Foreign Influence on Research Integrity

*presented by* Research Business Operations (RBO)

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Agenda

• Introduction
  • Event Timeline & Context
  • General Findings
• Foreign Influence
  • What is it?
  • How does it occur?
• Case Studies
• Actionable Steps
  • 4 Key Action Areas
• Solutioning
  • Examples
• Q&A
Weill Cornell Medicine

Timeline & Context
Understanding the Landscape
Foreign Influence Overview

August 2018
- "Dear Colleagues" Letter

Aug
- Director's Statement on Protecting the Integrity of US Biomedical Research

Aug
- Advisory Committee to the Director (ACD) formed a work group

December 2018
- ACD publishes findings & recommendations*

February 2019
- NIH communicates PI specific concerns to institutions
- (approx. 180 letters)

Feb
- Institutions research, review and respond to inquiries
Foreign Influence Overview

Feb

- PI's awards are placed on hold or terminated, funds are reimbursed to NIH, and in some cases more serious charges are brought

March 2019

- CU President Martha Pollack publishes an opinion piece on Undue Foreign Influence

Mar

- Dozens of News Articles Published

June 2019

- CU publishes a message to Research Faculty on Academic Integrity and Undue Foreign Influence

June

- Council on Government Relations (COGR) publishes summary of the history of Foreign Influence

June

- NIH publishes FAQs on Other Support and Foreign Components Revised July 23, 2019
Foreign Influence Overview

July 2019
- Association of American Medical Colleges (AAMC) publishes memo on Undue Foreign Influence

July 2019
- NIH publishes revisions to FAQs on Other Support and Foreign Components

July
- NOT-OD-19-114 “Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components”

July
- Forum on Conflict of Interest (FOCI) publishes a statement in response to "Open Mike" and inclusions in Other Support saying concerns will be reviewed

July
- Michael Lauer, Deputy Director for Extramural Research, posts NIH “Open Mike” Clarifying Long-Standing NIH Policies on Disclosing Other Support

July
- Bringing us to today
Undue Foreign Influence on Research

Federal Findings

1. Diversion of intellectual property (IP) in grant applications or produced by NIH supported biomedical research to other entities, including other countries;

2. Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and

3. Failure by some researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from other organizations, including foreign governments.
Deemed Export Controls: Releases of controlled technology to foreign persons (Non U.S. Nationals) in the U.S. are "deemed" to be an export to the person's country or countries of nationality.
Undue Foreign Influence ("What?")

- How pervasive is it?
- How do we protect our federal funding?
- How do we protect intellectual property?

Action steps

- Disclosures
  - Sponsored Research
  - NIH/OSRA
- Disclosures
  - Financial Conflict of Interest (FCOI, COI)
- Controls
  - Lab Data Integrity Security Measures
NIH Methodology
Pathway to Discovery
Pathway to Discovery
Pubmed and Research Performance Progress Reports

How did the NIH discover undisclosed resources and undue foreign influence?

1. Review of NIH supported publications meta-data included in annual reports (RPPRs)
2. Observation and reports of excessive foreign travel (doesn’t pass the “reasonable” test)
3. Other forms of direct investigation by federal agencies (F.B.I.)
Pathway to Discovery
Pubmed and Research Performance Progress Reports

How did the NIH discover undisclosed resources and foreign influence?

1. Crosschecked all reported publication authors against grant application and subsequent reports
   - Discovery of previously unmentioned/unexplained international authors and international entity credit

2. Review last author information – i.e. institutional credit and compare to Biosketch & Other Support
   - Discovery of unreported International Affiliations and Appointments (with or without financial benefits)

3. Crosscheck grant support on reported publications and find grants not listed on Key Personnel “Ongoing Support” or “JIT-Other Support”
   - Discovery of unreported international grants
PubMed Meta Data and RPPRs

Oncogenic KRAS Reduces Expression of FGF21 in Acinar Cells to Promote Pancreatic Tumorigenesis in Mice on a High-Fat Diet.


