Overview

1. Whole of Government Approach
2. Rules and Regulations
3. Building a Compliance Plan for Foreign Influence
4. Focus Not Changing Soon
National Institutes of Health (NIH)

NIH is among the largest public funders of biomedical research in the world and the second-largest U.S. research funder

- More than 80% of NIH’s $42 billion FY 2020 budget will go to extramural research
- NIH’s funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutes in the U.S. and around the world
NIH Initiates Inquiries

NIH has identified more than 100 instances of troubling foreign influence on extramural research, including withholding information about funding sources and conflicts of interests and violating the confidentiality of peer review, said Dr. Michael Lauer, NIH Deputy Director for Extramural Research.

“These all represent forms of theft,” said Lauer.

More than Sponsors:
Department of State
Department of Commerce
Department of Education
Department of Justice
Department of Homeland Security
Federal Bureau of Investigation
National Security Council
U.S. Congress
The White House, OSTP
**Bipartisan Support**

Higher Ed is Driving Technological Innovation:

- Approximately 1000+ start-up companies launched annually from academic research
- Up to $1.3 trillion in gross industrial output
- 4.3 million jobs supported

**The Focus Areas**

- Failure to disclose other support or affiliations in grant applications
- Inappropriate influence on peer review process on federal grants
- Intellectual property theft
- Cyber vulnerabilities related to research activity
- Concerns with foreign delegations
- Relationships with certain foreign companies
- Influence campaign on students, research, and decisions
- Export control
Agency Regulations

Federal Funding and Regulatory Agencies

- National Institute of Health (NIH)
  - Other Support
  - Foreign Component
- National Science Foundation (NSF)
  - Current and Pending
- Department of Education
  - Higher Education Act, §117
- Department of Health and Human Services
  - Financial Conflicts of Interest
- Department of Energy
  - DOE Order 142.3A
Other Support

NIH DISCLOSURE Requirements Grants Policy Statement, Section 2.5.1; NOT-OD-19-114 (July 10, 2019)

What to Disclose
All resources available in direct support of an individual’s research endeavors. Includes (but not limited to):

- All foreign and domestic entities
- Financial support for laboratory personnel
- Provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.)

When to Disclose
- Before the award (Just-in-Time)
- Annually in RPPR (Research Performance Progress Report)

Foreign Component

NIH DISCLOSURE Requirements Grants Policy Statement, Section 8.1.2; NOT-OD-19-114 (July 10, 2019)

What to Disclose
Any “significant scientific element or segment of a project” outside of the United States:

- Performance of work by a researcher or recipient in a foreign location
- Performance of work by a researcher in a foreign location employed or paid for by a foreign organization

When to Disclose
- Initial grant application
- Progress Reports
- Prior approval is always required!
Current and Pending Support

**NSF DISCLOSURE Requirements, Proposal and Award Policies and Procedures Guide (PAPPG) (NSF 20-1) Effective Date June 1, 2020**

**What to Disclose**
ALL resources made available to an individual in support of and/or related to ALL of his/her research efforts, regardless of whether or not they have monetary value.
IN-KIND contributions (such as office/laboratory space, equipment, supplies, employees, students).

**When to Disclose**
- Initial grant application
- Ongoing whenever new support is acquired
- Annual Progress Report

Conflict of Interest

**NSF Financial Conflict of Interest Policy Disclosure Requirements**

**Who must disclose?**
Investigators (anyone, regardless of title or position, responsible for design, conduct or reporting of research funded by NSF)

**What must be disclosed?**
Significant Financial Interests of Investigator (including spouse, registered domestic partner, and dependent children) that would reasonably appear to be affected by the research or that are in entities whose financial interests would reasonably appear to be affected by the research.

**When is disclosure required?**
- Before a proposal is submitted
- When a new investigator joins the project
- When new reportable SFI is acquired
Conflict of Interest

PHS Financial Conflict of Interest Policy, 42 CFR 50, Subpart F (FCOI) Disclosure Requirements

Who must disclose?

Investigators (anyone, regardless of title or position, responsible for design, conduct or reporting of research funded by PHS)

What must be disclosed?

Significant Financial Interests (SFI) of the Investigator (including spouse and dependent children) related to Investigator’s institutional responsibilities.

Professional responsibilities on behalf of the institution, including teaching, research, outreach, clinical service, and other activities in the course and scope of institution appointment/employment.

When is disclosure required?

• Before a proposal is submitted
• When a new investigator joins the project
• Within 30-days of acquiring a new SFI
• Before submission of progress reports
• Minimally, annually during life of the grant

Foreign Gifts and Contracting

Higher Education Act, Section 117

Who must disclose?

Generally, all domestic higher education institutions that receive any Federal financial assistance (directly or indirectly).

What must be disclosed?

