IMPLEMENTATION UPDATE – NIH COUNCIL OF COUNCILS, MAY 20, 2022

NIH POLICY FOR DATA MANAGEMENT & SHARING

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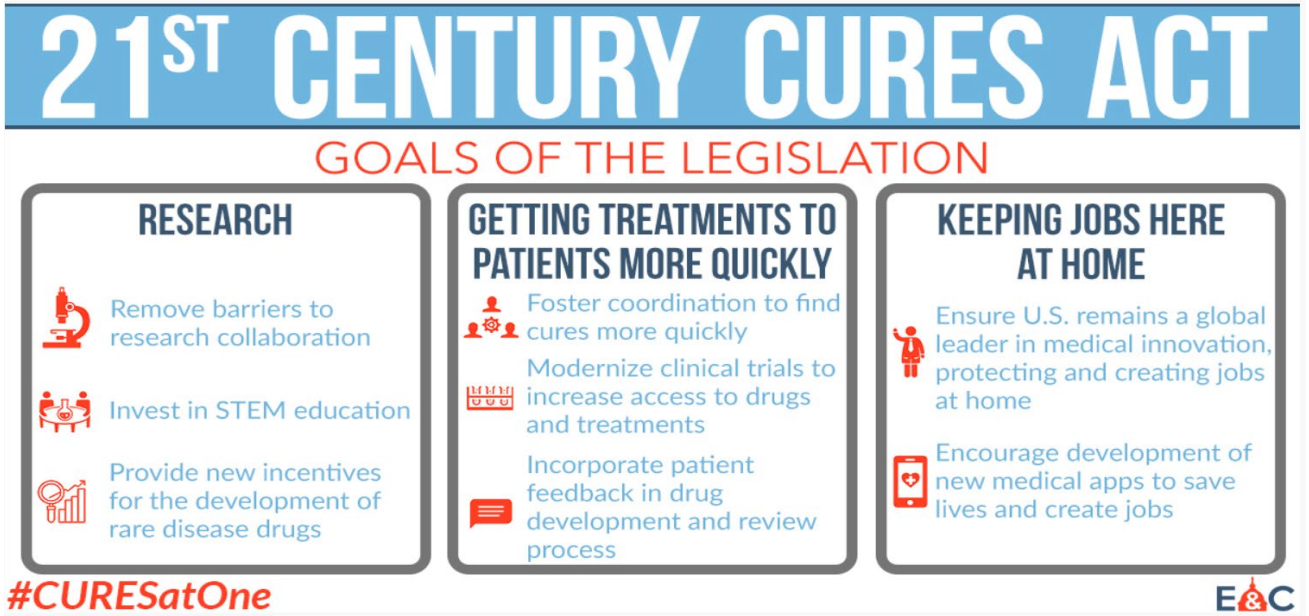
Cindy Danielson, PhD (Office of Extramural Research)
Julia Slutsman, PhD (Office of Extramural Research)
Taunton Paine, MA (Office of Science Policy)**

SOME CONTEXT

DATA SHARING IS EXPECTED

"Increasing the pool of researchers who can access data and decreasing the time it takes for them to review and find new patterns in that data ***is critical to speeding up development of lifesaving treatments for patients.****"*

- Joe Biden



"[The NIH Director] ***may require recipients of NIH awards to share scientific data****, to the extent feasible, generated from such NIH awards …"*

- 21st Century Cures Act

"Only now that the new Cures Act privacy protections are in place, are ***we moving forward on the exciting new authority to require data sharing****."*

