
IMPLEMENTATION UPDATE – NINR COUNCIL, SEPTEMBER 13, 2022

NIH POLICY FOR DATA MANAGEMENT & SHARING

Michael Lauer, MD

Deputy Director for Extramural Research

Director of the Office of Extramural Research

Thanks to: Lyric Jorgenson, PhD (Office of Science Policy)

Cindy Danielson, PhD (Office of Extramural Research)

Julia Slutsman, PhD (Office of Extramural Research)

Taunton Paine, MA (Office of Science Policy)

From the Highest Levels ...












"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

21ST CENTURY CURES ACT

GOALS OF THE LEGISLATION

<h4>RESEARCH</h4> <ul style="list-style-type: none"> Remove barriers to research collaboration Invest in STEM education Provide new incentives for the development of rare disease drugs	<h4>GETTING TREATMENTS TO PATIENTS MORE QUICKLY</h4> <ul style="list-style-type: none"> 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	<h4>KEEPING JOBS HERE AT HOME</h4> <ul style="list-style-type: none"> 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
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#CURESatOne 

"[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

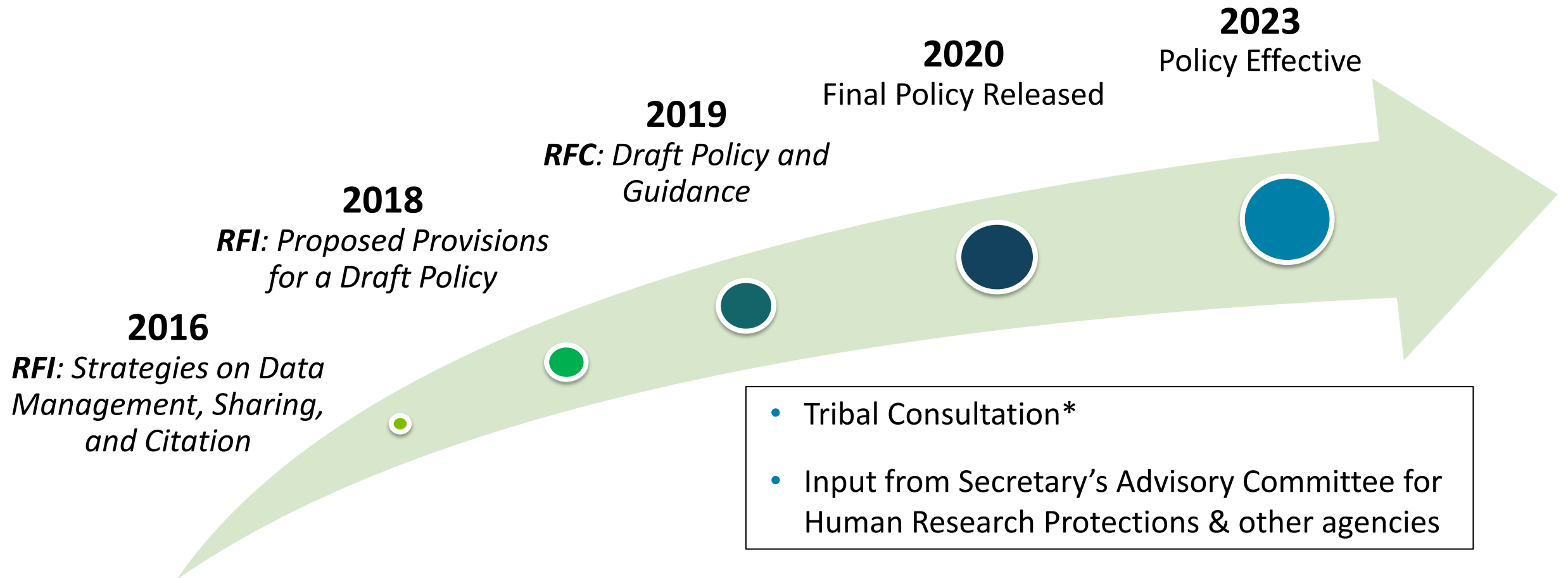
"Only now that the new Cures Act privacy protections are in place, are we moving forward on the exciting new authority to require data sharing."

