Foreign Influence on Research Integrity

presented at Office of the Research Dean’s Research Leadership Meeting February 3, 2020

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Foreign Influence on Research Integrity

Today’s Presentation

• A continuation of our previous dialogue
• Responsive to your prior questions and remarks
• Reasonable and actionable steps
• Risk mitigation not cessation of activities

A balanced approach that respects WCM’s dedication to international collaboration, and an open platform for scientific exploration that continues to allow us to be highly responsive to global health challenges.
Foreign Influence on Research Integrity
Federal Government Concerns

What?
- Intellectual Property theft
- Conflict of Commitment (time)
- Financial Conflict of Interest (FCOI)

Results?
- 180 faculty recommended for debarment by the FBI
- Dozens of active criminal litigation cases
- Federal funds frozen, terminated or returned to the NIH
- Faculty terminations at academic medical centers
Foreign Influence on Research Integrity
Four Areas of Focus

1. Foreign National Visitor Compliance
2. Foreign Grant Components
3. Faculty Disclosures
4. Data Theft Protections
Risk Mitigation
Compliance Plan
Foreign National Visitor Compliance
Foreign Influence on Research Integrity

Who is a Foreign National Visitor?

Key determinant
Is Foreign National on WCM payroll?
• If yes, focus on areas 2, 3 and 4
• If no, follow 5 Step Risk Mitigation Compliance Plan
Foreign Nationals Visitors (FNVs)

Who is excluded from the Visitor category?

For this discussion the Foreign Nationals below are not part of WCM’s Foreign National Visitor Compliance Plan. They are appropriately vetted employees.

- Appointed Faculty on Weill Cornell Medicine payroll
- Foreign Nationals holding a valid visa on WCM payroll (salary or stipend)
- Fellows funded by a foreign entity, funds are DEPOSITED with WCM &
  - Appointed as a Post Doc Associate by Office of Faculty Affairs
  - On WCM payroll (salary or stipend)
  - Hold a valid visa type per WCM HR-Immigration
- Pre and postdoc trainees appointed on federal training grants
- Pre and postdocs with federal fellowships (F30/31, F32)
- ACGME accredited Postdoc-Fellows and Residents (NYPH employees)
- Green card holders and non-U.S. Citizens that are U.S. Nationals
  - Persons born in American Samoa including Swains Island are U.S. Nationals (but not U.S. Citizens)
  - Persons born in US territories are U.S. Citizens

Use of the term employee in this context may differ from other WCM/HR contexts. In this context it is defined as a person receiving salary, wages or a stipend from WCM.
Foreign National Visitors (FNVs)

Who is included in the Visitor Category?

For this discussion these categories of FNVs are considered a foreign influence risk and are included in WCM’s Foreign National 5 Step Visitor Compliance Plan

- **Fellows** paid by a foreign entity, funds NOT DEPOSITED with WCM
  - MUST have letter of fiscal support and proof of bank deposit from foreign entity
  - MUST be appointed as a Visiting Fellow through the Office of Faculty Affairs
  - MUST hold a valid visa per WCM HR-Immigration

**Unpaid Foreign National Visitors**

- FNV on campus on a WCM Sponsored Visa, but not on WCM Payroll
  - Example: Exchange Program Participants
- FNV on campus not funded by a foreign entity or by WCM as a volunteer or intern with a WCM sponsored Visa
  - *NOT a Preferred Status not considered Best Practice*
  - MUST hold a valid visa type per WCM HR-Immigration
  - MUST complete WCM volunteer onboarding process

- **FNVs working, volunteering or interning in a lab while traveling on a U.S. Visitor’s Visa** is against federal law and WCM policy
Foreign National Visitor Compliance

I have a Foreign National Visitor participating in my lab. What are my responsibilities?

- Ensure they complete a Conflict of Interest Survey (COI-S)
- If present in lab 45 day or more
- Complete a Foreign National Visitor Survey on their behalf
- Available at: https://weillcornell.foreignnationalvisitorsurvey (10 minutes)
- Determine if FNV participation in lab constitutes a Foreign Grant Component
- Reporting on grants differs based on Foreign Component determination
- Report Foreign National Visitors in federally funded labs to sponsors
- For non-federal sponsors follow sponsor specific guidance
- Employ Data Theft Protection Measures
- Complete ITS High Risk Attestation Survey: https://attest.weill.cornell.edu

Questions for faculty regarding Foreign National Visitor compliance in labs:

1. Have Foreign National Visitors in my lab completed a COI Survey (if 45 days+ in lab)?
2. Have Foreign National Visitors in my lab completed a Foreign National Visitor Survey?
3. Has the participation of Foreign National Visitors in my lab been reported to sponsors on applications and progress reports?
5 Step Risk Mitigation Compliance Plan

1. Conflicts of Interest Survey
2. Foreign National Visitor Survey
3. Foreign Component Determination
4. Disclosure in Applications & Progress Reports
5. Data Theft Protections & High Risk Attestation Survey

Foreign National Visitor Compliance
FNVs and Foreign Grant Components

When does the participation of a Foreign National Visitor in my lab constitute a Foreign Grant Component?

- When a FNV will perform any of the project work in a foreign nation
- When a FNV will receive author credit on an NIH supported publication and list their foreign institution as an affiliation
  - If WCM is the only affiliation that will be listed on publications as it relates to the FNV – no indication of a foreign component is required

Questions for faculty about Foreign Nationals Visitors and their role in foreign grant components?

1. Will a FNV perform project work outside of WCM in a foreign nation?
2. Will a FNV’s foreign entity affiliation receive author credit on an NIH funded publication?
Foreign Grant Components
Foreign Grant Components
Most Frequently Overlooked

Is it a foreign grant component?

- FNV’s foreign entity will receive author affiliation credit on an NIH supported publication in PubMed (✔)
- Any time you include a foreign author that lists a foreign entity as an affiliation on an NIH supported publication in PubMed (✔)
- Any time a foreign grant funding mechanism will be credited with contributing support to an NIH funded publication in PubMed (✔)
- Receipt of foreign materials (under an MTA) when the WCM PI will give foreign faculty or a foreign entity author credit (✔)

Question for faculty about foreign grant components:

1. Have I explained all foreign components (foreign relationships and touchpoints) in my grant applications and progress reports?
NIH Supported Publications and Foreign Components

The presence of 1. WCM Foreign National Visitor authors affiliated with a foreign entity, or 2. other foreign authors affiliated with a foreign entity, or 3. foreign grant funding mechanism credit in PubMed on NIH supported publications must be disclosed and explained to the NIH in grant applications and progress reports in advance of publishing.

The NIH’s position is that these constitute foreign components, and that it is the PI’s responsibility to prove that they are not.
Faculty Disclosures
Faculty Disclosures
Most Frequently Overlooked

Disclosure of Foreign Resources & Relationships
1. Appointments & Affiliations (research, teaching, etc.)
2. Participation in the Thousand Talents Programs (TTP)
3. Disclosure of foreign grants and other foreign support

Questions for faculty:
1. Have I disclosed ALL foreign appointments and affiliations (whether paid or unpaid) in Section B of my Bio-sketch (NIH) and, if paid, on my COI Survey?
2. Have I declared ALL foreign grant funding of which I am a recipient to OSRA (including direct awards from foreign governments, for example the Chinese National Science Foundation, as well as subawards on foreign grants)?
3. Have I disclosed ALL foreign grants on my Current Support or Just-in-Time-Other Support?
4. Have I disclosed Talent Program membership on my COI Survey and to my Authorized Organization Representative (AOR)?
5. Have I disclosed foreign relationships (paid/unpaid) to an authorized official for evaluation?
6. Have faculty and lab staff in my Department, Center or Institute disclosed the same?
Data Theft Protections
Data Theft Protections
Recommendations and Best Practices

• Set clear expectations for Visitors
  • Visiting faculty, post-docs, students, etc., should be provided with clear instructions regarding what they can and cannot do in your labs
  • This includes appropriate computer access
  • And the ability to copy and share data

• Manage physical access to labs
  • Limit physical access to lab via swipe access
  • Monitor swipe access logs to see
    • who is gaining access?
    • is it during appropriate times of the day?
Data Theft Protections
Recommendations & Best Practices

• Limit access to computers in labs
  • Limit administrative rights to appropriate users (restrict to read access only), which limits the ability to download/upload information
  • Keep computers in a secure area (locked office or drawer)
  • Control the ability to copy and share data
  • Ensure lab faculty, staff and visitors do not share passwords
  • Ensure lab faculty, staff and visitors log-on using their unique CWID (provides audit trail)

• Ensure all computers used by faculty, staff and visitors are tagged by ITS

• Do not allow personal computers and/or devices to be used in the lab
Data Theft Protections
Recommendations & Best Practices

