



K&L GATES

Compliance Approaches to Foreign Influence Risk 2021

A Survey of U.S. Research Institutions

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I. EXECUTIVE SUMMARY

Within the past five years, the U.S. government has adopted several policy measures that increase the burdens and risks to universities, academic medical centers, and other entities engaged in federally funded research in the United States (referred to herein as research institutions) where the research involves foreign collaborations, foreign components, or investigators with foreign affiliations. Recognizing that institutional compliance programs are in a corresponding process of evolving to meet these emerging policy and regulatory expectations, K&L Gates LLP (K&L Gates) conducted an anonymous benchmarking survey to support peer institution learning. Specifically, K&L Gates collected and analyzed data derived from an anonymous survey of leading research institutions in order to better understand how these entities are currently confronting the issue of foreign influence risk in federally funded research programs. This report reflects the observations of K&L Gates in connection with this effort.

Section II of this report begins by outlining the need for this effort in the broader research compliance community during a formative time in the intersection of research collaboration and foreign policy considerations. Section III outlines the methodology used in conducting this initiative. Sections IV through IX detail the principal observations gleaned from participating institutions' responses. Section X concludes by offering perspective on how compliance programs might pragmatically enhance current efforts, as well as continue to evolve their approaches in light of the trajectory of government enforcement actions, anticipated regulatory changes, and the current state of institutional compliance.

Survey responses reflect compliance departments in transition that rely on traditional communication efforts to address a changing regulatory landscape.

Survey responses reflect compliance departments in transition that rely on traditional communication efforts to address a changing regulatory landscape. Institutions predominantly report that they do not use proactive monitoring efforts to identify potential gaps in required researcher disclosures, such as through a regularly scheduled internal audit, an assessment of foreign support during the onboarding process, or other pressure-testing of annual researcher disclosures. Instead, survey results indicate that institutions most commonly assess the sufficiency of disclosures only when raised by the researchers themselves—in the context of a researcher's self-initiated amendment to prior disclosures—or by the government in connection with a research integrity inquiry.

Institutions point to communication tools like researcher training and written procedures as key components in their efforts to address foreign influence risk. However, they also broadly acknowledge deficiencies in these tools, such as a lack of procedures to address less frequent but potentially higher-risk scenarios, such as vetting short-term visiting faculty, post-doctoral scholars, and other researchers. In addition, respondents

commonly raised the concern that, despite a compliance department's best efforts to streamline concepts and policies, researchers do not fully understand their disclosure obligations. In part, this may be attributable to a need for additional clarity from government authorities regarding the scope of disclosure requirements.

Institutions also uniformly agreed that they do not have enough resources to sufficiently monitor risks associated with potential foreign influence. While certain respondents reported creative uses of their limited resources, structural challenges, such as cross-department communication in a siloed environment, present barriers to efficient risk mitigation. For example, an institution may face difficulty fully integrating information from the unit receiving investigator disclosures with the unit administering grant submissions. The reality of many institutions is that a variety of stakeholders necessarily have a role in addressing potential issues associated with foreign influence disclosure.

In addition to the compliance officer and senior research administration, and representatives of an academic department, potential stakeholders might include the conflict of interest office (CIO), research compliance office (RCO), sponsored programs and grants contracting office (GCO), and office of general counsel (OGC).

Research institutions confront the issue of potential foreign influence while experiencing the resource realities of a pandemic-impacted world and juggling a myriad of other compliance issues that compete for their in-house professionals' time. Regardless of where a compliance program falls in the spectrum of historical responses to potential issues associated with foreign influence, research institutions should consider undertaking oversight efforts tailored to their unique research risk profile. In addition, research institutions should consider recalibrating existing educational efforts to maximize available resources.

Compliance Approaches to Foreign Influence Risk 2021: A Survey of U.S. Research Institutions was developed by the K&L Gates Academic Medical Centers and Higher Education Collaborative, with assistance from the firm's Health Care, Life Sciences, and Investigations, Enforcement, and White Collar practice groups.

II. CONTEXT

Beginning in March 2018, grant-making agencies like the National Institutes of Health began issuing guidance documents clarifying the need for U.S. research institutions to disclose financial and nonfinancial support from foreign entities.¹ Agencies have also made direct appeals to institutions in order to call for enhanced partnership in transparently assisting government stakeholders in identifying potential threats to national security and potential theft of valuable intellectual property of innovations designed with the support of federal funds.² Since November 2018, the Department of Justice (DOJ) has consolidated and coordinated resources across a variety of divisions, including the National Security, Criminal, Tax, and Civil divisions, in order to identify potential threats to research security and prosecute any attempts to engage in trade secret theft.³ The DOJ's efforts, commonly known as the "China Initiative" due to its focus on threats reportedly tied to the conduct of the Chinese government,⁴ has resulted in the criminal prosecution of academic researchers from a variety of disciplines and institutions for conduct relating to their affiliations with, or support received from, foreign institutions.

