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

# NIH POLICY FOR DATA MANAGEMENT & SHARING

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**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

# 21<sup>ST</sup> CENTURY CURES ACT

## GOALS OF THE LEGISLATION

### RESEARCH



Remove barriers to research collaboration



Invest in STEM education



Provide new incentives for the development of rare disease drugs

### GETTING TREATMENTS TO PATIENTS MORE QUICKLY



Foster coordination to find cures more quickly



Modernize clinical trials to increase access to drugs and treatments



Incorporate patient feedback in drug development and review process

### KEEPING JOBS HERE AT HOME



Ensure U.S. remains a global leader in medical innovation, protecting and creating jobs at home



Encourage development of new medical apps to save lives and create jobs

#CUREsatOne

E&C

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

- 21<sup>st</sup> 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

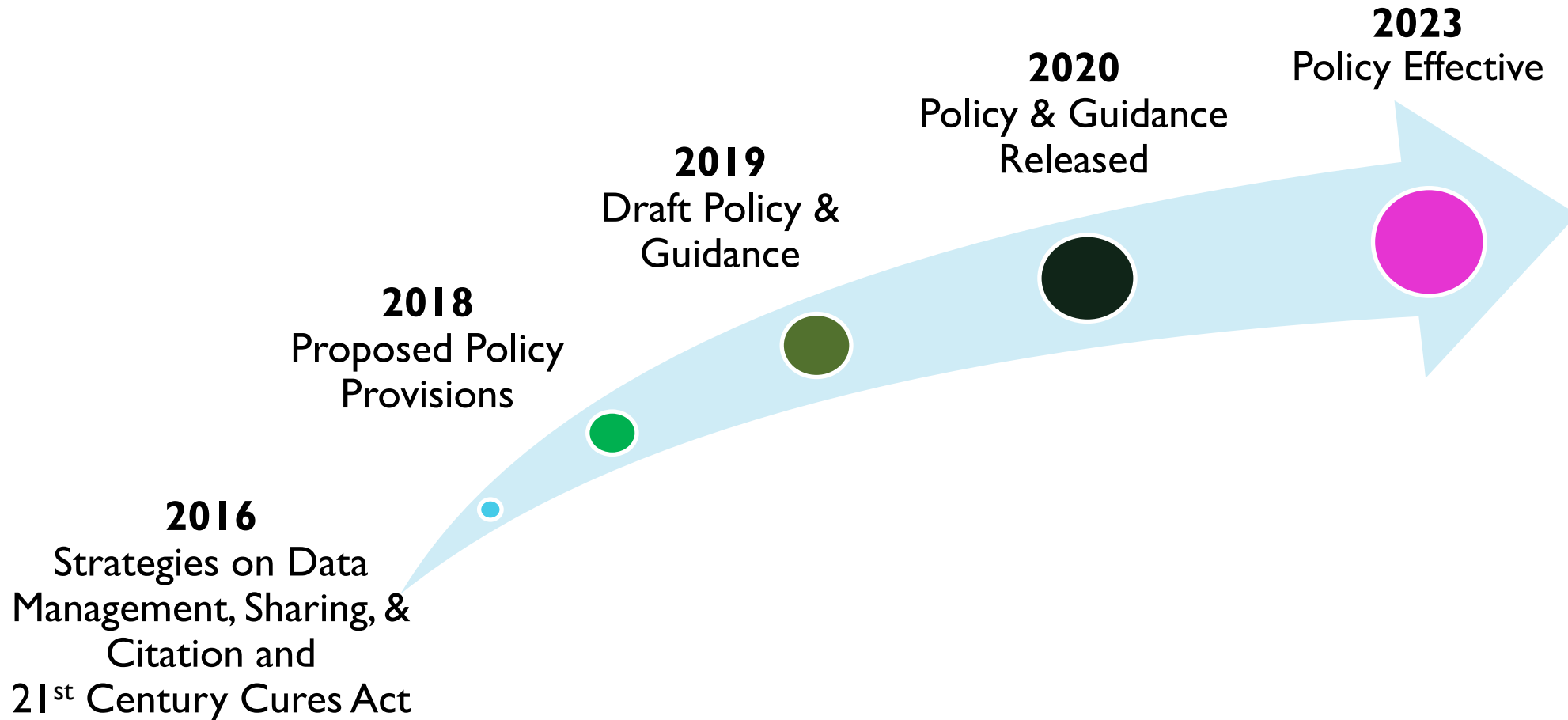
SOME CONTEXT

## 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 Data Science  
Policy Council WGs**

**Tribal Consultation**

**2016**  
Strategies on Data  
Management, Sharing, &  
Citation and  
21<sup>st</sup> Century Cures Act

**2018**  
Proposed Policy  
Provisions

**2019**  
Draft Policy &  
Guidance

**2020**  
Policy & Guidance  
Released

**2023**  
Policy Effective

**Secretary's Advisory Committee for  
Human Research Protections**

**White House Subcommittee  
on Open Science**





## 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

- **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



OPEN MIKE

*Helping connect you with the NIH perspective, and helpi*



**Just launched!**  
**Sharing.nih.gov**

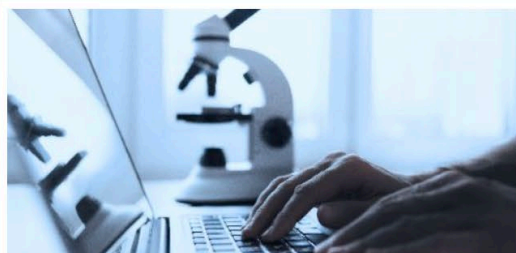
## Expediting the Translation of Research Results to Improve Human Health.

### LATEST NEWS & EVENTS

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

[View More](#)

## Explore the areas in which NIH has sharing policies.



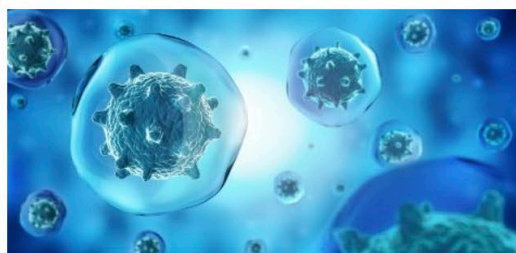
**Scientific Data**



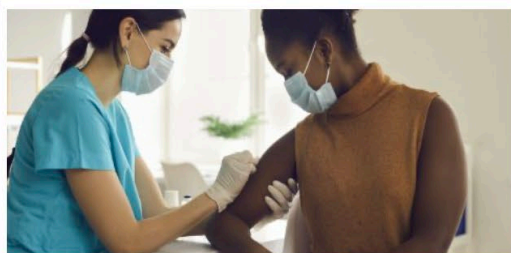
**Genomic Data**



**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](#)

# Site Structure



Search



[NIH Staff](#)  | [FAQ](#) | [Contacts & Help](#)

[DATA MANAGEMENT AND SHARING  
POLICY](#)

[GENOMIC DATA SHARING  
POLICY](#)

[OTHER SHARING  
POLICIES](#)

[ACCESSING  
DATA](#)

[ABOUT](#)

**Expediting the Translation of Research  
Results to Improve Human Health.**

