NIH Data Management Policy: New Resources

March 2, 2022

Moderators:

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David Kennedy, Director of Costing and Financial Compliance, COGR

Presenters:

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Science Policy

Greg Farber, PhD

National Institute of Mental Health

COGR
Council On Governmental Relations

IMPLEMENTATION UPDATE – MARCH 2, 2022

NIH POLICY FOR DATA MANAGEMENT & SHARING

Lyric Jorgenson, PhD
Acting NIH Associate Director for Science Policy
Acting Director of the Office of Science Policy

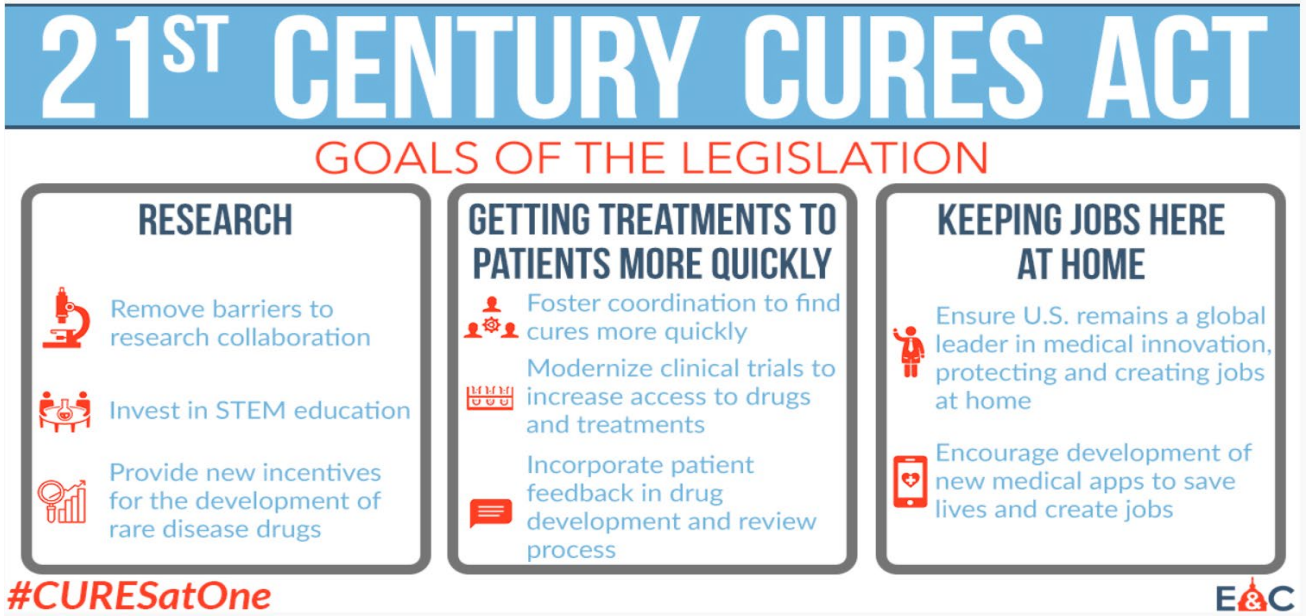
Greg Farber, PhD
Director, Office of Technology Development and Coordination
National Institute of Mental Health

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)
- 2015 NIH Intramural Human Data Sharing Policy
- 2016 NIH Policy on Dissemination of NIH-Funded Clinical Trial Information
- IC-specific policies and guidelines
- Program-specific policies and guidelines

