



Tomorrow's Doctors, Tomorrow's Cures®

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

GREAT/GRAND Community Forum
July 24, 2019

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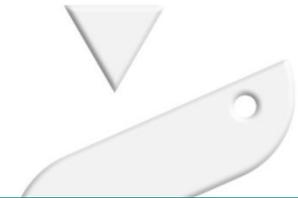
Tomorrow's Doctors, Tomorrow's Cures®

Data Sharing

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ICMJE Requirement for a Data Sharing Statement

Annals of Internal Medicine

EDITORIAL

Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors

The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk. In January 2016 we published a proposal aimed at helping to create an environment in which the sharing of deidentified individual participant data becomes the norm. In response to our request for feedback we received many comments from individuals and groups (1). Some applauded the proposals while others expressed disappointment they did not more quickly create a commitment to data sharing. Many raised valid concerns regarding the feasibility of the proposed requirements, the necessary resources, the real or perceived risks to trial participants, and the need to protect the interests of patients and researchers.

It is encouraging that data sharing is already occurring in some settings. Over the past year, however, we have learned that the challenges are substantial and the requisite mechanisms are not in place to mandate universal data sharing at this time. Although many issues must be addressed for data sharing to become the norm, we remain committed to this goal.

Therefore, ICMJE will require the following as conditions of consideration for publication of a clinical trial report in our member journals:

1. As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below.

2. Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. The ICMJE's policy regarding trial registration is explained at www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

Data sharing statements must indicate the following: whether individual deidentified participant data (including data dictionaries) will be shared; what data in particular will be shared; whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Illustrative exam-

ples of data sharing statements that would meet these requirements are in the Table.

These initial requirements do not yet mandate data sharing, but investigators should be aware that editors may take into consideration data sharing statements when making editorial decisions. These minimum requirements are intended to move the research enterprise closer to fulfilling our ethical obligation to participants. Some ICMJE member journals already maintain, or may choose to adopt, more stringent requirements for data sharing.

Sharing clinical trial data is one step in the process articulated by the World Health Organization (WHO) and other professional organizations as best practice for clinical trials: universal prospective registration; public disclosure of results from all clinical trials (including through journal publication); and data sharing. Although universal compliance with the requirement to prospectively register clinical trials has not yet been achieved and requires continued emphasis, we must work toward fulfilling the other steps of best practice as well—including data sharing.

As we move forward into this new norm where data are shared, greater understanding and collaboration among funders, ethics committees, journals, trialists, data analysts, participants, and others will be required. We are currently working with members of the research community to facilitate practical solutions to enable data sharing. The United States Office for Human Research Protections has indicated that provided the appropriate conditions are met by those receiving them, the sharing of deidentified individual participant data from clinical trials does not require separate consent from trial participants (2). Specific elements to enable data sharing statements that meet these requirements have been adopted at [ClinicalTrials.gov \(https://prinfo.clinicaltrials.gov/definitions.html#shareData\)](https://prinfo.clinicaltrials.gov/definitions.html#shareData). The WHO also supports the addition of such elements at the primary registries of the International Clinical Trials Registry Platform. Unresolved issues remain, including appropriate scholarly credit to those who share data, and the resources needed for data access, the transparent processing of data requests, and data archiving. We welcome creative solutions to these problems at www.icmje.org.

We envision a global research community in which sharing deidentified data becomes the norm. Working toward this vision will help maximize the knowledge gained from the efforts and sacrifices of clinical trial participants.

This article was published at Annals.org on 6 June 2017.

Annals.org

Annals of Internal Medicine

1

- 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-17-015](#)

[NOT-OD-18-134](#)

[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 Research (NIH Plan)*.² 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 Citation*³ and, in 2017 co-hosted with the National Science Foundation a joint workshop, focused on the value of data sharing.⁴ 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.⁵

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 cloud-based environment where researchers work with genomic datasets and associated phenotypic data. NHGRI funds and manages AnVIL.

