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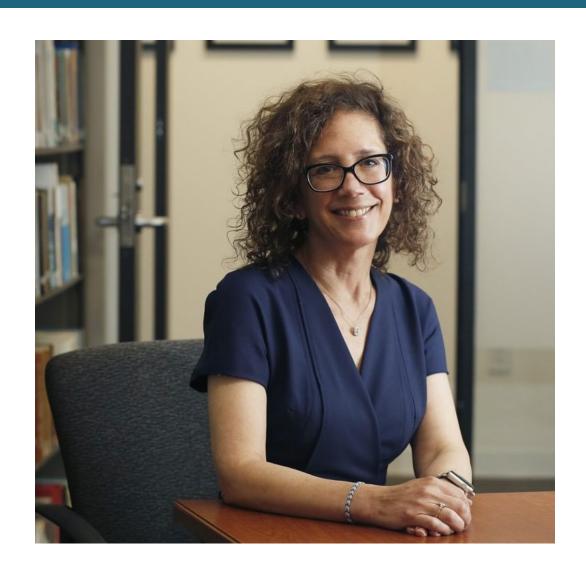
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Questions

Moderator



Penny Gordon-Larsen, PhD
Associate Dean for Research
Professor, Department of Nutrition
UNC Gillings School of Global Public Health

Speakers





Michael Lauer, MD NIH

Toby SmithAAU

Valarie Bonham, JD Rope & Gray

NEWS | IN DEPTH

BIOMEDICAL RESEARCH

Details revealed on NIH probe of foreign ties

Official overseeing inquiry reveals undisclosed firings and returned funds from universities

By Jeffrey Mervis

yearlong investigation by the National Institutes of Health (NIH) in Bethesda, Maryland, has fingered 180 scientists at more than 60 U.S. research institutions who NIH believes have violated the confidentiality of its peer-review system or failed to disclose financial ties to foreign organizations. But NIH has revealed few details of the investigation—including how it began and what it has learned.

Until now. Last week, the senior NIH official leading the agency's review of foreign ties talked with *Science* about the probe's substantial, and growing, scope.

This spring, two institutions—MD Anderson Cancer Center in Houston, Texas, and Emory University in Atlanta—announced that five faculty members had been dismissed in the wake of the NIH probe. But Michael Lauer, who directs NIH's \$20 billion-plus extramural research program, says several other universities have cut ties with researchers in cases that have remained confidential. Lauer says some institutions have repaid NIH "hundreds of thousands of dollars" in grants after confirming what he termed "egregious" violations.

Lauer understands why some universities have kept quiet about those outcomes. "No organization wants to discuss personnel actions in a public forum," he says. At the same time, Lauer says NIH is, "to the extent possible, engaged in outreach" to the scientific community about the importance of ensuring research integrity and



Michael Lauer of the National Institutes of Health says undisclosed foreign ties had gone on for years before the agency noticed them.

Science could not independently verify some of Lauer's comments because of the secrecy surrounding NIH's investigation. But here are highlights of the conversation:

 NIH's current effort began after it learned in mid-2016 of a Federal Bureau of Investigation (FBI) case involving an MD Anderson researcher serving as an NIH reviewer. The FBI probe revealed that, despite strict rules to protect confidentiality, the researcher had shared grant proposals with several people.
 NIH has since found similar violations researchers conduct studies in many fields, he adds.

- Many U.S. universities initially pushed back after receiving a letter, telling NIH that the named scientists had no such connections and that NIH "was blowing smoke." But those institutions later reversed course, Lauer says, after NIH supplied evidence such as grant numbers from foreign funders and employment contracts with foreign institutions. University officials were "surprised, shocked, and horrified" by the undisclosed ties, Lauer says.
- Some scientists targeted by the probe had NIH grants that provided salary for 8 months of work each year at their home institution. But investigations showed they had also agreed to work as much as 9 months a year at a foreign institution. A 17-month time commitment amounts to fraud, Lauer says. As a result, some institutions have returned salary funds to NIH.
- Some U.S.-based scientists participating in China's Thousand Talents
 Program, which seeks to build ties
 with scientists working outside China,
 signed contracts that stipulated their
 research results "must stay in China
 and cannot be reported to their American university." Others had contracts
 that required them to promote their
 Chinese affiliations in any publication.