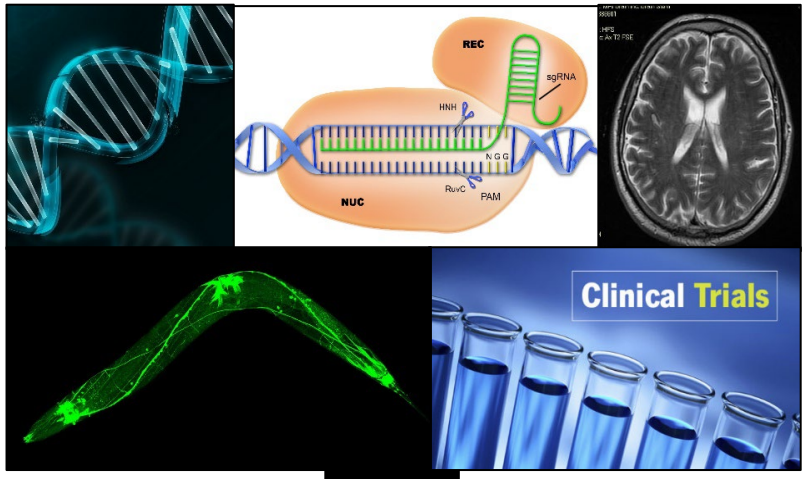
SOME CONTEXT

DATA SHARING ADVANCES THE NIH MISSION

Sparks New Research Collaborations

Enhances Rigorous Study Design

Makes High-Value Datasets Available



Enables Unique Data Combinations

Facilitates Study Validation

Stimulates New Research Inquiries

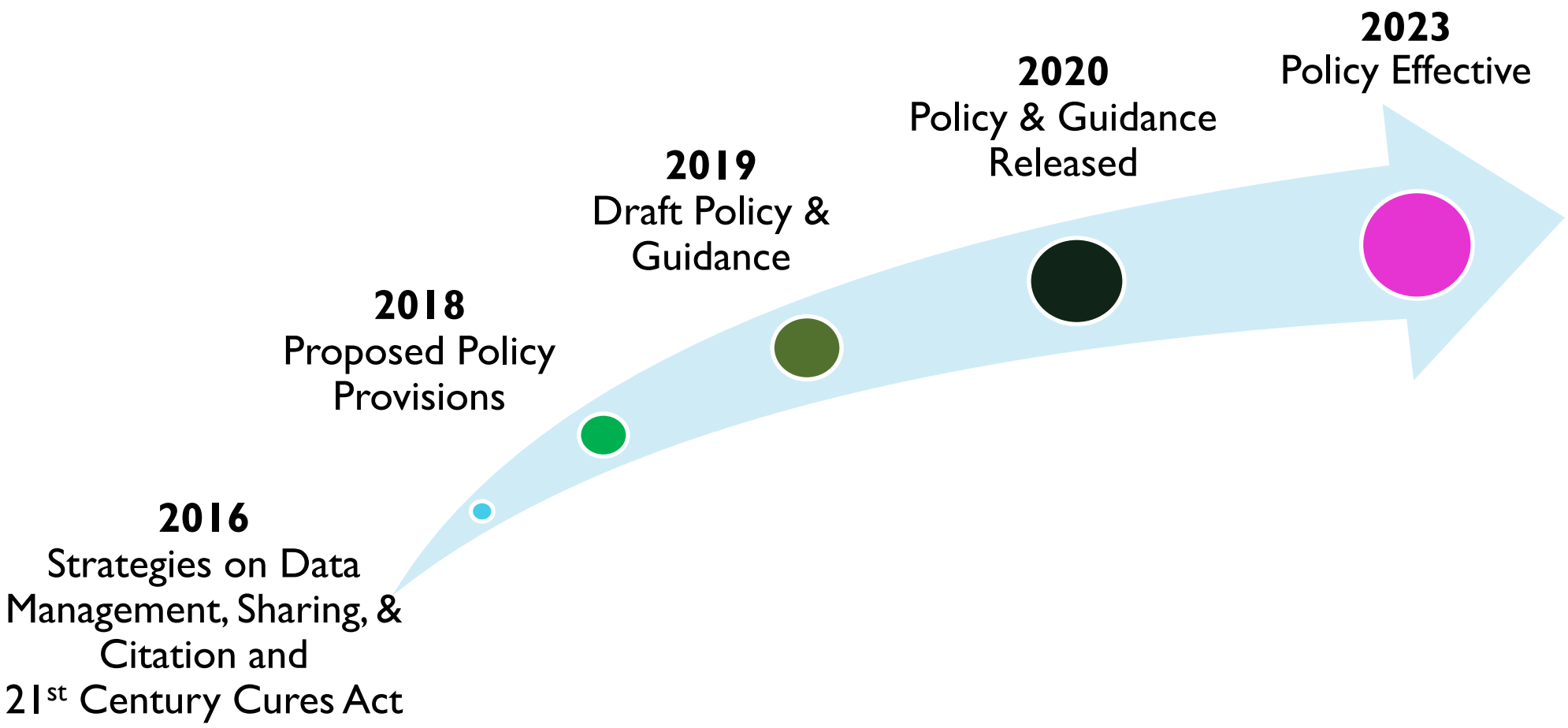
Maximizes Data Collection
(reduces redundancy/maximizes participant contributions)

Fosters Stewardship
(provides transparency/accountability for taxpayer funds)

Accelerates the Research Enterprise
(for all the reasons stated above!)

