PROMOTING EQUITABLE ACCESS TO RESEARCH RESULTS

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Meeting of the Advisory Committee
to the NIH Director
June 8, 2023

GOALS FOR TODAY'S CONVERSATION

Discuss importance of promoting access to research results

Review NIH's New Public Access Plan and associated proposal

Chart path forward for incentivizing a culture of open data
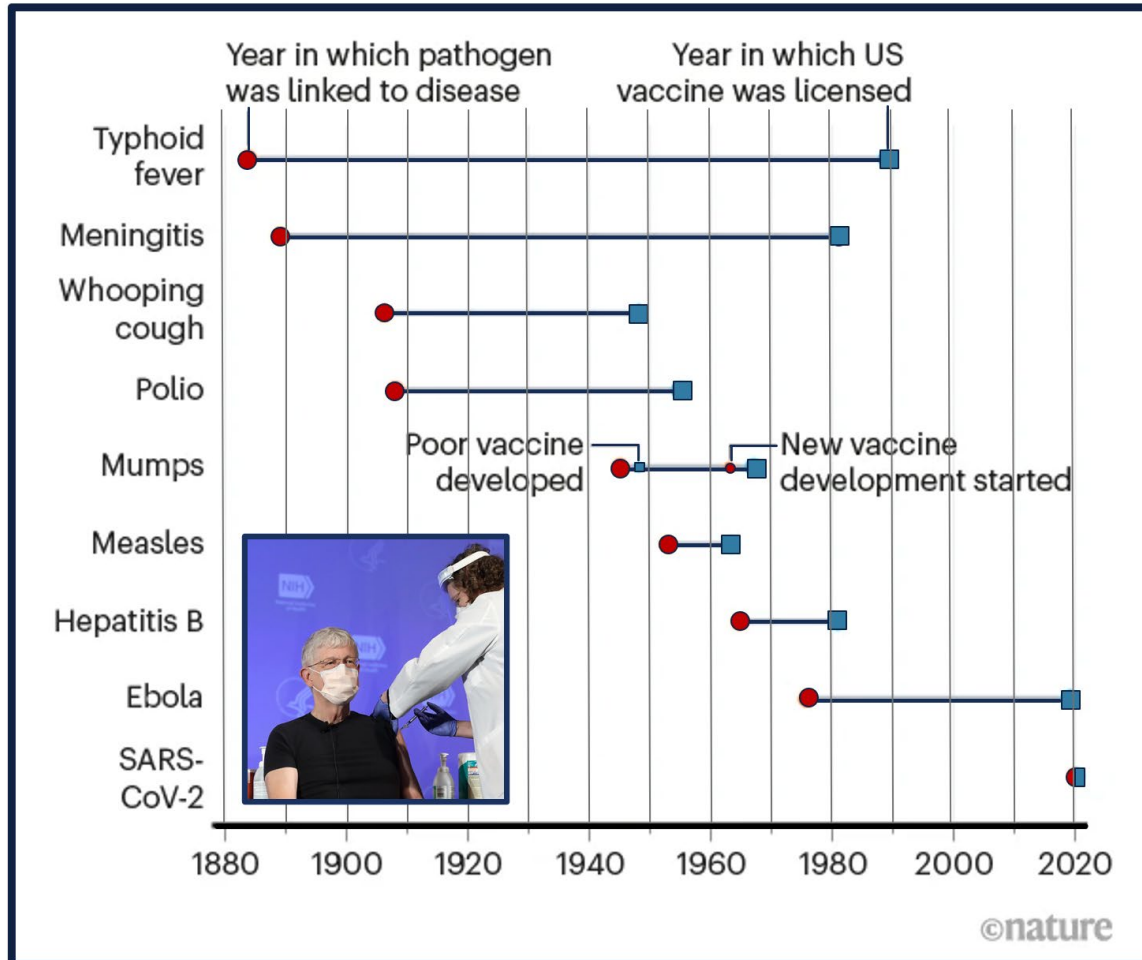
WHY WE'RE HERE

- **USG policy initiatives underway to increase meaningful and equitable access**
  - Access to federally funded research **data**
  - Access to federally funded research **publications**

- **NIH is a leader here, in access and transparency to biomedical research products**
  - Catalyzes research advances
  - Improves access to health knowledge and interventions
  - Is essential for building trustworthiness in science

Impacts of NIH policy initiatives are most often felt by the researchers we serve, whether it is change in practice or need for new systems.