Any contracts and gifts received from any foreign source exceeding, in the aggregate, $250,000 in any calendar year and

In February 2019 a bipartisan report of the United States Senate Permanent Subcommittee on Investigations found that one foreign entity directly provided over $156 million to U.S. colleges and universities since 2006 and that 70% of the recipient schools failed to report such funding as required by existing federal law and regulation.

Any ownership interests in or control over the institution by a foreign entity.
Foreign National Access

DOE Order 142.3A

Who must disclose?
Department of Energy locations, such as national laboratories.

What must be disclosed?
Prior DOE approval of Foreign Nationals (including Permanent Residents) for access to DOE sites
- Includes any person who is not a U.S. citizen by birth or naturalization.
- Includes foreign national access to DOE sites, information, technologies, equipment, programs or personnel.

NOTE: In December 2019, DOE removed the exemption for higher education institutions performing fundamental research.

UC Compliance Plan
As you are aware, federal agencies and policymakers have expressed concern that foreign entities may be using the academic research enterprise in an attempt to compromise our country's economic competitiveness and national security. The reality is that bad actors and some foreign governments from around the world are making concerted efforts to steal intellectual property and infiltrate systems. Our University community must address national security concerns while protecting the principles of academic freedom. We must protect the intellectual capital which creates jobs, new ideas, and innovation while enabling our faculty, staff, and students of all nationalities to pursue research, discuss ideas freely, and publish research results without regard to citizenship restrictions. Our teaching and research excellence make us a global leader in creating new knowledge and the destination of choice for many of the world's best scholars and students. We value their important contributions to UC's research leadership, to California's and the nation's prosperity, and to global scholarly excellence.

It is critically important to me that the entire UC community demonstrate leadership not only in research, but also in our responsibility and accountability through compliance, trainings, risk assessments, and protocols for investigations with a clear understanding of what is at stake. UC is committed to helping our faculty, staff, and students have the greatest global impact possible while educating our community about protecting the integrity of our research. This is not an "either or" proposition - it's both.

-compliance plan-

Training and Awareness Program
• Research Compliance Assessments to Identify Gaps
• Inventory of Certain Technology, Contracts, and Donations
• Audits of Research Grant Disclosures and Relationships with Denied Entities
• Research Cyber Vulnerability Assessments and Penetration Testing
• Standardized Investigations
• Strengthen export Control Processes throughout System
Training and Awareness

ECAS performed extensive federal outreach regarding Foreign Influence.

- Demonstrate understanding of the issues
- Develop strategic partnerships
- Protect UC’s interests

ECAS created internal awareness with senior leadership, academics and staff, including confidential and classified briefings around government concerns to ensure:

- Bipartisan nature of the USG’s concerns
- The seriousness of individual cases
- ECAS country agnostic approach

Training and Awareness Program

Foreign Influence Website – a comprehensive site pulling together policies, communications, regulatory changes, criminal indictments, etc. updated weekly.

https://www.ucop.edu/ethics-compliance-audit-services/compliance/research-compliance/foreign-influence.html
Foreign Influence Infographics
ECAS will continue to design and distribute a suite of infographics on the topics of Foreign Component, Other Support, Affiliations, Conflict of Interest, Conflict of Commitment and Export Control.

Ethics and Compliance Briefing for Researchers

- A mandatory online training module for all UC researchers receiving research funding
- Extensive focus on foreign influences on research integrity
- Content will cover disclosure requirements for federally funded research, export control, and UC policies on conflict of commitment and conflict of interest
Export Control Compliance Program

Partnership with IT Security and Risk Services to create international travel program:

- Physical Safety and Health
- Research Protection through Device Security (e.g., clean laptops and phones)
- Export Control Briefings

Leveraging automated travel insurance system

Systemwide Foreign Influence Audits

Grant Sample Testing

Audit sample of grants in emerging technologies as identified in the list of “Representative Technology Categories” in the Bureau of Industry and Security 11.19.2018 Proposed Rule and compare information in grant documents with publications to evaluate the accuracy of other support and affiliation reporting.
UC COMPLIANCE PLAN

Cyber Audits

- Cybersecurity Audit Team - Addressing foreign influence through internal audit
  - Threat Detection and Information (TDI) – Audit to ensure the TDI implementation is covering high risk research areas, and identify opportunities for improving the system to detect and respond to nation state attacks.
  - Penetration Testing – Audits focused on identifying weaknesses in high risk research systems using similar techniques as attackers to fix issues proactively.