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Abstract

BACKGROUND & AIMS: Obesity is a risk factor for pancreatic cancer. In mice, a high-fat diet (HFD) and expression of oncogenic KRAS lead

International Author and International Entity Information, not explained in application or annual progress report as a Foreign Component, may be flagged and investigated.
PubMed Meta Data and RPPRs

PI (Last Author) credits an International Entity in Author Information Section, that is not disclosed in Bio-sketch (Section B), or as a Foreign Component, may be flagged and investigated. The entity relationship must also be disclosed in COI Survey.

Abstract
BACKGROUND & AIMS: Obesity is a risk factor for pancreatic cancer. In mice, a high-fat diet (HFD) and expression of oncogenic KRAS lead
NIH investigates an international grant that has not been previously disclosed on key personnel JIT-Other Support, identifies the PI, flags and investigates. Multiple infractions: 1. It is the PI’s grant and is not included in Other Support. 2. It is an undisclosed grant belonging to other KP (same concerns). 3. The grant supports another author – foreign or domestic – which may equate to an undisclosed foreign component or foreign influence.
Case Studies
Case #1: Independent R01

NIH Concerns

- PI reports international authors and credits their foreign affiliated entities on NIH supported publications
  i.e. may be an **undisclosed** Foreign Component
- PI has **undisclosed** foreign affiliations and appointments
- PI (or KP) has **undisclosed** international grants
- PI (or KP) is/was participating in an **undisclosed** International Talent Program (*discovered via anonymous reports and F.B.I. investigation*)

Consequences

PI’s grants placed on hold

Inquiry began in February and concluded in September
Case #2: R01 Multi-PI, Multi-Institution

NIH Concerns
- PI at a peer institution reports international authors and affiliations credited on NIH supported publications reported in their annual progress report
  i.e. may be an undisclosed Foreign Component

Consequences
- The NIH froze the grants while investigating
- PI’s at other institutions, including the Contact PI were not provided with any notification or information
  The inquiry was ongoing from February through August and required a change of PI
Next Steps
What Do I need to Do?
What Do I Need to Do (NIH Standard)?

1. Faculty & PI Disclosures
2. Foreign Nationals
3. NIH & Foreign Components
3.a NIH Supported Publications
Area 1: Faculty & PI Disclosures
Most Frequently Overlooked

Disclosure of International Resources
1. International Appointments & Affiliations (research, teaching)
2. International Grants & Other Direct Research Support
3. International Talent Programs
   • Paid/unpaid all must be reported in either JIT-Other Support, Bio-sketches (Section B) and on COI Surveys as appropriate

Questions for faculty:
1. Have I disclosed all international relationships (paid/unpaid) on my COI Survey?
2. Have I disclosed all international appointments & affiliations (paid/unpaid) in Section B of my Bio-sketch (NIH) and on my COI Survey?
3. Have I disclosed all international grants, in-kind resources, and Talent Program participation on my COI Survey and JIT-Other Support pages?
4. Have all faculty and lab staff in my Department, Center or Institute done the same?
Area 2: Foreign Nationals
Most Frequently Overlooked

NIH Grants & Foreign Nationals

1. **Complete a Foreign National - Visitor Entrance Survey**
   - Available now through OSRA, and soon through other offices (Immigration, CMO, etc.)

2. **Complete a Conflict of Interest Survey (COI-S)**
   - If present in lab 45 day or more

3. **Report Foreign Nationals in NIH Funded Labs**
   - **New Submissions**: Report to NIH in Other Project Info Form G.220 (6, 6.a, 6.b & 12), include in budget; **Progress reports**: Section D Participants (RPPRs)

4. **Determine if Constitutes a Foreign Component**
   - Is participation 100% domestic or does it extend into foreign activities (NIH standard)?