We need to make change meaningful.

MAKING GOOD ON THE PUBLIC'S INVESTMENT IN SCIENCE

Year in which pathogen was linked to disease

Year in which US vaccine was licensed

Pandemic sharing and immediate access to:

- *> 2.5M SARS COV-2 genomic sequences*

- *> 1,300 SARS-CoV-2 protein structures*

- *> 300 reagents for biomedical research*

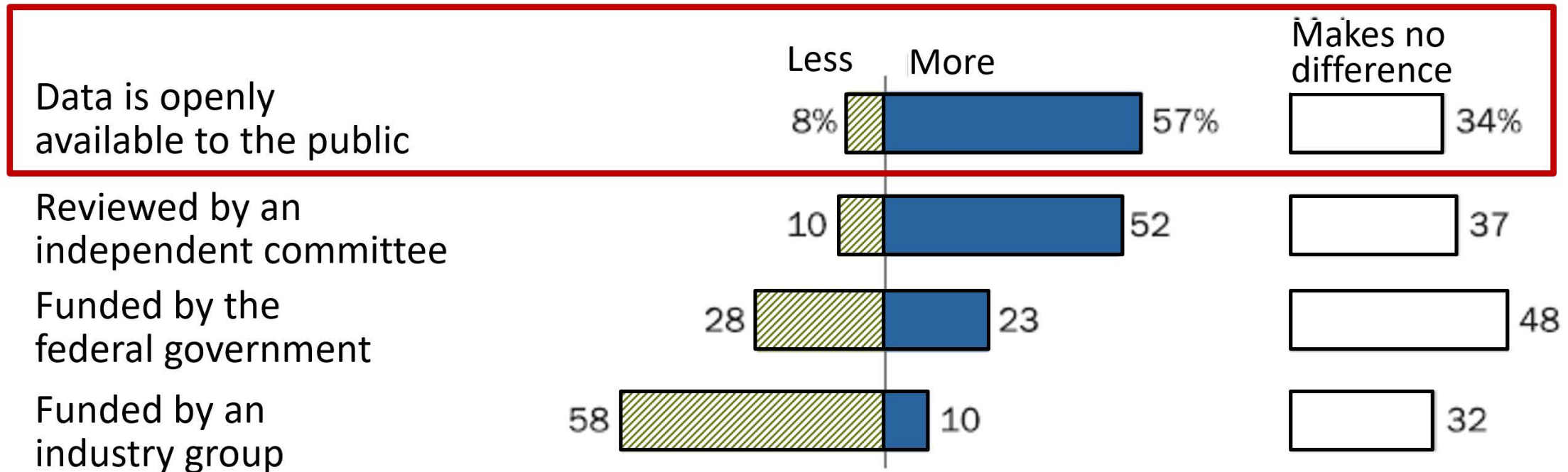- *> 7.3B rows of clinical data (N3C)*

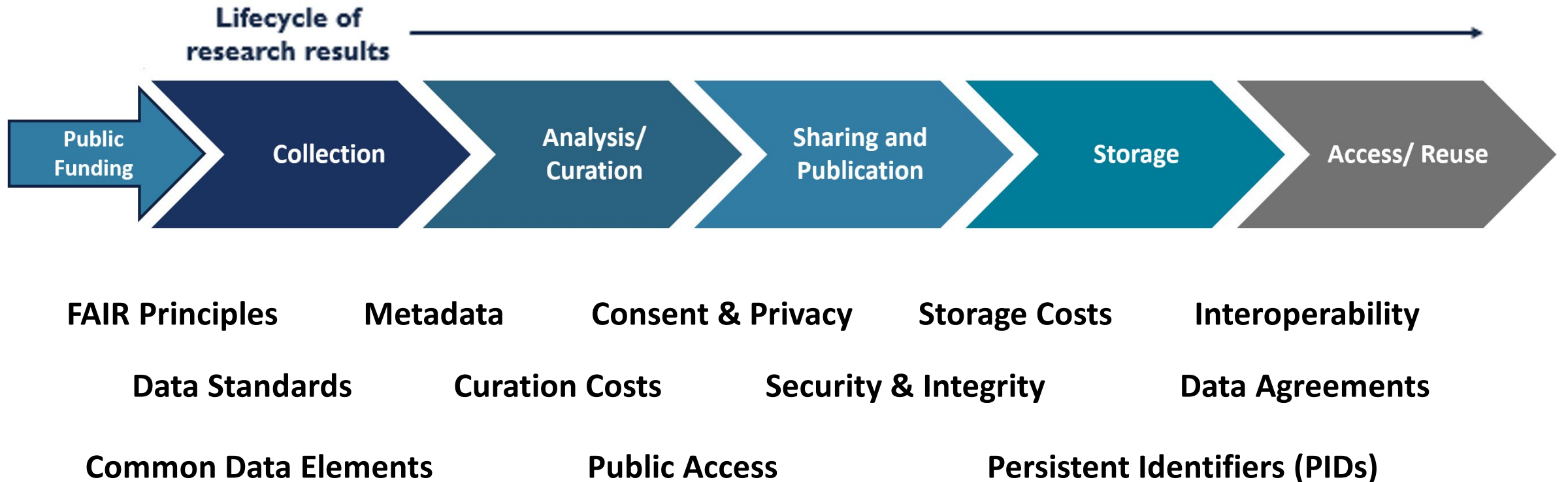- *> 150K papers*

Source:
niaid.nih.gov

MAKING GOOD ON THE PUBLIC'S INVESTMENT IN SCIENCE

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

