



Weill Cornell Medicine

Memorandum: Foreign Influence on Research Integrity

July 17, 2019

Context

Congress and the major federal funding agencies recently have taken action to publicize and protect against the potential for “foreign influence on research integrity” in research universities and academic medical centers.

These actions have been prompted by:

- Diversion of the intellectual property in grant applications, or produced by NIH-supported biomedical research, to other entities, including other countries
- Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities
- Failure by some researchers at NIH-funded institutions to disclose substantial resources from other organizations, including foreign governments

The National Institutes of Health, the Department of Energy, and the Department of Defense have all tightened policies and asked for detailed information about participation in federally funded research by foreign nationals, particularly those from China, Russia, Iran, Iraq, and Syria. The NIH has also stated that participation of *any* foreign person in an NIH-funded lab (even unpaid) could constitute a “foreign component” requiring disclosure

and NIH and State Department approval. What this means for students and post-doctoral fellows is still being clarified.

In response to recent developments, Weill Cornell Medicine is updating policies and procedures for ensuring comprehensive disclosures by our faculty and visitors in order to maintain compliance with NIH requirements.

Definition of Foreign Component

Foreign components as defined below require prior approval by the NIH and other federal granting agencies. It is important to remember that the NIH always has required disclosure of foreign components in connection with grant applications and support ([NOT-OD-19-114](#)).

NIH Grants Policy Statement (1.2 Definition of Terms)

Foreign component	<p>The performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are:</p> <ul style="list-style-type: none">• 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. <p>Foreign travel for consultation is not considered a foreign component. (See Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components chapter in IIB).</p>
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The presence of any foreign national within the United States, paid or unpaid, working in an NIH or other federally funded lab, or collaborating on NIH funded research in WCM labs on campus, or at WCM affiliated locations, may constitute a “foreign component” and in all cases requires NIH prior approval. Immediate disclosure to the NIH via the sponsored research office (OSRA) is required (unless the information has been fully disclosed in the initial application, or on annual progress reports (RPPRs)). Comprehensive guidance for where and how to disclose in NIH documents is located at the end of this memorandum.

Faculty and Visitor Disclosures

APPOINTMENTS AND AFFILIATIONS

What must I disclose?

All appointments and affiliations, worldwide, paid or unpaid, with a non-profit, for-profit, governmental, non-domestic institution of higher education, foreign entity, or other similar entity must be disclosed.

Where must I disclose?

This information must be disclosed, without exception, in your WCM Conflict of Interest Survey and on Bio-sketches in NIH applications in the section titled: **RESEARCH & RELATED Senior/Key Person Profile (Expanded)**, as well as in updated Bio-sketches requested by NIH, and other federal sponsors, at any time.

When must I disclose?

Initially, you must disclose within 30 days of employment with WCM on your COI Survey, and at the time of application on grant submissions.

Change in status after employment. You must disclose within 30 days from the date of your status change in your COI Survey, and in annual progress reports (RPPRs). In the case of a status change between NIH progress reports you must disclose to the NIH immediately through the Office of Sponsored Research Administration (OSRA).

OTHER SUPPORT

NIH Grants Policy Statement (1.2 Definition of Terms)

Other support	Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.
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What must I disclose?

All financial resources, worldwide, including funding and in-kind resources (i.e. access to the use of equipment, cores, etc.) at a non-profit, for-profit, governmental, non-domestic institution of higher education, foreign entity, or other similar entity must be disclosed.

Where must I disclose?

This information must be disclosed in your WCM Conflict of Interest Survey, and on “Other Research Pages” in grant applications, and on “Other Support pages” provided in “Just-in-Time” (JIT) requests subsequent to a sponsored research application.

When must I disclose?

Initially, you must disclose within 30 days of employment with WCM on your COI Survey, and in “Other Research Pages” in grant applications, and on “Other Support” pages provided in “Just-in-Time” (JIT) requests subsequent to a sponsored research application.

Change in status after employment. You must disclose within 30 days from the date of your status change in your COI Survey, as well as in the “Other Research Support” section in initial grant applications, upon requests for “Just-In-Time” (JIT) information, and in “Annual Progress Reports” (RPPRs). In the case of a status change between NIH progress reports you must disclose to the NIH immediately through the Office of Sponsored Research Administration (OSRA).

You and every member of your lab (wet or dry), including visiting professors, visiting post docs, fellows, and visiting students, volunteers and interns (paid or unpaid), who will be in the lab for a period longer than 45 days, must have completed a WCM Conflict of Interest Survey disclosing all sources of support including foreign support paid to you, or a member of your lab, in another country, before working in an NIH, or other federally funded, lab at WCM or any of its affiliates.

OTHER GRANT-RELATED ACTIVITIES THAT MAY BE SIGNIFICANT

Other grant-related activities that may be significant is a broad NIH category that requires close analysis of additional cases such as those listed below, and those not otherwise specified in NIH policy.

Examples include, but are not limited to:

- 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.

