Data & Resource Sharing:
Firming Foundations For Future Frontiers

NIH Virtual Seminar

NIH Office of Extramural Research (OER)

October 2020

National Institutes of Health
Office of Extramural Research

Julia Slutsman, PhD
Director, Genomic Data Sharing Implementation
julia.slutsman@nih.gov

J.P. Kim, JD, MBA, MSc, MPP, MA
NIH Extramural Data Sharing Policy Officer
jpkim@nih.gov

Office of Extramural Research (OER),
Office of the Director (OD),
National Institutes of Health (NIH), HHS

- Background for NIH data sharing initiatives and focus on three policies

- Overview of NIH Genomic Data Sharing (GDS) Policy

- Update: Development of NIH Data Management and Sharing Policy

- Refresher: NIH Research Tools Policy & Select NIH Grants Policy Excerpts

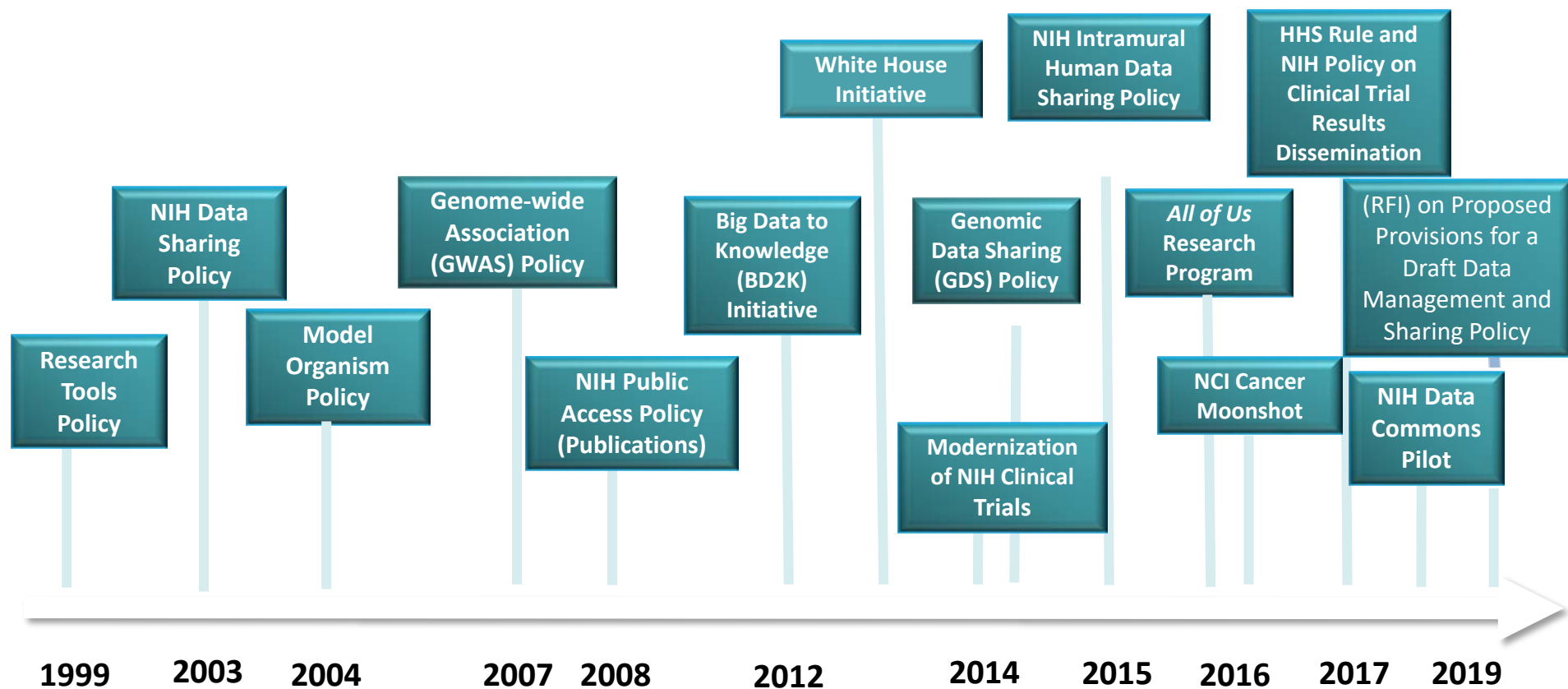- Resources: Links to NIH Data Sharing Policies & Notices

National Institutes of Health
Office of Extramural Research

NIH Commitment to & Investment in Data Sharing

"Consistent with both the NIH mission to improve public health through research and its longstanding legislative mandate to make available to the public the results of the research activities that it supports and conducts…."

