



Foreign Influence in Federally Funded Research: A Compliance Update

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ROPES & GRAY

October 29, 2019

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Agenda

- **Overview and Administrative Agency Update**
- Litigation Update and Industry Implications
- Due Diligence and Internal Investigations

Rising Tensions

Amid tensions with China, US emphasizes rules around research security

Scientists worry security concerns will taint valuable research collaborations

by *Andrea Widener*

SEPTEMBER 25, 2019 | APPEARED IN VOLUME 97, ISSUE 38

FBI Seeks Universities' Help Against Chinese Research Theft

ASSOCIATED PRESS October 2, 2019



Universities Face Federal Crackdown Over Foreign Financial Influence

By *Erica L. Green*

Aug. 30, 2019

EDITORIAL

Chinese scientists and security

NEWS | 17 SEPTEMBER 2019

CORRECTION 17 SEPTEMBER 2019

Trump's top scientist outlines plan to reduce foreign influence on US research

Kelvin Droegemeier is arranging a listening tour of US universities in the coming months.

Bloomberg Law News Oct 10, 2019

Holes Found in NIH Oversight of Conflicts, Foreign Influence (2)

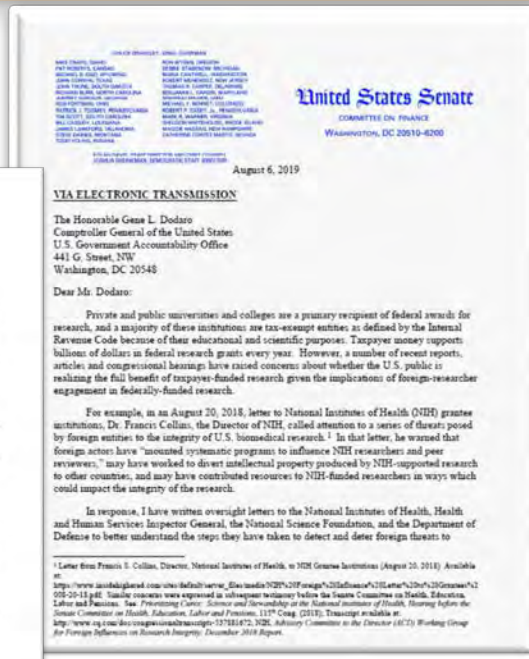
By *Jeannie Baumann* Sep 27, 2019

- OIG reports cover foreign influence, peer review, conflicts of interest
- Recommendations offered to improve policies, procedures

Increased Attention From Multiple Directions

Government focus on federal awardees is expanding from multiple directions:

- Funders:
 - National Institutes of Health
 - Department of Energy
 - National Science Foundation
 - Department of Defense
- Department of State
- Department of Commerce
- Department of Education
- Department of Justice
- U.S. Congress and the White House



Changing Landscape & Government Priorities

■ National Institutes of Health (“NIH”)

- NIH is among 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 is facing significant pressure from Hill and internal criticism from DHHS OIG.



<https://www.finance.senate.gov/chairmans-news/grassley-calls-for-immediate-action-on-three-hhs-oig-reports-that-raise-concerns-about-nih-research-oversight>

