Key Issues in Science and Research Policy: Data Sharing and Foreign Government Influence

GREAT/GRAND Community Forum
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Data Sharing
ICMJE Requirement for a Data Sharing Statement

- July 2018: Manuscripts must contain a data sharing statement
- Jan 2019: Clinical trial registration must include a data sharing plan (clinicaltrials.gov)
- Key takeaway: The policy does not mandate data sharing, only the existence of a plan
# Proposed Provisions for an NIH Data Sharing Policy

**Request for Information (RFI) on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research**

**Notice Number:** NOT-OD-19-014

**Key Dates**
- **Release Date:** October 10, 2018
- **Response Date:** December 10, 2018

**Related Announcements**
- NOT-OD-18-035
- NOT-OD-18-104
- NOT-OD-19-034

**Issued by**
- National Institutes of Health (NIH)

**Purpose**
- **Introduction**
  - The purpose of this Notice is to solicit public input on proposed key provisions that could serve as a foundation for a future NIH policy for data management and sharing.

**Background**
- NIH has a longstanding commitment to making the results and accomplishments of the research that it funds and conducts available to the public. In NIH’s view, data should be made as widely and freely available as possible while safeguarding the privacy of participants and protecting confidential and proprietary data. Increasing access to scientific data resulting from NIH funding or support offers many benefits and reflects NIH’s responsibility to maintain stewardship over taxpayer funds. Specifically, sharing of scientific data and results enables researchers to more vigorously test the validity of research findings, strengthen analyses by combining data sets, access hard-to-generate data, and explore new frontiers. Data sharing also informs future research pathways, increases the return on investment of scientific research funding, and accelerates the translation of research results into knowledge, products, and procedures to improve health and prevent disease. Effective data sharing practices rely upon appropriate identification, adoption, and crediting of good data management and sharing practices; thus, NIH encourages data sharing consistent with the FAIR (Findable, Accessible, Interoperable, and Re-usable) data principles.1

> In 2015, NIH released its Plan for Increasing Access to Scientific Publications and Digital Scientific Data from NIH-Funded Scientific Researcher (NIH Plan). To help NIH establish priorities for data management and sharing, NIH in 2016 released a Request for Information on Strategies for NIH Data Management, Sharing, and Citation1 and, in 2017, co-hosted with the National Science Foundation a joint workshop focused on the value of data sharing.1 Public input from these events has helped to inform NIH’s thinking about key provisions for a future NIH policy for the management and sharing of data, which would replace the 2003 NIH Data Sharing Policy.2

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**RFI issued Oct 10, 2018**

**Draft policy expected by fall 2019**

**Agency-wide**

**Key takeaway:** **Data sharing and management plan** requirement for applications that produce scientific data

**Term and condition of award**
IC and Data-Specific Sharing Policies and Repositories

**Notice of New NIH-Designated Data Repository: NHGRI’s Genomic Data Science Analysis, Visualization, and Informatics Lab-space (AnVIL)**

**Notice Number:** NOT-HG-19-024

**Key Dates**
- **Release Date:** July 05, 2019

**Related Announcements**
- None

**Issued by**
- National Human Genome Research Institute

**Purpose**
- The NHGRI Genomic Data Science Analysis, Visualization, and Informatics Lab-space (AnVIL) is a web-based environment where researchers can store, manage, and share genomics and associated phenotypic data. AnVIL implements security configurations and controls for accredited PIPRA Moderate Risk systems. AnVIL complies with the NIH Security Best Practices for Cyber Security and Analysis of Controlled-Access Data. AnVIL has been approved as an NIH-designated data repository.

**Notice of Data Sharing Policy for the National Institute of Mental Health**

**Notice Number:** NOT-MH-19-033

**Key Dates**
- **Release Date:** June 17, 2019

**Related Announcements**
- NOT-MH-06-108
- NOT-MH-06-005
- NOT-MH-14-013
- NOT-MH-15-012

**Issued by**
- National Institute of Mental Health (NIMH)

**Purpose**
- Widespread data sharing by research communities adds significant value to research and accelerates the pace of discovery. The National Institute of Mental Health (NIMH) has established an informatics infrastructure to enable the responsible sharing and use of data collected from and about human subjects by the entire research community. Consistent with authorities under the 21st Century Cures Act, researchers who are funded by NIMH are required to share data.
Nonprofit and Foundation Data Sharing Policies

The foundation will require that data underlying the published research results be immediately accessible and open.

We expect our researchers to maximize the availability of research data, software and materials with as few restrictions as possible. As a minimum, the data underpinning research papers should be made available to other researchers at the time of publication, as well as any original software that is required to view datasets or to replicate analyses.

Any factual data that is needed for independent verification of research results must be made freely and publicly available in an AHA-approved within 12 months of the end of the funding period.

