Protecting US Science From Undue Foreign Influence
The NIH Experience

Jodi B Black, PhD
Deputy Director, Office of Extramural Research
National Institutes of Health

APLU Annual Conference
San Diego, CA
11.11.2019
As a fellow researcher … I know firsthand that the open and internationally collaborative nature of the U.S. research enterprise has been critical to our success in research, … has underpinned our Nation’s prosperity and security … the values we cherish, … the freedom to explore new frontiers, the open sharing of methods and results, … and the passion to work with and improve the lives of others. By adhering to these values and operating with honesty, integrity, excellence and transparency, your work has made America the world leader in science and technology.

The Nation is indebted to you.
some nations have exhibited efforts to exploit, influence, and undermine our research activities and environments. Features of some talent programs are unacceptable and inconsistent with our research values. These activities prevent the allocation of Federal funding in a fair manner based on merit. Undermines the integrity of the research enterprise. Others reap the substantial benefits of your hard work.
The inclusion of international scholars at U.S. colleges and universities entails both substantial benefit---and notable risk.
NIH letter of August 18, 2019: “The Scientists whose work NIH is proud to help support come from all over this country and the world, bringing rich, diverse perspectives and backgrounds to the biomedical research enterprise.”

State Department: Last summer the U.S. government determined that it was in our interest to renew our bilateral framework S&T agreement with China, with increased oversight and scrutiny
1) failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds;

2) diversion of proprietary information included in grant applications or produced by NIH-supported biomedical research to other entities, including other countries; and

3) failure by some peer reviewers to keep information in grant applications confidential; including, in some instances, disclosure to foreign entities or other attempts to influence funding decisions.
What We’ve Seen

• Shadow laboratories; undisclosed employment and grant research support
• Undisclosed FCOI
• Peer review breaches
WHAT IS CHINA’S THOUSAND TALENTS PLAN?

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

By He Peng Jia

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

https://www.nature.com/articles/d41586-018-00538-z
Nature January 17, 2018
“China’s most systematic channel for identifying foreign-based 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.”
Undisclosed Foreign Employment Agreements

• 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
• Chinese institution primary affiliation in publications
• Creates conflicts of commitment (>100% effort), interest
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.

https://inewsourcing.org/2019/07/06/thousand-talents-program-china-fbi-kang-zhang-ucsd/
LETTER

doi:10.1038/nature14650

Lanosterol reverses protein aggregation in cataracts

Ling Zhao1,2,3,4,†, Xiang-Jun Chen1,4, He Zhu3,5,*, Yi-Bo Xi4,*, Xu Yang6,*, Li-Dan Hu4,*, Hong Ouyang7,3, Sherrina H. Patel1, Xin Jin6, Dannii Lin6, Frances Wu6, Ken Flagg1, Huimin Cai1,2, Gen Li1, Guiquan Cao1, Ying Lin1,2, Daniel Chen1, Cindy Wen6, Christopher Chung3, Yandong Wang6, Austin Qiu3,4, Emily Yeh1, Wenqiu Wang6,9, Xun Han2, Scanna Grob3, Ruben Abagyani10, Zhiguang Su1, Harry Christiano Tjondro1, Xi-Juan Zhao4, Hongrong Luo1, Rui Hou1, J. Jefferson P. Perry11, Weivei Gao5,12, Igor Kozak13, David Granet1, Yingrui Li6, Xiaodong Sun6, Jun Wang6, Liangfang Zhang1,12, Yizhi Liu4, Yong-Bin Yan6,6 & Kang Zhang1,2,3,12,14,15