- Francis Collins

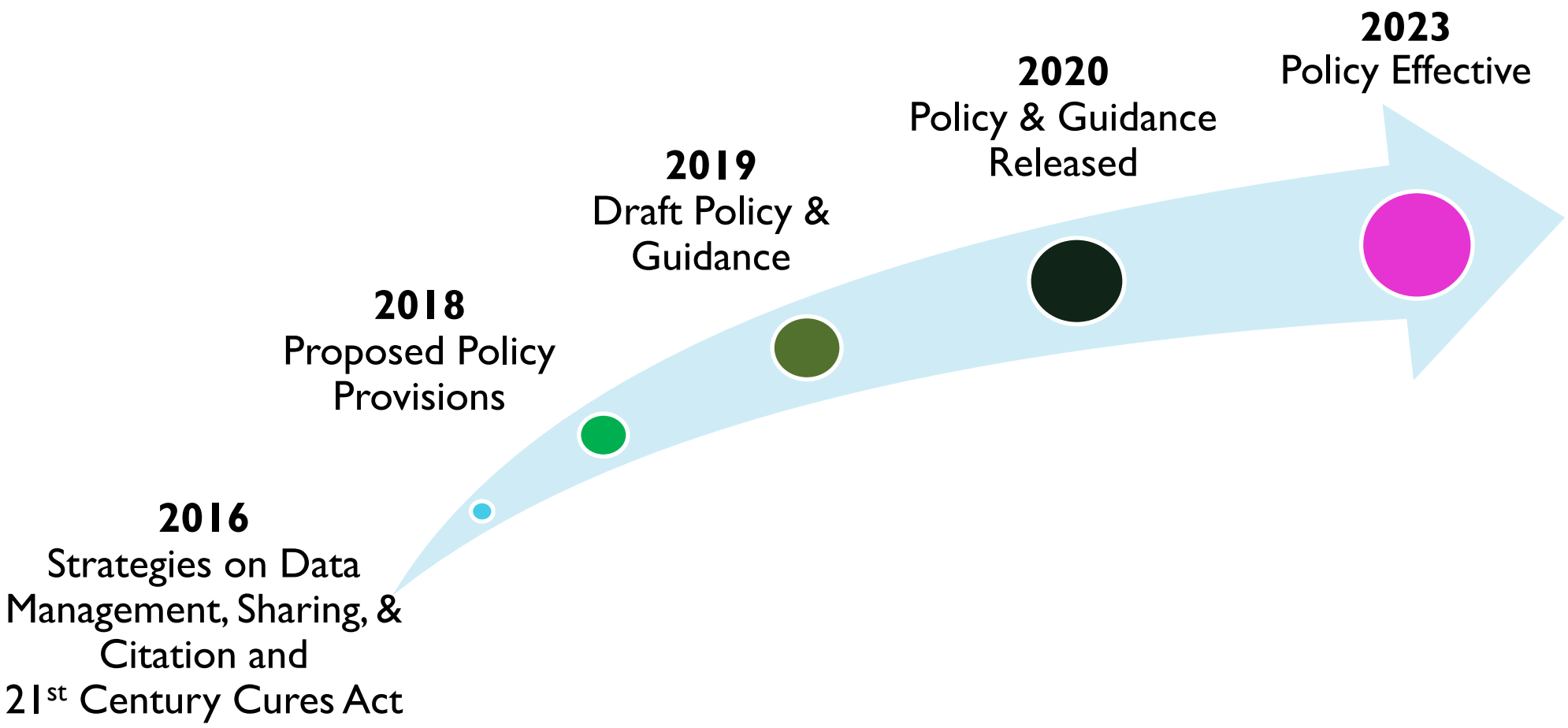
SOME CONTEXT

DATA SHARING POLICIES AREN'T NEW

- 2003 NIH Data Sharing Policy (awards >500K)
- 2014 NIH Genomic Data Sharing Policy (human & non-human genomic data)
- 2016 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information
- Autism Data Sharing Policy (NIMH, NICHD, NIDCD, NIEHS, NINDS)
- IC-specific policies and guidelines (e.g., NHLBI, NIAID, NIMH)
- Program-specific policies and guidelines (e.g., Cancer Moonshot, HEAL, BRAIN)

