Evaluation of NIH Policy Development Process

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Introduction

NIH has a history of investment in data sharing that is driven in part by implementation of policies and initiatives. The NIH Data Sharing Policy was released in 2003 and represented the first agency-wide program established to increase sharing of research data. The policy requires researchers who are seeking NIH funding for projects with annual budgets of $500,000 or more in direct costs to submit a data sharing plan in their funding applications. However, NIH and other federal leaders recognized that an updated policy was needed to further drive data sharing of federally funded research. The Final NIH Policy for Data Management and Sharing was released in 2020 and will go into effect in January 2023.

The purpose of this project is to critically evaluate the NIH policy development and implementation process, using the Final NIH Policy for Data Management and Sharing as the representative example.

Development Process

Important Events

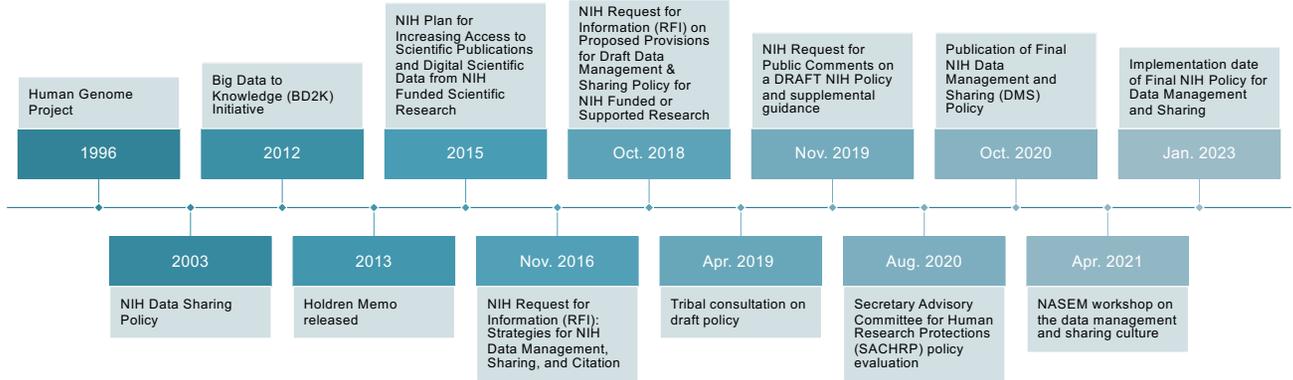|	
Holdren Memo	• Written by the Director of the Office of Science and Technology Policy John Holdren, PhD, the memorandum states that federally-funded scientific research must be made available to the public, including peer-reviewed publications and digital data.
NIH Plan	• To increase access to all NIH-funded data and publications, NIH released a plan that included expanding their original 2003 Data Sharing Policy. • This plan began the process for the development of a new data sharing policy at NIH.
2016 Request for Information	• The RFI addressed considerations for data sharing that included sharing purpose, reusing and reproducing shared data, data uniqueness, ethics, priority of data, length of data availability, and barriers to data sharing.
2018 Request for Information	• This RFI allowed NIH to receive feedback on provisions for an updated policy, which helped inform development of a draft of the Final NIH Policy. • Proposed provisions for the new policy included direction for submission of data management and sharing plans by researchers applying for NIH funding. This RFI requested feedback on defining scientific data to establish to which data the policy would be applicable.
Tribal Consultation	• The recommendations included increasing trust and communication between researchers and Tribal Nations, preventing unauthorized use of Tribal data, training researchers to manage American Indian/Alaskan native data, and guaranteeing that research practices will respect preferences, sovereignty and laws of the Tribal communities.

Working Groups & Committees

- **NIH Steering Committee**
  - **Data Science Policy (DSP) Council**
    - Working groups of Data Science Policy Council
    - Data Science Policy Subgroup for Data Management & Sharing (DMS) Plans
  - **Trans-NIH committees**
    - Program Leadership Committee – Extramural Program Management Committee DMS Policy Implementation Working Group

Timeline

1996	2012	2015	Oct. 2018	Nov. 2019	Oct. 2020	Jan. 2023
Human Genome Project	Big Data to Knowledge (BD2K) Initiative	NIH Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH Funded Scientific Research	NIH Request for Information (RFI) on Proposed Provisions for Draft Data Management & Sharing Policy for NIH Funded or Supported Research	NIH Request for Public Comments on a DRAFT NIH Policy and supplemental guidance	Publication of Final NIH Data Management and Sharing (DMS) Policy	Implementation date of Final NIH Policy for Data Management and Sharing

2003	2013	Nov. 2016	Apr. 2019	Aug. 2020	Apr. 2021
NIH Data Sharing Policy	Holdren Memo released	NIH Request for Information (RFI): Strategies for NIH Data Management, Sharing, and Citation	Tribal consultation on draft policy	Secretary Advisory Committee for Human Research Protections (SACHRP) policy evaluation	NASEM workshop on the data management and sharing culture