- Francis Collins

Data Sharing Policies are Not New

- 2003 NIH Data Sharing Policy (awards >500K)
- 2014 NIH Genomic Data Sharing Policy
- 2016 NIH Policy on 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 (e.g., Cancer Moonshot, HEAL, BRAIN)

Iterative Policy Development through Consistent Community Engagement



*See "[NIH Tribal Consultation Report: NIH Draft Policy for Data Management and Sharing](#)"

Why does NIH Want Data to be Shared?

- **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



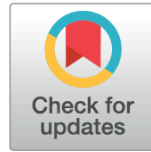
REPRODUCIBILITY IN CANCER BIOLOGY

Challenges for assessing replicability in preclinical cancer biology

- 193 experiments from 53 high-impact papers
- “Despite contacting the authors of the original papers, we were unable to obtain these data for 68% of the experiments.”



ELSEVIER



Journal of Clinical Epidemiology 150 (2022) 33–41

**Journal of
Clinical
Epidemiology**

ORIGINAL ARTICLE

Many researchers were not compliant with their published data sharing statement: a mixed-methods study

Mirko Gabelica^a, Ružica Bojčić^b, Livia Puljak^{c,*}

^a*Department for otorhinolaryngology, with head and neck surgery, University Hospital Centre Split, Spinčićeva 1, 21000, Split, Croatia*

^b*Institute of Emergency Medicine of Karlovac County, Ul. Dr. Vladka Mačeka 48, 47000, Karlovac, Croatia*

^c*Center for Evidence-Based Medicine and Health Care, Catholic University of Croatia, Ilica 242, 10000, Zagreb, Croatia*

Accepted 24 May 2022; Published online 30 May 2022

- 1,792 BioMed Central papers Jan 2019; data availability statements
- Only 7% provided the requested data

The NEW ENGLAND JOURNAL *of* MEDICINE

SPECIAL ARTICLE

Use of the National Heart, Lung, and Blood Institute Data Repository

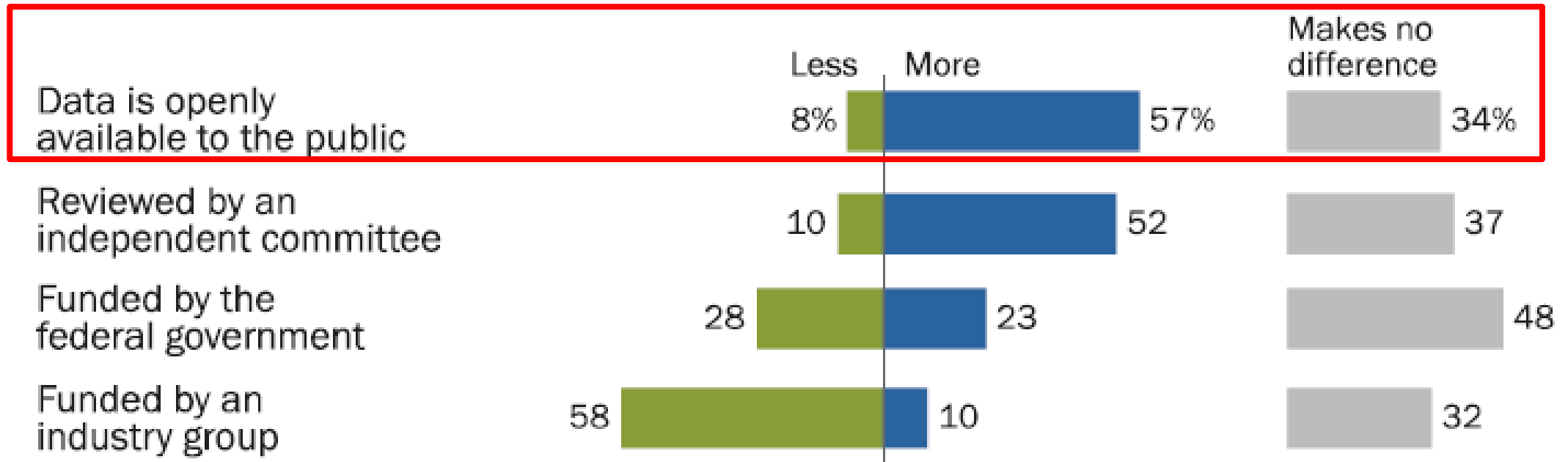
Sean A. Coady, M.S., M.A., George A. Mensah, M.D.,
Elizabeth L. Wagner, M.P.H., Miriam E. Goldfarb, B.S., A.S.N.,
Denise M. Hitchcock, B.S., and Carol A. Giffen, D.V.M.