US researchers on front line of battle against Chinese theft





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

EDITORIAL

Chinese scientists and security

any scientific and economic successes in
the United States are owed to the work of
foreign-born scientists. Today, a substantial percentage of U.S patents and scientific
publications are contributed by Chineseborn scientists. But there is increasing concern that China is unfairly and systematically attempting to capture intellectual property, trade
secrets, and advanced technologies from the United
States, all detrimental to productive long-term relationships. As part of the U.S. response to these threats,
tenured Chinese-American scientists at top institutions of biomedical research were recently dismissed
for purported violations of disclosure rules, breaches
of confidentiality, or outright suspicion of espionage.

As Congress seeks to protect the open and collaborative approach to science and technology from nefarious activities of foreign states, the scientific community must weigh in on the path forward.

We should remember that for years, scientific exchanges and collaborations with China were encouraged by U.S. policy-makers, including implicit support of China's Thousand Talents Program. productive Chinese-American scientific diaspora trained and supported for years in the United States?

In my experience in academia, government, and industry, most Chinese-born scientists prefer to stay in the United States for personal and family preferences. One can imagine the glee of Chinese officials at the prospect of thousands of Chinese-American scientists, whom they were unable to recruit until now, relocating back to China. So, what should be done?

Congress is conducting hearings and considering passing the Securing American Science and Technology Act of 2019 as part of the Defense Authorization bill—a good step forward. Although this bill is progressing at its usual pace in the legislative branch, time is not on our side. The executive branch should

> promptly establish a blue-ribbon panel composed of security experts, agencies representatives, academics, and prominent scientists and engineers under the auspices of the Office of Science and Technology Policy and the National Security Council to fully debate the facts, ways, and means to effectively protect U.S. science and technology while preserving the attractiveness of the United States to talented



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Institutes of
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relies heavily on
for and attracting the best
ers, and brightest..."

"...the United States

Michael Lauer, MD



Science and Security: NIH Concerns

Michael S Lauer MD

NIH Deputy Director for Extramural Research

Webinar hosted by the Association of Schools and Programs in Public Health Friday, October 11, 2019

Via Webinar



NATUREJOBS CAREER GUIDE

CHINA

WHAT IS CHINA'S THOUSAND TALENTS PLAN?

The nation's bid to lure back ex-pat scientists and recruit highly-skilled foreign researchers is now in its tenth year.

BY HEPENG JIA

https://www.nature.com/articles/d41586-018-00538-z
Nature January 17, 2018

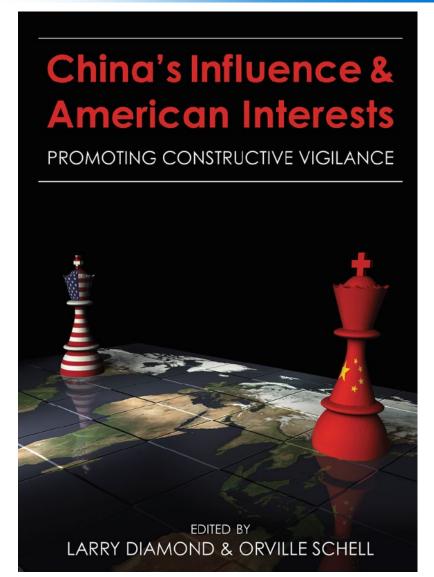


Keys to Winning a Talents Award

- "To apply, you must already have a firm job offer from a Chinese institution ...
- The scheme is open to Chinese scientists under 55 years of age, and foreigners younger than 65. All applicants must have worked at renowned universities outside China
- All applications to the Thousand Talents scheme go through your Chinese university employer."



Undisclosed Foreign Employment



"China's most systematic channel for identifying foreignbased non-traditional collectors is its ... Thousand Talents Program (TTP) ... aims to recruit leading overseas scientists ... Official Chinese TTP websites list more than three hundred US government researchers and more than six hundred US corporate personnel who have accepted TTP money. In many cases, these individuals do not disclose receiving the TTP money to their employer, which for US government employees is illegal and for corporate personnel likely represents a conflict of interest that violates their employee agreement."