What must I disclose?

Example: Co-authorship

Applies to foreign nationals working in your lab, at any site on or off campus, that are affiliated with foreign entities and

- Will receive author credit on publications,
- Or if their associated foreign entity will be given research funding support credit (including in-kind support) on publications.

Cases such as these must be disclosed to, and receive prior approval from, the NIH and other federal granting agencies. This includes co-authorship where no funding is exchanged between or in support of authors at various sites foreign and domestic.

Examples: Visiting Scientist

Case No. 1

A visiting student, intern, post-doc, fellow, volunteer, or other, sponsored by their country, will be working in my NIH or other federally funded lab. Do I need to disclose this information to the NIH or other federal granting agencies?

Yes. Whether or not you intend the visiting scientist to work on projects or publications, this information must be disclosed to the NIH or other federal granting agencies prior to the visitor entering a lab (wet or dry), via the Office of Sponsored Research Administration (OSRA). Additionally, visitors who will be in the lab for a period longer than 45 days must complete a WCM Conflict of Interest Survey disclosing the source of their support, and any affiliations with foreign entities (paid or unpaid), and your lab (wet or dry) must be properly safeguarded to prohibit access to restricted data and materials.

Case No. 2

A visiting professor, sponsored by their country (or a foreign organization), will be working in my NIH, or other federally funded lab. Do I need to disclose this information to the NIH, or other federal granting agencies?

Yes, disclosure and prior approval is required in all cases and principally if the visiting professor will be:

- Working on your NIH or other federally funded research
- Named as key personnel
- An author on publications
- Have access to restricted data or materials

Where is Faculty and Visitor information disclosed?

Disclosure to the National Institutes of Health (NIH)

There are three locations to disclose information to the NIH: 1. New and Renewal Applications, 2. Annual Progress Reports (RPPRs), and 3. In-between Annual Progress Reports via the Office of Sponsored Research Administration (OSRA). The precise sections of these documents in which you must disclose are detailed below. For all other federal funding agencies contact OSRA for case-by-case guidance.

1. Disclosure of Foreign Components in New and Renewal NIH submissions:

Application Package Location: **Other Project Information page** (Form G.220: questions 6, 6a and 6b).

<p>6. Does this project involve activities outside of the United States or partnerships with international collaborators?</p>	<p>This field is required. Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check “Yes” or “No.”</p> <p>Applicants to NIH and other PHS agencies must check “Yes” if the applicant organization is a foreign institution or if the project includes a foreign component.</p> <p>See NIH Glossary for a definition of a foreign component.</p>
<p>12. Other Attachments</p>	<p>If you have checked “Yes” to Question 6, you must include a “Foreign Justification” attachment in Field 12, Other Attachments.</p> <p>Describe special resources or characteristics of the research project</p>

(e.g., human subjects, animals, disease, equipment, and techniques), including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting. In the body of the text, begin the section with a heading indicating "Foreign Justification" and name the file "Foreign Justification."

2. Disclosure of Foreign Components on NIH Progress Report (RPPR) submissions:

Section D – Participants

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.

D.1 What individuals have worked on the project?	Disclose paid and unpaid foreign nationals here.
Is the individual's primary affiliation with a foreign organization?	<p>Check "Yes" or "No."</p> <p>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.</p> <p>If Yes, provide the name of the organization and country. Select the Add/New button to add the data to the table.</p>

**Disclosure of Foreign Components on NIH Progress Report (RPPR) submissions:
Section E – Impact**

E.4 What dollar amount of the award's budget is being spent in foreign country(ies)?

For domestic awardees provide the dollar amount obligated to first-tier subawards to foreign entities for this reporting period. For foreign awardees provide the award, excluding all first-tier subawards to U.S. entities, for this reporting period. Dollars provided should reflect total costs.

If more than one foreign country, identify the distribution between the foreign countries. 

Nothing to Report(zero dollars)

or provide the following for each foreign country: Dollar Amount \$ Country Please select a Country ▼

E.4 What dollar amount of the award's budget is being spent in foreign country(ies)?

For domestic awardees provide the dollar amount obligated to first-tier subawards to foreign entities for this reporting period.

For foreign awardees provide the dollar amount of the award, excluding all first-tier subawards to U.S. entities, for this reporting period.

Dollars provided should reflect total costs.

**Disclosure of Foreign Components on NIH Progress Report (RPPR) submissions:
Section G – Special Reporting Requirements**

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.)

G.9 Foreign component.

Provide the organization name, country, and description of each 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;

	<p>extensive foreign travel by grantee project staff to collect data, or conduct surveys or sampling activities; or any grantee activity that may have an impact on U.S. foreign policy.</p> <p>Examples of other grant-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.</p>
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Other Federal Funding Agencies

For assistance with disclosing to other federal funding agencies contact your OSRA Grants Specialist or OSRA Authorized Official. Each non NIH case will be addressed on an individual basis.

Sincerely,

Augustine M.K. Choi, M.D.

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