“Data from 88 of 100 available clinical trials were requested at least once, and the median time from repository availability to first request was 235 days. A total of 277 articles were published on the basis of data from 47 trials.”

N Engl J Med 2017;376:1849-58.
DOI: 10.1056/NEJMsa1603542

A Matter of Trust

% of U.S. adults who say when they hear each of the following, they trust scientific research findings ...



https://www.pewresearch.org/science/wp-content/uploads/sites/16/2019/08/PS_08.02.19_trust.in_scientists_FULLREPORT.pdf



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*)

Details [of the Policy] Matter!

- **What's in:** Scientific data, meaning “Recorded factual material... of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications”
- **Research generating data:** Excludes T, F, C06, R13, resource, S, ...
- **What's out:** Lab notebooks, preliminary analyses, case report forms, objects
- **When to share?** No later than publication or end of award (unpublished)
- **How long?** other considerations (e.g., journal policies, repository policies)

Additional Expectations for Plans: Sharing Should Be...

- **Maximized (default)**
 - All data should be managed; not all shared
- **Responsibly implemented**
 - Plans should outline protection of privacy, rights, and confidentiality
 - Abide by existing laws, regulations, and policies
- **Prospectively planned for at all stages of the research process**



Potential Limitations on Sharing

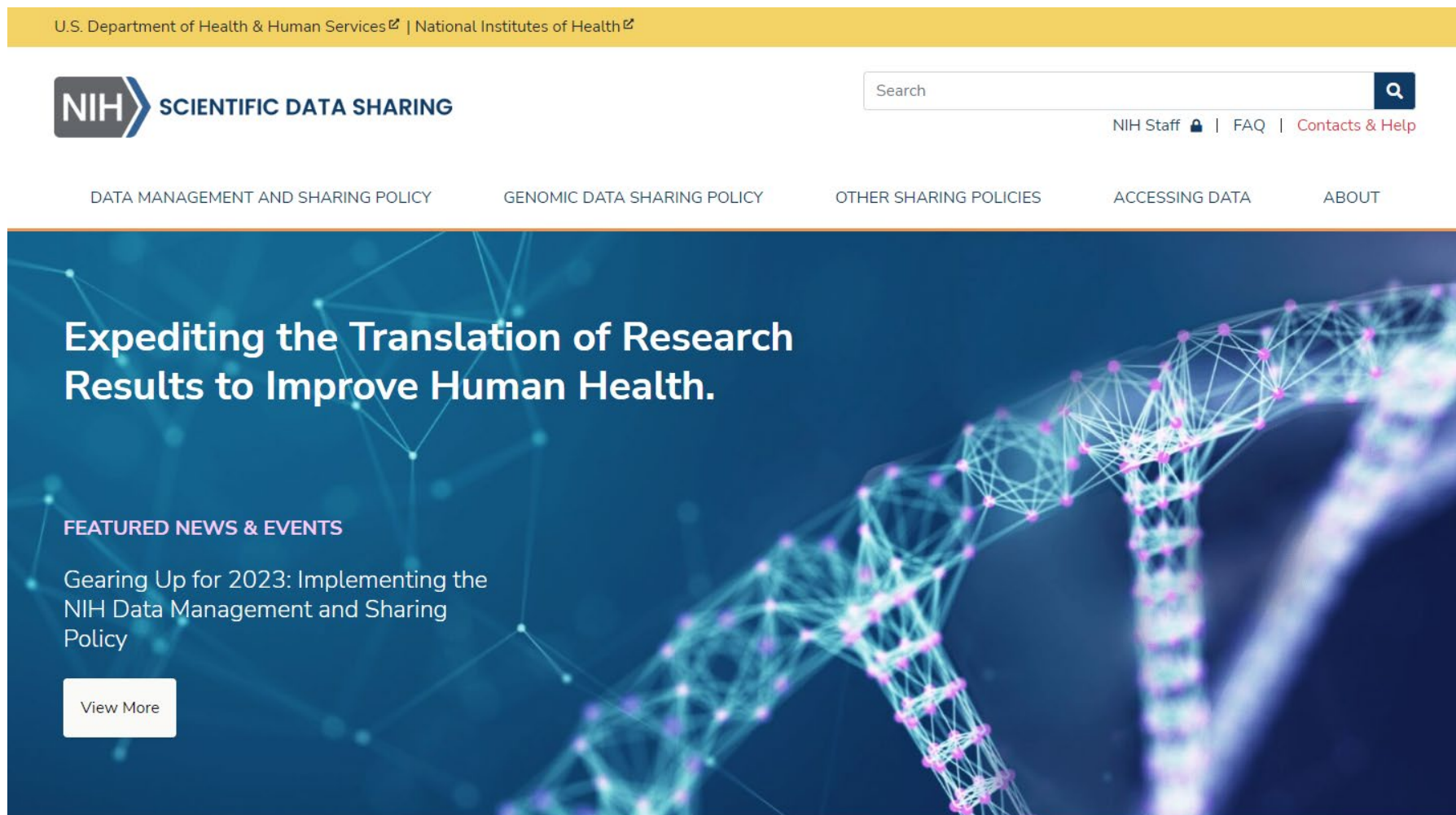
- **Justifiable ethical, legal, and technical factors include:**
 - Informed consent will not permit or limits scope of sharing or use
 - Privacy or safety of research participants would be compromised and available protections insufficient
 - Explicit federal, state, local, or Tribal law, regulation, or policy
 - Restrictions by existing or anticipated agreements with other parties
 - Datasets cannot practically be digitized with reasonable efforts