<https://www.nytimes.com/2019/03/25/science/duke-settlement-research.html>

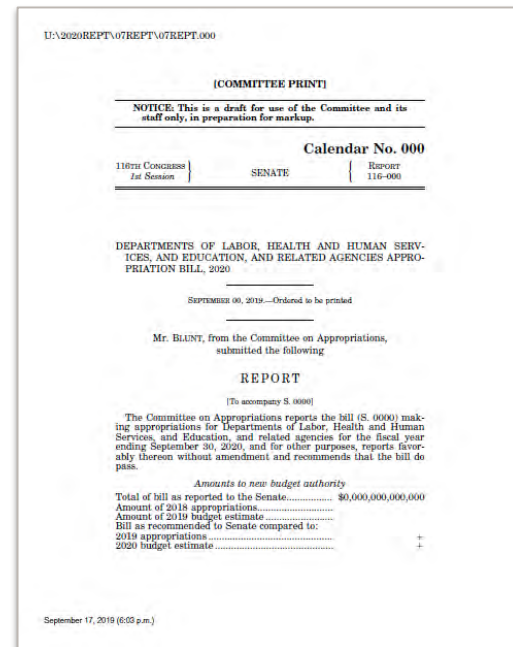
NIH Activities

- NIH Foreign Influence actions have included:
 - New advisory committee, policies and clarifications
 - *Concern about “non-traditional collectors” of “intellectual property” (including pre-publication data and sensitive information)*
 - Inquiries and investigations
 - *Est. 70+ institutions have received inquiry letters from NIH asking them to conduct internal investigations and report on one or more investigators*
 - Referrals to OIG and DOJ
 - Termination of funding, and
 - Investigator removal

NIH Activities— FY 2020 Draft Senate Directions

Quarterly reporting on investigations, including institutions, scientists, and research affected:

Foreign Threats to Research.—The Committee remains deeply concerned about foreign threats to the research infrastructure in the United States. In particular, the Chinese government has started a program to recruit NIH-funded researchers to steal intellectual property, cheat the peer-review system, establish shadow laboratories in China, and help the Chinese government obtain confidential information about NIH research grants. ***As the Federal Bureau of Investigation, HHS, and NIH continue to investigate the impact the Thousand Talents and other foreign government programs have had on the NIH research community, the Committee expects to be notified quarterly on the progress of the investigation, as well as institutions, scientists, and research affected. Further, the Committee directs NIH to carefully consider the NIH Advisory Committee’s recommendations, including to implement a broad education campaign about the requirement to disclose foreign sources of funding and develop enhanced cybersecurity protocols.***



Source: Senate Draft Report released, 9/18/19, <https://www.appropriations.senate.gov/news/fy2020-labor-hhs-and-education-appropriations-bill-released>

NIH Activities– FY 2020 Senate Directions (cont'd)

Enhanced education and security protocols, and funds diversion:

As recommended, NIH should use this campaign to help institutions develop best practices for how to handle these challenges, including training, communications materials, and how to improve vetting, education, and security. Further, NIH shall evaluate the peer-review system and their internal controls through a lens that takes into account national security threats. This includes holding those accountable who inappropriately share information from the peer-review process or illegally share intellectual property. The Committee appreciates the partnership between NIH and HHS' Office of National Security [ONS] on this issue and ONS's implementation of a formal NIH CI/Insider Threat program on NIH's behalf. *The Committee believes this work should be expanded in fiscal year 2020 and directs NIH to allocate no less than \$5,000,000 for this work that ONS does on behalf of NIH.*

Source: Senate Draft Report released, 9/18/19, <https://www.appropriations.senate.gov/news/fy2020-labor-hhs-and-education-appropriations-bill-released>

NIH Issue Spotting

- In addition to FCOI reporting, NIH is concerned about awardees' and investigators' **failures to disclose Other Support and Foreign Components** resulting in:
 - “Shadow laboratories”
 - Time commitment – sometimes full-time
 - Substantial funding for research (including start-up funds)
 - Laboratory, equipment, personnel
 - Signing bonus, salary, housing, other benefits
 - Deliverables: training personnel, papers, patents/IP
 - Creates conflicts of commitment (>100% effort), interest
- NIH believes that failures to disclose leads NIH to make **inappropriate and distorted funding decisions.**

NIH Applicant Reporting Duties: Summary

- **Financial Conflict of Interest (FCOI):** Investigators engaged in PHS-supported research must disclose to their institutions *all significant financial interests as well as reimbursed and sponsored travel*.
- **Other Support:** “*all financial resources*, whether Federal, non-Federal, commercial or institutional, available *in direct support of an individual’s research endeavors*, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes or gifts are not included.” NIH GPS § 2.5.1.
- **Foreign Component:** “[t]he performance of any *significant scientific element or segment of a project* outside of the United States, either by the recipient or by a researcher employed by a foreign organization, *whether or not grant funds are expended*.” NIH GPS § 8.1.2.10
 - NIH issued policy guidance in June, July and August 2019 (more expected).

Bottom Line:

Reporting duties need to be managed carefully, and expectations are evolving.