The most common fact pattern to appear in these cases involves a researcher's—and, by extension, an institution's—failure to disclose foreign support or affiliations to a federal grant-making agency. As the research community is aware, grantees are required by federal regulation to coordinate with principal investigators and other associated researchers and to disclose various types of foreign touchpoints to the federal government. These touchpoints can be relevant either to a specific grant project, such as whether a component of grant research will occur abroad, or to a specific researcher, such as whether that individual receives financial or nonfinancial support from an institution, company, or government agency abroad.⁵ Grant-making agencies acknowledge that such touchpoints are not per se illegal, but failures to disclose these affiliations or support, either prior to receipt of a grant or during interim updates following the award of the grant, have formed the basis for criminal charges based on theories of (1) a researcher making false statements during the course of a government investigation,⁶ (2) a researcher committing fraud in connection with the receipt of support from the federal government,⁷ or (3) a researcher committing tax violations for failing to disclose income derived from foreign affiliations.⁸ Only rarely has an institution itself been held liable for the failures of researchers to disclose foreign affiliations.⁹

By virtue of being ultimately responsible for the disclosures of their researchers and for conducting initial investigations

in response to allegations of inadequate disclosure, institutions shoulder a heavy burden in ensuring that their research community's ties with foreign sources of financial and nonfinancial support comply with applicable federal regulations. As regulators continue to remain focused on

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disclosures from nontraditional collectors, it behooves research institutions to ensure that their internal compliance program efficiently gathers information and, using a risk-based approach, undertakes testing to ensure that its program is working. This survey serves as a collection point for institutions to benchmark the triumphs and opportunities for improvement in their programs as currently constituted.

III. METHODOLOGY

The survey was individually distributed to in-house lawyers and compliance officers at 40 U.S.-based research institutions. Prospective respondents were selected based on their roles in directly or indirectly influencing decisions relating to institutional policies, procedures, and internal controls regarding research integrity issues. K&L Gates endeavored to curate an overall potential respondent pool of leading research institutions to assure the process would result in meaningful benchmarking data. Within this parameter, K&L Gates also sought to include an array of diverse institutions based on the following additional factors: size of potential respondent institutions (by number of full-time equivalent researchers employed by the institution), geographic location, and public or private affiliation.

Respondents were asked to complete an online survey containing 28 questions divided into the following categories:

- 1. Areas of Risk**
- 2. Institutional Policies**
- 3. Researcher Obligations and Conduct**
- 4. Foreign Components/Other Support and Institutional Compliance**
- 5. Contacts With Government Authorities**
- 6. Institutional Resources**

Responses were submitted anonymously and collected through a secure online platform. Based on self-reported survey responses, respondent institutions reflected a cross-section of the institutional research landscape in that they reported receiving anywhere from US\$100 million to in excess of US\$500 million in federal research grants within the past 12 years. In all cases, the individual responding to the survey on behalf of the institution was either a compliance officer, legal counsel, or designee of same.

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IV. RESPONDENT OVERVIEW

A majority of responding institutions classified the issue of undisclosed foreign support for research associated with federal grants as a “high priority” for institutional compliance departments. More specifically, responding institutions most commonly pointed to the following four research areas as highest-risk (listed in order of frequency):

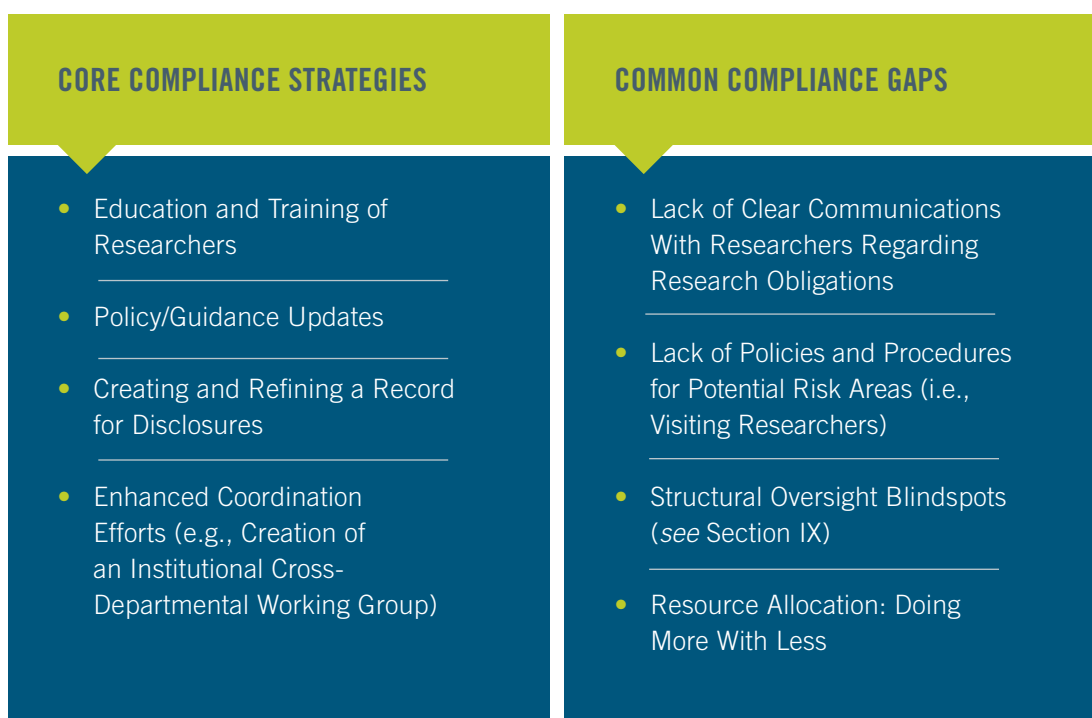
1. **Biological Sciences**
2. **Computer/Information Science and Mathematics**
3. **Physical Sciences**
4. **Engineering**