Potential Limitations on Sharing (2)

- **Reasons not generally justifiable to limit sharing include:**
 - Data are considered too small
 - Researchers anticipate data will not be widely used
 - Data are not thought to have a suitable repository
- **Additional considerations:**
 - NIH respects Tribal sovereignty and supports responsible management/sharing of AI/AN participant data
 - SBIR/STTR Program Policy Directive permits 20 years withholding

New website released April 5: sharing.nih.gov

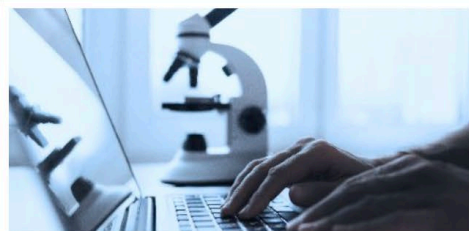
- Central source of guidance
- Data Management and Sharing, Genomic Data Sharing, Model Organisms, and Research Tools policies
- Content will be updated



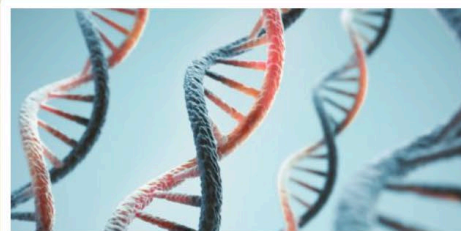
The screenshot shows the homepage of the NIH Scientific Data Sharing website. At the top, a yellow banner contains the text "U.S. Department of Health & Human Services | National Institutes of Health". Below this is the NIH logo and the text "SCIENTIFIC DATA SHARING". To the right is a search bar with the text "Search" and a magnifying glass icon. Further right are links for "NIH Staff", "FAQ", and "Contacts & Help". A navigation menu below the header includes "DATA MANAGEMENT AND SHARING POLICY", "GENOMIC DATA SHARING POLICY", "OTHER SHARING POLICIES", "ACCESSING DATA", and "ABOUT". The main content area features a large blue background with a network diagram of nodes and lines. The headline reads "Expediting the Translation of Research Results to Improve Human Health." Below this is a section titled "FEATURED NEWS & EVENTS" with a sub-headline "Gearing Up for 2023: Implementing the NIH Data Management and Sharing Policy" and a "View More" button.