	Less	More	Makes no difference
Data is openly available to the public	8%	57%	34%
Reviewed by an independent committee	10	52	37
Funded by the federal government	28	23	48
Funded by an industry group	58	10	32

https://www.pewresearch.org/science/wp-content/uploads/sites/16/2019/08/PS_08.02.19_trust.in_.scientists_FULLREPORT.pdf
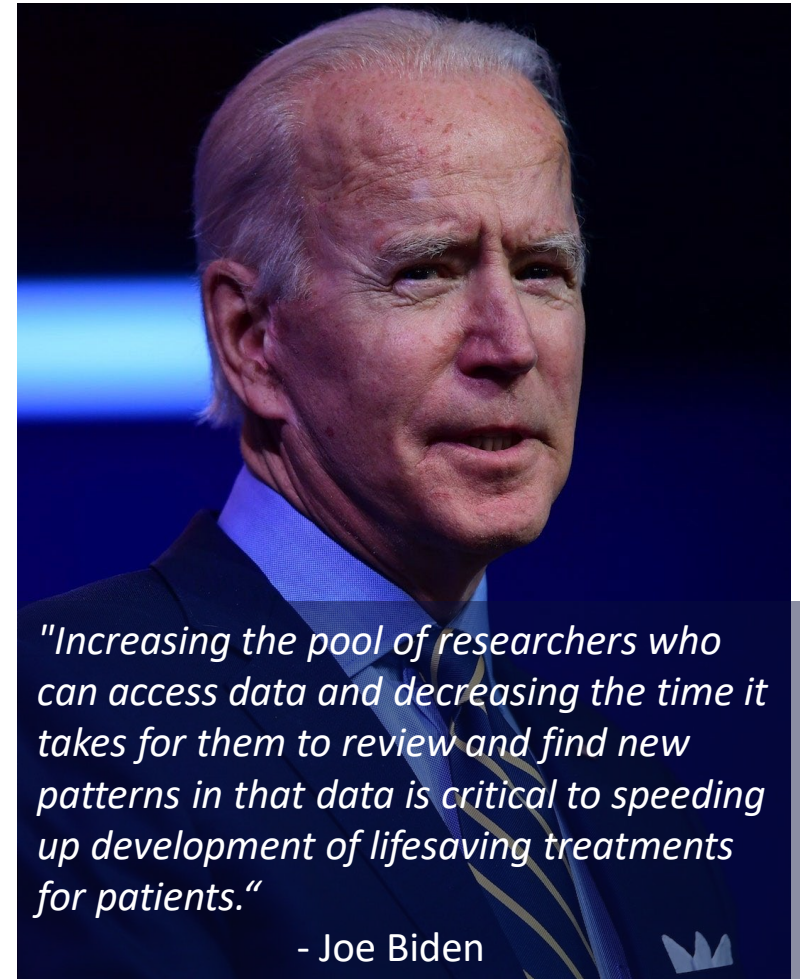
NIH'S LONG-STANDING COMMITMENT TO ACCESS

- ✓ 2003 NIH Data Sharing Policy (awards >500K)

- ✓ 2008 NIH Public Access Policy

- ✓ 2014 NIH Genomic Data Sharing Policy (human & non-human genomic data)