AnVIL is implementing security configurations of certified [FISMA Moderate systems](#). As part of its management, data sharing, and data security, 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-OD-14-124](#)

Rescinded Announcements

[NOT-MH-06-108](#)

[NOT-MH-09-005](#)

[NOT-MH-14-015](#)

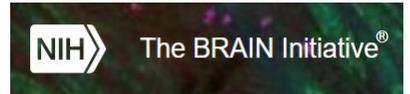
[NOT-MH-15-012](#)

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



Notice of Data Sharing Policy for the BRAIN Initiative

Notice Number: NOT-MH-19-010

Key Dates

Release Date: January 22, 2019

Issued by

National Institute of Mental Health (NIMH)

National Eye Institute (NEI)

National Institute on Aging (NIA)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

National Institute on Deafness and Other Communication Disorders (NIDCD)

National Institute on Drug Abuse (NIDA)

National Institute of Neurological Disorders and Stroke (NINDS)

National Center for Complementary and Integrative Health (NCCIH)

Purpose

The purpose of this notice is to inform prospective applicants and current awardees of a new policy concerning data collected with support from awards that are funded by the BRAIN Initiative. Specifically, this Notice clarifies the expectation that applicants to BRAIN Initiative funding opportunity announcements: 1) submit their data to one of the BRAIN data archives for sharing; 2) include specific required elements in the Resource Sharing Plan as further detailed below; and 3) include costs attributed to data preparation and submission to a data archive in grant applications.

[BRAIN Initiative Overview](#)

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® is aimed at revolutionizing our understanding of the human brain. By accelerating the development and application of innovative technologies,

Nonprofit and Foundation Data Sharing Policies

BILL & MELINDA
GATES *foundation*

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



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.

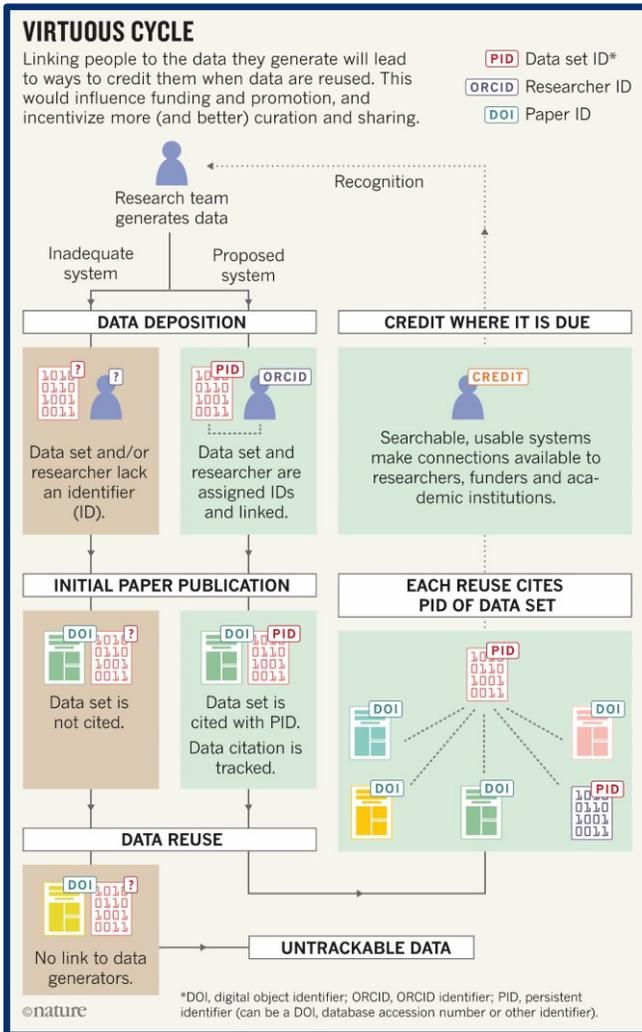


We expect our researchers to maximize the availability of research data, software and materials with as few restrictions as possible. As a minimum, the data underpinning research papers should be made available to other researchers at the time of publication, as well as any original software that is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

GORDON AND BETTY
MOORE
FOUNDATION

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



Pierce, et al. Credit Data Generators for Data Reuse. *Nature*. 2019 Jun;570(7759):30-32.

