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.

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.

Introduction

NIH Plan

2003 - NIH Data Sharing Policy
2013 - Holdren Memo released
2015 - NIH Request for Information (RFI): Strategies for NIH Data Management, Sharing, and Citation
2016 - Tribal consultation on draft policy
2019 - Secretary Advisory Committee for Human Research Protections (SACHRP) policy evaluation
2020 - Publication of Final NIH Data Management and Sharing (DMS) Policy
2023 - Implementation date of Final NIH Policy for Data Management and Sharing

Policy Comparison

NIH DMS 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, supporting timely sharing of scientific data as appropriate
- Retains publication requirements of NIH’s Public Access Policy

Cancer Moonshot PADS 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

Analysis & Comparison

Table: NIH Plan and Policy Comparison

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2003</td>
<td>NIH Data Sharing Policy released</td>
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<tr>
<td>2013</td>
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</tbody>
</table>

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.
- Delays in 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.

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Literature Cited


NIH Data Sharing Policy was published in 2003 and represented the first agency-wide program established to increase sharing of research data.