

# Considerations in Building a Foreign Influence Compliance Program

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# Overview

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This presentation focuses on three main topics:

1. Understanding the Government's (e.g., NIH, NSF, DoD) recent focus on increased transparency concerning foreign elements and connections in applications for research grants.
2. Identifying and overcoming operational challenges to maintaining foreign influence compliance.
3. Mitigating legal exposure for investigators/institutions by implementing an effective foreign influence compliance program.

# Presentation Contents

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Government Focus on Transparency

Requirements for Disclosure

Examples of Requires Disclosures

Applicant and Institution Responsibilities

Prevention and Action

Investigating Grant Fraud

Typical OIG Investigation

Foreign Influence Compliance Program



# Government Focus on Transparency

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“It is critical for NIH-supported institutions and their researchers to be wholly transparent about financial support from and affiliations with international institutions.”

- Protecting U.S. Biomedical Intellectual Innovation



# Government Focus on Transparency

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In August 2018, NIH Director Francis Collins authored a letter addressing “threats to the integrity of U.S. biomedical research.” In doing so, he identified three primary areas of concern for NIH:

1. Diversion of intellectual property;
2. Sharing of confidential information; and,
3. Failure by some researchers to disclose substantial resources from other organizations, in particular foreign governments.

In the year following this letter, NIH investigated nearly 200 scientists from more than 65 institutions for failing to report foreign connections. NIH has continued these reviews and investigations and in April 2021 said that they had identified over 500 scientists of concern.

# Requirements for Disclosure

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The NIH disclosure requirements focus on three main categories:

1. Financial and Resources Support;
2. Foreign Relationships/Activities; and
3. Conflicts of Interest and Conflict of Commitment

NIH requires “full transparency” in each of these categories throughout the life of an NIH grant.



# Examples of Required Disclosures

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By way of illustration, NIH's Financial Conflict of Interest Policy (FCOI) includes the following disclosure requirements:

All positions and affiliations held by a researcher (including volunteer or unpaid positions) that are relevant to the grant application;

1. All relevant appointments at foreign institutions (including guest, adjunct, and honorary appointments, i.e. those without pay);
2. All income, salary, consulting fees, and other honoraria that support the research endeavors;

# Examples of Required Disclosures Cont'd

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4. Any participation in foreign talent or other similar programs;
5. All resources and other support—domestic and foreign—for ongoing research projects;
6. All contributions from domestic and foreign institutions or governments to support research activities;
7. Any travel paid by a foreign institution or government in excess of \$5,000/year; and,
8. Any financial interests received from a foreign institution of higher education or a foreign government.



# Applicant and Institutional Responsibilities

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NIH also requires individual applicants, and their institutions to do the following:

1. Ensure all applications, progress reports, and other submissions include accurate and complete accounts of all sources of research support and relevant affiliations for senior/key personnel;
2. Ensure that all researchers working on a grant disclose their significant financial interests in according with regulations and institutional policies;
3. Ensure that all reports and communications to NIH are complete and accurate;



# Applicant and Institutional Responsibilities Cont'd

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4. Protect proprietary information and sensitive and confidential data;
5. Take reasonable and appropriate steps to prevent the inadvertent disclosure, release, or loss of sensitive personal information;
6. Immediately notify NIH of any developments that significantly impact NIH-supported activities;
7. Disclose information throughout the grant process (e.g., updating PI's biosketch); and,
8. Obtain NIH approval for inclusion of any foreign components to an NIH award.

# Prevention and Action

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The OIG has adopted a two-pronged approach to grant fraud: prevention and action.

- Prevention: OIG works collaboratively to educate key stakeholders (e.g., HHS operating divisions, grant recipient organizations, etc.) on how to detect and prevent grant fraud.
- Action: OIG will take action against grant fraud by investigating allegations and making appropriate referrals for criminal, civil, and administrative action.

# Investigating Grant Fraud

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The primary agency responsible for investigating possible grant fraud—including that which involves foreign influence—is the HSS Office of Inspector General (OIG).

*How do OIG investigations start?*

- Many OIG investigations start with a referral from NIH. However, the OIG itself utilizes analytics and other tools to identify potential targets.

*What types of allegations do OIG investigations primarily involve?*

- OIG investigations primarily deal with the failure of the grantee PI to disclose foreign government affiliations.

# Typical OIG Investigation

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Following are some of the steps typically taken by the OIG in a grant fraud investigation:

1. OIG receives an allegation of fraud.
  - OIG hotline complaint;
  - Referral from NIH operating division or law enforcement partner;
  - Whistleblower; or,
  - Proactive data analysis



# Typical OIG Investigation Cont'd

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2. OIG evaluates the allegation to decide next step.
  - Open an investigation;
  - Refer the matter to another agency;
  - Refer the matter back to the HHS operating division for administrative review
3. If there is sufficient factual information to support an investigation, the OIG will proceed.
  - OIG works collaboratively with the FBI, Department of Homeland Security, the Office of National Security, and NIH.
4. At the conclusion of the investigation, OIG will present the facts to the Department of Justice for criminal or civil prosecution.

# Foreign Influence Compliance Program

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1. Prevention Through Training and Education. Any institutional compliance program should consider how to prevent grant fraud by educating key stakeholders.
  - Enhanced training on key issues like unauthorized use/transfer of IP and scope of disclosure requirements.
  - Utilization of different training media, e.g. online modules, webinars, and in person training sessions.



# Foreign Influence Compliance Program Cont'd

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## 2. Identify System Vulnerabilities Through Self Assessments.

Effective compliance programs recognize that vulnerabilities will exist, and take steps to identify and mitigate them.

- Conduct root cause analyses any time a violation occurs to identify the person or department that caused the failure.
- When problematic activities occur, identify processes that can prevent recurrence in the future (e.g., IT subgroup that provides support to researchers traveling abroad with institutional laptops)



# Foreign Influence Compliance Program Cont'd

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3. Conduct Audits. An effective compliance program should outline the scope of frequency of periodic audits all processes and procedures. For example:
  - Conduct risk-based review of grants to ensure all required disclosures have been made.
  - Conduct penetration testing on key network systems and infrastructure.
4. Consistent Enhancements. A compliance program should not be stagnant; when vulnerabilities or gaps are identified, the program should be altered to account for it.
  - Update policies and procedures to require additional information if incomplete disclosures are identified.
  - Make personnel changes (or change the responsibilities of existing personnel) when violations occur.

# Foreign Influence Compliance Program Cont'd

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5. Investigate Complaints and Potential Violations. A compliance program is only as good as an institution's commitment to compliance. This requires institutions to investigate potential violations.
- Offer multiple reporting methods, including anonymous reporting (e.g., hotline), so that individuals can raise concerns internally before becoming a whistleblower.
  - Dedicate sufficient personnel to reviewing reports and investigating those that warrant follow up.
  - Ensure investigation personnel have a direct line to report findings to institutional decision makers.

# QUESTIONS?

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