PHS Conflict of Interest Regulations Requiring Investigator Disclosure of Personal Financial Interests/Income

- PHS regulations provide that:

“[t]he term *significant financial interest* **does not include** the following types of financial interests . . . income from seminars, lectures, or teaching engagements **sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education**; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.” 42 C.F.R. § 50.603.

PHS Conflict of Interest Regulations Requiring Investigator Disclosure of Personal Financial Interests/Income

- As a matter of grammar, how do we read this?
 - ... income from seminars, lectures, or teaching engagements **sponsored by a Federal, state, or local government agency** ...*
- Does this mean that all state, provincial, and local government agencies, or only those within the U.S.?

PHS Conflict of Interest Regulations Requiring Investigator Disclosure of Personal Financial Interests/Income

- As a matter of grammar, how do we read this?

... income from ... [Institution of higher education as defined at 20 U.S.C. 1001(a)], [an academic teaching hospital], [a medical center], or [a research institute that is affiliated with an Institution of higher education];

OR

... income from ... an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital [that is affiliated with an institution of higher education], a medical center [that is affiliated with an institution of higher education], or a research institute that is affiliated with an Institution of higher education;

PHS Conflict of Interest Regulations

- On March 30, 2018, NIH released guidance clarifying that financial interests with ex-U.S. institutions and governments do not fall within the PHS regulations' disclosure exception:

“One such area of the FCOI regulation requiring clarity is Investigator disclosures with respect to foreign financial interests. The regulation refers to exclusions of Institutions of higher education as defined in 20 U.S.C. 1001(a) or a federal, state or local government agency when disclosing financial interests. However, ***these references refer to a U.S. Institution of higher education or a federal, state, or local government agency within the U.S.*** Therefore, Investigators, including subrecipient Investigators, ***must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country).***” Guide Notice NOT-OD-18-160.

NIH Grants Policy Statement – “Other Support”

- Additional, non-NIH sources of support for an investigator’s research must be submitted to NIH for review to ensure there is no scientific, budgetary or commitment overlap between the “other support” and the NIH support:

“Information on other active and pending support will be requested as part of the Just-in-Time procedures. Other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual’s research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes or gifts are not included.”

“Other support is requested for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project.”

– NIH GPS § 2.5.1.

NIH Grants Policy Statement – “Foreign Component”

- NIH’s prior approval must be obtained to add a “foreign component” to a project supported by an NIH grant.
- NIH defines a foreign component as:

“[t]he performance of ***any significant scientific element or segment of a project outside of the United States***, either by the recipient or by a researcher employed by a foreign organization, ***whether or not grant funds are expended.***”

– NIH GPS § 8.1.2.10.

NIH Grants Policy Statement – “Foreign Component”

“**Activities that would meet [NIH’s definition of a foreign component]** include, but are not limited to:

- (1) the involvement of human subjects or animals,
- (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or
- (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country.

Examples of other grant-related activities that may be significant are:

- **Collaborations with investigators at a foreign site anticipated to result in coauthorship;**
- Use of facilities or instrumentation at a foreign site; or
- Receipt of financial support or resources from a foreign entity.

[However,] foreign travel for consultation is not considered a foreign component.” NIH GPS § 1.2.

NIH Summary

- Concerns are **broader than disclosure failures**, and include:
 - Operating undisclosed “shadow labs” in foreign countries may create plausible claim that work generating IP occurred outside the U.S.
 - Theft of biomedical IP, e.g., trade secrets, from awardees and applications.
 - Breaking confidentiality of peer review of grant applications to influence award decisions.