- ✓ 2015 NIH Intramural Human Data Sharing Policy

- ✓ 2016 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

- ✓ 2020 NIH Data Management and Sharing Policy (effective 2023)

- ✓ IC/program-specific policies and guidelines (i.e., HEAL Initiative and Cancer Moonshot Public Access and Data Sharing Policies)

WHAT'S NEW IN 2023

White House Directive on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research *(released in 2022)*

- Ensure federally funded publications freely available, publicly accessible **without embargo**

- Make scientific data underlying publications accessible **at time of publication**

- Develop approaches for sharing **all scientific data**

- Establish policies for use of metadata and persistent identifiers to make research products more findable and transparent

"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."
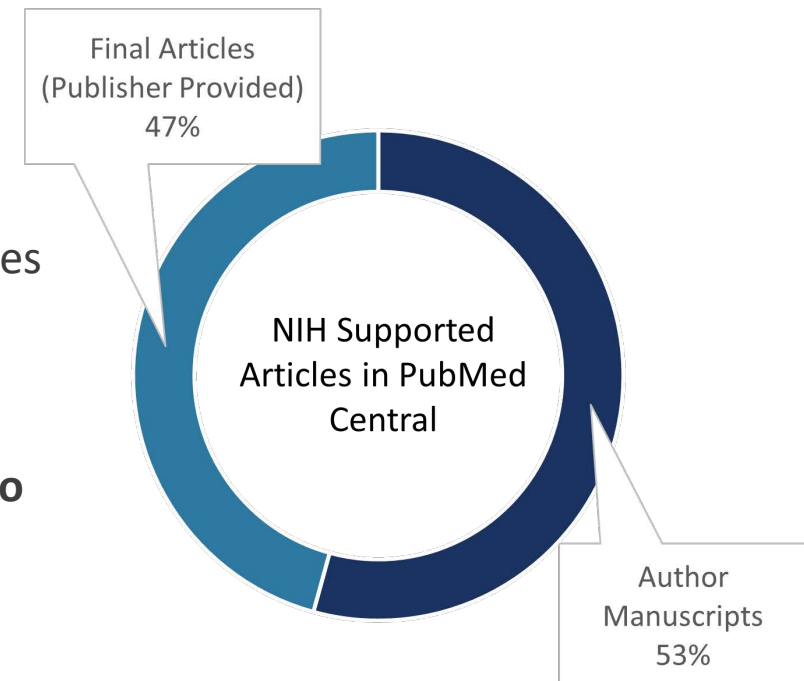
- Joe Biden

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NIH BUILDING OFF AN ALREADY STRONG FOUNDATION

✓ **2020 Data Management and Sharing Policy**

- Makes scientific data underlying publications accessible **at time of publication**

- Develops approaches for sharing **all scientific data**

✓ **2008 Public Access Policy**

- 1.4 million NIH-supported articles (2008-present)

- > 100,000 added annually

- 1/3 submitted with **NO embargo**

Final Articles (Publisher Provided) 47%

NIH Supported Articles in PubMed Central

Author Manuscripts 53%

HOW TO GET TO ZERO EMBARGO

CURRENT POLICY PROPOSAL *(CONT.)*

**On or by
Dec 31, 2025**
Revised Public Access
Policy Effective

Expectation from 2022 OSTP Memo	Current Practices To Continue	New Practices NIH Will Institute	New Practices Proposed
Peer-reviewed scholarly publications… made freely available, publicly accessible in agency-designated repositories without embargo after publication	• PMC serves as repository • Manuscripts submitted to PMC at time of acceptance OR • Journals with agreements with NIH will submit on authors' behalf when published	• Articles will be available post-publication in PMC as soon as processing is complete, without an embargo period	• Clarify rights necessary to comply • Clarify official date of publication (online vs. print)
Maximize equitable reach of public access to peer-reviewed scholarly publications…in formats that allow for machine-readability	• PMC converts submissions to human- and machine- readable formats and allows for use of metadata	• Work with community to develop/update standards for article accessibility procedures, for submission to PMC	*Actively seeking public input and ideas*
Allow researchers to include reasonable publication costs… as allowable expenses in all research budgets	• GPS already allows reasonable publication costs • No specific publication business model required		• Continue to monitor trends in publication fees and policies to ensure that they remain reasonable and equitable

