### Foreign Influences on Research Integrity: NIH Experience

Michael S Lauer MD NIH Deputy Director for Extramural Research

14<sup>th</sup> Joint Meeting of the Board of Scientific Advisors and the National Cancer Advisory Board December 3, 2019 (11:00 AM) National Cancer Institute, Shady Grove Campus, Terrace Level, Room TE 406

**Disclosures: None** 

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### **Breaking Stories in April, November 2019: Three Problems**



#### MD ANDERSON RESEARCHERS OUSTED AS NIH AND FBI TARGET DIVERSION OF INTELLECTUAL PROPERTY

By Paul Goldberg



IN F.B.I.'S SIGHTS: STOLEN RESEARCH FLOWING TO CHINA

FEAR AMONG SCIENTISTS

Nearly 200 Investigations Underway at Major Academic Centers

#### By GINA KOLATA

The scientist at M.D. Anderson Cancer Center in Houston was hardly discreet. "Here is the bones and meet of what you want," he wrote in a misspelled email to researchers in China.

- Shadow laboratories; Thousand Talents; foreign grants
- Undisclosed FCOI
- Peer review breaches

Cancer Letter, April 26, 2019 New York Times, November 4, 2019

National Institutes of Health Office of Extramural Research

# Shadow Laboratories; Undisclosed Chinese Employment and Grant Research Support



Not Even Two Years Ago



# 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



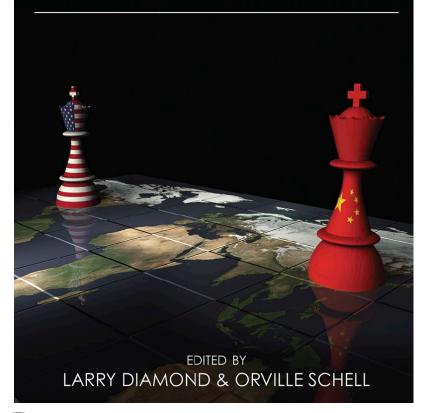
- "To apply, you must already have a firm job offer from a Chinese institution ...
- The scheme is open to Chinese scientists under 55 years of age, and foreigners younger than 65. All applicants must have worked at renowned universities outside China
- All applications to the Thousand Talents scheme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

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



# China's Influence & American Interests

PROMOTING CONSTRUCTIVE VIGILANCE

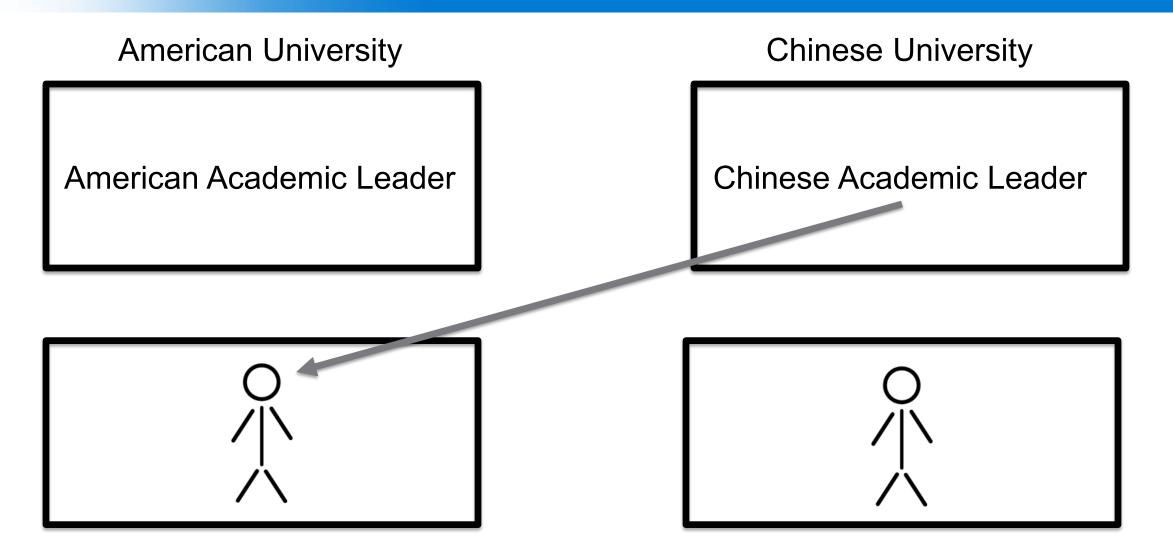


"China's most systematic channel for identifying foreignbased non-traditional collectors is its ... Thousand Talents Program (TTP) ... aims to recruit leading overseas scientists ... Official Chinese TTP websites list more than three hundred US government researchers and more than six hundred US corporate 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