Discussion: Data Sharing



Facilitator:

Jabbar Bennett, PhD - GREAT Group Chair

Northwestern University

Associate Provost and Chief Diversity Officer

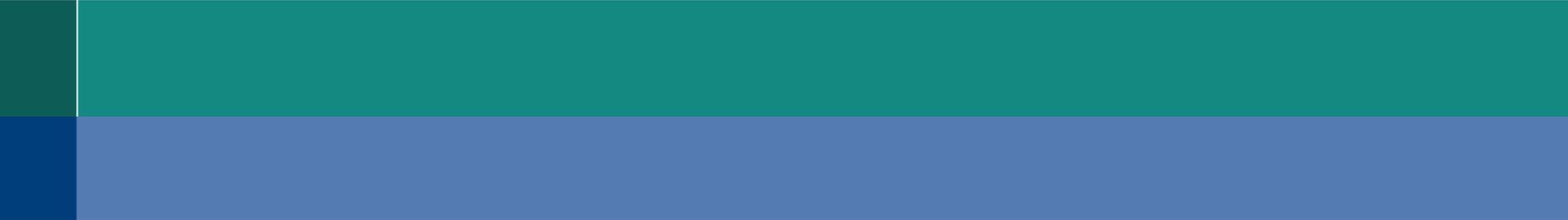
Associate Professor of Medicine, Feinberg School of
Medicine



Heather Pierce, JD, MPH

AAMC Senior Director of Science Policy and
Regulatory Counsel

Foreign Government Influence



Selected Timeline: Foreign Government Influence Concerns

Aug 2018

NIH Director sends a letter to over 10,000 grantee institutions, outlining areas of concern

Dec 2018

NIH ACD releases report recommendations for communication and risk mitigation

Jun 2019

NIH testifies on the Hill, cites follow-up investigations at 60+ institutions. Congress introduces legislation on securing science

July 2019

NIH releases a guide notice on reporting “foreign activities,” including other support, FCOIs, and foreign components

Initial Concerns Expressed by NIH



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

August 23, 2018

Statement on Protecting the Integrity of U.S. Biomedical Research

NIH research is built on the bedrock principles of scientific excellence, unassailable integrity, and fair competition. NIH's commitment to these principles is unwavering. The robustness of the biomedical research enterprise is underpinned by the integrity of peer review, the integrity of intellectual property and the integrity of grant applications and practices, but these risks are increasing. Three areas of concern are: 1) failure of researchers at NIH-funded institutions to disclose substantial conflicts of interest to other organizations, including foreign governments, which threatens the integrity of NIH funds; 2) diversion of intellectual property in grant applications to other entities, including other countries; 3) sharing of confidential information by peer reviewers with others, including other organizations, otherwise attempting to influence funding decisions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

August 20, 2018

Dear Colleagues:

For many decades, the National Institutes of Health (NIH) and institutions like yours have participated in productive partnerships that greatly advance biomedical science. Scientists at universities and academic medical centers, supported by NIH, have made seminal biomedical discoveries that have led to dramatic improvements in human health. The scientists whose work NIH is proud to help support come from all over this country and the world, bringing rich, diverse perspectives and backgrounds to the biomedical research enterprise.

The NIH-funded biomedical enterprise depends on a competitive system, which, to be successful, must be fair, transparent, and trustworthy.

Unfortunately, threats to the integrity of U.S. biomedical research exist. NIH is aware that some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers and to take advantage of the long tradition of trust, fairness, and excellence of NIH-supported research activities. This kind of inappropriate influence is not limited to biomedical research; it has been a significant issue for defense and energy research for some time. Three areas of concern have emerged:

1. Diversion of intellectual property (IP) in grant applications or produced by NIH-supported biomedical research to other entities, including other countries;

Policy Violations and Key Public Cases

The New York Times

Wary of Chinese Espionage, Houston Cancer Center Chose to Fire 3 Scientists



The MD Anderson Cancer Center said it decided to fire three scientists who, among other allegations, failed to disclose international collaborators. Two of them resigned. Scott Dalton for The New York Times

By Mihir Zaveri

April 22, 2019

简体繁体中文网 · 繁體繁體中文网

Science Contents News Careers Journals

SHARE



The entrance to Emory University in Atlanta ISTOCK.COM/AIMINTANG

Emory ousts two Chinese American researchers after investigation into foreign ties

By David Malakoff | May 23, 2019, 4:00 PM

Emory University in Atlanta has ousted two veteran biomedical researchers and shuttered their laboratory after the National Institutes of Health (NIH) in Bethesda, Maryland, expressed concern about their foreign ties. The researchers "had failed to fully disclose foreign sources of research funding and the extent of their work for research institutions and universities in China," the university said in a statement first reported today by *The Atlanta Journal-Constitution*.