Resources for: Understanding Sharing Policies

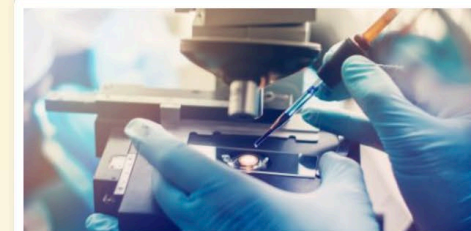
Explore the areas in which NIH has sharing policies.



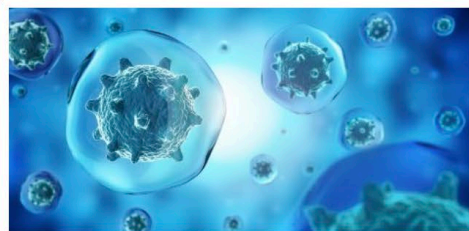
Scientific Data



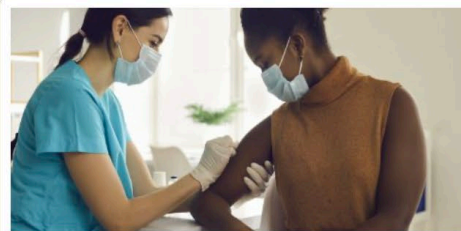
Genomic Data



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](#)

Resources for: Which Policies Apply to You?

Which Policies Apply to My Research?

Question

First, let's start by identifying what type of outputs your research will generate.

Some projects generate **data** such as DNA sequences, medical imaging, or statistical analyses of other data. Others may generate novel **model organisms** or **research tools** such as algorithms, mice, or laboratory equipment.

Note that activities such as training, infrastructure development, and other non-research activities may not directly generate research outputs at all.

Your research may produce more than one of these types of outputs. Please go through the decision tool for one output at a time and then select the "start over" button to explore additional outputs.

- DATA
- MODEL ORGANISMS
- RESEARCH TOOLS
- NONE OF THE ABOVE

Need help answering this question? See these resources:

[Definitions of Model Organisms and Related Resources](#)

[Definition of Research Tools](#)

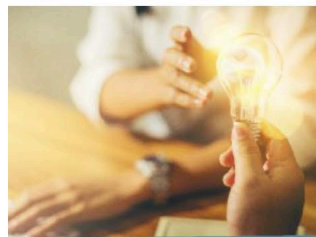
BACK

NEXT

Resources for: Sharing Scientific Data

Sharing Scientific Data

Sharing scientific data accelerates biomedical research discovery, enhances research rigor and reproducibility, provides accessibility to high-value datasets, and promotes data reuse for future research studies. 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.



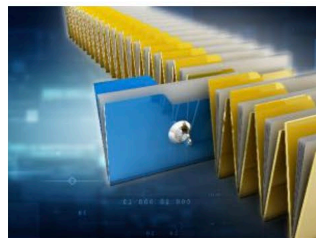
Data Sharing Approaches

Get familiar with how and when NIH expects data to be shared and learn how to safeguard the privacy of human participants while sharing scientific data.



Selecting a Data Repository

Learn how to evaluate and select appropriate data repositories.



Repositories for Sharing Scientific Data

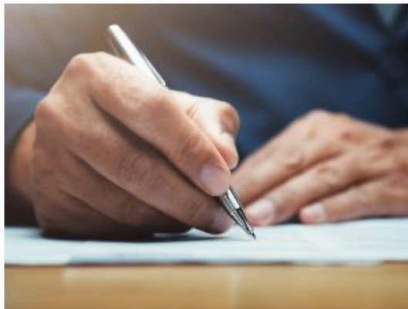
Browse a list of NIH-affiliated repositories for sharing scientific data.