SEEKING COMMENT ON A FUTURE POLICY

Request for Information on the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research

Notice Number:

NOT-OD-23-091

Key Dates

Release Date:	February 21 2023
Response Date:	April 24, 2023

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-091.html

- Coordinating across US government
- Reaching out to communities
  - Listening session (April 12, 2023):   https://videocast.nih.gov/watch=49504
  - Request for information (open February 21 - April 24, 2023)
- Summary and analysis of 143 RFI response on the following slides

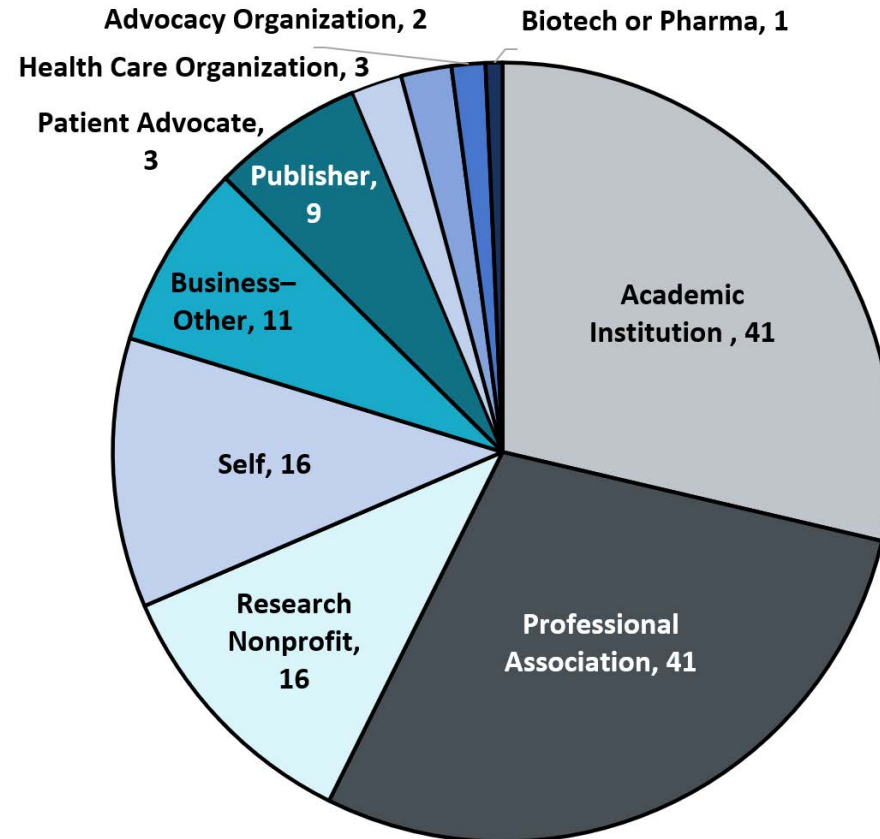# FEEDBACK ON PUBLIC ACCESS POLICY PROPOSAL

Topics for feedback (RFI)

- Improving equity in access and accessibility of publications

- Ensuring equity in publication opportunities

- Monitoring evolving costs and impacts

- Increasing findability and transparency of research

Demographics of Respondents

Pie chart segments:
- Advocacy Organization, 2
- Biotech or Pharma, 1
- Health Care Organization, 3
- Patient Advocate, 3
- Publisher, 9
- Business—Other, 11
- Self, 16
- Research Nonprofit, 16
- Professional Association, 41
- Academic Institution, 41

Role within organization
Institutional Official: 50
Researcher: 40
Member of the Public: 30
Undesignated: 23

FEEDBACK ON PUBLIC ACCESS POLICY PROPOSAL *(CONT.)*

In general, respondents supported removing year embargo period

- Current embargo window limits availability

- Access further limited to the public who invested in the research

Many cautioned that "available" is not the same as "accessible" and NIH will need to implement additional strategies to support this goal

- Publications can be difficult to find, more support for metadata, identifier use, and indexing of articles in PMC is needed