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-013.html

National Institutes of Health
Office of Extramural Research

NIH's Data Sharing Initiatives & Milestones

Benefits of Sharing Data & Research Resources

- Accelerates ideas for future research inquiries and their application
- Facilitates research integrity
- Fosters rigor and reproducibility
- Maximizes contributions of participants in research enterprise
- Preserves scientific record
- Increases efficiency and maximizes investment and stewardship
- Facilitates reuse of hard to generate data or data from limited sources
- Enables researchers to combine data types to strengthen analyses

Ethical Considerations for Data Sharing

Making data as available as possible to maximize societal benefit from research participants' contributions to research while maintaining participants' privacy, respecting their autonomy, and ensuring that confidential/proprietary data are appropriately protected

- – Controlled access for individual patient-level data
- – Participant control of data
- – Merging of datasets
- – Review of data access requests to maintain public trust

- **Time and effort**
  - Determine which data to preserve (not necessarily all data)
  - Clean data, put in accessible format (consistency; standardized elements)
  - Provide metadata

- **Requires infrastructure**
  - Repositories for long-term archiving
  - Procedures for providing data access

National Institutes of Health
Office of Extramural Research

- **Policy coordination**
  - Across agencies, funders, publishers, journals
  - Lack of rewards/incentives
  - Citations/publications used for academic credit
  - How to cite/credit data collection and sharing
  - Considerations for ethical, legal, and social implications, human participant protections, privacy, and trust

- **Human Resources**
  - Limited training in data management and sharing

- **Proprietary Interests/Culture**
  - Investigators want to analyze and publish first
  - Institutions/Investigators want to maintain competitive advantage

- **Compliance and Enforcement**
  - Especially after the award has ended

NIH National Institutes of Health
Office of Extramural Research

NIH Genomic Data Sharing Policy

- Purpose
  - Sets expectations and responsibilities for investigators and institutions to ensure broad, responsible, and timely sharing of genomic research data
- Scope
  - Applies to all NIH-funded research generating **large-scale human** or **non-human** genomic data <u>and</u> secondary research using these data
  - Applies to all funding mechanisms (grants, contracts, intramural support) regardless of cost
- Effective January 25, 2015

  NIH Intramural – August 31, 2015
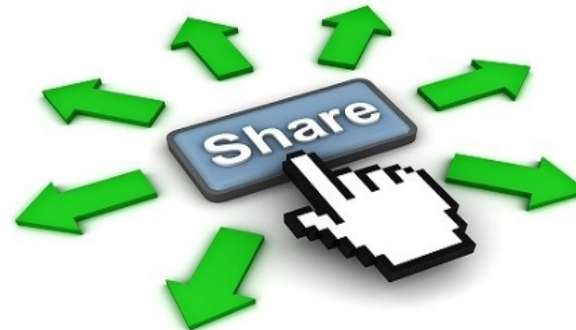
Two-tiered access for human data:

– **Unrestricted-access**: Data are publicly available to anyone (e.g., The 1000 Genomes Project)

– **Controlled access**: Investigators must obtain approval from NIH Data Access Committees (DACs) to use data from NIH-designated data repositories (e.g., dbGaP)

Process for Submitting or Accessing Data

Data Submission

➢ **Data use limitations specified**
➢ **Institutional Certification provided**

Submitted to NIH-Designated Data Repository (e.g. dbGaP)

Unrestricted-Access Data:
- Study Protocol
- Descriptive Information

Controlled-Access Data:
- Coded Genotypes
- Phenotypes
- Genomic Summary Results

Data Access

Data Access Request
- Co-signed by institution
- Agree to terms of use in Data Use Certification
- PI agrees to Code of Conduct

Data Access Committee
- Review research proposal and compare with data use limitations
- Verify PI credentials
- Consider the potential for group harm (e.g., stigmatization)

NIH
National Institutes of Health
Office of Extramural Research

Responsibilities When Accessing/Using Data

- <u>To be approved for access</u>, PIs submit a Data Access Request co-signed by their Institutional Signing Official agreeing to the Data Use Certification and Addendum
- In the Data Use Certification & Addendum <u>PIs agree to these terms and conditions</u>:
  - Use the data only for the approved research
  - Protect data confidentiality
  - Follow applicable laws, regulations, and policies for data use
  - Not to attempt to re-identify individual participants
  - Share the data only with individuals listed in the data access request
  - Report immediately any GDS Policy violations to the appropriate NIH Data Access Committee
  - Provide annual updates to NIH on research