> Hoover Institution Press Publication No. 702 Hoover Institution at Leland Stanford Junior University, Stanford, California 94305-6003



Undisclosed Foreign Employment Agreements

- "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

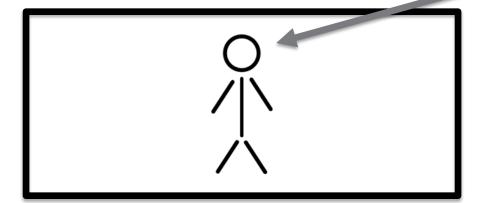
An "Obvious" Question: What is a Recruitment?

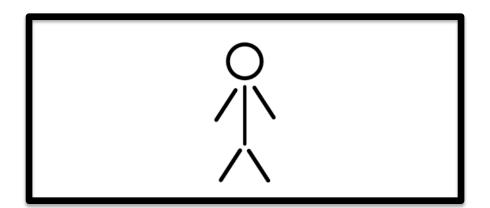
American University

American Academic Leader

Chinese University

Chinese Academic Leader







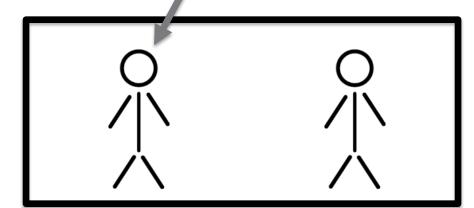
Clean Recruitment

American University

American Academic Leader

Chinese University

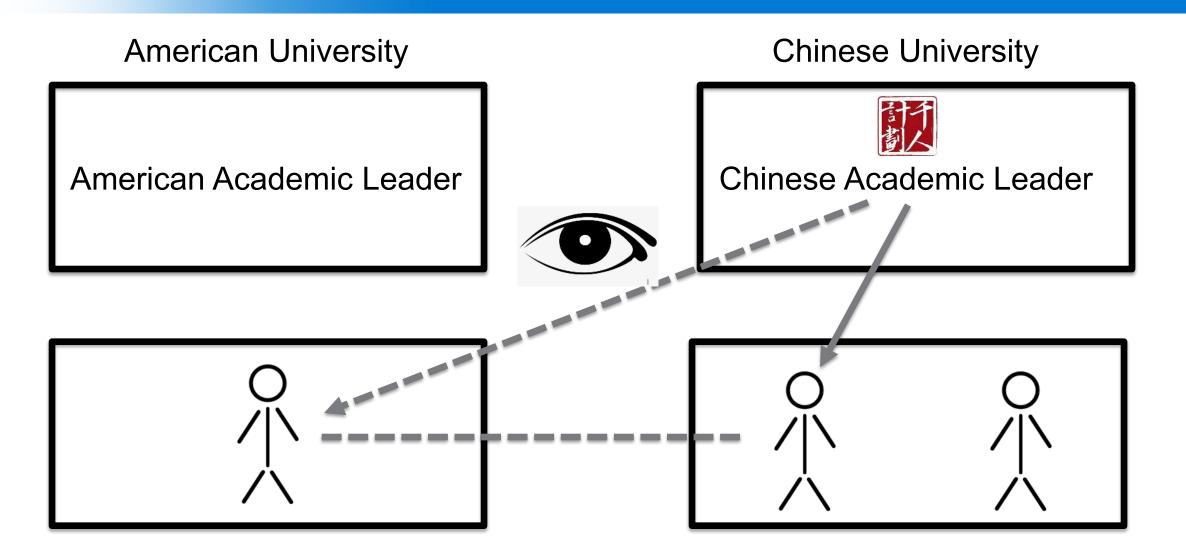
Chinese Academic Leader







Talents Recruitment







Undisclosed Talents Program or Grants

Acknowledgements: This work was supported by a grant from Talents Program to XY

Supported by the National Basic Research Program of China (973 Program ...)