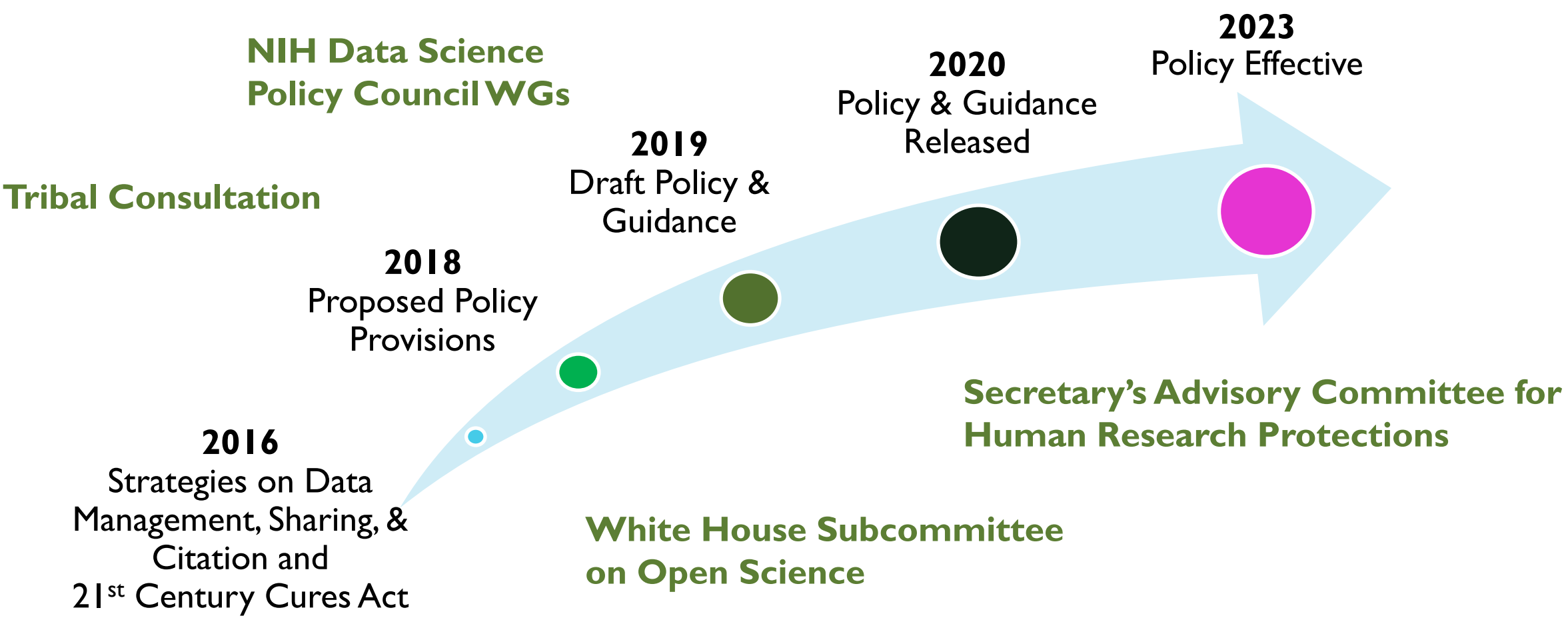
SOME CONTEXT

LONG ARC OF ITERATION



SOME CONTEXT

LONG ARC OF ITERATION



NIH POLICY FOR DATA MANAGEMENT & SHARING

- TWO BASIC REQUIREMENTS
  - Submission of a Data Management & Sharing "Plan" for all NIH-funded research
  - Compliance with the ICO-approved Plan
- Effective January 25, 2023 *(replaces 2003 Data Sharing Policy)*

POLICY EXPECTATIONS

SHARING SHOULD BE …

- **The default practice**
  - Data sharing should be maximized
  - Justifiable limits for technical/ethical/legal factors
- **Responsibly implemented**
  - Outline protection of privacy, rights, and confidentiality
  - Abide by existing laws, regulations, and policies
- **Prospectively planned for at all stages of the research process**

PLAN SUBMISSION & REVIEW *(*EXTRAMURAL)*

Plan Submission

With application

Brief Plan description in Budget Justification

Full Plan as a separate attachment

Plan Assessment

Peer review comment on (not score) budget

NIH program staff assess Plans

Plans can be revised

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*

FLEXIBLE POLICY – KEY PARAMETERS

- **All data should be managed but not all data needs to be shared**
  - **What's in:** All NIH-supported research generating *scientific data* "Recorded factual material… of sufficient quality to validate and replicate research findings" – published or unpublished
  - **What's out:** lab notebooks, preliminary analyses, case report forms, physical objects

- **Data should be accessible as soon as possible**
  - No later than publication or end of award
  - Considerations regarding how long data should be shared (e.g., journal policies, repository policies)

'Which brings us to my next point.'