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

INSIGHTS | LETTERS



Policies that single out certain groups can stifle scientific collaboration.

LETTERS Edited by Jennifer Sills

Racial profiling harms science

On behalf of the Society of Chinese Biologists in America (SCBA), the Chinese American Hematologist and Oncologist Network (CAHON), and the Chinese Biological Investigators Society (CBIS), we write to express our concerns about the recent political rhetoric and policies that single out students and scholars of Chinese descent working in the United States as threats to U.S. national interests (e.g., (1) and pp. 4-7 in (2)). These developments have led to confusion, fear, and frustration among these highly dedicated professionals, who are in danger of being singled out for scapegoating, stereotyping, and racial profiling. U.S. policies must avoid targeting, as Representative Judy Chu (D-California) put it, "an entire ethnic group of people for suspicion that they're spies for China" (3).

Existing U.S. laws are in place to safeguard America's interests and to punish perpetrators for stealing trade secrets or engaging in illegal activities. We absolutely support the well-established policies regarding intellectual property, employment, and governance of conflicts of interest. Such policies have been further enhanced in recent years with more detailed and specific requirements from various federal and state agencies, including the National Institutes of Health (NIH) (4). The vast majority of scientists and students of Chinese descent are law-abiding citizens, residents, or visitors who have followed these rules.

Open data access and data sharing are important for accelerating research advancement and can be implemented must be established through official channels. NIH also suggests more disclosure requirements for foreign collaborators than domestic colleagues (pp. 12-13 in (2)), which could hinder collaborations. In recent decades, there have been several high-profile cases in which Chinese-American scientists were wrongfully accused of spying (e.g., (6-10)). Although all charges were eventually dropped and/or the individuals legally exonerated, the lawsuits have had not only devastating effects on the careers of these individuals but also a chilling and negative impact on the Chinese-American scientific community at large. It has also become increasingly difficult for Chinese students and scholars to obtain visas to enter the United States for scientific meetings, visits, and research opportunities (5).

It is our sincere hope that these actions, which we believe amount to racial profiling, will stop increased scrutiny used to tarnish limit normal exchanges. We and local government academic to create a res

"[We] hope that...increased security measures will not be used to tarnish law-abiding scientists..."

without putting U.S. security at risk. NIH has espoused such policies for years (5). Most Chinese-American scientists believe that biomedical research benefits all mankind and that multinational collaborations accelerate scientific progress and discovery. However, some NIH recommendations could target collaborations if implemented with bias. For example, NIH recommends fostering "trusted relationships" (p. 12 in (2)) with foreign partners but does not specify whether the trust

1290 22 MARCH 2019 • VOL. 363 ISSUE 6433
Published by AAAS

The Washington Post
Democracy Dies in Darkness

Education

Scrutiny of Chinese American scientists raises fears of ethnic profiling



Xiao-Jiang Li, left, and Shihua Li were fired in May from their faculty positions at Emory University in Atlanta. They are known for studies on Huntington's disease. (Xiao-Jiang Li)

By Nick Anderson
July 19

Two years ago, the director of the National Institutes of Health hailed genetic research from Emory University as a promising advance in the quest to treat Huntington's disease, a devastating neurological disorder.

Northwestern message to international students

June 07, 2019

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 University's mission, and we are committed to assisting them in the visa process. To date, we have seen no visas denied 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 those goals, we envision an increase in the number of Chinese and international students and scholars at Northwestern in the years to come.

FYI
SCIENCE POLICY NEWS FROM AIP

Bulletin

Universities Under Pressure as Lawmakers Push Research Security

SHARE THIS

Publication date: 12 July 2019 Number: 61

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.



NIH Guide Notice on Reporting “Foreign Activities”

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



Facilitator:

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