ALLEGATIONS

The Need to Properly Investigate

“For immediate release
Thursday, December 19, 2019

Department of Justice Reaches $5.5 Million Settlement With Van Andel Research Institute To Resolve Allegations Of Undisclosed Chinese Grants To Two Researchers

WASHINGTON — The Department of Justice announced today that Van Andel Research Institute (VARI) has agreed to pay $5,500,000.00 to resolve allegations that it violated the False Claims Act by submitting false grant applications and progress reports to the National Institute of Health (NIH) in which VARI failed to disclose Chinese government grants that funded two VARI researchers. The settlement further resolves allegations that in a Dec. 21, 2018 letter, VARI made certain material representations to NIH with deliberate ignorance or reckless disregard for the truth regarding the Chinese grants.

“The government alleged that while VARI had institutional policies and procedures in place to address conflicts of interest, VARI did not take adequate additional steps to investigate the researchers’ foreign funding sources despite receiving specific information about their Chinese affiliations.”
Investigate Allegations Thoroughly

- Review with multi-disciplinary team and involve leadership
- Prepare investigation plan
- Seek relevant records
- Interview relevant witnesses
- Document process
- Determine whether disclosure is required

UC Standardized FI Investigations

Escalation Protocol
Office of General Counsel and ECAS involved early
Document Collection Procedures
Standardized Questions for Interviews
Quality Control of Reports and Disclosures
Document Review

We review **internal documents** related to the grants in question:

- Internal Disclosure Forms
- Form 700-U's
- Public Health Science COI disclosures (associated with grants and the outside interests noted in the NIH letter)
- Foreign component disclosures
- Personnel record of Principal Investigator
- Grant applications (associated with grants noted in the NIH letter)
- Research Performance Progress Reports (RPPRs)
- Other Support forms
- Travel documentation (for trips outside of the US by the investigators)
- Distribution of Payroll Expense Reports
- Lab staff, especially unpaid “volunteers”

We also review **external documents** related to the grants in question.

Conduct targeted, multi-lingual media searches for publicly available information:

- Affiliation with foreign and other non U.S.-based university and medical institutions (including consulting)
- Participation in foreign government Talent programs
- Affiliation with commercial entities
- Non-U.S. patents filed based on results of U.S.-funded research
- Foreign grants
- Foreign components in active research and awards
- Publications
Continued Focus on Foreign Influence

§117 Enforcement and Scrutiny is Increasing.

Nine investigations and records requests:
- Georgetown University (June 13, 2019)
- Texas A&M University (June 13, 2019)
- Cornell University (July 3, 2019)
- The State University of New Jersey ("Rutgers University") (July 3, 2019)
- Massachusetts Institute of Technology (September 26, 2019)
- University of Maryland (September 26, 2019)
- Harvard University (February 11, 2020)
- Yale University (February 11, 2020)
- University of Texas (April 24, 2020)
Global Focus

Focus is not only China - recent investigations include requests for information on Singapore, Qatar, Saudi Arabia, and Russia.

COVID-19 Research

Increased cyberattacks by nation-states seeking COVID-19 research and data-sets.
Emergent Technology

- Biotechnology
- Artificial Intelligence and Machine Learning
- Position, Navigation & Timing
- Microprocessor
- Advanced computing
- Data analytics
- Quantum information & sensing
- Logistics
- Additive manufacturing (e.g., 3D printing)
- Robotics
- Brain-computer interfaces
- Hypersonics
- Advanced Materials
- Advanced surveillance
CONTINUED FOCUS ON FOREIGN INFLUENCE

Confucius Institutes

SENATOR CHUCK GRASSLEY ISSUES STERN WARNING ABOUT CONFUCIUS INSTITUTES

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Closing Questions
Appendix

NIH DISCLOSURE Requirements Grants Policy Statement, Section 2.5.1; NOT-OD-19-114 (July 10, 2019)

OTHER SUPPORT

Applicants must report ALL resources (regardless of whether they have monetary value), whether Federal, non-Federal, commercial, or institutional, available in support of ALL of an individual’s research endeavors (regardless of where that research is conducted), including but not limited to research grants, cooperative agreements, contracts, institutional awards, support for lab personnel, provision of high-value materials not freely available (e.g., biologics, chemicals, model systems, technology).

• Applicants must list ALL positions and scientific appointments (domestic and foreign) held by Senior/Key Personnel that are relevant to an application. Includes affiliations with foreign entities or governments; titled academic, professional or institutional appointments, whether paid or unpaid, full- or part-time, or voluntary (including adjunct, visiting and honorary).

• Report ALL resources and other support (domestic and foreign) for all individuals designated in an application as Sr./Key Personnel and for others who contribute to the scientific development or execution of a project in a substantive measurable way (regardless of whether they request salary support/compensation). Info must be provided re ALL current support for ongoing projects, regardless of whether such support is provided thru the applicant organization, thru another organization, or directly to an individual that support’s the Sr/Key personnel’s research efforts.