ROADMAP TO 2023 & BEYOND

OPEN MIKE

Helping connect you with the NIH perspective, and helpi

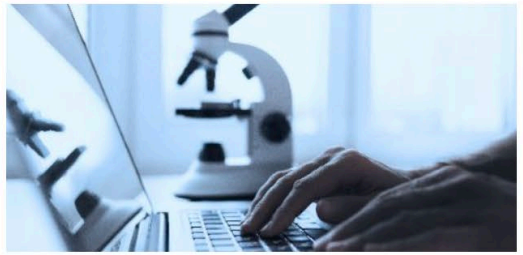
UNDER THE POLISCOPE

- **Out now!**
  - Webinars & FAQs
  - DRAFT Guidance for Researchers working with AI/AN Participants
- **Before 2023:**
  - Additional supplemental information (e.g., cost considerations, protecting privacy)
  - Sample plans
  - Harmonization of GDS Policy
- **Beyond 2023:**
  - Ongoing assessment of the Policy for short- and long-term goals
  - Incentives for data sharing

Just launched!
Sharing.nih.gov

https://sharing.nih.gov

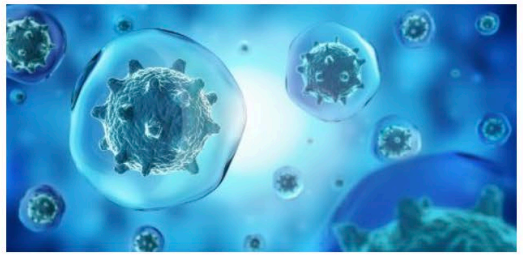
Explore the areas in which NIH has sharing policies.



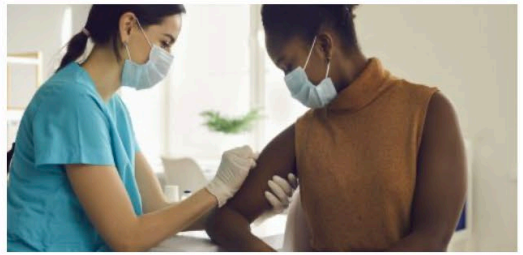
Scientific Data

Genomic Data

Research Tools



Model Organisms



Clinical Trials

Research Publications
NIH expects that all peer-reviewed manuscripts be publicly available on PubMed Central.

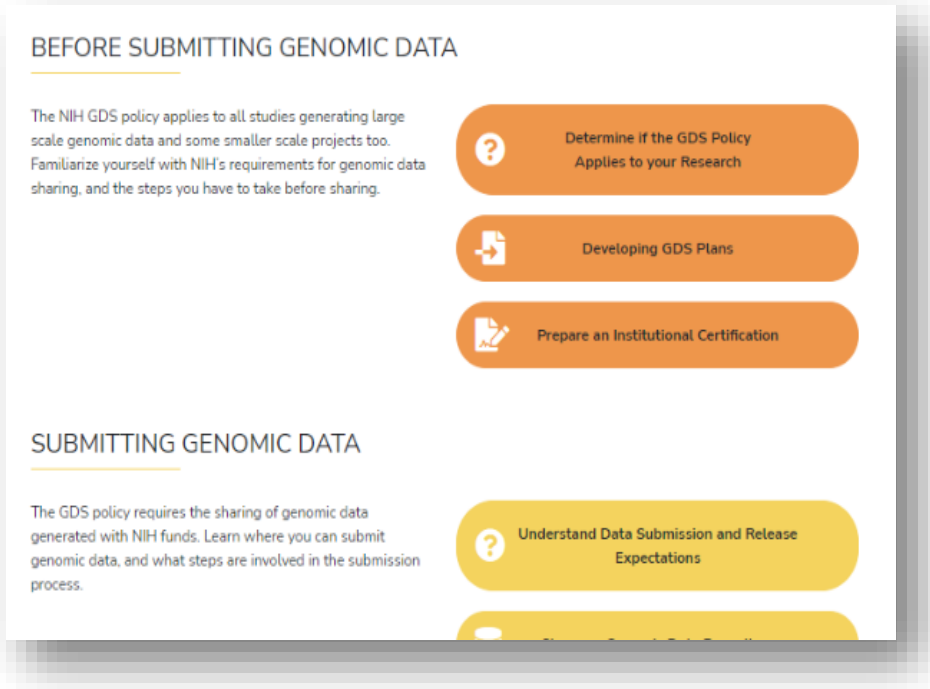
Not sure where to start?