Questions about Foreign Nationals visiting/working in labs:

1. Have all Foreign Nationals in my Lab (paid/unpaid) completed a Visitor Entrance Survey?
2. Have all Foreign Nationals in my Lab (paid/unpaid) completed a COI Survey (if 45 days+ in lab)?
3. Has the presence and participation of Foreign Nationals in my lab been reported on NIH applications and progress reports? Applies even if the person is not working on an NIH grant.
Area 3: Foreign Components & NIH Grants
Most Frequently Overlooked

Could it be a Foreign Component?
1. International Author Credit (✔)
2. International Author Affiliation or Entity Credit (✔)
3. Foreign Nationals Present in NIH Funded Labs (✔)
4. Receipt of/Transfer to Mice Models with Another Country (✔)
5. Participation in International Talent Programs (✔)

• All of these are less obvious potential Foreign Components (or doorways to Foreign Influence) that require disclosure/explanation to the NIH

Question:
1. Have I explained all foreign components (or potential doorways to foreign influence) on my grant applications, progress reports and JIT-Other Support?
Area 4: NIH Funded Publications
Most Frequently Overlooked

NIH Supported Publications
Could it be a Foreign Component?
1. International Author Credit (√)
2. International Author Affiliation or Entity Credit (√)
3. International Grant Support Credit (√)

• The presence of International Authors, Entities, Affiliations and Grant support in PubMed on NIH supported publications must have been disclosed/explained to the NIH in advance for prior approval
• The NIH position is that these inclusions are foreign components, and that it is the PI’s responsibility to prove that they are not

Question:
1. Have I disclosed and explained all International Authors, International Author Affiliations/Entities and International Grant support that will appear on my NIH supported publications?
Recommendations
Applications and Progress Report Examples
Example – New Application

Dr. [Redacted] is a Foreign National
• Sponsored/funded by a University in China
• Status: Visiting Scientist
• Will train in WCM lab for 1 year
• Will work on an NIH grant in WCM Lab
• Will receive author credit on publications
• Affiliated institution on publications will be WCM

New NIH Application
• Complete R&R G.220 Other Project Info Form
  • Question 6: Is there a Foreign Component? Yes.
  • 6.a: List Countries. China.
  • 6.b: Optional explanation with 55 character limit.
  • G.12: Mandatory Foreign Component Justification Document Upload (see next slide)
Example – New Applications
Example – New Applications

Foreign justification Upload

China

The proposed work will be carried out in part by a visiting scholar from Harbin Medical University in China. She is presently an Attending Physician at the Fourth Affiliated Hospital of Harbin U. She has research experience in cardiovascular cell biology and was awarded a Ph.D. from Harbin. Dr. Zhang has obtained funds to support one year in the U.S. to broaden her research skills, and hopes to extend her stay for a second year.

will receive training in necessary techniques in our laboratory, and then will pursue an independent project related to the project proposed in this application. The work will be carried out entirely at Weill-Cornell Medical College in New York. Harbin Medical University will fund her stay but is not a collaborating site. If publications arise from the work done by Dr. Zhang she will be credited as a co-author but her affiliation will be Weill-Cornell. Harbin Medical University will be listed as her permanent address.

No materials will be transferred between Harbin and Weill Cornell.
Example – New Applications

Include externally sponsored Non U.S. National in budget
Example – Annual Progress Report

Daisy is a Foreign National
• Sponsored/funded by University in China
• Status: Visiting Scientist
• Will train in WCM lab for 1 year
• Will work on an NIH grant in WCM lab
• Will receive author credit on publications
• Affiliated institution on publications will be WCM

Research Performance Progress Report (RPPR)
• Complete Sections G.9: Foreign Component, and Section D: Participants
• Add a previously undisclosed foreign component; add participant

Interim Reporting: prepare an NIH request for prior approval and submit it to OSRA. Include: Name of Individual, Name of Organization/Entity, Scope of Work, and a Justification detailing why the work is best performed outside the U.S. Submit to OSRA for review and counter-signature, and OSRA will submit to the NIH.
G.9 Foreign Component

“Foreign component” is defined as significant scientific activity that was performed outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds were expended. The following grant-related activities are significant and must be reported:

- involvement of human subjects or research with live vertebrate animals;
- extensive foreign travel by awardee project staff to collect data, or conduct surveys or sampling activities; or
- any awardee activity that may have an impact on U.S. foreign policy.