Responding institutions also provided examples of key compliance strategies and significant compliance risks that they perceive. As indicated in Figure 1, institutions most frequently cited researcher education efforts and timely policy updates as the principal “tools” of their compliance trade. Other institutions noted the importance of creating a disclosure record through the use of questionnaires, enhanced disclosure forms, affiliation diligence, and other

internal processing forms. One institution described a proposal for creating a cross-departmental working group to address foreign influence risk.

The list of common risks mirrored the key “tools” of compliance, in that respondents cited fears of inadequate training and unclear, or nonexistent, policies and procedures leading to a misinformed research community. Institutions also pointed to the structural challenges of coordinating compliance across various institutional stakeholders in a dynamic environment as a significant challenge. Finally, respondents pointed to two kinds of resource conundrums: (1) a lack of funds, and (2) a lack of understanding as to how best to use available funds.

Figure 1.



V. OBSERVATION #1

Most Institutions Do Not Employ Proactive Monitoring Efforts, and They Perceive This Failure as a Significant Risk

Survey responses reflect that institutions do not commonly assess foreign collaborations, affiliations, and contacts during the recruiting and onboarding processes for new researchers. Instead, institutions most commonly rely on annual disclosure forms to collect such information.

Respondents primarily learned of disclosure gaps through channels outside of an institutional monitoring system. Specifically, responding institutions stated that they learned of previously undisclosed affiliations either from researchers themselves or as a result of government inquiries. Only a small minority of respondents pointed to internal monitoring efforts as a means of proactively identifying disclosure issues.

More than half of respondent institutions confirmed that they do not perform disclosure audits. Those that did perform such audits reported assessing only a “few” such researchers. Even where institutions identified a formal audit process for researcher disclosures, none reported having identified failures to disclose through such reviews. This could mean the institution has achieved perfect compliance, or perhaps more likely that audit tools could be refined and strengthened to dig deeper.

Figure 2. How do you normally become aware of issues associated with nondisclosure of foreign components and other support? (Please mark all that apply.)



Figure 3. What factors contribute to your institution's decision to select a researcher for an audit?

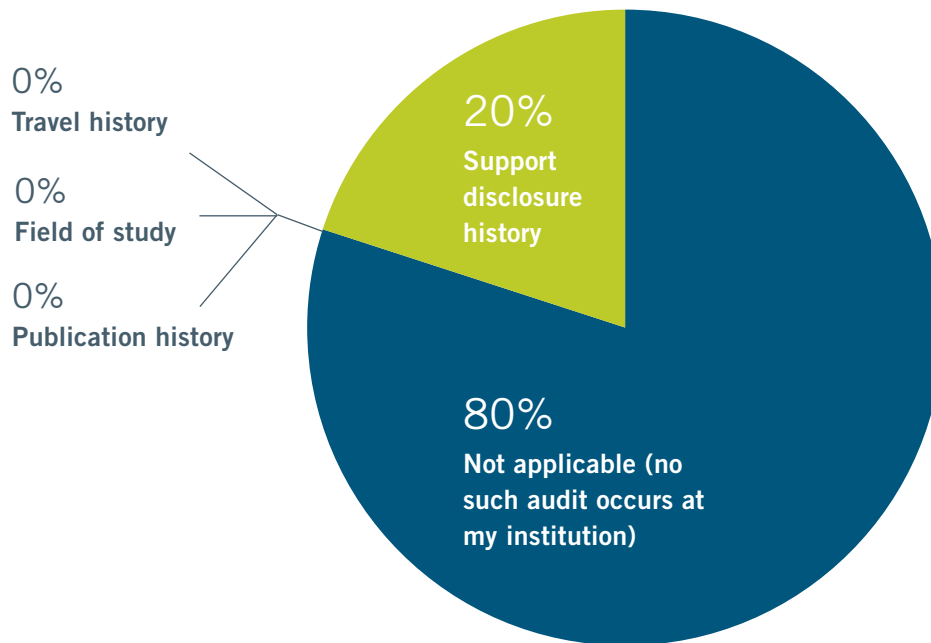
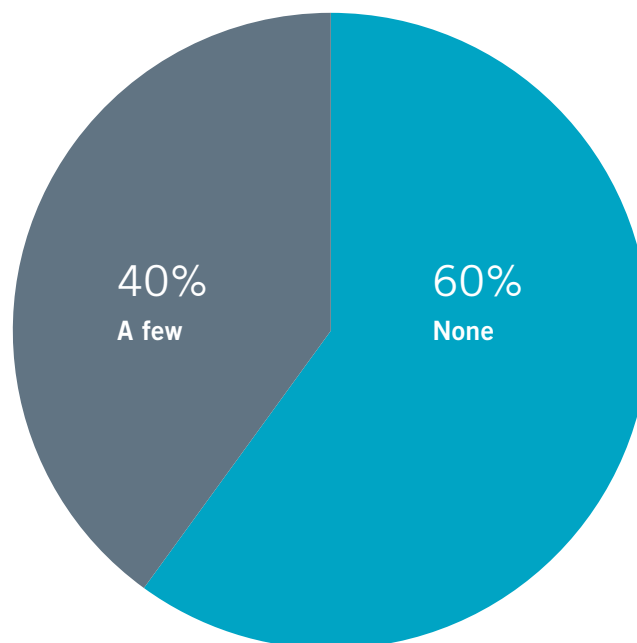