Find which policies apply to you

https://sharing.nih.gov

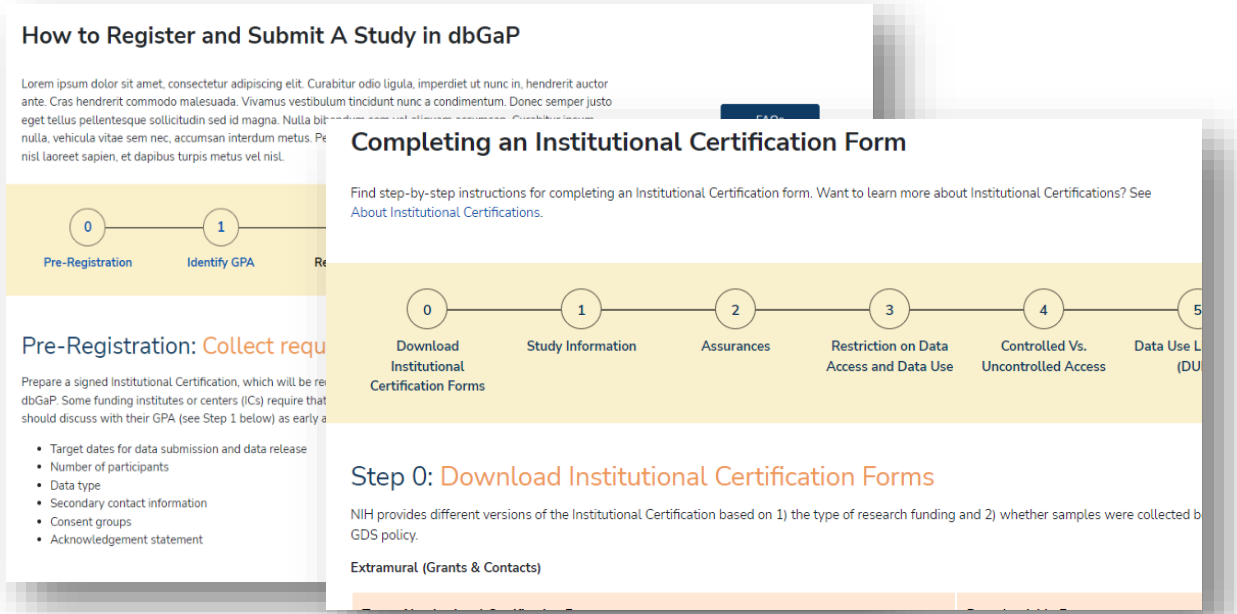
Site Structure

Key Resources



Policy Overview Infographics

Decision Tool



Step-by-Step Instructions

Data Management and Sharing Policy

NIH has a longstanding commitment to making the results of NIH-funded funded research available. Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, and providing accessibility to high-value datasets.

About the Data Management and Sharing Policy →

Planning and Budgeting for Data Management & Sharing

Find out what NIH expects in a Data Management & Sharing plan and what costs are allowed in a request.

Data Management

Proper data management is crucial for maintaining scientific rigor and research integrity. Learn about best practices for scientific data management.