Duplicate Grants

US Grant

Aim 1: AAAAA

Aim 2: BBBBB

• Aim 3: CCCCC

Foreign Grant

Aim 1: AAAAA

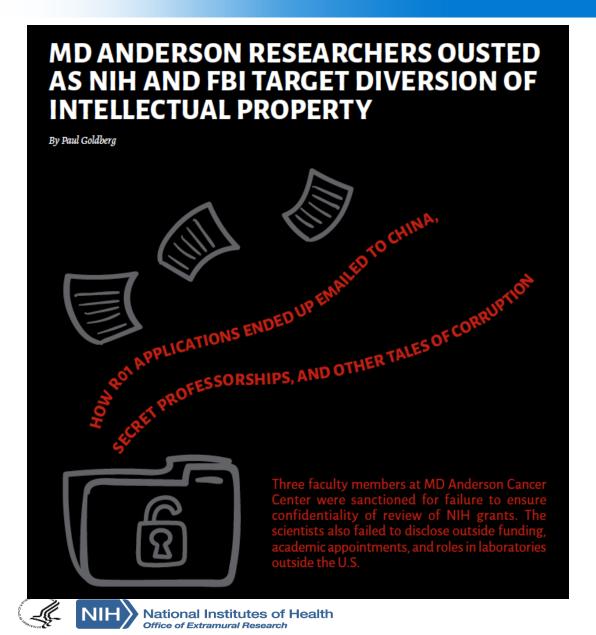
Aim 2: BBBBB

Aim 3: CCCCC

- NIH is funding grants identical or highly similar to Chinse grants
- Investigators are "double-dipping" and not disclosing



Stealing



The researcher was also accused of "quid pro-quo exchanges of personal and professional benefits in pursuit of foreign 'Talents Program' membership," Weber's report alleges.

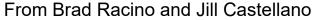
In the process, he "delivered know-how, data, and samples" to an entity in China. This appears to include primers designed and sequenced by his post-doc at MD Anderson. "Legal Services does not find any documentation showing any approved Material Transfer Agreements" associated with that delivery, the report states.

Cancer Letter, April 26, 2019

Undisclosed \$11.7 Million China-Based Business

广州康睿生物医药科技股份有限公司 GuangZhou KangRui Biological Pharmaceutical Technology Co.,Ltd.





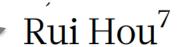
FCOI Undisclosed

LETTER

doi:10.1038/nature14650

Lanosterol reverses protein aggregation in cataracts

Ling Zhao^{1,2,3}*†, Xiang-Jun Chen⁴*, Jie Zhu^{3,5}*, Yi-Bo Xi⁴*, Xu Yang⁶*, Li-Dan Hu⁴*, Hong Ouyang^{2,3}, Sherrina H. Patol³, Xin Jin⁶, Danni Lin³, Frances Wu³, Ken Flagg³, Huimin Cai^{1,7}, Gen Li¹, Guiqun Cao¹, Ying Lin^{2,3}, Daniel Chen³. Cindy Wen³, Christopher Chung³, Yandong Wang², Austin Qiu^{3,8}, Emily Yeh³, Wenqiu Wang^{3,9}, Xun Hu¹, Seanna Grob³, Ruben Abagyan¹⁰, Zhiguang Su¹, Harry Christianto Tjondro⁴, Xi-Juan Zhao⁴, Hongrong Luo³, Rui Hou⁷, J. Jefferson P. Perry¹¹, Weiwei Gao^{3,12}, Igor Kozak¹³, David Granet³, Yingrui Li⁶, Xiaodong Sun⁹, Jun Wang⁶, Liangfang Zhang^{3,12}, Yizhi Liu², Yong-Bin Yan⁴ & Kang Zhang^{1,2,3,12,14,15}