- Ensure all faculty, staff and visitors complete the ITS high risk attestation survey found at: https://attest.weill.cornell.edu
- Do not allow personal email addresses to be used for WCM communication
  - Use a WCM provided email account
- Consider the use of encrypted external drives for lab computers and monitor who has access
- Consider limiting visitors from remotely logging into WCM systems
- Consider storing research data in WCM provided Box service
  - Box data storage is unlimited and controlled by use of a CWID and password
Foreign Influence Resources

For assistance with:

Conflicts of Interest disclosure
Conflicts Management Office (CMO)
Email: conflicts@med.cornell.edu
Link to Conflicts of Interest Survey:
  a. Log into WRG (https://wrg.weill.cornell.edu) with your CWID and password.
  b. Once in WRG, click on Conflicts of Interest.
  c. Click on Create Initial Conflicts Survey.
Contact: Thomas Blair, Chief Research Compliance Officer

Sponsored Research reporting
Office of Sponsored Research Administration (OSRA)
Email: grantsandcontracts@med.cornell.edu
Foreign National Visitor Survey: https://weillcornell.foreignnationalvisitorsurvey
Additional Resources: https://research.weill.cornell.edu/node/6381
Contact: Aleta Gunsul, Director, Sponsored Research Administration
Authorized Organization Representative (AOR)

Data Theft Protections consult
Information Technologies and Services (ITS)
High Risk Attestation Survey Link: https://attest.weill.cornell.edu
Contact: Brian Tschinkel, Chief Information Security Officer (ITS)
Questions and Discussion
Questions

• ?
Appendix: Grant Application and Progress Report Disclosure
Example FNV New Application

Dr. Z is a Foreign National Visitor

- 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
- Sponsoring entity will not receive author affiliation credit on NIH supported publications

This DOES NOT constitute a Foreign Component:

- Complete COI Survey (if in lab 45 days or longer)
- Complete Foreign National Visitor Survey
- Complete High Risk Attestation
- Include the FNV on budget at $0 and mark primary affiliation as foreign in the budget section of the submission
FNV & Foreign Grant Component

New Application Example

Dr. Z is a Foreign National Visitor

• 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 is foreign sponsoring entity

This DOES constitute a FNV Foreign Component:

Complete steps outlined on prior slide, and
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)
FNV & Foreign Grant Component
New Application Example cont.

Other Project Info

Text in PDF attachments must follow these minimum requirements:
- **Text color:** No restriction. Though not required, black or other high-contrast text colors are recommended since they print more clearly.
- **Font size:** must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible).
- **Type density:** must be no more than 15 characters per linear inch (including characters and spaces).
- **Line spacing:** must be no more than six lines per vertical inch.

Since some PDF converters may reduce font size, it is important to confirm that the final PDF document complies with the font size requirements (both serif and non-serif) are acceptable if they meet the above requirements.

- Arial
- Georgia
- Helvetica
- Palatino Linotype

Legibility is of paramount importance. Applications that include PDF attachments that do not conform to the minimum requirements will be penalized.

1. Are Human Subjects Involved? **Yes** **No** (see on Setup Questions tab)
2. Are Vertebrate Animals Used? **Yes** **No** (see on Setup Questions tab)
2.a. IF YES to Vertebrate Animals
   Is the IACUC review Pending? **Yes** **No**
   Animal Welfare Assurance Number: D16-00186
3. Is proprietary/privileged information included in the application? **Yes** **No**
4.a. Does this Project have an Actual or Potential Impact - positive or negative - on the environment? **Yes** **No**
5. Is the research performance site designated, or eligible to be designated, as a historic place? **Yes** **No**
6. Does this project involve activities outside of the United States or partnerships with international collaborators? **Yes** **No**
6.a. If yes, identify countries: China and Japan
6.b. Optional Explanation:
7. Project Summary/Abstract
8. Project Narrative
9. Bibliography & References Cited
10. Facilities & Other Resources
11. Equipment
12. Other Attachments

Weill C...
FNV & Foreign Grant Component

New Application Example

Foreign justification Upload

China

The proposed work will be carried out in part by Dr. Z, a visiting scholar from Medical University in China. S/he is presently an Attending Physician at the Fourth Affiliated Hospital of China U. S/he has research experience in cardiovascular cell biology and was awarded a Ph.D. from China U. Dr. Z 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.