Figure 4. On an annual basis, approximately how many researchers are subjected to audits of their disclosures by their institution?



VI. OBSERVATION #2

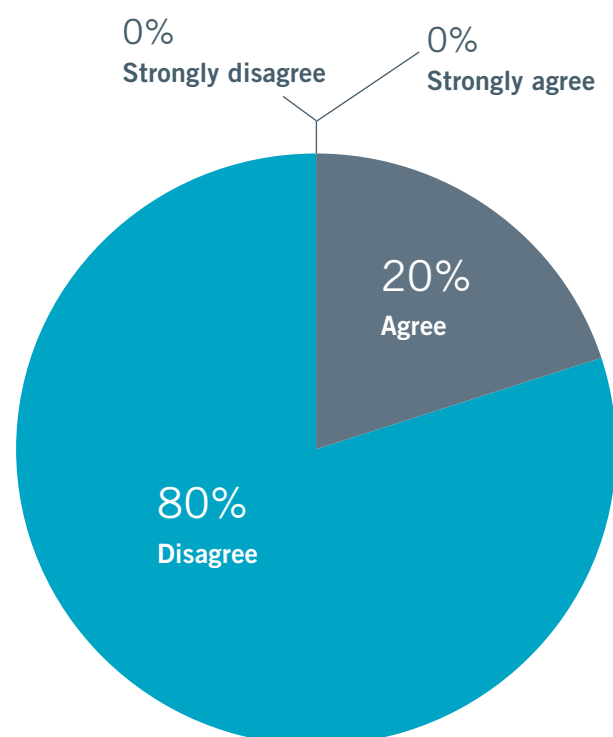
Policy Deficiencies Remain a Reality—and a Significant Perceived Risk—for Institutions

While responding institutions commonly pointed to research education programs and development of relevant internal policies and procedures as key compliance strategies in mitigating foreign influence risk, institutions nonetheless agree that there is more work to be done in this area. The overwhelming majority of respondents—80 percent—do not think that their institutions’ policies and procedures clearly describe the obligations for disclosure of foreign support and the consequences for nondisclosure. Indeed, 40 percent of all respondents cited inadequate policies and procedures as one of the principal identified gaps in their institutions’ compliance programs.

However, respondents did not appear to perceive weaknesses in describing the processes for proposing grants or submitting disclosures. With regard to each of these policies, a majority of respondents—80 percent for the grant proposal process and 60 percent for the disclosure process—believed their procedures to be sufficient. Put more simply, respondents appeared to view the most deficiencies in addressing what must be disclosed rather than how to disclose.

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Figure 5. My institution’s policies clearly describe researchers’ obligations regarding disclosure of foreign support and the consequences for nondisclosure.



VII. OBSERVATION #3

Institutions Differ in the Use of Their Resources, but They Agree that They Do Not Have Enough to Adequately Monitor

While institutions differed with respect to resource allocation in this domain, all respondents disagreed with the statement that institutions devote sufficient resources to monitoring and review of potential foreign influence. When prompted on how resource allocation had changed in the past 12 months, 40 percent of respondents noted an increase in resources, whereas 60 percent noted that it had either stayed the same or decreased. The impact of the COVID-19 pandemic on research institutions, of course, places additional strain on resources available.

Figure 6. Did your institution dedicate more or less resources to foreign influence compliance issues than in the previous 12 months?

