Institutional Strategies for the NIH Data Management and Sharing Policy: Infrastructure, Policies, and Services

Association of Academic Health Science Libraries Association of American Medical Colleges Association of Research Libraries

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Background

In the fall of 2020, the National Institutes of Health (NIH) released its new policy for data management and sharing that will go into effect in January 2023. This policy applies to all NIH-funded research and requires investigators to submit data management and sharing (DMS) plans.

As research data sharing has started to become an enforced requirement from funders and publishers, many academic institutions, libraries, and individual researchers have developed services, technology, and workflows to meet this requirement. As institutions gear up to meet what will be a greater demand for support among researchers on their campuses given the upcoming NIH DMS policy, identifying and sharing existing tactics and expected strategic opportunities for academic institutions is critical to meeting this demand.

The Association of Academic Health Science Libraries (AAHSL), the AAMC (Association of American Medical Colleges), and the Association of Research Libraries (ARL) conducted a mixed methods research project to identify and share these existing or proposed innovations for other institutions to reuse, build upon, or otherwise leverage to meet this upcoming NIH requirement.

About the Research Project

In the fall of 2021, representatives from AAHSL, the AAMC, and ARL collaboratively drafted a survey to identify these tactics and activities from the AAHSL and ARL membership. The AAMC also queried constituents separately about their plans to prepare for the policy. The survey asked the following questions:

- How many full-time equivalent (FTE) positions does your library designate for data management and sharing support?
- What processes, workflows, and services does your institution **currently have in place** that will be used to meet the requirements in the upcoming NIH data management and sharing policy?
- What processes, workflows, and services are your institution **developing or planning to develop** to meet the requirements in the upcoming NIH data management and sharing policy?
- Is there anything else you want to share about your institution's processes, workflows, and services that specifically support biomedical and health research data generated by NIH-funded projects?

Once the survey was completed, the research team reached out to responding institutions to conduct brief interviews about their local strategies for meeting the upcoming NIH policy. These interviews took place in spring and fall of 2022. The following sections describe the key themes that emerged from the research.

Five Areas of Institutional Support



Coordination and Communication



Addressing the institutional implications of the NIH DMS is not solely the responsibility of the library or the researcher. Rather, coordination across campus stakeholders emerged as a key first step in strategically building infrastructure and services to comply with the policy.

Campus-Wide Task Forces

Many institutions have formed or are currently forming campus-wide teams or task forces to meet the NIH DMS requirements. These teams are composed of representatives from the following offices and units and often include components from the university as well as the medical school or health sciences school:

- Office of the provost or dean.
- Office of research or sponsored projects.
- University libraries.
- Research compliance.
- Research computing.
- Campus information technology.
- NIH-funded faculty representatives.

The charge and activities of these teams vary depending on the institutional context but may include some or all of the following:

- Evaluating institutional readiness and expected impact.
- Developing strategic plans to address researcher needs, roles and responsibilities, governance, outreach and engagement, services, and infrastructure.
- Creating workflows or service referral processes for support among institutional stakeholders.
- Benchmarking with peer institutions.

In some cases, institutions have used these impending requirements as an opportunity to establish working groups focused on broader research data management and sharing needs, in which case they are evaluating requirements across different federal, nonprofit, and philanthropic funders as well as various publishers.

Governance and Compliance



Several institutions had research data governance and compliance practices and policies in place or were in the process of establishing formal documents. These documents included institutional data policies as well as data strategy.

Resources

Institutional Research Data Policies

Briney K, Goben A, Zilinski L. Do you have an institutional data policy? a review of the current landscape of library data services and institutional data policies. *J Libr Sch Commun.* 2015;3(2):p.eP1232. <u>https://doi.org/10.7710/2162-3309.1232</u>

Research Data Strategy

Hosch BJ. Key elements of a data strategy. In: Powers K, ed. *Data Strategy in Colleges and Universities: From Understanding to Implementation*. Routledge; 2019. doi: 10.4324/9780429437564-2

Examples:

- East Carolina University: Data Governance Policies and Standards.
- Indiana University School of Medicine Research Data Ownership and Retention Policy.
- <u>The Ohio State University: Research Data Policy</u>.
- Virginia Commonwealth University: Research Data Ownership, Retention, Access, and Security.
- <u>Yale University Research Data and Materials Policy</u>.

Informed Consent and Sensitive Data

Clinical and translational research often produces data from human research participants, subject to additional policies and regulations at the institutional, state, federal, and international level. Explicitly outlining these requirements for investigators producing such data is a key component of compliance. Below are some links to examples of institutional guidance or initiatives for managing and sharing sensitive health data:

- <u>Brown University: Guidance and FAQs for Sharing Information with Data</u> <u>Repositories</u>.
- <u>Western Michigan University School of Medicine Virtual Data Warehouse.</u>

Services and Processes



Cross-campus services that involve multiple stakeholders are critical activities for institutions. These services include consultation and review services and training and education.

Consultations

The following types of in-depth consultations were indicated by institutions:

- Data management plan (DMP) drafting.
- Human subjects and privacy.
- Security.
- Informed consent for research data sharing.
- Curation.
- Storage.

Training and Education



Training, education, and outreach is a core tactic for institutions to support the NIH DMS with researchers on their campuses. Training has differed based on institutional context. Respondents indicated they would be focusing their training activities on graduate students, faculty, and library staff.

Methods of educating and engaging the community include:

- Creating regularly scheduled brown bag events open to the university research community on specific aspects of the policy
- Scheduling trainings and presentations at existing departmental meetings
- Offering on-demand webinars for researchers through a campus resource portal
- Incorporating research data management training into graduate student coursework
- Providing a centralized email for researchers to ask questions
- Training the trainers: providing opportunities for library, IT, or research office staff to gain knowledge about the policy, existing resources, and referral information to share with researchers

Infrastructure



Institutions have invested significant resources in building and maintaining tools to help researchers meet funding agency requirements for the sharing and management of research data. Infrastructure and staffing varied significantly depending on the institution's local context; libraries had on average one FTE employee in research data services. Below are some of the various tactics used by institutions.

Repository Tools

Hosting or providing access to a repository platform is a key component of infrastructure for many institutions. These included:

- **Data catalog** a local repository of metadata about datasets produced on a campus.
- **Hosted data repository** a hosted repository of datasets produced on a campus (examples included Dryad, Vivli, and Isilon).
- **Local data repository** a locally operated repository of datasets produced on a campus.

Data Management Tools

Many institutions adopted data management and sharing tools to assist faculty with managing active data and developing funding-agency-compliant DMPs. These included:

- Local data management planning application some institutions are developing their own institutional DMP tools that integrate more closely with existing institutional applications
- **DMP repository** a number of institutions have created a repository or a clearinghouse of DMPs created by researchers on their campuses
- **DMPTool** many institutions indicated they would be highly customizing the California Digital Library's DMPTool for the upcoming NIH Policy.
- **ORCID** institutions have adopted the use of ORCID, a persistent digital identifier that assists researchers with creating an ID to tie to their research data.
- Electronic Lab Notebook (ELN) software institutions have subscriptions to programs such as LabArchives, which allow investigators to organize, store, and share data.

Conclusion

The NIH data sharing policy becomes effective on Jan. 25, 2023. As the date approaches, we hope the recommendations here provide a useful starting point and reference for institutions as they prepare to meet the policy requirements. AAHSL, the AAMC, and ARL will continue to share information on policy implementation with constituents through our listservs.

This document is available at aamc.org/nihdatasharing, which will be continuously updated with links to new resources and services to support researchers in complying with the NIH data sharing and management policy.