### An "Obvious" Question: What is a Recruitment?

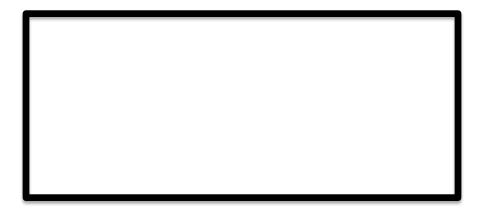




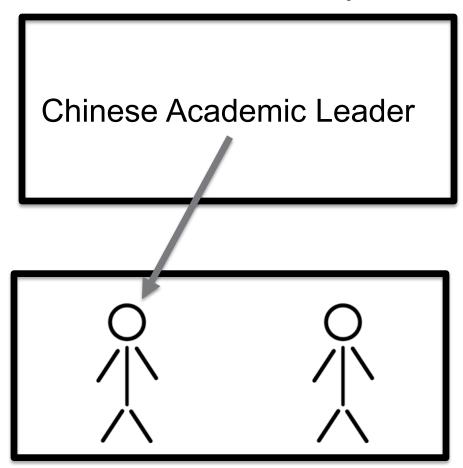
### **Reminder: Clean Recruitment**

### American University

### American Academic Leader

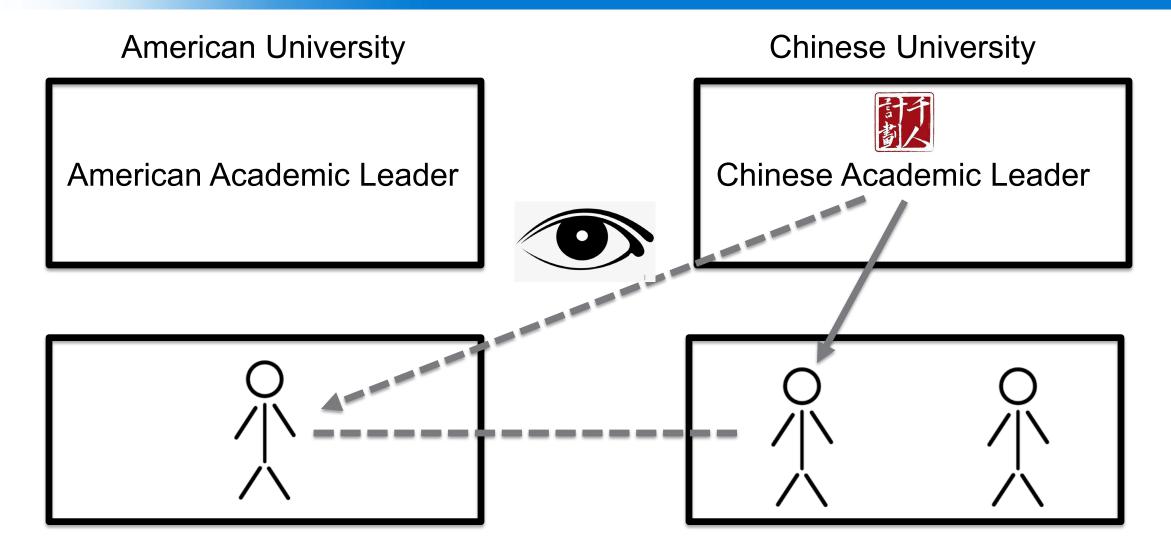


### **Chinese University**





### **Talents Recruitment**





- Time commitment sometimes full-time
- Substantial funding for research (including start-up funds)
- Laboratory, equipment, personnel
- Signing bonus, salary, housing, other benefits
- Deliverables: papers, patents/IP, training / personnel
- Creates conflicts of commitment (>100% effort), interest



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

Supported by the National Natural Science Foundation of China (grants XXXXXXX, YYYYYYY) and NIH grants ...