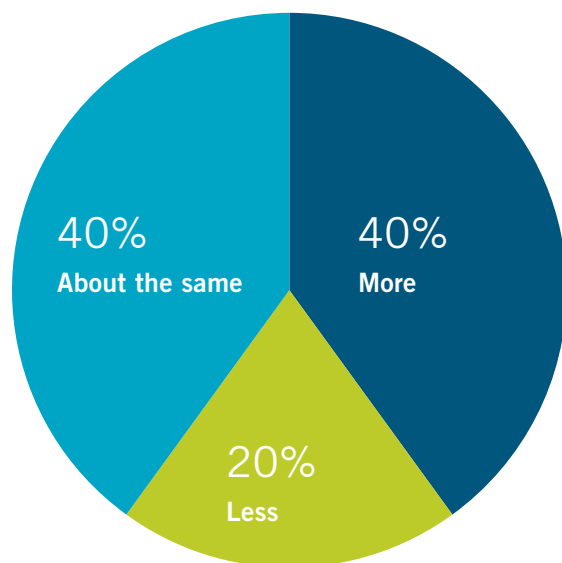
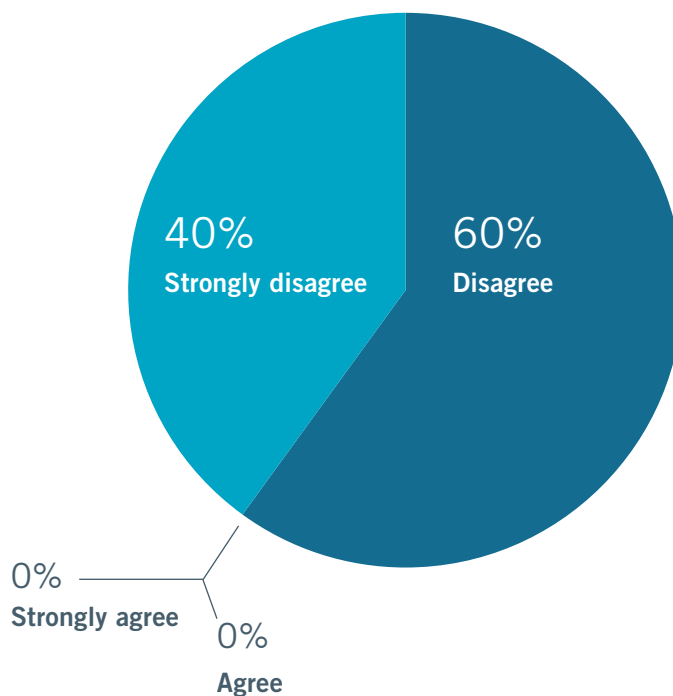


Figure 7. I believe my institution has enough resources to support monitoring and review efforts.



Respondents also indicated a wide range of responses regarding resource allocations for researcher education, audits, or internal reviews, with most institutions in the range of 10 - 20 percent of total legal and compliance spend.

Separately, institutions appear to more commonly allocate resources for researcher education initiatives rather than proactive monitoring efforts. Sixty percent of responding institutions reported conducting at least one training session for researchers regarding disclosure of foreign support

within the past 18 months. On the other hand, a minority of institutions—40 percent—reported relying on internal resources to conduct either native language review or translation of foreign language documentation in connection with foreign influence inquiries. However, survey results indicate that institutions have not adopted the strategy of employing dedicated full-time employees to work exclusively on foreign support compliance issues.

Figure 8. Does your institution utilize internal resources to translate or review relevant foreign language sources?

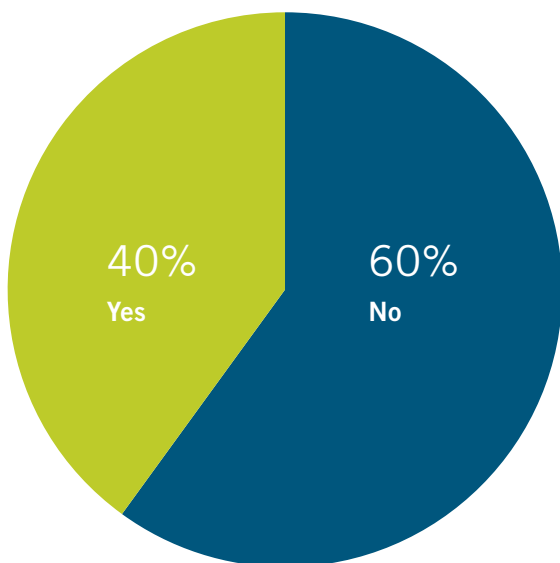
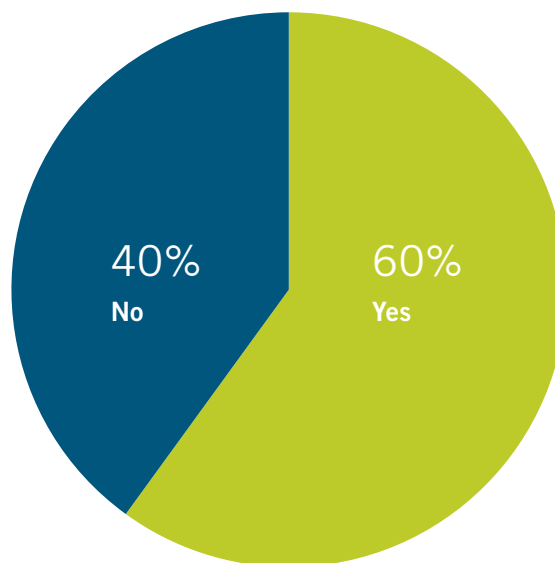


Figure 9. Has the legal/compliance department trained researchers regarding foreign component and other support disclosures within the past 6-18 months?