SOME CONTEXT

LONG ARC OF ITERATION



SOME CONTEXT

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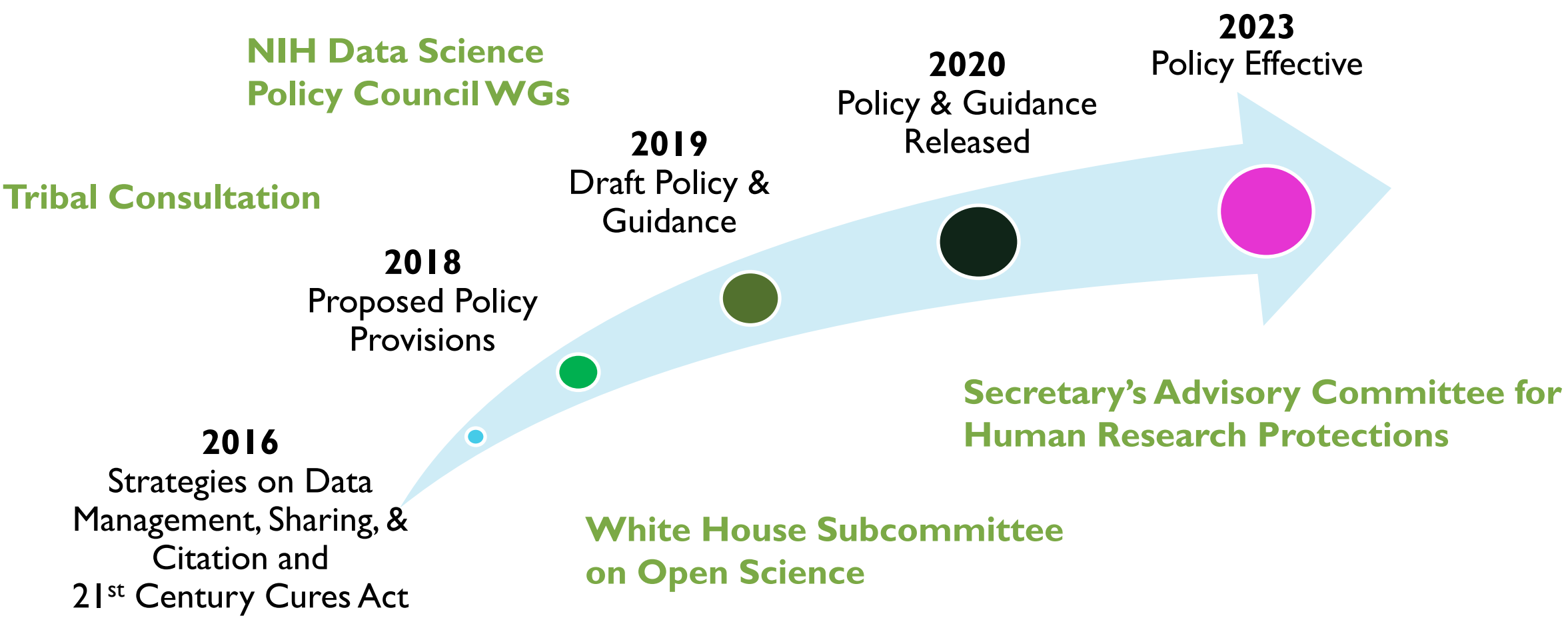

NIH POLICY FOR DATA MANAGEMENT & SHARING

- 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*

FROM POLICY TO IMPLEMENTATION

- Some implementation considerations built into the Policy provisions (i.e., Plan review, compliance infrastructure, etc.)
- OSP & OER working in tandem to sustain **trans-NIH engagement** in implementation approach, including:

Leveraging external entities

Developing guidance with NIH program officers

Meeting with external stakeholders

Regular NIH leadership engagement

APRIL 28-29, 2021

NASEM WORKSHOP

Changing the Culture of Data Management and Sharing: A Workshop

SH

- About
- Description
- Committee
- Sponsors
- Past Events
- Contact

This two-day virtual workshop may explore challenges and opportunities for researchers, institutions, and funders in establishing effective data management and sharing practices. Workshop presentations and discussions may examine strategies, resources, and promising practices for developing and evaluating data management and sharing plans. Participants may also discuss how researchers can effectively share scientific data over the course of the data life cycle.

Potential topics include:

- Overarching strategies for managing and sharing data
- Assessing the value of shared data
- Monitoring and evaluating data management and sharing practices
- Educational and resource needs for responsible data sharing

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Committee

CO-CHAIR
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Nick Lindsay

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Daniela M. Witten

ROADMAP TO 2023 & BEYOND

OPEN MIKE

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

- **Out now!**
  - FAQs and webinars
  - DRAFT Guidance for Researchers working with AI/AN Participants
- **Before 2023:**
  - Additional supplemental info (e.g., budgeting, protecting privacy)
  - Educational Resources (webinars, sample plans, FAQs)
  - Plans for harmonization with other data sharing policies
- **Beyond 2023:**
  - Ongoing assessment of the Policy for short- and long-term goals
  - Incentives for data sharing

UNDER THE POLISCOPE

***New* Blog Post**
Jan 25th, 2022

osp.od.nih.gov/blog/

BUDGETING FOR EFFECTIVE DATA MANAGEMENT & SHARING

- NIH's mission is to seek fundamental knowledge … data are that knowledge!
- Effective data management & sharing **is essential to a research project**
- NIH is investing in data stewardship
  - Supplemental info on allowable costs issued with the Policy
  - Additional guidance on "what to consider" when developing a budget
    - Budgeting within the scope of proposed project
    - Management/sharing activities across the research lifecycle
    - Will supplement existing resources for cost frameworks, estimators, and models
- **WILL SEEK PUBLIC INPUT!!!**

ADDITIONAL RESOURCES

PARTNERING TO INCENTIVIZE CULTURE CHANGE

Lyric Jorgenson
Office of Science Policy

Greg Farber
National Institute of Mental Health

Cindy Danielson
Office of Extramural Research

Taunton Paine
Office of Science Policy

New Website In The Works!

- FAQs on DMS Policy and responsible management of data
- Harmonizing expectations for data sharing policies
- Educational Resources (webinars, sample plans, FAQs)
- Updated information on protecting participant privacy
- Budgeting considerations for managing and sharing data

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