NEW!

NIH Policy for Data Management & Sharing

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Taunton Paine, MA
Director, Scientific Data Sharing Policy Division
Office of Science Policy
National Institutes of Health
sciencepolicy@mail.nih.gov
Overview

• Evolution of NIH Scientific Data Sharing Efforts

• Developing the NIH Data Management and Sharing Policy

• Overview of the NIH Data Management and Sharing Policy

• Implementation Activities

• Questions/Discussion
Why Share Research Data?

• **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 research**
  – Foster transparency and accountability
  – Demonstrate stewardship over taxpayer funds
  – Maximize research participants’ contributions
  – Support appropriate protections of research participants’ data
1980s: Grantee Data & Federal Records

• 1980 SCOTUS: *Forsham v. Harris*\(^1\)
  - NIH-funded University Group Diabetes Program found commonly prescribed diabetes drug had 2.5x increased risk of death from heart disease; FDA used the findings to create labeling requirements
  - A group of scientists requested raw data (data forms and computer tapes) through the Freedom of Information Act (FOIA); Supreme Court affirmed grantees’ data were not agency records and were not subject to FOIA

• 1988 PHS Policy on Distribution of Research Resources
  - Expected unique research resources be made readily available for research purposes to the scientific community after publication

• 1989 NHLBI “L’Enfant Memo”\(^2\)
  - NHLBI Director Claude L’Enfant created policy that grantees and contractors would data available from clinical trials, epidemiological studies, and other large-scale studies within three years of major publications
  - Intended to maximize the Federal government’s investment in research

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2- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4286227/
1990s: Sharing and Transparency

• 1996 Human Genome Project “Bermuda Principles”
  – Expected immediate and broad sharing of data

• 1997 FDA Modernization Act and ClinicalTrials.gov
  – Established ClinicalTrials.gov

• “Six Cities Study” and 1999 Shelby Amendment
  – NIH-funded “Six Cities Study” found in 1993 that fine particle air pollution (>2.5 microns) reduced lifespans
  – Study findings were used by EPA in 1997 for regulations
  – Findings were challenged by groups who sought access to data, but access was denied on the basis of informed consent and privacy
  – Sen. Shelby created “Shelby Amendment,” later interpreted that federally-funded data underlying regulations must be made available
  – Beginning of broad consensus that data underlying publicly-funded studies should be made available
2000s: Towards Sharing by Default

- **2003 NIH Data Sharing Policy**
  - Expects applicants seeking $500,000 or more to submit a data sharing plan

- **2006 and 2014 NIH GWAS and Genomic Data Sharing policies**
  - Established expectation that NIH-funded studies generating “large-scale” genomic data would rapidly submit those data to NIH-designated repositories
  - Expects consent for generation, future use, and sharing of human data; institutional certification indicating data use limitations; and oversight by NIH Data Access Committees

- **2013 “Holdren Memo”**
  - Required by 2010 America COMPETES Reauthorization Act
  - White House Office of Science and Technology Policy directed all Federal Depts. and Agencies with R&D budgets $100 million+ to work toward requiring data management and sharing plans be submitted from all applicants
An Iterative Policy Development Process

- Sought public comment at multiple points throughout development
- Tribal Consultation*
  *Details provided in “NIH Tribal Consultation Report: NIH Draft Policy for Data Management and Sharing”
- Obtained input from other government agencies & Secretary’s Advisory Committee for Human Research Protections

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

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

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

2020: Policy Release Date

2023: Policy Effective Date
NIH Policy for Data Management and Sharing

- Aims to foster a culture of data stewardship
- Submission of Data Management & Sharing Plan for all NIH-funded research *(how/where/when)*
- Compliance with the NIH-approved Plan *(may affect future funding)*
- Effective January 25, 2023 *(replaces 2003 Data Sharing Policy)*
- Additional resources available to assist
The Devil is in the Details...

- **Scope:** All NIH-supported research generating *scientific data*, i.e., those data commonly accepted in scientific community “as of sufficient quality to validate and replicate research findings”

- **SHARING SHOULD BE ...**
  - **The default practice**
    - Maximize appropriate data sharing; Plans may justify exceptions (i.e., ethical, legal, technical factors)
  - **Responsibly implemented**
    - Plans should outline protection of privacy, rights, and confidentiality; existing laws, regulations, and policies continue to apply
  - **Timely**
    - **When to share data?** No later than *publication* or *end of award* (if unpublished); other relevant requirements and expectations (e.g., repository policies, retention requirements, journal policies) for minimum time frames
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

- **Plan Compliance**
  - Incorporated into Terms and Conditions
  - Monitored at regular reporting intervals – mechanisms and tools to support oversight under development
  - Compliance may factor into future funding decisions

*Analogous requirements for contracts, OTAs, IRP*
Repository Selection for Managing and Sharing Data

- Use of established repositories are encouraged
  - e.g., NIH BMIC list of repositories

- Supplemental information provided to help investigators identify appropriate data repositories
  - e.g., use of persistent unique identifiers, attached metadata, facilitates quality assurance

- NIH ICs may designate specific data repository(ies)
Supplemental Info to the Policy: Allowable Costs

• Reasonable costs allowed in budget requests
  – Curating data/developing supporting documentation
  – Preserving/sharing data through repositories
  – Local data management considerations

• **NOT** considered data 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)
What’s Next?

- **Outreach activities**: engaging community to make aware of the policy and understand implementation challenges (e.g., *April 28-29 2021 NAS workshop on the culture of data management & sharing*)

- **Enhance compliance mechanisms**: building tools to streamline compliance and facilitate tracking, public posting of Plans

- **Harmonize data sharing expectations** and reduce redundancy

- **Develop resources**: develop FAQs, guidance, additional supp. information (i.e., for AI/AN data), cost estimating tools

- **Strengthen incentives** for data sharing, e.g., through data citation

~2-year implementation window!
Thank You!

- **OSP Data Management and Sharing Website**
- **NOT-OD-21-013** — Final NIH Policy for Data Management and Sharing
- **NOT-OD-21-014** — Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan
- **NOT-OD-21-015** — Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing
- **NOT-OD-21-016** — Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research

Questions? sciencepolicy@mail.nih.gov