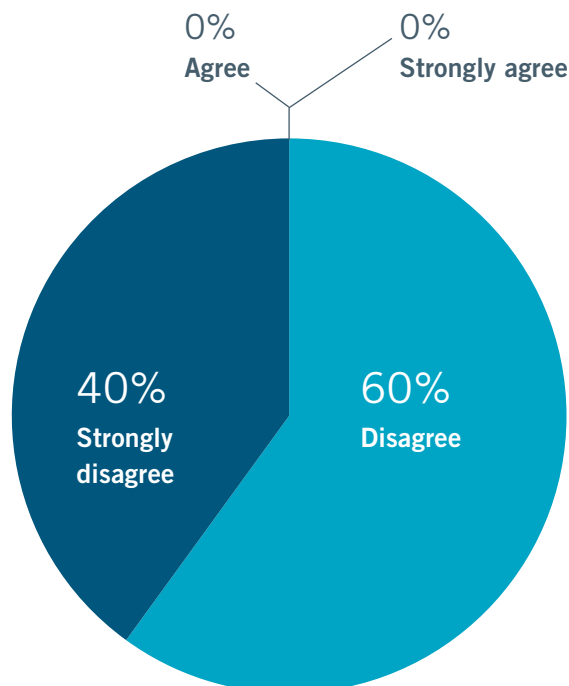


VIII.OBSERVATION #4

Lack of Clear Government Guidance

Despite evolving prior efforts on the part of U.S. government stakeholders to clarify the scope of foreign components, other support and conflicts of interest to be disclosed, and increased direct coordination between federal enforcement authorities and institutions in this arena, respondents reported continued ambiguity in government guidance. All respondents disagreed on the statement that government stakeholders have provided clear guidance regarding how to identify potential research integrity issues associated with foreign influence.

Figure 10. I believe that government regulators and enforcement authorities have provided clear guidance regarding how to identify potential issues.



IX. OBSERVATION #5

Structural Compliance Shortcomings as a Significant Challenge

Institutions reported challenges in making various compliance processes work in unison. Specifically, respondents noted the risk of decentralization in development and enforcement of relevant procedures—a dynamic not unique to, but certainly complicating, foreign influence compliance initiatives. A hegemony of stakeholders within an institution could result in either the development of conflicting policies or the failure to apply the same procedures equally. Either result yields inefficiencies for already resource-constrained compliance programs. Respondents also noted the challenges of decentralization in collection and review of disclosure and grant documentation. Absent centralized oversight from compliance stakeholders, different approaches among different research specialties could yield deficiencies in the adequacy of both initial disclosure information and supplementary post-award disclosures.

Survey responses indicated a crowded field of internal stakeholders involved in addressing foreign influence issues. While most institutions appeared to receive annual disclosures through their respective CIO and at least one other functional area (usually the GCO) or RCO, the unit responsible for investigating perceived disclosure deficiencies differed greatly. Sixty percent of respondents

utilized the RCO, 40 percent used the GCO, 80 percent used the CIO, 60 percent used the OGC, and 20 percent utilized the internal audit function. Only 20 percent of respondents relied on one institutional stakeholder to conduct these investigations, with the majority of institutions sharing said responsibility across two to four different stakeholders.

Figure 11. Which stakeholder(s) within your institution receive(s) initial disclosures? (Please mark all that apply.)

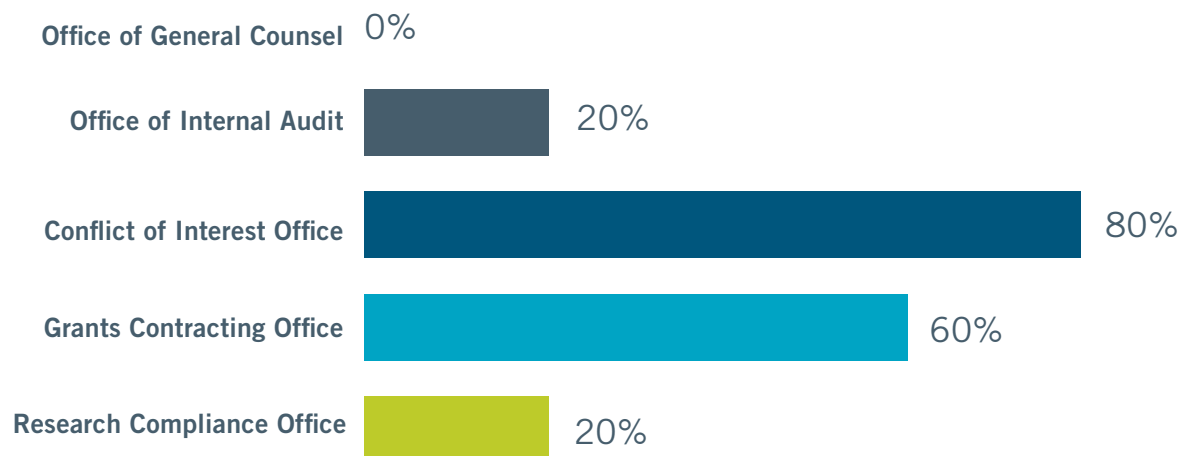


Figure 12. How many stakeholders receive initial disclosures?