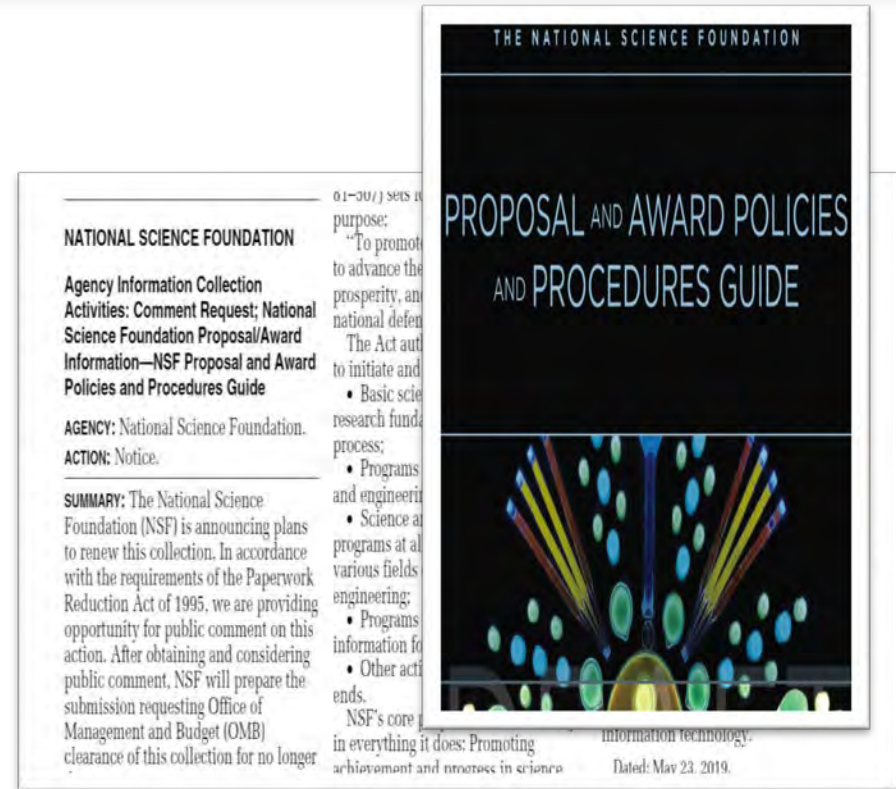
Department of Energy – Barring Talent Program Participation

- **DOE Order 486.1:**
 - Prohibits DOE employees and contractors from participating in certain Foreign Government Talent Recruitment Programs
 - Pass-through to reporting, disclosure, and certification by subcontractors to be barred from DOE work
 - Grantee prohibition still in the works
 - Labs are developing processes to manage

National Science Foundation – PAPPG Update – Widening Reporting Duties

Proposal and Award Policies and Procedures Guide (PAPPG):

- Revisions to Current and Pending Support text seen as a significant departure from current practice:
 - would require reporting from all sources of support regardless of whether salary support is requested



National Science Foundation – PAPPG Update

- Questions relate to reporting outside professional activities, conflicts of commitment and in-kind support
- Unusually high volume of comments
- Typical timeline (final revisions in October) will not be met
 - Revisions expected in January (estimated)
- 2019 PAPPG remains in place

Department of Defense – Looking for More Data

- ***National Defense Authorization Act for 2019 (NDAA): SEC. 1286.*** Directs SecDef to establish an initiative to work with academic institutions performing defense research and development activities:
 - (1) to support protection of intellectual property, controlled information, key personnel, and information about critical technologies relevant to national security
 - (2) to limit undue influence, including through foreign talent programs by countries to exploit United States technology within the Department of Defense research, science and technology, and innovation enterprise.
- *March 20, 2019: Memorandum requiring collection of information on all current and pending support from proposers for research and research related educational activities;*
- *Research Protection Initiative Pilot Program* ongoing with 6 universities to collect data about individuals working on DOD projects (including students) and specifies what DOD will and won't do with the data collected.

Department of State – Seeking Advance Notice of Certain Chinese Visitors

- **October 21, 2019** – *Federal Register* notice requiring individuals from Chinese “foreign missions” pre-clear with the Dept. of State’s Office of Foreign Missions:
 1. All official meetings with representatives of state, local, and municipal governments in the United States and its territories;
 2. All official visits to educational institutions (public or private) in the United States and its territories; and
 3. All official visits to research institutions (public or private), including national laboratories, in the United States and its territories.