1Molecular Medicine Research Center, State Key Laboratory of Biotherapy, West China Hospital, Sichuan University, Chengdu 610041, China.
2Guangzhou KangRui Biological Pharmaceutical Technology Company, Guangzhou 510005, China.
3Department of Ophthalmology, National Eye Institute, National Institutes of Health, Bethesda, MD 20892, USA.
4School of Life Sciences, Shanghai Jiao Tong University, Shanghai 200240, China.
5Department of Molecular Biology, Harvard Medical School, Boston, MA 02115, USA.
6Department of Pharmacology, University of California, San Diego, La Jolla, CA 92037, USA.
7Department of Ophthalmology, Harvard Medical School, Boston, MA 02115, USA.
8Department of Ophthalmology, Massachusetts Eye and Ear, Harvard Medical School, Boston, MA 02114, USA.
9Institute of Pharmacology, Sun Yat-Sen University, Guangzhou 510005, China.
10Department of Ophthalmology, Massachusetts Eye and Ear, Harvard Medical School, Boston, MA 02114, USA.
11Department of Ophthalmology, Harvard Medical School, Boston, MA 02115, USA.
12Institute of Pharmacology, Sun Yat-Sen University, Guangzhou 510005, China.
13Department of Ophthalmology, Massachusetts Eye and Ear, Harvard Medical School, Boston, MA 02114, USA.
14Department of Ophthalmology, Massachusetts Eye and Ear, Harvard Medical School, Boston, MA 02114, USA.
15Institute of Pharmacology, Sun Yat-Sen University, Guangzhou 510005, China.

Author Information Reprints and permissions information is available at www.nature.com/reprints. The authors declare no competing financial interests. Readers are welcome to comment on the online version of the paper. Correspondence and requests for materials should be addressed to K.Z. (kang.zhang@gmail.com), Y.-B.Y. (ybyan@tsinghua.edu.cn), Y.Z.L. (yzliu62@yahoo.com) or L.Zhang (zhang@ucsd.edu).
UCSD Doctor Resigns After inewssource Raised Questions About His China Business Ties And More Local News

San Diego News Matters / July 8, 2019
Peer Review Breach

Thousand Talents Member NIH Peer Reviewer

Different NIH Peer Reviewer same Study Section

Confidential Information

Favored PI

Attempted Influence
Another Kind of Peer Review Breach

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.
Bottom Line: It Boils Down to Theft

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.
Types of Theft

• Employee theft – not clean legitimate recruitments
  – Undisclosed outside employment contracts
  – Excessive time away “on company time”
  – Working for a competing employer “on company time”
• Theft from the public – distorted NIH funding decisions
• Theft of data, documents, know-how, identical applications
• Undisclosed COI – theft of proprietary information, “ip”
• Undisclosed FCOI – royalties, economic development theft
• Peer review breaches – theft of nascent ideas
Other Preliminary Observations

- At least 120 scientists, not all ethnically Chinese
- 70+ institutions, many fields of biomedicine, all over US
- Nearly all in pre-clinical research
- Denials in spite of documents to the contrary
- Other explanations:
  - “I allowed XXX to use my name as PI”
  - “I knew nothing about this grant…”
  - “I didn’t actually do the work…”
NIH and the U.S. biomedical research community at large have a vested interest in mitigating these unacceptable breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research.

1) improve accurate reporting of all sources of research support, financial interests, and affiliations;
2) mitigate the risk to intellectual property security while continuing NIH’s long tradition of collaborations, including foreign scientists and institutions; and
3) explore additional steps to protect the integrity of peer review.

Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director, NIH
Growing Institutional Awareness

International Relationships and Activities

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)

https://www.research.psu.edu/international_affiliations
“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.”
Actions Taken by Universities to Address Growing Concerns about Security Threats and Undue Foreign Influence on Campus

*Updated - April 22, 2019*

AAU and APLU are identifying and sharing practices that universities are employing to ensure the security of research, protect against intellectual property theft and academic espionage, and prevent actions or activities by foreign governments and/or other entities that seek to exert undue foreign influence or which infringe on core academic values (e.g. free speech, scientific integrity, etc.).
• For NIH, a new type of threat
• Failure to disclose: COI, FCOI, and CoC
  – Distorts funding decisions, contributes to hypercompetitive funding environment
• Extensive institutional outreach has yielded results
• Working closely with other agencies and stakeholders towards harmonized disclosure requirements
• Together, there is much more to do and learn
• 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