Research Administration Platform for Innovation and Discussion

R.A.P.I.D.
Foreign Influence on Research Integrity
presented by R.A.P.I.D.

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Agenda

• Overview & Event Timeline
• General Findings
• Foreign Influence (what and how?)
• Cases
• Q&A – Guest Panel
• Fund to WBS
• Salute
Foreign Influence Overview

**August 2018**
- "Dear Colleagues" Letter

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

**August**
- Advisory Committee to the Director (ACD) formed a topical 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**
- NOT-OD-19-114 “Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components”

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

**July 2019**
- NIH publishes revisions to FAQs on Other Support 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**
- Bringing us to today
Undue Foreign Influence

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 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 this influence?
- How do we protect 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
Pathway to Discovery

How did the NIH discover undisclosed information 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
3. Other forms of direct investigation by federal agencies
Pathway to Discovery

How did the NIH discover undisclosed information and foreign influence?

1. Crosscheck authors against grant application and subsequent reports
   1. Unreported authors

2. Review author information – i.e. institutional credit and compare to Biosketch & Other Support
   1. Unreported Affiliations and Appointments (with financial benefits)

3. Crosscheck grant support and find grants not listed on any Key Personnel “On-Going Support” or “JIT - Other Support”
   1. Unreported grants
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...
Conflict of interest statement

The authors declare no competing financial interest.

Grant support

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Q&A – Case #1 – Independent R01

**NIH Concerns**

- PI has undisclosed international authors with credit to associated international affiliations
  
  *i.e. an undisclosed Foreign Component*

- PI has undisclosed international affiliations and appointments of his or her own

- PI has multiple undisclosed international grants

- PI is/was participating in an undisclosed Talent Program

**Consequences**

**PI’s grants placed on hold (indefinitely)**

*No determination timeline provided*
NIH Concerns

- PI at another institution has undisclosed international authors and affiliations credited
  i.e. an undisclosed Foreign Component

Consequences

- The NIH placed the award in a pending status while investigating the PI (no determination timeline)

- PI’s at other institutions were not provided with any notification about the grant being placed on hold or the reasons why
Provides methods by which to disclose previously undisclosed information
Q&A Discussion

- Adam Garriga, Chief Administrative Officer, Research
- Thomas Blair, Chief Research Compliance Officer
- Jim Kahn, Deputy University Counsel (UC)
- Brian Tschinkel, Chief Information Security Officer (ITS)
- Michele Fuortes, Assistant Professor (ITS)