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

- collaborations with investigators at a foreign site anticipated to result in co-authorship;
- use of facilities or instrumentation at a foreign site, or
- receipt of financial support or resources from a foreign entity.

Foreign travel for consultation does not meet the definition of foreign component.

☐ No foreign component

or provide the organization name, country, and description of each foreign component

<table>
<thead>
<tr>
<th>Organization Name</th>
<th>Country</th>
<th>Please select a country</th>
</tr>
</thead>
</table>

Description of Foreign Component (Limit is 700 characters or approximately 1/4 of a page.)

Add/New | Clear
Annual Progress Report – Section D

D.1 What individuals have worked on the project?

Provide or update the following information for: (1) program director(s)/principal investigator(s) (PDs/Pis); and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours or 8.3% of annualized effort).

Provide the name and identify the role the person played in the project. Indicate the nearest whole person month (Calendar, Academic, Summer) that the individual worked on the project. Show the most senior role in which the person has worked on the project for any significant length of time. For example, if an undergraduate student graduates, enters graduate school, and continues to work on the project, show that person as a graduate student.

- Co-Investigator
- Faculty
- Postdoctoral (scholar, fellow or other postdoctoral position)
- Technician
- Staff Scientist (doctoral level) • Statistician
- Graduate Student (research assistant)
- Non-Student Research Assistant
- Undergraduate Student
- High School Student
- Consultant
- Other (specify)

eRA Commons User ID

First Name
Middle Name
Last Name
Senior/Key Personnel?
Yes
No
Degree(s)
Project Role
Please select a role
Other (Project Role)
Supplement Support (SS)
Not Applicable
Person Months
Calendar
Academic
Summer
Is the individual’s primary affiliation with a foreign organization?
Yes
No
Check “no” if the individual’s primary affiliation is with a foreign organization but the individual is working on this award solely while in the U.S.

Organization Name
Country
Please select a country
Add/New
Clear

List of Participants

Commons ID
S/K
Name
Degree(s)
Role
Person Months
Foreign Affiliation
SS
Action

Report externally sponsored Foreign Nationals in Section D: Participants even if they did not work on the grant. Project Role: “Other”, Describe “Visiting Intern”. Complete the rest of this section based upon where the work will be completed.
Example – New NIH Application

Materials from Japan
• WCM PI will receive genetically modified mice from Japan

New NIH Application
• Complete R&R G.220 Other Project Info Form
  • Question 6: Is there a Foreign Component? Yes.
  • 6.b: Optional explanation with 55 character limit.
  • G 12. Mandatory Foreign Component Justification Document Upload (see next slide)
Example – New Application

Foreign justification

Japan

A strain of genetically modified mice will be provided by Prof. [redacted] from the Tokyo Medical and Dental University in Japan. Dr. [redacted] will ship animals to us as part of a Materials Transfer Agreement. Animals will be bred at Weill-Cornell and all the experimental work will be done here. If publications come from this work Dr. [redacted] will be credited as a co-author for his role in providing this resource, and his affiliation will be listed as Tokyo Medical and Dental University.
Example – NIH Annual Progress Report

Materials from Japan
• The PI will receive genetically modified mice from Japan

Research Performance Progress Report (RPPR)
• Use the Add/New Button in Section G.9
  • Add a previously undisclosed foreign component

Interim Reporting: prepare an NIH request for prior approval and submit it to OSRA. Include: Faculty and Staff, Name of Organization/Entity, Scope of Work, and a Justification detailing why the work is best performed outside the U.S. ...Submit to OSRA for review and counter-signature, and OSRA will submit to the NIH.
Dean’s Memorandum July 18, 2019

- Provides methods by which to disclose new or previously undisclosed information
Duke University Case
A Cautionary Tale

Education or espionage? A Chinese student takes his homework home to China

Ruopeng Liu believes his work at a Duke lab was simply "fundamental research" that he brought back to China. His former professor thinks otherwise.

Q&A Discussion

• ?