February 2013: White House OSTP/Holdren Memo

February 2015: "NIH Plan" released

- Publications: NIH Public Access Policy
- Digital Scientific Data: Plan for Public Access to Digital Scientific Data
  - Consider how to require data sharing
  - Consider how to require and evaluate data management and sharing plans
  - Encourage the use of existing repositories and standards
  - Promote FAIR (Findable, Accessible, Interoperable, Reusable) principles

> **Plan ≠ Policy; NIH to establish priorities for data sharing**

National Institutes of Health
Office of Extramural Research

Feb. 2013: White House Office of Science and Technology Policy (OSTP) released memorandum entitled "Increasing Access to the Results of Federally Funded Scientific Research"

– Development of agency Plans

– Applies to peer-reviewed publications and digital scientific data

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

February 22, 2013

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: John P. Holdren
Director

SUBJECT: Increasing Access to the Results of Federally Funded Scientific Research

1. **Policy Principles**

The Administration is committed to ensuring that, to the greatest extent and with the fewest constraints possible and consistent with law and the objectives set out below, the direct results of federally funded scientific research are made available to and useful for the public, industry, and the scientific community. Such results include peer-reviewed publications and digital data.

Scientific research supported by the Federal Government catalyzes innovative breakthroughs that drive our economy. The results of that research become the grist for new insights and are assets for progress in areas such as health, energy, the environment, agriculture, and national security.

Access to digital data sets resulting from federally funded research allows companies to focus resources and efforts on understanding and exploiting discoveries. For example, open weather

National Institutes of Health
Office of Extramural Research
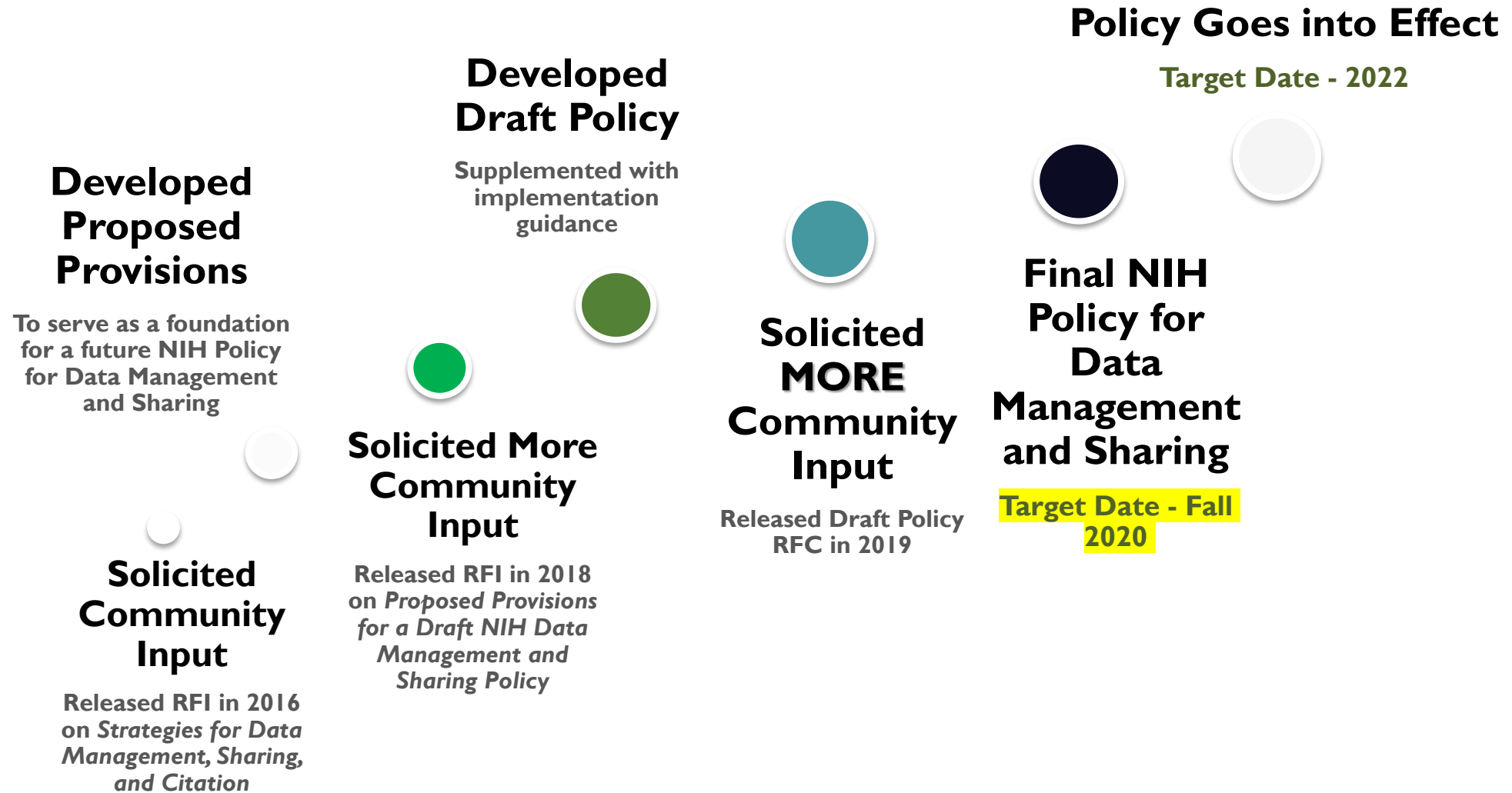
Digital Data