Federal Register / Vol. 84, No. 203 / Monday, October 21, 2019 / Notices 56281

DEPARTMENT OF STATE
[Public Notice: 19029]
Designation and Determination Pursuant to the Foreign Missions Act
Pursuant to the authority vested in the Secretary of State under the Foreign Missions Act, 22 U.S.C. 4301, et seq. (“the Act”), and delegated pursuant to Department of State Delegation of Authority No. 214 of September 20, 1994, I hereby designate all official meetings planned with representatives of state, local, and municipal governments in the United States and its territories involving members of the People’s Republic of China’s foreign missions in the United States as a benefit under the Act and hereby determine it is reasonably necessary to achieve one or more of the purposes set forth in section 204(b) of the Act (22 U.S.C. 4304(b)) to require all Chinese dependents and members of their households to submit prior notification to the Office of Foreign Missions of:

1. All official meetings with representatives of state, local, and municipal governments in the United States and its territories;
2. All official visits to educational institutions (public or private) in the United States and its territories; and
3. All official visits to research institutions (public or private), including national laboratories, in the United States and its territories.

This Designation and Determination will apply to all Chinese entities that are designated as “foreign missions” as defined in the Foreign Missions Act. The implementation of these requirements is subject to any additional terms and conditions approved by the Director or Deputy Director of the Office of Foreign Missions.
Stephen J. Akard,
Director, Office of Foreign Missions.
DPR Doc. 2019-22078 Filed 10-16-19; 04:03 am
BILLING CODE 4710-01-P

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration
[Docket No. FAA-2019-0756]
Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Aging Aircraft Program (Widespread Fatigue Damage)
AGENCY: Federal Aviation Administration (FAA), DOT.
ACTION: Notice and request for comments.
SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the FAA invites public comments about our intention to request Office of Management and Budget (OMB) approval to renew an information collection. The “Aging Aircraft Program (Widespread Fatigue Damage)” final rule amended FAA regulations pertaining to certification and operation of transport category airplanes to preclude widespread fatigue damage in those airplanes.
DATES: Written comments should be submitted by December 20, 2019.
ADDRESS: Please send written comments:
By Electronic Docket: www.regulations.gov (Enter docket number into search field).
By Mail: Walter M. Stippel, Federal Aviation Administration, Transport Standards Branch, 2290 South 216th Street, Des Moines, WA 98198.
By Fax: 206-231-3216.
FOR FURTHER INFORMATION CONTACT: Walter M. Stippel by email at: Walter.Stippel@faa.gov; phone: 206-231-3216.
SUPPLEMENTARY INFORMATION: Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for FAA’s performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB’s clearance of this information collection. OMB Control Number: 2120-0743.

Background: FAA regulations require that type certificate and supplemental type certificate holders use documentation to demonstrate to their FAA Oversight offices that they have complied by establishing a limit of validity of the engineering data that supports the structural maintenance program (the number referred to as LJV) for certain airplane models. Operators will submit the LJV to their Principal Maintenance Inspectors to demonstrate that they are compliant.
Responses: Approximately 30 operators.
Frequency: Information is collected on occasion.
Estimated Average Burden per Response: 20 hours.
Estimated Total Annual Burden: 167 hours.
Issued in Washington, DC, on October 16, 2019.
Ivy Wolf,
Director of Policy Management Officer (DMP/PMO), Aircraft Certification Service.
DPR Doc. 2019-22078 Filed 10-16-19; 04:03 am
BILLING CODE 4910-13-P

DEPARTMENT OF THE TREASURY
Office of Foreign Assets Control
Notice of OFAC Sanctions Actions
AGENCY: Office of Foreign Assets Control, Treasury.
ACTION: Notice.
SUMMARY: The Department of the Treasury’s Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC’s Specially Designated Nationals and Blocked Persons List based on OFAC’s determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.
DATES: See **SUPPLEMENTARY INFORMATION** section.
FOR FURTHER INFORMATION CONTACT: OFAC Associate Director for Global Targeting, tel: 202-622-2420; Assistant Director for Sanctions Compliance & Evaluation, tel: 202-622-2490; Assistant Director for Licensing, tel: 202-622-2400; or Assistant Director for

Department of Commerce – Export Controls

- The Commerce Department’s export control restrictions (Export Administration Regulations, “EAR”) are the government’s long-standing means to address some of the concerns at issue, e.g., theft of intellectual capital.
- EAR apply to:
 - Physical movement of goods or equipment across international borders;
 - Release or disclosure of controlled U.S. technology (e.g., technical data) to a foreign national is considered an export of such technology to the country of citizenship of the foreign national (“**deemed export**”); and
 - Release or disclosure of controlled U.S. technology in a foreign country to a national of another foreign country (“**deemed re-export**”).
 - **Note:** For purposes of deemed exports and deemed re-exports, technology and software are considered to be “released” for export by visual inspection by a foreign national or through oral exchanges of information with a foreign national, e.g., to foreign national employees and for research collaborations involving foreign national students/lab assistants.
 - 15 CFR 730.