*Kang Zhang^{1,2,3,12,14,15}

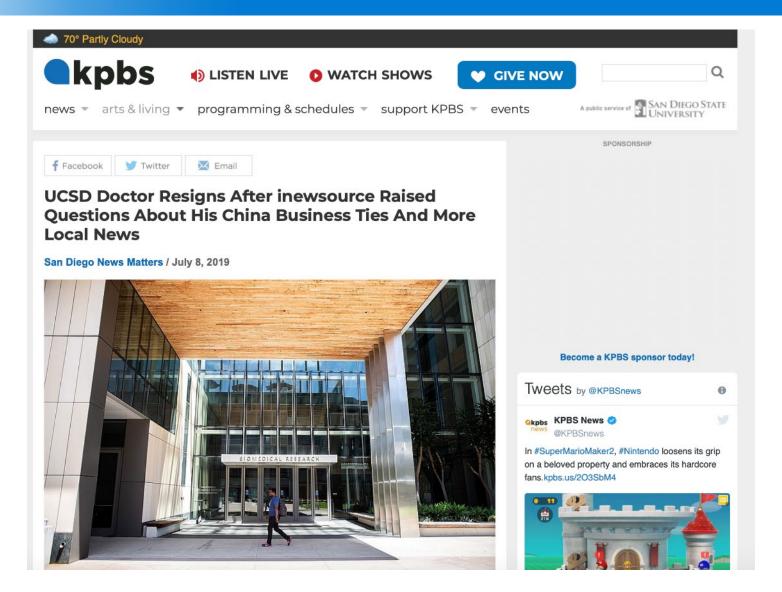
¹Molecular Medicine Research Center, State Key Laboratory of Biotherapy, West China Hospital, Sichuan University, Chengdu 610041, China.

⁷Guangzhou KangRui Biological Pharmaceutical Technology Company, Guangzhou 510005,

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Outcome to Date





Peer Review Breaches

Case 3: "Keep this confidential."

This MD Anderson researcher was alleged to have "emailed an NIH grant application to a scientist based in the People's Republic of China."

According to Weber's report, the researcher "also may have sent at least two NIH grant applications to U.S.-based scientists who were not designated by the NIH to review the material."

In one instance, the researcher instructed the recipient of the information to "keep it to yourself."

In another instance, the accompanying note read, "Here is bone and meet [sic] you need."

On yet another occasion, the researcher sent an NIH grant application to a department within the National Cancer Center/Cancer Hospital Chinese academy of Medical Science. The transmittal email read: "Some methods you may learn from this proposal. Keep this confidential."

The researcher received all of these applications from NIH legitimately, for the purposes of conducting peer review.

Cancer Letter, April 26, 2019



Growing Institutional Awareness

Search: This Site | People | Departments | Penn State



ABOUT -

CAPABILITIES -

FUNDING FIND RESEARCH

CYBERINFRASTRUCTURE

PARTNERSHIPS & INDUSTRY -

FOR PENN STATE -

Related Resources for Investigators Collaborating Internationally:

University Research Council & Associate
Deans for Research (ADRs)

Global Programs - Collaborating Internationally

Data & Information Security (Report IT Threats or Compromised Accounts)

Penn State International Travel Requirements

Export Compliance Manual

Export Compliance & Foreign Transactions

Office of Sponsored Programs - Export Controls Info

Related Policies:

AD89 - Policy on Export Compliance

RA40 - Policy on Federal Export Regulations

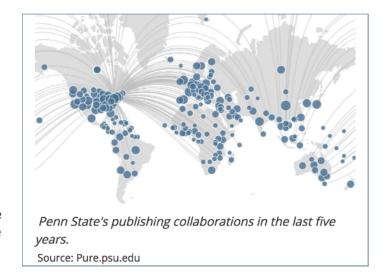
International Relationships and Activities

Background | How to Protect Yourself | Outcomes | Get Assistance | FAQ

Introduction

The U.S. Government has expressed serious growing concerns regarding inappropriate influence by foreign entities over federally funded research (see Sources below). One issue that has moved to the forefront is the failure of federally-funded researchers at U.S. institutions to disclose their relationships and activities with foreign institutions and funding agencies. Several Federal agencies have indicated that failure to disclose foreign relationships and activities may jeopardize eligibility for future funding.

Penn State encourages international collaborations, but it is important for our investigators to be transparent about their foreign relationships and activities. Penn State's Office of the Vice President for Research (OVPR) has compiled the following information to provide guidance and resources to remind Penn State researchers of their compliance obligations to federal sponsors.



Rising Concern (Background)





Key Point: Encourage but be Transparent

- "While most international collaborations are acceptable and encouraged, we urge researchers to err on the side of transparency."
- "It protects everyone's interests the Federal government, Penn State, individual researchers, and their international collaborators – to have international relationships disclosed and vetted to determine if there are any potential conflict of commitments, duplications of research, and/or diversion of intellectual property in the performance of federally funded research."