- **Maximize free access while**
  - Protecting privacy and confidentiality, national security
  - Recognizing intellectual property rights
  - Balancing costs & benefits of long-term preservation
- **Require data management plans (DMPs)**
- **Allow inclusion of costs in applications for funding**
- **Ensure appropriate evaluation of DMPs**
- **Monitor compliance by investigators**
- **Encourage deposit of data in public repositories, where possible**
- **Cooperate with the private sector**
- **Develop approaches for data citation & attribution**
- **Support training, education and workforce development**
- **Assess long-term needs for preservation and options for repositories**

Scholarly Publications

- Public can read, download, analyze in digital form
- 12-month post-publication embargo as guideline, with stakeholder petitions to change
- Easy public search, analysis of, and access to publications
- Full public access to metadata without charge upon first publication
- Public-private collaboration
- Attribution to authors, journals, and original publishers
- Archival solutions that provide long-term preservation without charge
  - Uses widely available, nonproprietary standards/formats
  - Provides access for persons with disabilities (consistent with Section 508 of Rehabilitation Act)
  - Enables integration and interoperability with other Federal archival solutions and other appropriate archives

National Institutes of Health
Office of Extramural Research

NIH Policy for Data Management & Sharing Timeline

Developed Proposed Provisions

To serve as a foundation for a future NIH Policy for Data Management and Sharing

Solicited Community Input

Released RFI in 2016 on *Strategies for Data Management, Sharing, and Citation*

Developed Draft Policy

Supplemented with implementation guidance

Solicited More Community Input

Released RFI in 2018 on *Proposed Provisions for a Draft NIH Data Management and Sharing Policy*