Department of Commerce – Export Controls

- **Fundamental Research Exemption** has removed many activities from the Export Control system:
 - EAR 734.8 – Information arising during or resulting from “fundamental research” is exempt from EAR licensing, meaning “basic and applied research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly for the research community, and for which the researchers have not accepted restrictions for proprietary or national security.” This means:
 - University research historically much lower risks of being seen as an “export.”
 - Proprietary research, industrial development, design, production, and product utilization are not considered fundamental research (whether conducted in a university setting or not), and export control restrictions do apply to the outcomes of this broader category of research.
- **But now:** Commerce Department preparing to expand the scope of U.S. export control restrictions for certain categories of biotechnology, artificial intelligence/machine learning, and advanced data analytics technologies.

Department of Commerce – Export Controls

- Commerce Department is in the process of identifying “emerging and foundational” technologies with potential national security implications.
 - Identified technologies will be subject to export control restrictions on a going-forward basis.
- Commerce Advanced Notice of Proposed Rulemaking that preliminarily identified certain categories of biotechnology, artificial intelligence, machine learning, and advanced data analytics technologies as expected categories of “emerging technology.” 83 Fed. Reg. 58201 (Nov. 19, 2018)
 - Explicitly preserves “fundamental research” as defined in Part 734.8 of the EAR
 - But, in defining emerging technologies, risk is that some current fundamental research will become restricted
 - Concern is overly broad or vague controls

Representative Technology Categories

The representative general categories of technology for which Commerce currently seeks to determine whether there are specific emerging technologies that are essential to the national security of the United States include:

(1) Biotechnology, such as:

(i) Nanobiology;

(ii) Synthetic biology;

(iv) Genomic and genetic engineering;

or

(v) Neurotech.

(2) Artificial intelligence (AI) and machine learning technology, such as:

(i) Neural networks and deep learning (e.g., brain modelling, time series prediction, classification);

(ii) Evolution and genetic computation (e.g., genetic algorithms, genetic programming):

Department of Education—Reporting Foreign Gifts

- Higher Education Act of 1965, Pub. L. No. 89-329 - Requires colleges to report all gifts and contracts from foreign sources that exceed \$250,000.
 - Agency believes duty to report is clear on face of law. It has said reporting is for: “gifts from, or contracts entered into, with any campus or affiliated association, foundation, or entity that operates substantially for the benefit or support of, or under the auspices of, any institution” covered by the law, and includes in-kind.
 - July 2019: Dept. of Education announced it is investigating at least four institutions in connection with gifts and contracts from foreign sources that exceed \$250,000.
 - Schools are expected to turn over thousands of records in foreign aid for overseas campus operations, academic research, and other partnerships.

Agenda

- Overview and Administrative Agency Update
- **Current Litigation and Industry Implications**
- Due Diligence and Internal Investigations

Department of Justice: Criminal Litigation

Indictments increasing for failure to disclose foreign conflicts of commitment, conflicts of interest, etc.:

- *United States v. Liu* (indictment filed Sept. 13, 2019 in US District Court for the Southern District of New York).
 - Conspiracy to fraudulently obtain U.S. visas for Chinese government employees to serve as research scholars as a pretext for serving as recruiters of U.S. experts to PRC talent programs [18 U.S.C. §§ 371, 1546; up to 5 years in prison]
- *United States v. Tao* (indictment filed Aug. 21, 2019 in US District Court for the District of Kansas).
 - Failure to disclose a talent program, financial conflict of interest and fraud involving NSF & DoE contracts [18 U.S.C. §§ 666, 1343; up to 20 years in prison & up to \$250,000]