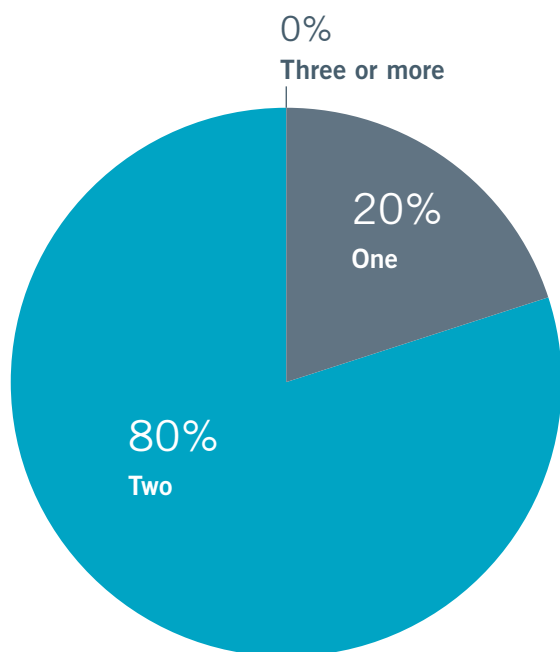


Figure 14. How many stakeholders review and investigate disclosure deficiencies?

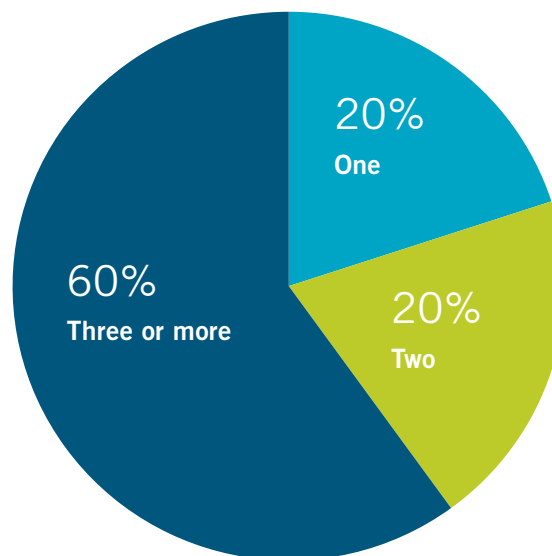
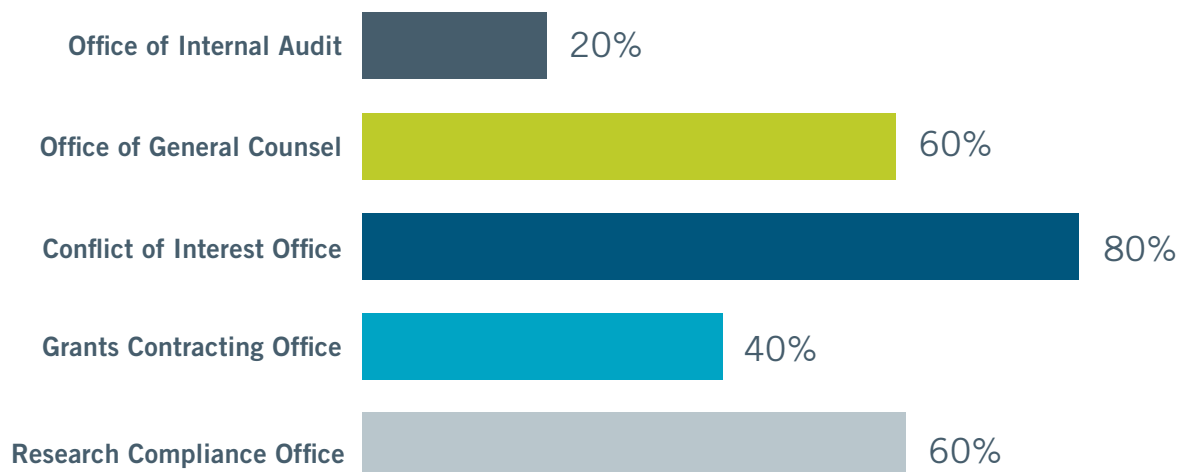


Figure 13. Which institutional stakeholder(s) review(s) and investigate(s) deficiencies associated with disclosure of foreign support? (Please mark all that apply.)