# Key Resources

## BEFORE SUBMITTING GENOMIC DATA

The NIH GDS policy applies to all studies generating large scale genomic data and some smaller scale projects too. Familiarize yourself with NIH's requirements for genomic data sharing, and the steps you have to take before sharing.

- Determine if the GDS Policy Applies to your Research
- Developing GDS Plans
- Prepare an Institutional Certification

## SUBMITTING GENOMIC DATA

The GDS policy requires the sharing of genomic data generated with NIH funds. Learn where you can submit genomic data, and what steps are involved in the submission process.

- Understand Data Submission and Release Expectations
- Download Institutional Certification Forms


Policy Overview Infographics

## Which Policies Apply to My Research?

NIH has a variety of sharing policies in place for research that it funds. This tool will assist in helping you determine which of the following NIH policies apply to a particular project:

- Genomic Data Sharing Policy
- 2003 Data Sharing Policy
- Data Management & Sharing Policy (in effect January 25, 2023)
- Model Organism Sharing Policy
- Research Tools Policy

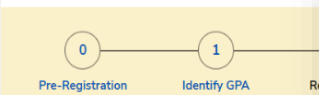
[START HERE](#)



Decision Tool

## How to Register and Submit A Study in dbGaP

Placeholder text for the registration and submission process.



### Pre-Registration: Collect required information

Prepare a signed Institutional Certification, which will be required to submit your data to dbGaP. Some funding institutes or centers (ICs) require that you should discuss with their GPA (see Step 1 below) as early as possible.

- Target dates for data submission and data release
- Number of participants
- Data type
- Secondary contact information
- Consent groups
- Acknowledgement statement

## Completing an Institutional Certification Form

Find step-by-step instructions for completing an Institutional Certification form. Want to learn more about Institutional Certifications? See [About Institutional Certifications](#).



### Step 0: Download Institutional Certification Forms

NIH provides different versions of the Institutional Certification based on 1) the type of research funding and 2) whether samples were collected by an intramural or extramural investigator.

Extramural (Grants & Contacts)

Step-by-Step Instructions

# Data Management and Sharing Policy

NIH has a longstanding commitment to making the results of NIH-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

Applications for Receipt Dates  
BEFORE Jan 25 2023

Applications for Receipt Dates  
ON/AFTER Jan 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>)