Dr. Z 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. China Medical University will fund her stay but is not a collaborating site. If publications arise from the work done by Dr. Z she will be credited as a co-author and her affiliated entity will be the Medical University in China. China Medical University will be listed as her permanent address.
FNV & Foreign Grant Component

New Application Example

Include foreign funded Foreign National Visitor in budget.
FNV Annual Progress Report
Not a foreign component

Dr. Z 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

This DOES NOT constitute a Foreign Component:
- Complete COI Survey (if in lab 45 days or longer)
- Complete Foreign National Visitor Survey
- Complete High Risk Attestation
- Add as a participate in Section D of the RPPR
### 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.

#### Instructions
- An individual’s Commons user ID may be used to partially populate his or her information.
- A Commons ID is required for all individuals with a postdoctoral role and/or supported by a Reentry or Diversity Supplement.
- Individuals with a postdoctoral-like role should be identified as "Postdoctoral (scholar, fellow, or other postdoctoral position)."
- Do not include Other Significant Contributors who are not committing any specified measurable effort to this project.
- Do not report personnel for whom a FHS 2271 Appointment form has been submitted through xTRAIN.
- Required fields are marked with an *.

#### eRA Commons User ID
- Populate from Profile

**First Name** | **Middle Name** | **Last Name**
--- | --- | ---

**Degree(s)** | **Project Role** | **Supplement Support (SS)** | **Senior/Key Personnel**?
--- | --- | --- | ---

**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.

### List of Participants

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<th>S/K</th>
<th>Name</th>
<th>Degree(s)</th>
<th>Role</th>
<th>Person Months</th>
<th>Foreign Affiliation</th>
<th>SS</th>
<th>Action</th>
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**Organization Name** | **Country**
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Add/New | Clear

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**Weill Cornell Medicine**
Example FNV Annual Progress Report

Foreign Component

Dr. Z is a Foreign National Visitor

- 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 foreign affiliation

This DOES constitute a Foreign Component:

- Complete COI Survey (if in lab 45 days or longer)
- Complete Foreign National Visitor Survey
- Complete High Risk Attestation Survey

Research Performance Progress Report (RPPR)

- Complete Sections G.9: Foreign Component, and Section D: Participants
- Add a previously undisclosed foreign component; add participant
Annual Progress Report – Section G

Foreign Component cont.

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

Organization Name Country Please select a country

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

Total remaining allowed limit is 700 characters.

Add/New Clear
Annual Progress Report – Section D

Foreign Component cont.

### 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.

### Instructions

- An individual's Commons user ID may be used to partially populate his or her information.
- A Commons ID is required for all individuals with a postdoctoral role and/or supported by a Reentry or Diversity Supplement.
- Individuals with a postdoctoral-like role should be identified as "Postdoctoral (scholar, fellow, or other postdoctoral position)."
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<th>Supplement Support (SS)</th>
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<td>Please select a role</td>
<td>Not Applicable</td>
<td>Calendar □ Academic □ Summer □</td>
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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.

If yes, provide the name of the organization and country.

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Add/New | Clear

### List of Participants

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Example – New NIH Application
MTA as a Foreign Grant Component

Materials from Japan
• WCM PI will receive genetically modified mice from Japan
• Foreign faculty/entity will receive author credit and affiliation on NIH supported PubMed publication

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 NIH Application
MTA as a Foreign Grant Component

Foreign justification Example

Japan

A strain of genetically modified mice will be provided by Prof. S.U. from the Tokyo Medical and Dental University in Japan. Dr. S.U. will ship animals to WCM as part of a Material Transfer Agreement. Animals will be bred at Weill Cornell Medicine and all the experimental work will be done here. If publications come from this work Dr. S.U. will be credited as a co-author for his/her role in providing this resource, and his/her affiliation will be listed as Tokyo Medical and Dental University.
Example – NIH Annual Progress Report
MTA as a Foreign Grant Component cont.

Materials from Japan
• WCM PI will receive genetically modified mice from Japan
• Foreign faculty/entity will receive author credit and affiliation on NIH supported PubMed publication

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: Name of Faculty (responsible party), Name of Organization/Entity, Scope of Work, or materials supplied or other information. Submit to OSRA for review and counter-signature, and OSRA will submit to the NIH.
Annual Progress Report – Section G
MTA as a Foreign Grant Component cont.

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:

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- No foreign component

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

Organization Name

Country

Please select a country

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

Total remaining allowed limit is 700 characters.

Add/New

Clear