• Report ALL current projects/activities involving Sr/Key Personnel, even if support is received only in-kind (e.g., office/lab space; equipment, supplies, employees). All research resources must be reported – includes financial support, research/lab personnel, lab space, scientific materials, includes selection to a foreign “talent” program.

• Provide total award amount for the entire award period covered (including F&A costs), as well as person-months (full or partial) per year to be devoted to the project by the Sr/Key personnel involved.
NIH DISCLOSURE Requirements Grants Policy Statement, Section 2.5.1: NOT-OD-19-114 (July 10, 2019)

FOREIGN COMPONENT

NIH defines a foreign component as the existence of any “significant scientific element or segment of a project” outside of the United States, in other words:

• Performance of work by a researcher or recipient in a foreign location, whether or not NIH grant funds are expended and/or
• Performance of work by a researcher in a foreign location employed or paid for by a foreign organization, whether or not NIH grant funds are expended.

Some examples of a significant scientific element or segment of a project are:

• Collaborations with investigators at a foreign site
• Anticipated to result in co-authorship
• Use of facilities or instrumentation at a foreign site
• Receipt of financial support or resources from a foreign entity
• Extensive foreign travel
• Activities with an impact on U.S. foreign policy

Prior approval is required!

• Initial Disclosure: You must disclose in your grant proposal all foreign components.
• Ongoing Grants: If you want to add a foreign component to an ongoing NIH grant, you must seek prior approval from NIH.
• Do not allow the performance of work by a researcher or recipient at a foreign institution BEFORE you seek and receive prior approval from NIH.

Note: Foreign university appointment and lab on research with no overlap with NIH research would be “other support” but not a “foreign component.”

NIH: https://grants.nih.gov/grants/faq-other-support-foreign-components.htm#B

NSF DISCLOSURE Requirements, Proposal and Award Policies and Procedures Guide (PAPPG) (NSF 20-1) Effective Date June 1, 2020

CURRENT AND PENDING SUPPORT

Current and pending support information must be separately provided through use of an NSF-approved format, for each individual designated as senior personnel on the proposal.

Current and pending support includes ALL resources made available to an individual in support of and/or related to ALL of his/her research efforts, regardless of whether or not they have monetary value.

Current and pending support also includes in-kind contributions (such as office/laboratory space, equipment, supplies, employees, students). In-kind contributions not intended for use on the project/proposal being proposed also must be reported.

Current and pending support information must be provided for this project, for ongoing projects, and for any proposals currently under consideration from whatever source, irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.

The total award amount for the entire award period covered (including indirect costs) must be provided, as well as the number of person-months (or partial person-months) per year to be devoted to the project by the individual.

Concurrent submission of a proposal to other organizations will not prejudice its review by NSF, if disclosed. If the project (or any part of the project) now being submitted has been funded previously by a source other than NSF, information must be provided regarding the last period of funding.

See NSF FAQs on Current and Pending Support
APPENDIX

PHS Financial Conflict of Interest Policy, 42 CFR 50, Subpart F (FCOI) Disclosure Requirements

A financial conflict of interest exists when the institution’s designated official(s) reasonably determines that an investigator’s significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS funded research.

**WHO MUST DISCLOSE?**
Investigators (anyone, regardless of title or position, responsible for design, conduct or reporting of research funded by PHS)

**WHAT TRIGGERS DISCLOSURE?**
Proposing or receiving grant, cooperative agreement, or contract funding from a PHS agency (e.g., CDC, FDA, HRSA, NIH)

**WHAT MUST BE DISCLOSED?**
Significant Financial Interests (SFI) of the Investigator (including spouse and dependent children) related to Investigator’s institutional responsibilities (professional responsibilities on behalf of the institution, including teaching, research, outreach, clinical service, and other activities in course and scope of institution appointment/employment).

**WHEN IS DISCLOSURE REQUIRED?**
- Before a proposal is submitted
- When a new investigator joins the project
- Within 30-days of acquiring a new SFI
- Before submission of progress reports
- Minimally, annually during life of the grant

UNIVERSITY OF CALIFORNIA

NSF Financial Conflict of Interest Policy Disclosure Requirements

**WHO MUST DISCLOSE?**
Investigators (anyone, regardless of title or position, responsible for design, conduct or reporting of research funded by NSF)

**WHAT TRIGGERS DISCLOSURE?**
Proposing or receiving grant, cooperative agreement, or contract funding from NSF

**WHAT MUST BE DISCLOSED?**
Significant Financial Interests of Investigator (including spouse, registered domestic partner, and dependent children) that would reasonably appear to be affected by the research or that are in entities whose financial interests would reasonably appear to be affected by the research

**WHEN IS DISCLOSURE REQUIRED?**
- Before a proposal is submitted
- When a new investigator joins the project
- When new reportable SFI is acquired

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