- Inadequate communication of primary research to diverse audiences, including sensory impaired, multilingual audiences, and the public
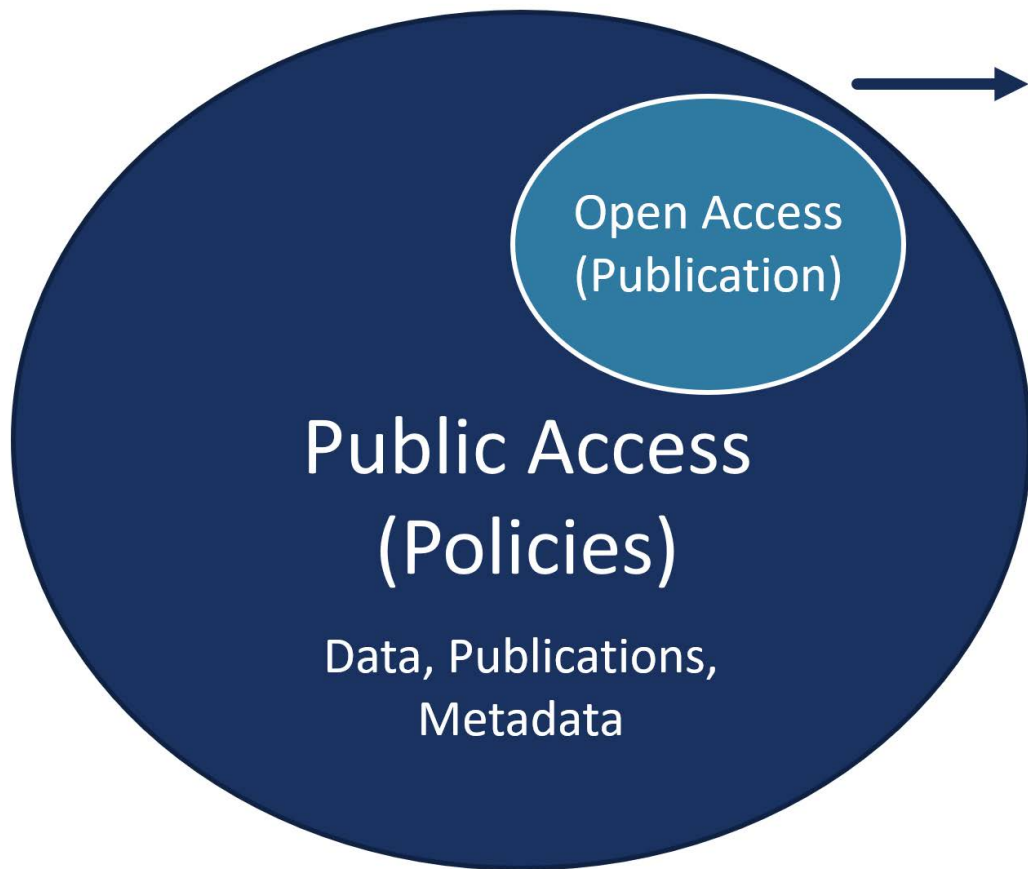
SOME COMMON THREADS

(WHAT WE HAVE BEEN WORKING THROUGH AND WHAT WE ARE HEARING)

PUBLIC ACCESS VS. OPEN ACCESS

Open Access
(Publication)

Public Access
(Policies)

Data, Publications,
Metadata

- **Public Access Policies**
  - Free availability of federally funded scholarly materials to the public

  - Includes scientific data, publications, associated metadata

- **Open Access Publication**
  - Publishing model for scholarly communication that makes research information available immediately to readers at no cost (publishers may charge authors to publish)
  - In contrast, traditional models give readers access to scholarly information through subscription (usually via libraries)
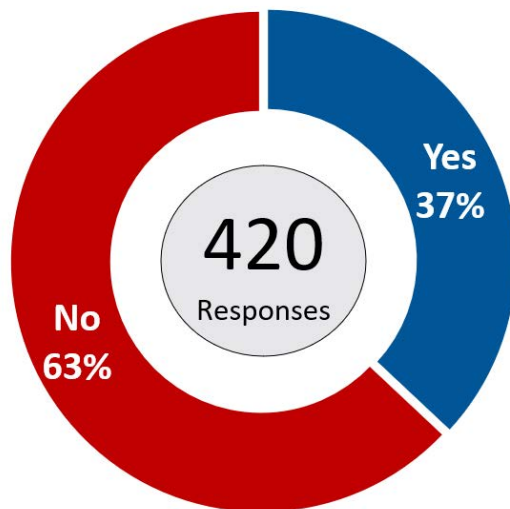
IMPLICATIONS FOR EQUITY

! **This is not an open access policy.** NIH does not anticipate requiring a specific publication model as part of a revised NIH Public Access Policy