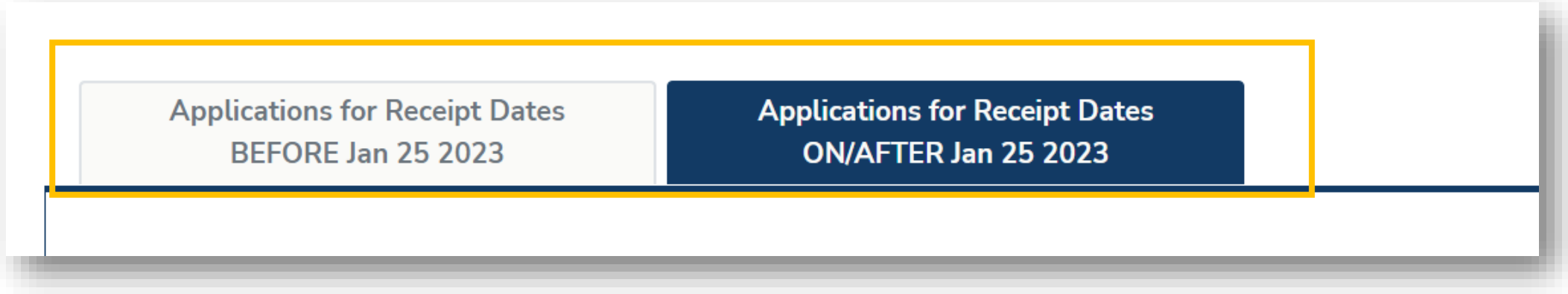
Sharing Scientific Data

Under the NIH Data Management & Sharing Policy, investigators are empowered to choose the most appropriate methods for sharing scientific data. Learn more about methods for data sharing and selecting data repositories.

Representing 2003 vs. 2023 Data Sharing Policies

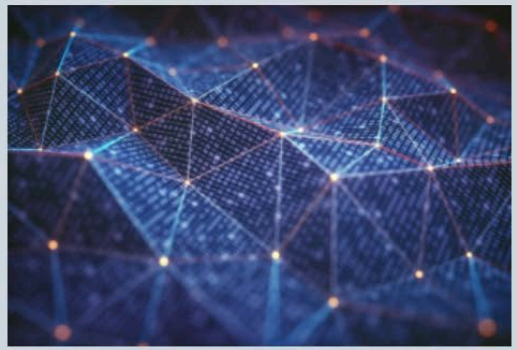
Content represented on 2 tabs based on date

- Applications submitted before January 25, 2023
- Applications submitted on/after January 25, 2023



News & Events

Sticky



Gearing Up for 2023: Implementing the NIH Data Management and Sharing Policy

January 25, 2022

Latest News

Gearing Up for 2023 Part II: Implementing the NIH Data Management and Sharing Policy

May 12, 2022

NIH's All of Us Research Program Releases First Genomic Dataset of Nearly 100,000 Whole Genome Sequences

Upcoming Events

NNLM Seminar Series on NIH Data Management and Sharing Part 5: Policy Recap and Q&A

Webex Webinar

May 24, 2022
02:00 pm - 03:30 pm EST

WHAT WE'RE HEARING

- **One person's flexibility is another's ambiguity**
  - *How to interpret scientific data definition?*
  - *Where should data be shared?*
  - *How does this relate to other ICO data sharing policies?*
- **Where is the money coming from?**
  - *Is NIH going to raise budget caps?*
  - *What happens after the award ends?*
  - *How will program officers assess plans?*
- **Bottom line: who is paying attention to this?**
  - *Will Plans be public?*
  - *How will NIH enforce compliance?*

CLOSING THOUGHTS

- Data sharing has long been expected
- New policy raises level, extent, and depth of data sharing
- Implementation January 2023 with continuous learning thereafter
- Requirements: Data management and sharing plan; compliance with agreed-upon plan
- Elements: Data management, budgeting, repository
- Please pay attention to outreach activities and our website (https://sharing.nih.gov)