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 research**
  – Foster transparency and accountability
  – Demonstrate stewardship over taxpayer funds
  – Maximize research participants’ contributions
  – Support appropriate protections of research participants’ data
NIH Policy for Data Management and Sharing

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

- Sought public comment repeatedly
- Tribal Consultation*
  *Details provided in “NIH Tribal Consultation Report: NIH Draft Policy for Data Management and Sharing”
- Intersection with 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
The Devil is in the Details...

• **Scope:** All NIH-supported research generating *scientific data*

• **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    • **When to share data?** No later than publication or end of award (if unpublished); other relevant requirements and expectations (e.g., repository policies, retention requirements, journal policies) for minimum time frames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
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)
Supplemental Info 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

• NIH ICs may designate specific data repository(ies)
Resources for Implementation

What’s Next?

- Outreach and engagement – additional supplemental information to come (including tribal-specific considerations)

- Develop tools for estimating data management and sharing costs (e.g., [2020 NASEM report on forecasting costs](https://www.nas.edu) & [April 2021 NASEM workshop on the culture of data management & sharing](https://www.nas.edu))

- Develop mechanisms, tools, and approaches for incentivizing good data sharing practices

- Clarify interactions with other NIH-wide (e.g., GDS Policy) and ICO-specific data sharing policies

- Developing FAQs and other resources to aid policy implementation

~2-year implementation window!
Next Steps: Interaction with the GDS Policy

• Working with OER in consultation with trans-NIH stakeholders to compare and clarify areas of overlap with the GDS Policy
  
  – Harmonizing compliance mechanisms, tools, and approaches to minimize burden for projects subject to both policies  
  – Developing resources to help navigate policy expectations and simplify workflows

• Aim to reduce community burden whenever possible and ensure consistency across NIH
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](mailto:sciencepolicy@mail.nih.gov)