Beyond risks associated with inconsistent policies and practices, respondents also cited the risk of nonexistent policies from common touchpoints with foreign sources. For example, lack of procedures associated with visitors to research laboratories and the review and approval processes for researchers' engagements in external activities—such as speaker programs, nonprofit affiliations, and conference participation—were identified as key compliance risks. Absent clear guidance, researchers are less likely to understand their obligations regarding disclosure, and by extension, compliance personnel are more likely to be uninformed in advance of necessary disclosure deadlines.

X. THE FUTURE OF FOREIGN INFLUENCE COMPLIANCE

Institutions find themselves caught between competing perceptions of international collaboration in U.S. research initiatives. On one hand, collaboration fosters the free exchange of ideas and, ultimately, technological innovation. On the other hand, this exchange can just as effectively enable good ideas to flow out of the country as it does allow them to flow in. By extension, this could lead to the misappropriation of valuable and confidential information, as well as the abuse of federal funds. It is this criticism of foreign collaboration that motivates current government scrutiny and informs the government's expectations for institutional compliance programs.

The responses to this survey reflect institutional compliance programs that, at present, confront the issue of failures to disclose foreign influence in two situations (1) when training researchers on recently drafted or updated policies and procedures, or (2) when speaking with government investigators or researchers themselves to learn about an apparent gap in disclosure. Institutions do not commonly conduct proactive monitoring efforts. Rather, the predominant focus at present is on updating policies and procedures, educating researchers, and maintaining disclosure files.

As the tools of the compliance trade in this emerging area evolve alongside changing expectations of enforcement authorities, institutions continue honing the internal controls that enable them to better understand the nature of their risks associated with foreign touchpoints. Informed by this benchmarking survey in addition to their continuing efforts, institutions should consider evaluating their respective research footprints to understand whether they are currently receiving federal funds for projects with potential applications to critical technologies, as defined by the U.S. government. Institutions may then consider tailoring their monitoring and educational efforts to prioritize researchers associated with those projects. Among other potential measures, institutions might also consider seeking more frequent disclosures from certain researchers in order to remind them of their ongoing responsibilities to maintain accurate information.

Separately, institutions may consider enhancements to proactive monitoring of researcher disclosures. This could include:

- Reviewing all supporting documentation (provided by the researcher) relating to existing foreign support and comparing it against publicly available sources to confirm the sufficiency of the researcher's representations;
- Reviewing a sampling of recent publications from the researcher in question and comparing the list of supporting "sources" against those appearing on the researcher's disclosure form; and
- Utilizing native language resources to conduct supplementary public-record inquiries to the extent the initial review indicates that additional information might be visible only outside of the United States.

Controls like these will require institutions to look beyond the traditional components of a "paper program"—codes of conduct, policies, procedures, and training materials—and evaluate the extent to which education efforts have taken hold with the research community. Overall, establishing compliance programs that reliably accomplish required disclosures of foreign affiliations will further position research institutions for the next potential phase of regulatory requirements. In addition, program enhancements may better prepare institutions in the event government stakeholders shift their expectations of institutions from cooperating witnesses in enforcement actions to targets by virtue of the conduct of their researchers.

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ENDNOTES

¹ See Notice No. NOT-OD-18-180, Nat'l Insts. of Health, *Financial Conflicts of Interest: Investigator Disclosures of Foreign Financial Interests* (Mar. 30, 2018) (reminding U.S. institutions that researchers' financial interests in foreign institutions and government agencies are not excluded from disclosure requirements); see also Notice No. NOT-OD-19-114, Nat'l Insts. of Health, *Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest* (July 10, 2019) (clarifying that institutions must disclose a researcher's selection in a foreign talents program as "other support" as part of grant proposals or updates to previously awarded grants).

² See Letter from Dr. Francis Collins, Director, Nat'l Insts. of Health, to Nat'l Insts. of Health Grantee Insts. (Aug. 20, 2018).

³ See Press Release, Dep't of Just., *The China Initiative: Year-in-Review (2019-20)* (Nov. 16, 2020).

⁴ See *id.*

⁵ See, e.g., Nat'l Insts. of Health Grants Pol'y Statement § 1.2 (2019) (defining "foreign components" and "other support"); 42 C.F.R. pt. 50.603 (defining financial conflicts of interest).

⁶ See, e.g., Press Release, Dep't of Just., *Harvard University Professor and Two Chinese Nationals Charged in Three Separate China Related Cases* (Jan. 28, 2020).

⁷ See, e.g., Press Release, Dep't of Just., *Former West Virginia University Professor Pleads Guilty to Fraud That Enabled Him to Participate in the People's Republic of China's 'Thousand Talents Plan'* (Mar. 10, 2020).

⁸ See, e.g., Press Release, Dep't of Just., *Former Emory University Professor and Chinese 'Thousand Talents' Participant Convicted and Sentenced for Filing a False Tax Return* (May 11, 2020).

⁹ See Press Release, Dep't of Just., *Department Of Justice Reaches \$5.5 Million Settlement With Van Andel Research Institute To Resolve Allegations Of Undisclosed Chinese Grants To Two Researchers* (Dec. 19, 2019).

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