Resources for: Planning and Budgeting

[Home](#) > [Data Management and Sharing Policy](#) > [Planning and Budgeting for Data Management & Sharing](#)

Planning and Budgeting for Data Management & Sharing

NIH expects applicants to submit a plan for how they will manage and share their data and allows applicants to include certain costs associated with data management and sharing in their budget.



Writing a Data Management & Sharing Plan

Learn what NIH expects Data Management & Sharing plans to address.



Budgeting for Data Management & Sharing

Find out what data sharing related costs may be requested in an application for funding.

Elements of a Data Management and Sharing Plan

- Data type
- Related tools, software, code (to access and manipulate data)
- Standards (data and meta-data)
- Data preservation, access, timelines (repositories, identifiers)
- Access, distribution, reuse considerations
- Oversight of data management
 - Plan compliance will be monitored/ managed and by whom

See [Writing a Data Management & Sharing Plan](#) for details

Repository Selection

- Encourages use of established repositories
- Helps investigators identify appropriate data repositories
- NIH ICs may designate specific data repository(ies)



See [Selecting a Data Repository](#) for details

Specialized Data Repositories

- Prioritizes data-type and discipline-specific data repositories
- Refers to [NIH-supported data repository list](#) outlining:
 - Repository description and supportive NIH IC(s),
 - Whether and when new data are accepted, and how to submit
- **Examples include:**
 - dbGaP
 - GenBank
 - NIMH Data Archive
 - BioData Catalyst
 - ImmPort
 - BioLINCC

Other Established Data Repositories

- Institutional repositories
- PubMed Central (small datasets only)
- Generalist data repositories, including:
 - Dataverse
 - Dryad
 - Figshare
 - IEEE Dataport
 - Mendeley Data
 - Open Science Framework
 - Synapse
 - Vivli
 - Zenodo



Allowable Costs

- **Reasonable costs (during the performance period)**
 - 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
- **NIH hopes to learn more about what constitutes reasonable costs** for various data management and sharing activities

See [Budgeting for Data Management & Sharing](#) for details

Plan Submission and Review: A Guide

Extramural Grant Awards*

Plan Submission

With application
Brief Plan description in
Budget Justification
Full Plan as separate
attachment

Plan Assessment

Peer reviewers 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, Other Transaction Awards, NIH Intramural Research Program*

Format of a Data Management and Sharing Plan

- ✓ Plans should be no more than 2 pages in length
- ✓ Optional format page will be available

DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on [sharing.nih.gov](https://www.nih.gov/data-management/data-sharing). The Plan is recommended not to exceed two pages. Text in italics should be deleted.

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:
Summarize the types and estimated amount of scientific data expected to be generated in the project,

B. Scientific data that will be preserved and shared, and the rationale for doing so:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

C. Metadata, other relevant data, and associated documentation:
Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Element 2: Related Tools, Software and/or Code:
State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they

DMS Plan format page will be added to list of [Format Pages](#) and incorporated into FORMS-H application instructions by Fall 2022

Data Management and Sharing Plan Submission

- A new “**Other Plan(s)**” field will be added to the PHS 398 form
- Data Sharing Plans and Genomic Data Sharing Plans will no longer be submitted to the “Resource Sharing Plan(s)” field

Research Plan Section			
5. Vertebrate Animals	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
6. Select Agent Research	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
7. Multiple PD/PI Leadership Plan	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
8. Consortium/Contractual Arrangements	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
9. Letters of Support	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
10. Resource Sharing Plan(s)	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
11. Other Plan(s)	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>
12. Authentication of Key Biological and/or Chemical Resources	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/> <input type="button" value="View Attachment"/>

Submitting Data Management and Sharing Budgets

- Direct costs to support the activities proposed in the DMS Plan must be indicated as “**Data Management and Sharing Costs**”
 - **R&R Budget Form:** line item in section F. Other Direct Costs

F. Other Direct Costs		Funds Requested (\$)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.	Data Management and Sharing Costs	
9.		
10.		