- **Concerns.** Embargo removal will lead to drops in subscriptions; publishing costs shift to investigators via "article processing charges" (APCs)

  - Greater impact on those with fewer resources and without NIH funding

  - Diminished choice in where to publish

  - Proliferation in "predatory" journals

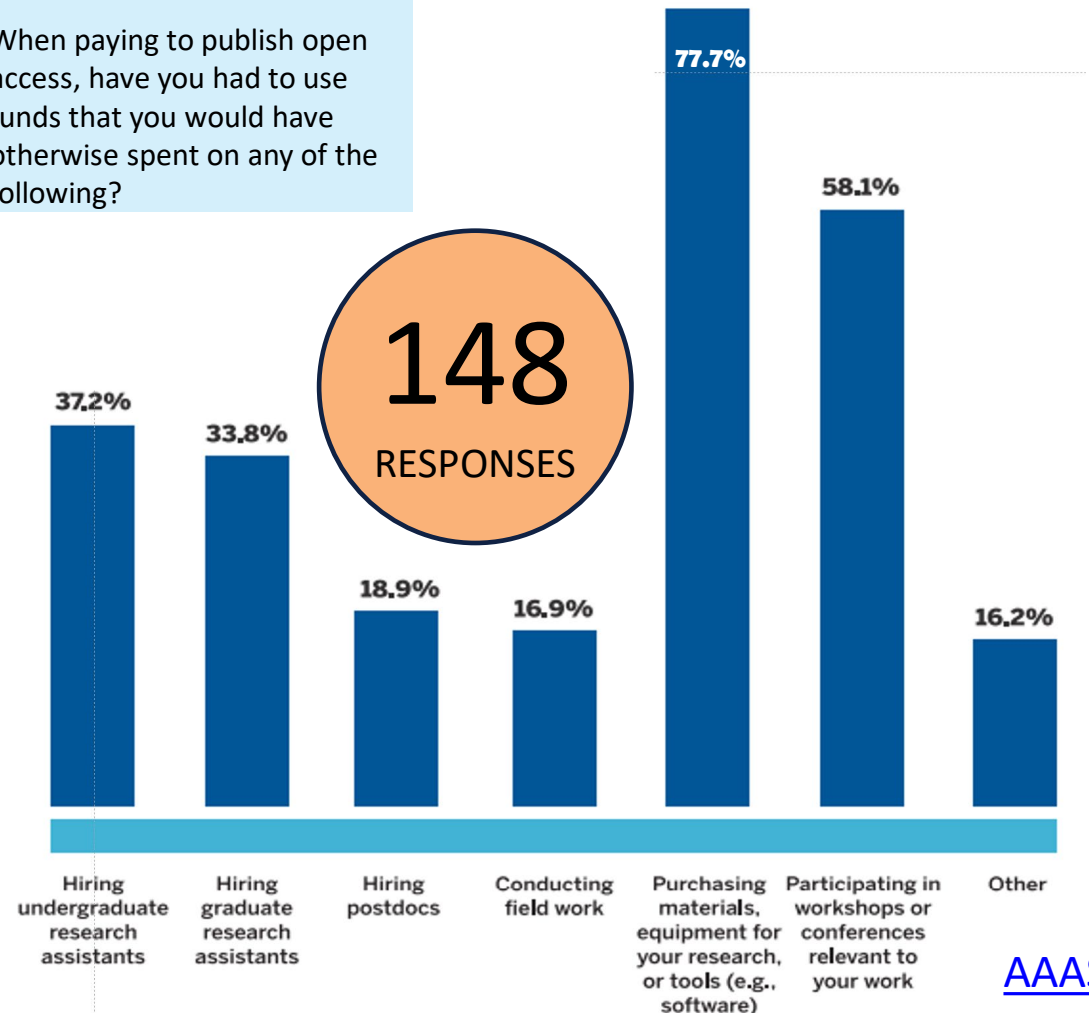# AAAS SURVEY ON SCHOLARLY PUBLICATION EXPERIENCES & PERSPECTIVES

KEY FINDINGS

Most Researchers Do Not Currently Budget for Publishing Costs & Many Have Not Yet Paid APCs

Do you budget for costs associated with publishing your research?

Yes 37%

No 63%

420 Responses

When paying to publish open access, have you had to use funds that you would have otherwise spent on any of the following?