NIH Actions

- Close work with institutions
 - Institutional actions, refunds, renegotiated grants
- Referral to OIG and FBI
 - Seek debarment or suspension
 - Assist other Federal agencies
- What we're looking for: full disclosure and vetting
 - Oversight and stewardship over faculty activities



Incomplete Thank You

NIH

- Larry Tabak, Carrie Wolinetz, Jodi Black,
 Patricia Valdez, Sally Amero, Michelle
 Bulls, Julie Muroff, Kate Tapley, Mike
 Shannon, Bill Cullen, Liza Bundesen,
 Megan Columbus, Renate Myles, Katrina
 Pearson, Rick Ikeda, Jess Mazerik,
 Nicole Garbarini, Minna Liang, Francesca
 Bosetti, Tara Schwetz, others
- FBI, DOJ, DNI
 - John Brown, Don Lichay, Tam Dao,
 Melody Hounsell, Jeff Stoff, others
- Non-federal organizations
 - Wendy Streitz, Lisa Nichols, Sarah
 Rovito, Toby Smith, Lizbet Boroughs,
 Ross McKinney, Marcia McNutt, others

DHHS

 Michael Schmoyer, Les Hollie, Francis Montoya, Justin Bidwell, Jason Scalzo, Adam Layton, others

State

- Andrew Hebbeler, Megan Frisk, Staci Rijal, others
- OSTP and other research agencies
 - Rebecca Keiser, Jeremy Ison, Bindu Nair, Helena Fu, Aaron Miles, others
- Dozens of VPRs and institutional compliance / integrity leaders



Toby Smith



Current Congressional & Federal Context and University Response

Tobin L. Smith
Vice President for Policy, AAU
Association of Schools and Programs of Public Health
Friday, October 11, 2019





FBI chief says Chinese operatives have infiltrated scores of 'naive' U.S. universities



Associated Press

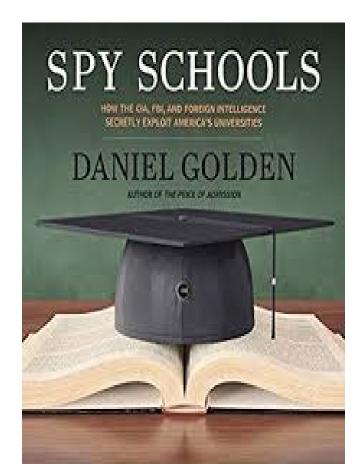
Published: 9:03am, 14 Feb. 2018





Federal & Congressional Pressure to Re-Examine Research Protections

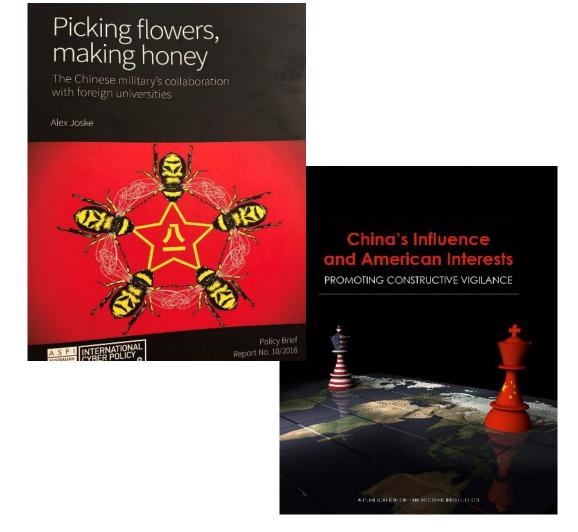
- Intelligence agencies sound the alarm
- Numerous reports raise concerns
- Agencies send out letters and are clarifying old and developing new policies
- Congressional pressure to address security concerns builds; but Congress lacks understanding of the controls already in place
 - Result: Several ill-informed and potentially damaging proposals to U.S. science have been introduced in Congress





Specific Concerns

- Huawei and other university funding relationships
- Talent recruitment programs
- Faculty relationships and failure to disclose foreign funding sources/affiliations
- Shadow laboratories
- Breaches in peer-review
- Foreign investment/CFIUS
- Confucius Institutes
- Student groups
- Sharing of Genetic Information





National Institutes of Health

- August 2018 letter and <u>statement</u> from Dr. Collins
- ACD Working Group Recommendations December 13, 2018
- "Reminders on Other Support" <u>Guide Notice and FAQs</u> July 10, 2019
- 60 current letters of inquiry to institutions, 17 referrals to HHS
 OIG
- Meanwhile:
 - 2 Congressional hearings
 - -- FY20 Senate Appropriation hearing focus
 - -- Media Focus





National Science Foundation

Sen. Grassley Letter to NSF Director (April 15) & NSF Response (April 26)

Current & Pending Support requirements

- Revised C&P language in draft PAPPG released on May 29. Comments were due July 29.
- NSF is developing a template.