Department of Justice: Criminal Litigation

- *United States v. Zhou* (indictment filed July 24, 2019 (unsealed in Sept) in US District Court for the Southern District of Ohio)
 - Husband and wife allegedly stole trade secrets from their laboratory work at Nationwide Children's Hospital to establish separate companies, and patenting some of the technology in China. The 27 counts include charges of conspiracy to commit the theft of trade secrets, theft of trade secrets and wire fraud. The trade secrets related to treatment of a range of pediatric medical conditions (Conspiring to, attempting to, and committing theft of trade secrets [18 U.S.C. §§ 1343, 1349, 1832; up to 20 years in prison])
- *United States v. Y. P. Zhang* (Indictment filed on Nov. 21, 2017 in US District Court for the Western District of Virginia; judgment filed 2/19; Sentence filed Sept. 6, 2019)
 - Convicted for one count of conspiracy to defraud the United States, three counts of making false statements, and one count of obstruction by falsification in connection with Small Business Innovation Research awards from NSF and DOE where work was previously completed in China.

Civil Litigation and DHHS OIG Actions

- Civil actions are increasing for grants issues generally.
- *In the last two years, the HHS-OIG has:*
 - Received more than 16 referrals from the NIH raising issues related to foreign influence
 - Allegations primarily concern failure of principal investigators to disclose foreign government affiliations
 - Engaged in significant False Claims Act (FCA) cases and brought multiple Civil Monetary Penalty (CMP) actions involving grants and contracts

DHHS OIG Audit Activities

- In September 2019, the OIG published three reports raising questions about NIH policies and practices for peer review, conflicts of interest, and other concerns in extramural research grants.
- OIG is continuing to review NIH's peer review process, pre-award process for assessing risk of grant applications, and post-award oversight, reviews expected to be published in 2020.
 - *Potential Duplication of NIH Research Grant Funding*
 - *NIH's Peer Review Process for Evaluating Grants*

Department of Health and Human Services
OFFICE OF
INSPECTOR GENERAL

THE NATIONAL INSTITUTES OF
HEALTH HAS LIMITED POLICIES,
D CONTROLS IN
ING TO ENSURE
NS REPORT ALL
ARCH SUPPORT,
ERESTS, AND
TIONS

U.S. Department of Health and Human Services
Office of Inspector General

NIH Has Made Strides in
Reviewing Financial
Conflicts of Interest in
Extramural Research,
But Could Do More

U.S. Department of Health and Human Services
Office of Inspector General

Vetting Peer
Reviewers at NIH's
Center for
Scientific Review:
Strengths and
Limitations

Suzanne Murrin
Deputy Inspector General
for Evaluation and Inspections

0160
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0160-03-19-00150
September 2019
oig.mil.gov

Suzanne Murrin
Deputy Inspector General
for Evaluation and Inspections

Implications for Industry

- Increased international collaboration, international procurement, international offices and hiring, and proliferation of multi-site, trans-national trials lead to multiple risks:
 - Export control requirements, including “deemed exports”
 - Violation of IP licenses to the industry entity if IP leakage occurs
 - Dual loyalties of employees/colleagues re their ex-U.S. affiliations
 - Sponsored research to universities and AMCs using investigators who have any inappropriate ex-U.S. ties or collaborations
 - Receipt of NIH, FDA, DoD, DoE grants or procurement contracts may directly subject industry entity to risks outlined in this session

Agenda

- Overview and Administrative Agency Update
- Current Litigation and Industry Implications
- **Due Diligence and Internal Investigations**

Responding to U.S. Govt Agency Inquiries

- Potential deficiencies are identified through law enforcement referrals, complaints from co-workers or other scientists, institutional self-reporting, and agency staff review.
- Federal funders may inquire directly, or requests come from OIG, DOJ, etc.
 - e.g., subpoenas for records
- Institutions receiving such letters must engage in fact-finding investigations to respond.
 - **Agencies may question the adequacy of the institutions' investigation and whether independent analysis was brought to bear.**
- Risks include federal sanctions and reputational risks.