148 RESPONSES

37.2% — Hiring undergraduate research assistants

33.8% — Hiring graduate research assistants

18.9% — Hiring postdocs

16.9% — Conducting field work

77.7% — Purchasing materials, equipment for your research, or tools (e.g., software)

58.1% — Participating in workshops or conferences relevant to your work

16.2% — Other

AAAS.org

INCREASE CLARITY AROUND PAYING TO PUBLISH

- Some advocated for publishing business models in which authors don't have to pay APCs; we've heard from some publishers that APCs may be their path forward

- **Perception of some:** Investigators will pay APCs from grant funding without commensurate increases in that funding and will have less money for research, community development, etc.

- Commenters suggested NIH:

  - Continue requirements for authors to deposit their author-accepted (peer-reviewed) manuscript in PubMed Central (meets compliance expectations at no cost)

  - Pay more for the costs of open access publication (several models suggested)

  - Work with publishers to clarify "reasonable" costs and share that information with the public

  - Consider the impact of these changes on publications of research that is not NIH-supported

MONITOR PUBLICATION COSTS

- **Define what constitutes "reasonable" costs**

- **Potential approaches floated**
  - Look at application budgets and annual reports
  - Work with publishers to understand publishing model and/or discipline specific requirements
  - Reference currently existing resources (e.g. Journal Comparison Service)

- **NIH should also monitor equity issues associated with publication costs!**
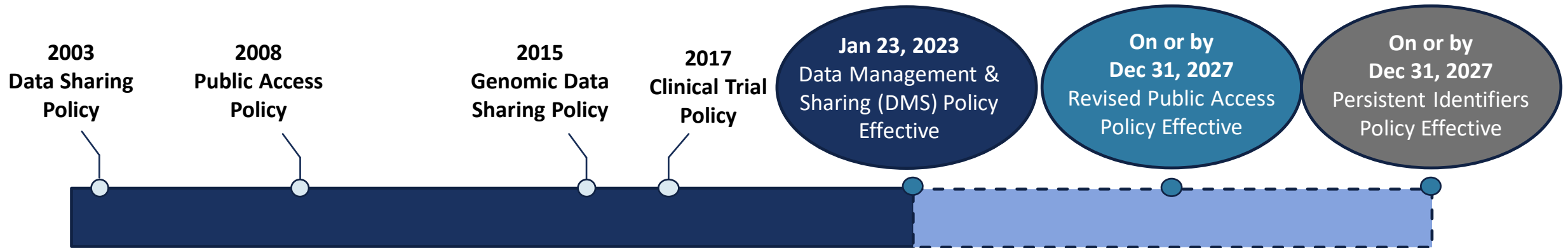
EASE ADMINISTRATIVE BURDEN

- **Clarify and ease mechanisms for compliance:**
  - Concise guidance for depositing manuscripts and/or articles
  - Resources to ensure requirements are met (e.g. template language for licensing and rights retention)

- **Coordinating across federal agencies**
  - White House led interagency groups
  - Externally-driven stakeholder meetings to create incentives

GOING FORWARD
POLICY DEVELOPMENT/IMPLEMENTATION TIMELINE

2003
Data Sharing Policy

2008
Public Access Policy

2015
Genomic Data Sharing Policy

2017
Clinical Trial Policy

Jan 23, 2023
Data Management & Sharing (DMS) Policy Effective

On or by Dec 31, 2027
Revised Public Access Policy Effective

On or by Dec 31, 2027
Persistent Identifiers Policy Effective

A DRAFT POLICY WILL BE RELEASED FOR PUBLIC COMMENT!

PLAN IS TO HAVE A DELAY BETWEEN POLICY RELEASE AND EFFECTIVE DATE!

QUESTIONS FOR DISCUSSION WITH ACD

- NIH has been working across the USG and with the community to make the open data ecosystem a reality and will continue to do so. NIH recognizes the need for a coordinated effort at all levels.

- For the ACD, some big picture questions still need to be addressed to achieve these policy aims:

  - **Given that NIH is the world's largest public funder of biomedical research, what roles and responsibilities do awardees have in making research results available to the public immediately and free of cost?**

  - **What future opportunities and challenges do you see for public access to research products?**

  - **Though the USG is developing these policies, what incentives are needed to achieve policy aims, and who should provide these incentives?**

STAY IN TOUCH WITH THE OFFICE OF SCIENCE POLICY

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OSP's Blog

SciencePolicy
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