- **PHS 398 Modular Budget Form:** within Additional Narrative Justification

2. Budget Justifications			
Personnel Justification	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
Consortium Justification	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
Additional Narrative Justification	<input type="text"/>	Add Attachment	Delete Attachment View Attachment

Justifying Data Management and Sharing Budgets

- Brief summary of DMS Plan and description of DMS costs must be included within the budget justification attachment
 - R&R Budget Form: section L. Budget Justification

L. Budget Justification
(Only attach one file.)

- PHS 398 Modular Budget Form: Additional Narrative Justification

2. Budget Justifications

Personnel Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Consortium Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>
Additional Narrative Justification	<input type="text"/>	<input type="button" value="Add Attachment"/>	<input type="button" value="Delete Attachment"/>	<input type="button" value="View Attachment"/>

Monitoring Compliance with DMS Plans

- Approved DMS Plan becomes a Term and Condition of Award
- Report progress in Research Performance Progress Report (RPPR)
- NIH reviews compliance annually
 - Failure to comply may result in an enforcement action, including additional special terms and conditions or termination of award, and may affect future funding decisions

Roadmap to 2023 and Beyond



OPEN MIKE

Helping connect you with the NIH perspective, and helping connect us with yours.

- **OSP *Under the Poliscope* and *Open Mike* blogs**
- **Out now!**
 - Webinars & FAQs
 - DRAFT supplemental information for researchers working with AI/AN Participants
 - DRAFT supplemental information for protecting privacy when sharing research data
- **Before 2023:**
 - Plan templates, budget considerations, additional webinars
 - Harmonization of GDS Policy
- **Beyond 2023:**
 - Ongoing assessment of the Policy for short- and long-term goals
 - Incentives for data sharing

Preparing for 2023—No Time like the Present

Steps you can take to begin preparing for the Policy:

- **Identify existing resources within your institution** (librarians)
- Try **drafting a data management and sharing plan** for your work based on the recommended elements ([NOT-OD-21-014](#))
- **Review your past data sharing practices** to meet other funder or publisher expectations and consider what you may need to update

Lots of Interest!

PLOS COMPUTATIONAL BIOLOGY

EDUCATION

Ten simple rules for maximizing the recommendations of the NIH data management and sharing plan

Sara Gonzales^{1*}, Matthew B. Carson¹, Kristi Holmes^{1,2}

1 Galter Health Sciences Library & Learning Center, Northwestern University Feinberg School of Medicine, Chicago, Illinois, United States of America, **2** Department of Preventive Medicine (Health and Biomedical Informatics), Northwestern University Feinberg School of Medicine, Chicago, Illinois, United States of America

2022; *PLoS Comput Biol* 18(8): e1010397. <https://doi.org/10.1371/journal.pcbi.1010397>

A Conversation with NIH: Implementing the New Data Management and Sharing Policy

2 - PART WEBINAR



Taunton Paine, M.A.

Director, Scientific Data Sharing Policy Division,
NIH Office of Science Policy



Julia Slutsman, Ph.D.

Director, Genomic Data Sharing
Policy Implementation,
NIH Office of Extramural Research



Cindy Danielson, Ph.D.

Associate Director, Systems Integration,
NIH Office of Extramural Research



Thursday, August 11, 2022 / 1:30 - 3:00 PM EDT

*Understanding the New NIH Data Management
and Sharing Policy*

[August 11 Session Registration](#)

Thursday, September 22, 2022 / 1:30 - 3:00 PM EDT

*Diving Deeper into the New NIH Data Management and
Sharing Policy*

[September 22 Session Registration](#)

Thank You!

Policy and Supplemental Information:

- [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
- [NOT-OD-22-189](#) – Implementation Details for the NIH Data Management and Sharing Policy

Resources:

- [NIH Data Sharing Website](#) – sharing.nih.gov
- [NIH Office of Science Policy DMS Policy Website](#) – history and background on the NIH DMS Policy
- [Frequently Asked Questions](#) – sharing.nih.gov/faqs
- [Webinar](#) – on implementation of the NIH DMS Policy
- [News & Events](#) – Latest news and upcoming events

Contact:

- Questions – sharing@nih.gov