Solicited MORE Community Input

Released Draft Policy RFC in 2019

Final NIH Policy for Data Management and Sharing

Target Date - Fall 2020

Policy Goes into Effect

Target Date - 2022

National Institutes of Health
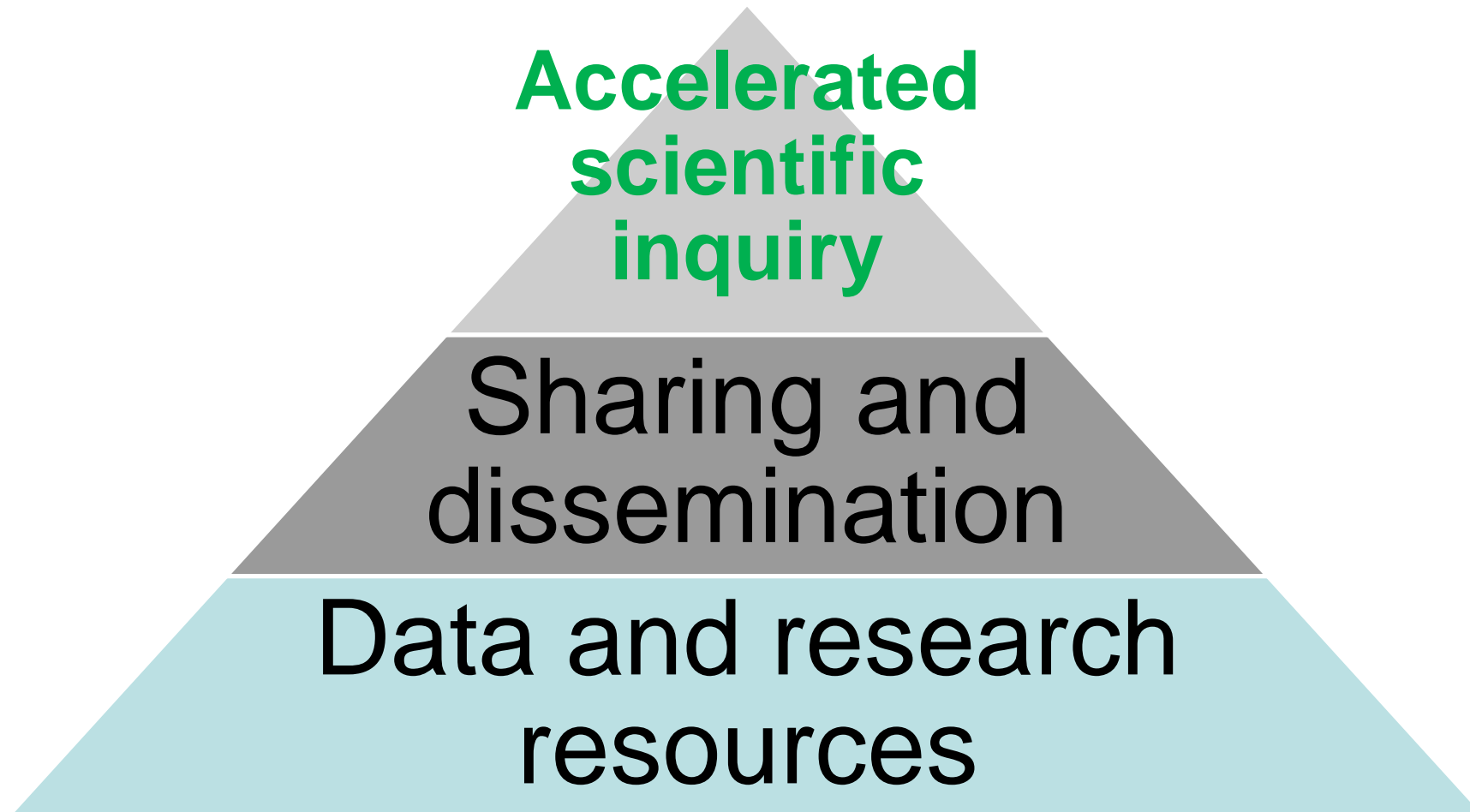Office of Extramural Research

Development of an NIH Data Management and Sharing Policy

Policy Development Highlights

- November 14, 2016: NIH Request for Information (RFI): Strategies for NIH Data Management, Sharing, and Citation (NOT-OD-17-015; Response by January 19, 2017)

- October 10, 2018: Request for Information (RFI) on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research (NOT-OD-19-014; Response by December 10, 2018)

- November 6, 2019: Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance (NOT-OD-20-013; Response by January 10, 2020)

National Institutes of Health
Office of Extramural Research

National Institutes of Health
Office of Extramural Research

NIH Research Tools Policy

"Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants & Contracts" (1999)

- **Principles**
  - Ensure Academic Freedom and Publication
  - Ensure Appropriate Implementation of the Bayh-Dole Act
  - Minimize Administrative Impediments to Academic Research
  - Ensure Dissemination of Research Resources Developed With NIH Funds
- **Guidelines**
  - Appendix: Guidelines for Disseminating Research Resources Arising Out of NIH-Funded Research

National Institutes of Health
Office of Extramural Research

Select NIH Grants Policy Excerpts

- Grantees own the data they develop with federal funds.
  - NIH Grants Policy Statement 8.2.1.

- Public Access Policy Final peer reviewed manuscript, upon acceptance for publication must be published at: http://www.pubmedcentral.nih.gov.
  - NIH Grants Policy Statement 8.2.2.

- NIH Research Tools Policy requires sharing of unique research materials/biological materials ("research tools").
  - NIH Grants Policy Statement 8.2.3.

- NIH Genomic Data Sharing
  - https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/
- NIH Research Tools Policy
  - https://grants.nih.gov/grants/intell-property_64FR72090.pdf
- NIH Public Access Policy
  - http://publicaccess.nih.gov/
- NIH Data Sharing Policies
  - https://grants.nih.gov/policy/sharing.htm

National Institutes of Health
Office of Extramural Research

We would like to thank

Kristofor Langlais (NIH/OSP),
Erin Luetkemeier (NIH/OD),
Cheryl Smith (NIH/OSP),
Ellen Wann (NIH/OSP), and
Dina Paltoo (NIH/NHLBI)

for their contributions to this presentation.

NIH National Institutes of Health
Office of Extramural Research

Thank you!