National Science Board (NSB) Discussion of Science and Security on July 18.

JASON Study

Risk assessment & mitigation strategies including pre-publication information.

- How has the research ecosystem changed?
- Are there additional safeguards that should be in place?
- Which areas are more sensitive and have security implications?



DOD and **DOE**

Department of Defense

- Section 1286 of the National Defense Authorization Act of 2019
- Task Force on Protecting Critical Technologies
- March 20, 2019 Memo on current and pending support requirements

Department of Energy

- December 14, 2018 Memo on developing S&T Risk Matrix
- January 31, 2019 Memo on prohibiting DOE personal from participating in foreign talent programs
- June 7, 2019 Implements prohibition for DOE employees but NOT universities



Recent Legislative Proposals

- H.R. 3038, "Securing American Science and Technology Act (SASTA)," Rep. Sherrill (D-NJ)
 & Rep. Gonzalez (R-OH)
- S. 2133, "Secure American Research Act," Sen. Cornyn (R-TX) & Sen. Rosen (D/NV)
- H.R. 1678 / S. 1879, "Protect Our Universities Act," Rep. Banks (R-IN) / Sen. Hawley (R-MO)
- H.R. 618 / S. 29, "Critical Technologies and Security Act," Rep. Ruppersberger (D-MD) / Sen. Warner (D-VA)
- H.R. 602 / S. 152, "Telecommunications Denial Order Enforcement Act," Rep. Gallagher (R-WI) / Sen. Cotton (R-AR)
- S. 480, "Countering the Chinese Government and Communist Party's Political Influence Operations Act," Sen. Rubio (R-FL)
- H.R. 1811, "Countering the Chinese Government and Communist Party's Political Influence Operations Act," Rep. Smith (R-NJ)
- S. 937, "Protecting American Technology Act," Sen. Kennedy (R-LA)
- H.R. 2244, "Higher Education Transparency Act," Rep. Gosar (R-AZ)
- S. 1451 / H.R. 2713, "People's Liberation Army (PLA) Visa Security Act," Sen. Cotton (R-AR) / Rep. Gallagher (R-WI)



Congressional Hearings & Roundtables

- April 2018 "Scholars or Spies: Foreign Plots to Targeting America's Research & Development," House Science Subcommittee on Oversight and Subcommittee on Research and Technology
- June 2018 "Student Visa Integrity: Protecting Educational Opportunity and National Security," Senate Judiciary Subcommittee on Border Security and Immigration
- Sept 2018 House Science Committee Roundtable with higher education leadership, federal science agencies, FBI
- Feb 2019 "China's Impact on the U.S. Education System," Senate Homeland Security Permanent Subcommittee on Investigations
- May 2019 House Armed Services Roundtable with higher education leadership
- June 2019 "Foreign Threats to Taxpayer Funded Research: Oversight Opportunities and Policy Solutions," Senate Finance Committee



Simple Summary of Legislative Proposals & Federal Actions

- Increased institutional reporting of funding received from foreign gifts and contracts (HEA Section 117)
- Restrictions on participation in foreign talent programs
- Creation of new categories of "critical technologies" or "sensitive research" which limit access to foreign students & scholars to certain labs and research projects
- Focus on clarifying and enforcing agency disclosure requirements
- Increased visa delays and some intl. students recently denied readmission into the U.S.
- Better interagency coordination and forums for dialogue between federal agencies and the university/scientific community



OSTP Coordination of Federal Agency Policies

- H.R. 3038 SASTA Legislation
 - -- supported by over 100 institutions
- Joint Committee on Research Environments (JCORE) announced by OSTP on May 7
- Subcommittee on Research Security
 - -- Two OSTP staff & 3 staff Co-chairs
- 18 federal agencies; have already had nine meetings.
- Initial discussions have focused on:
 - -- Coordination of Federal communications/outreach efforts to academic and research institutions; four regional meetings planned
 - -- Providing guidance and best practices for research institutions
 - Standardizing conflict of interest and commitment disclosure requirements and enforcement