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



### **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



# Undisclosed Financial Conflicts of Interest



# 广州康睿生物医药科技股份有限公司

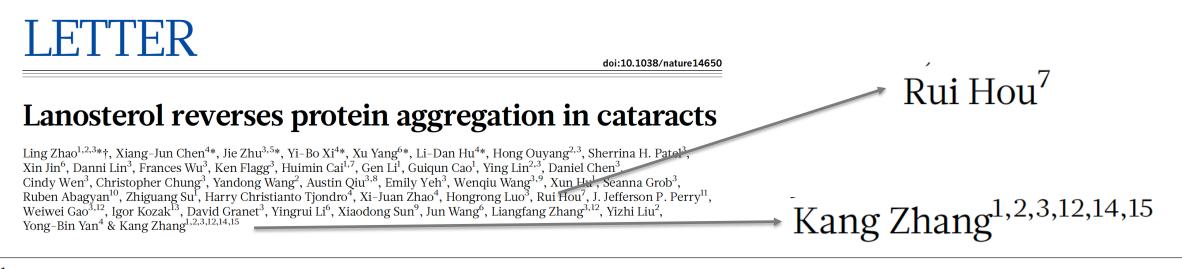
# GuangZhou KangRui Biological Pharmaceutical

### Technology Co., Ltd.



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





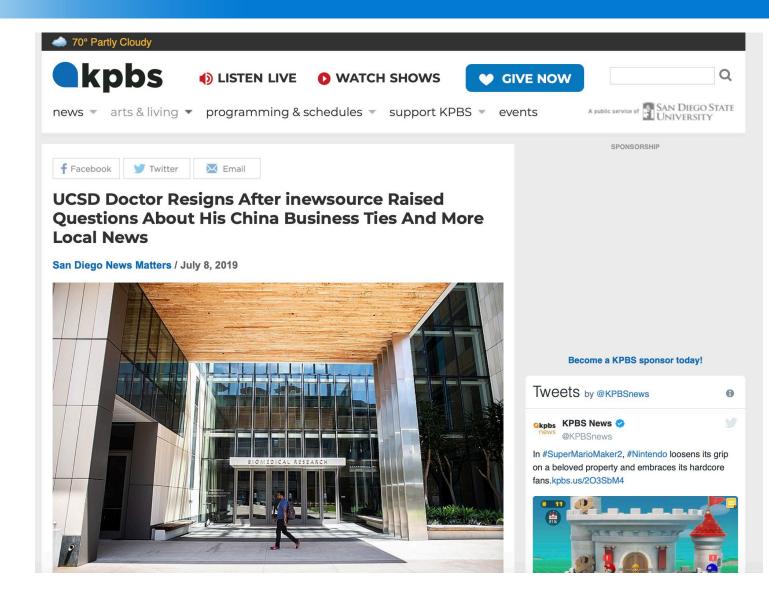
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### **Outcome to Date**





# **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."

Cancer Letter, April 26, 2019



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.

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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

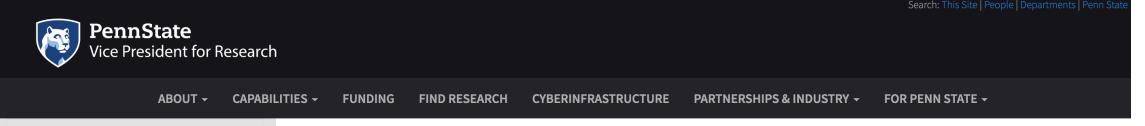
- Employee theft not clean legitimate recruitments
  - Undisclosed outside employment contracts
  - Working for a competing employer "on company time"
- Theft from the public distorted NIH funding
- Theft of data, documents, know-how
- Undisclosed COI theft of proprietary information, "ip"
- Peer review breaches theft of nascent ideas



- 70+ institutions, mostly pre-clinical research, all over US
- Denials despite documents to the contrary; explanations
  - "I allowed XXX to use my name as PI / on the grant"
  - "I knew nothing about this grant..."
  - "I didn't actually do the work..."
  - "The affiliations [in published papers] were in error ..."
  - "It was just honorary ..."



### **Growing Institutional Awareness**



#### 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)**



https://www.research.psu.edu/international affiliations



### **National Awareness**

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- "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
  - 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

