide
  - Existing laws, regulations, and policies continue to apply

- **Reflect applicable NIH Institute, Center, & Office expectations**

- **Address elements in 2 pages or less**

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 doc

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

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 id
   - 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 Associat

Example 1: Data Type

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

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

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

Example 2: Data Preservation, Acces Associated Timelines

Preservation	Data will be publicly shared and pres **Zenodo** (https://zenodo.org/).
Access	**Zenodo is freely available** to anyor securely stored in the CERN Data C Zenodo and published, the data set will be findable via a web search, the feature, or by the assigned DOI.
Timelines	The data will be published **concurre publication**, but no later than the en data will **be available for at least 20** (https://about.zenodo.org/policies/) c retained for the lifetime of the reposit lifetime of the host laboratory CERN, experimental programme defined for

Recommended practices for p

- Start early

- Know your data

- Understand applicable requirements & gu

- 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 C
Prepare for January

Sara Samuel

Informationist, University of Michig

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
- Research support staff & units (research/gra
  library)
  - 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 use agreements
- Institutional Data Repository
- Champions – committed and vocal to help v

Other resources

- Online Tutorials or MOOCs - Learn abou
  management

- Repositories – deposit guides

- DMPTool - https://dmptool.org/
  - Offers institutional affiliations
  - Member institutions can provide tailored guid

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 projec
- Addressing ambiguity: who owns researc

Opportunities

- Recognizing data as valuable research o

  - Incentives, promotion & tenure

  - More opportunities for researchers to collabo

- Building collaborations with different offic
  campus

- Preparing institution and researchers to f
  requirements from other funding sources

- Creating or updating an institution-wide d

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. January 2023 will need to include a data manag would like to talk more with you about this. Wher

Actions to take now

1. Start conversations!
2. Review institutional policies

Review institutional policies

- Check your campus faculty/researcher h

  - Research Data Policy

  - Institutional Data Policy

  - Data Ownership

  - Copyright Policy

- Examples:

  - Harvard University - https://researchdatamanagem

  - University of Wisconsin-Madison - https://data.wisc

Actions to take now

1. Start conversations!

2. Review institutional policies

3. Conduct a Services Gap Analysis

Conduct a Services Gap Analy

What services do you have? What will facul

- Planning for data

- Identifying data repository options

- Documenting data

- Protecting sensitive information

- Understanding funder and publisher data

- Curation, documentation, and managem

How
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mon

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 informatio

- Frequently Asked Questions

- Resource list or website
  - Point to both local and outside resources (do
    wheel!)

- Workflows
  - Which service can help with each part of dat

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?

Dat

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 f

  - Videos, flyers, digital signs, workshops, mee

- Write an "elevator speech" and/or preser
  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_sha

- Selecting a Repository for Data Resulting fro Research - https://grants.nih.gov/grants/guid 21-016.html

- re3data (Registry of Research Data Reposit https://www.re3data.org/

- Briney KA, Coates H, Goben A (2020) Foun Research Data Management. Research Ide e56508. https://doi.org/10.3897/rio.6.e56508

Thank You - Quest

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