All data used in or developed in whole or in part by foundation-funded projects (and that can be shared in a manner consistent with applicable laws) will be made widely available and freely shared as soon as possible.
Credit for Data Sharing: Making the Case for Data Impact

- **Goal:** Track the use, reuse, and impact of scientific data
- **Aligns with:**
  - Increasing mandates for sharing
  - Requirements for ORCID ID and depositing data
- **Relies on the consistent adoption of unique identifiers for both data sets and investigators**
- **Leverages existing initiatives**
- **Resources at:** aamc.org/datasharing

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Discussion: Data Sharing

Facilitator:
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Northwestern University
Associate Provost and Chief Diversity Officer
Associate Professor of Medicine, Feinberg School of Medicine

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AAMC Senior Director of Science Policy and Regulatory Counsel
Foreign Government Influence
### Selected Timeline: Foreign Government Influence Concerns

<table>
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<tr>
<th>Date</th>
<th>Event Description</th>
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<tr>
<td>Aug 2018</td>
<td>NIH Director sends a letter to over 10,000 grantee institutions, outlining areas of concern</td>
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<td>Dec 2018</td>
<td>NIH ACD releases report recommendations for communication and risk mitigation</td>
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<tr>
<td>Jun 2019</td>
<td>NIH testifies on the Hill, cites follow-up investigations at 60+ institutions. Congress introduces legislation on securing science</td>
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<tr>
<td>July 2019</td>
<td>NIH releases a guide notice on reporting “foreign activities,” including other support, FCOIs, and foreign components</td>
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Aug 2018 letter identified three areas of concern:

- Diversion of intellectual property
- Sharing of confidential information in grant applications by NIH peer reviewers
- Failure to disclose substantial resources from other organizations
Policy Violations and Key Public Cases

July 2019 Open Mike blog:

Depending on the severity and duration of the noncompliance... we may contact the affected institutions, impose specific award conditions, disallow costs, withhold future awards for the project or program, suspend the award activities, make a referral for investigator suspension or debarment, or terminate the award.
Concerns about Discrimination and Profiling

Scrutiny of Chinese American scientists raises fears of ethnic profiling

Mounting efforts by U.S. lawmakers and agencies to prevent federally funded research from being exploited by foreign governments have elicited increasing pushback from university leaders.

Northwestern message to international students

In light of the Chinese government’s recent warning about the risks of studying in the United States, we want to reassure our Chinese students and scholars that they are critical to Northwestern’s mission, and we are committed to assisting them in the visa process. To date, we have seen no visible decline for Chinese students and scholars who are coming to Northwestern, and we will continue to make efforts to help them in the process if they experience problems.

Northwestern is committed to being an inclusive and welcoming place for all international students. We cannot fulfill our mission to produce the highest caliber of research and solve problems of global significance without attracting the best talent in the world. To meet these goals, we envision an increase in the number of Chinese and international students and scholars at Northwestern in the years to come.
Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components

Notice Number: NOT-OD-19-114

Key Dates
Release Date: July 10, 2019

Related Announcements
None

Issued by
OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH (OD)

Purpose
The intent of this notice is to remind the extramural community about the need to report foreign activities through documentation of other support, foreign components, and financial conflict of interest to prevent scientific, budgetary, or commitment overlap. NIH has long required full transparency for all research activities both domestic and foreign and does not consider these clarifications to be changes in policy. The requirements referenced in this Notice, along with the other obligations in the NIH Grants Policy Statement (NIHGPS) and other terms and conditions of award, are instrumental to achieving the mutual goal of NIH and the extramural community, to protect the integrity of biomedical research.

Background
On August 23, 2018, the NIH Director issued a statement regarding the protection of the integrity of biomedical research conducted in the United States, and convened a working group of the Advisory Committee to the NIH Director

• Goal: Prevent scientific, budgetary, or commitment overlap
• Outlines responsibilities for investigators
• Covers other support, foreign components, and financial COI
• AAMC and other higher ed orgs working with NIH to clarify Guidance and FAQ
Policies and Initiatives Across the Federal Government

- Requires rotators working onsite to be US citizens or have applied for citizenship
- Released draft award policies to clarify disclosure requirements
- Prohibits NSF personnel from participating in foreign talent recruitment

- Prohibits personnel from participating in foreign talent recruitment programs (currently: China, Iran, N Korea, and Russia)
- Restricts DOE-funded researchers working in "emerging research areas and technologies" from collaborating with scientists from "sensitive" countries

- Directed by Congress to "support protection of national security academic researchers from undue influence," including foreign recruitment programs
- Requires grant applicants to disclose information about all research projects that key personnel are working on, regardless of their funding source
Where Should You Go to Learn More?

NIH Policies and FAQs: https://grants.nih.gov/grants/frequent_questions.htm

AAMC COI Resources: www.aamc.org/coi

AAMC Issue Briefs

GREAT/GRAND Meetings and Community Webinars!

(Links to all resources discussed today and PDF of slides will be emailed to all participants)
Discussion: Foreign Government Influence

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