Analysis & Comparison

Policy Comparison

The Cancer Moonshot[SM] is an initiative funded by the 21st Century Cures Act and has the goals of accelerating scientific discovery in cancer, fostering collaboration, and improving data sharing. NCI established the Public Access and Data Sharing Policy for Moonshot-funded projects.
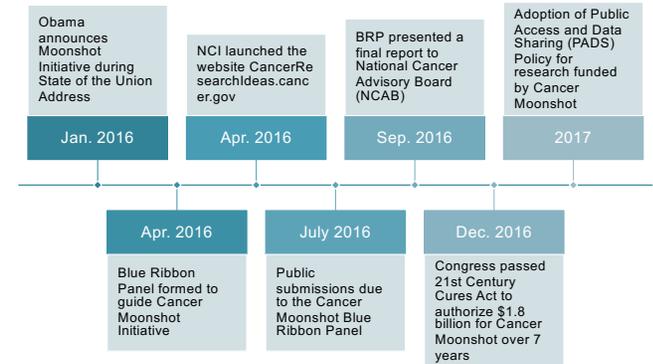
NIH DMS Policy	Cancer Moonshot PADS Policy
• Development of the policy extended over several years • NIH released multiple RFIs for public comments and then posted a draft of the policy on the Federal Register to receive public comments. • Delayed implementation allowed additional community outreach through modules and webinars • Policy is more flexible, suggesting "timely sharing of scientific data as appropriate. • Retains publication requirements of NIH's Public Access Policy	• Development in about a year • NCI launched portal for public comment submissions, and then the final report on public comments was presented to the NCAB. • Due to appropriation process, policy was implemented in the fiscal year in which the Moonshot Initiative was funded. • Requires data to be shared widely and immediately after publication. • Contains unprecedented provision requiring publications to be available without embargo.

National Cancer Institute's Moonshot Timeline

Jan. 2016	Apr. 2016	Sep. 2016	2017
Obama announces Moonshot Initiative during State of the Union Address	NCI launched the website CancerResearchIdeas.cancer.gov	BRP presented a final report to National Cancer Advisory Board (NCAB)	Adoption of Public Access and Data Sharing (PADS) Policy for research funded by Cancer Moonshot

Apr. 2016	July 2016	Dec. 2016
Blue Ribbon Panel formed to guide Cancer Moonshot Initiative	Public submissions due to the Cancer Moonshot Blue Ribbon Panel	Congress passed 21st Century Cures Act to authorize $1.8 billion for Cancer Moonshot over 7 years

Conclusions

- Developing a policy is a lengthy process, and there are many key factors to consider for the policy to be effective.
- Transparency with the policy development process and additional outreach during policy development beyond RFIs is essential for better compliance.
- Detailed policy language and appropriate supplemental documents help with adherence to the policy.
- Community outreach and engagement following the publication of policy allows for policy requirements to be made clear to stakeholders.
- Delaying the implementation of the policy in order to have time for an infrastructure to be in place when the policy is released can facilitate smoother implementation of policy.
- Collecting metrics on compliance and using enforcement mechanisms for non-compliance can also improve the effectiveness of the policy.

Acknowledgments

Literature Cited

- Kaiser, J. (2019, November 11). *Why NIH is beefing up its data sharing rules after 16 years*. Retrieved from https://www.science.org/content/article/why-nih-beefing-its-data-sharing-rules-after-16-years
- National Institutes of Health. (2016, November 14). *NIH Request for Information (RFI): Strategies for NIH Data Management, Sharing, and Citation*. Retrieved from https://grants.nih.gov/grants/guide/notice-files/not-od-17-015.html
- National Institutes of Health. (2019, November 8). *Request for Public Comments on a DRAFT NIH Policy for Data Management and Sharing and Supplemental DRAFT Guidance*. Retrieved from https://www.federalregister.gov/documents/2019/11/08/2019-24529/request-for-public-comments-on-a-draft-nih-policy-for-data-management-and-sharing-and-supplemental
- National Institutes of Health. (2020, November 3). *NIH Data Sharing Policy and implementation guidance*. Retrieved from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm
- National Institutes of Health. (2021, May 25). *NIH Public Access Policy details*. Retrieved from https://publicaccess.nih.gov/policy.htm
- Office of The Director, National Institutes of Health. (2021, July 1). *Request for Information: Developing consent language for future use of data and biospecimens*. Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-131.html
- Paine, T., & Danielson, C. (2021, September 22). *Update on the NIH Policy for Data Management & Sharing and implementation activities* [Conference session]. Presentation to Federal Demonstration Project, National Institutes of Health, United States.
- Stebbins, M. (2013, February 22). *Expanding public access to the results of federally funded research*. Retrieved from https://obamawhitehouse.archives.gov/blog/2013/02/22/expanding-public-access-results-federally-funded-research
- U.S. Department of Health & Human Services. (2020, September 17). *Attachment A - NIH Data Sharing Policy*. Retrieved from https://www.hhs.gov/ohrp/sachrp-committee/recommendations/august-12-2020-attachment-a-nih-data-sharing-policy/index.html