Universities Seeking to Balance Science & Security Concerns

- 1) Take security concerns seriously and must comply with existing requirements
- 2) Defend core principles of openness & value of foreign students/scholars
- 3) AAU APLU survey on effective practices to address foreign security threats
 - 140 examples submitted by 39 institutions
 - Several "Buckets"

Communication; coordination; training; enhanced reviews; cyber and data security; IP protection; security agency interaction; foreign travel; international visitors; export controls

- 3) Memo to AAU Presidents and Chancellors
 - What does your institution already do?
 - What responsibilities do faculty have?
 - What more can your institution do?
- 4) Editorial, Inside Higher Education, "We Must Have Both" August 5, 2019
- 5) Several national/regional meeting & briefings with more to come!

(e.g. Loyola Chicago, Sen. Warner/Rubio Roadshow, FBI Academic Summit)



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Valarie Bonham, JD





Managing Compliance Challenges Involving Global Collaborators

Association of Schools and Programs of Public Health Friday, October 11, 2019

Val Bonham (Valerie.Bonham (Va

Guidance for Faculty

- Recognize the news and changing landscape
- Communicate, communicate....
- Faculty need to understand:
 - Applicable disclosure requirements for reporting to school and to funder.
 - Philosophy of school, values, and commitments.

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.

Horizon Scanning

- 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.

Responding to U.S. Govt Agency Inquiries

- Potential deficiencies are identified through law enforcement referrals, complaints from co-workers or other scientists (including to Congress), 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 included.
- Risks include federal sanctions and reputational risks.

- 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).
 - Prohibition extends to considering such characteristics in making decisions about discipline or discharge.

 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.

- Examine:
 - Previous and current annual financial disclosures
 - Consulting
 - 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
- Interviews with named faculty will be necessary and may be difficult.

- Institutions may find that Investigators did not understand the need to disclose to the institution:
 - 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.

Corrective Actions & Communication

- Develop specific corrective actions for individual cases
- Review and update 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.

Contact Information

Questions?

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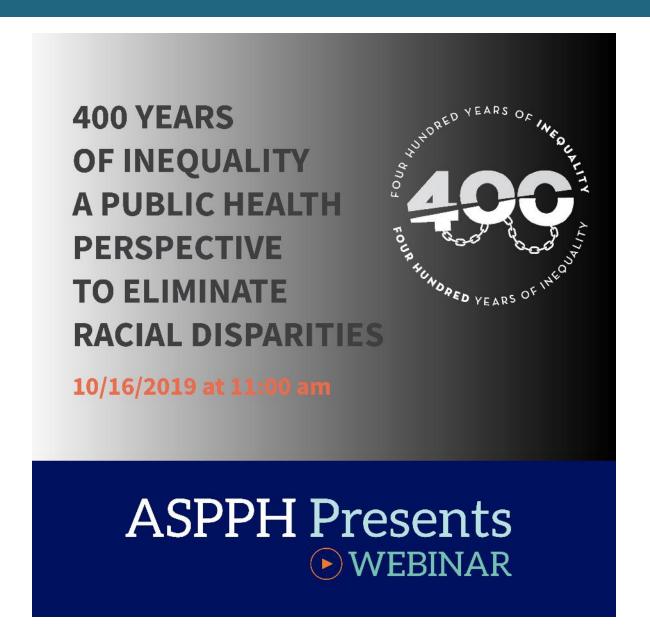


Michael Lauer, MD NIH

Toby SmithAAU

Valarie Bonham, JD Rope & Gray

Coming Attractions



Coming Attractions



https://www.aspph.org/event/2020ugphsummit/



MARCH 20

https://www.aspph.org/event/2020annualmeeting/

Thank You!

This webinar has been recorded and will be available on the webinar event page on the ASPPH website soon:

https://www.aspph.org/event/aspph-presents-webinar-managing-compliance-challenges-involving-global-collaborators/

Contact: advocacy@aspph.org