Institutional Investigations

- Prepare investigation plan
- Keep records
- Certify translations
- Be sensitive to federal anti-discrimination requirements.
 - Employers may not discriminate against an employee in any aspect of employment because of the employee's **race, color, or national origin** (or other protected classes). [See, e.g., Civil Rights Act of 1964, Title VII.]
 - Prohibition extends to considering such characteristics in making decisions about **discipline or discharge**.

Search for Relevant Records – In U.S. and PRC

- If presented with an inquiry in connection with grant or peer review questions, conduct targeted, multi-lingual media searches into the following, as applicable, typically by use of internet:
 - Affiliation with PRC-based and other non U.S.-based university and medical institutions (including consulting)
 - Affiliation with commercial entities
 - PRC and other non-U.S. patents filed based on results of U.S.-funded research
 - Foreign grants
 - Foreign components in active awards
 - Participation in foreign government talent programs

Institutional Investigations

- Institutions' anti-discrimination legal exposure is limited when the investigation involves cooperating with a specific government request for information.
- Sanctions:
 - Employees' violations of laws or policy are actionable.
 - Sanctions should be applied consistently, without regard to the person's race, color, or national origin.
 - Difficult when USG agencies are focused on one country – PRC – and not on the many others with which institutions and investigators may have close relationships.

Institutional Investigations

- Examine:
 - Previous and current annual financial disclosures
 - Consulting engagements and income
 - Travel to and from foreign jurisdiction and time spent there
 - Lab staff, especially unpaid “volunteers”
 - Publications, especially when collaborations may suggest undisclosed “foreign components” or “other support”
 - Time and effort issues
 - Internet sources within the country involved – most often, PRC – in order to check against faculty disclosures
 - In depth background/reputational checks (be cognizant of local laws)
- **Interviews with named faculty will be necessary and likely difficult.**
- Act to preserve and log records as quickly as possible.

Institutional Investigations

- Institutions may find that Investigators **did not understand the need to disclose to the institution**:
 - Institutional policies and forms may have been unclear in this area
 - Foreign sources of support for research that did not have direct scientific overlap with their U.S.-based research.
 - Foreign institutions' sponsorship of the investigators' travel expenses or per diem expenses when visiting the foreign institutions.
 - Collaboration with foreign investigators resulting in co-authorship (which may be a "foreign component").
- Investigators have not realized that they are targets of foreign intelligence gathering efforts.

Key Issues: Visitors, Collaborations, and Foreign Activities

- *Are the processes for managing visitors and collaborations sufficient?*
- *What about research activities outside the US?*
 - Collaboration agreements
 - Gifts and travel reimbursement,
 - Technology Transfer Agreements, and
 - Procurement.
- Consider escalation and review process for high-risk collaborations.

Scanning the Horizon

- Communicate First; enable understanding and application.
- Consider not-for-cause **sampling and auditing COI disclosures**.
- Consider not-for-cause **sampling and auditing of applications and progress reports**.
 - Tool for risk assessment, education, and defense, as needed.
 - Include both awards with known foreign components and those without foreign components to assess faculty understanding of disclosure requirements.
 - Focus on recently completed awards, for which manuscripts are published or in process, for a full picture of the current foreign support landscape.
- Consider self-disclosure for any significant problems identified.
- Possible extension of this effort into private industry: pharma, biotech, IT, science-heavy industrial concerns

Corrective Actions & Communication

- Develop specific corrective actions for individual cases.
- Review and update disclosure forms, guidance documents, policies, and procedures to ensure that they are current, comprehensive, and easy to understand.
 - FAQs and other guidance should be made readily accessible to faculty online.
- Conduct training for research administrators.
 - Informational sessions for faculty and other stakeholders
- Involve institutional leaders to:
 - Review sensitive arrangements,
 - Provide feedback regarding existing risk mitigation strategies, and
 - Coordinate responses between departments.

Take-Aways

- Disclosures are the area in which **institutions' own obligations** under federal funding requirements are most likely to be affected.
 - Conflict of Interest reporting and management
 - Time and Effort
- Adequacy and independence of internal investigation will be key concern for funders like NIH
- Agencies' interpretation of applicable rules is evolving/subject to clarification
- Reputational and Legal risks need to be considered.

Thank you!

QUESTIONS