The National Institutes of Health (NIH) and Foreign Influences on Research Integrity
A Guide to Navigating through NIH Policy and Procedure

Rev. 6/27/19
Introduction

The GCO released a series of email communications on the NIH and Foreign Influences on Research Integrity. This document contains all of the communications as follows:

1. NIH - Foreign Influences on Research Integrity
2. Helpful Hints #1 on Foreign Influence and Disclosure to the NIH - Acknowledging Support
3. Helpful Hints #2 on Foreign Influence and Disclosure to the NIH - Application Requirements
4. Helpful Hints #3 on Foreign Influence and Disclosure to the NIH - Biosketch
5. Helpful Hints #4 on Foreign Influence and Disclosure to the NIH - Travel
6. Helpful Hints #5 on Foreign Influence and Disclosure to the NIH - Other Support

We hope this helps the research community navigate through these complex processes designed to protect the integrity of federally-funded biomedical research.
Dear Faculty and Staff,

We are sharing with you the presentation slides from a teleconference entitled "NIH Inquiries into Foreign Affiliations, Research Support, and Award Components" presented by the law firm Ropes & Gray. Below are excerpts and adaptations from the teleconference.

In the past year, the National Institutes of Health ("NIH") has partnered with the Federal Bureau of Investigation ("FBI") to investigate possible foreign interference with the integrity of federally-funded biomedical research.

Depending on the severity and duration of the noncompliance, NIH may decide to take one or more actions, including imposing specific award conditions, disallowing costs, withholding future awards for the project or program, suspending the award activities, making a referral for suspension or debarment, terminating the award, or revoking or taking title to the inventions made with the Federal support and pursuing patent protection or licensing the invention itself.

Potential Deficiencies
NIH has identified potential deficiencies in institutions’ reporting of investigators’ interests to NIH by reviewing investigators’ publications in which there are disclosed both (1) NIH support and (2) foreign support, affiliations, or components, such as:

- Investigators’ dual appointments with foreign universities or institutes.
- Foreign grant support.
- Foreign components of supported projects (such as many foreign co-authors listed on publications of research supported by NIH).

Summary
NIH’s concerns are broader than disclosure failures, and include:

- Operating undisclosed “shadow labs” in foreign countries, creating plausible claim that work generating IP occurred outside the U.S.
- Theft of biomedical IP from confidential grant applications under review by NIH or from research supported by NIH.
- Breaking confidentiality of NIH peer review of grant applications to influence NIH award decisions.
- Disclosures are the area in which institutions’ own obligations under federal
funding requirements are most likely to be affected.

Action Plans
Please be reminded that investigators must disclose all forms of other support and financial interest, including support from foreign governments or other foreign entities. Please refer to the slides for additional important details.

1. Conflicts of Interest Disclosures
2. Other Support Disclosures
3. Obtaining NIH Prior Approval to Add a Foreign Component on an NIH grant.

Mount Sinai Contacts and Resources
Please contact the offices below with any questions you may have. Relevant policies and procedures are also included.

- **Conflicts of Interest (COI) Office**
  - Instructions for Completing the Financial Interests in Research Disclosure Form
  - Instructions for Completing the Annual Report of Outside Relationships
  - Message from Dean Charney re: Consulting and Other Paid Activities
  - Faculty Consulting - Attestation of Compliance Form

- **Grants and Contacts Office (GCO)**
  - NIH Other Support Instructions: Just in Time (JIT) Applications
  - NIH Other Support Instructions: Research Performance Progress Reports (RPPRs)
  - NIH Prior Approval Requirements

- **Mount Sinai Innovations Partners (MSIP)**
  - Intellectual Property Policies and Procedures

Thank you for your attention to this matter.

Sincerely,

Jessica Ruth Moise
Grants and Contracts Officer
Senior Associate Dean for Sponsored Programs
Dear Faculty and Staff,

Pursuant to the email communications that the GCO sent on 4/4/19 entitled “NIH - Foreign Influences on Research Integrity,” we are following up and providing more specific information on disclosing foreign affiliations and best practices.

This communication focuses on the proper acknowledgment of NIH support.

**Do Thank the NIH - Requirements for Acknowledging NIH-Supported Research**

Investigators must acknowledge support in the following publications and works funded *in whole or in part* with Federal money:

- research publications
- press releases and other public statements
- other publications or documents about research that is funded by NIH
- requests for proposals and bid invitations
- other documents describing projects or programs

For complete instructions on how to do so, please refer to the NIH web page “[Communicating and Acknowledging Federal Funding](http://www.nih.gov).” You may also wish to review this FAQ “Should I cite my NIH grant when I publish?”

**Do Not Thank the NIH - Pitfalls of Over Acknowledging**

Sometimes investigators would like to thank the NIH for their support *in general* and may disclose all the sources of support for his/her lab and/or all the sources of his/her salary in a publication. This is not appropriate. Only acknowledge support when the project is funded either completely or partially with Federal funds. Only acknowledge the grant(s) that supported the research described in the publication.

The investigator may also wish to include all sources of support in an effort to comply with a publication’s broad standards for disclosing financial interests. This is also not appropriate.

Over acknowledging support can lead to an NIH investigation of noncompliance of the following “false positive” activities:
• Undisclosed/Unapproved Foreign Involvement
• Undisclosed Scientific Overlap
• Undisclosed/Unapproved Change of Scope
• Undisclosed/Unapproved Human Subject or Vertebrate Animal Activity

In addition, acknowledging multiple awards in a publication may be taken as an indicator of scientific overlap among the cited projects. This becomes important when a Principal Investigator’s next competitive application is being considered by reviewers, Advisory Council members and NIH staff. 

Statement above adapted from “Why Is It important to Accurately Acknowledge NIGMS Grants in Publications?”

We plan on posting this communication series on foreign influence and disclosure to the NIH on the GCO webpage. In the meantime, if you need the original communications from 4/4/19, please do contact me.

Sincerely, Allison Gottlieb

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Dear Faculty and Staff,

Pursuant to the email communications that the GCO sent on 4/4/19 entitled “NIH - Foreign Influences on Research Integrity,” we are following up and providing more specific information on disclosing foreign affiliations and best practices.

Before we go into those details, we thought we’d share with you a timely article from Science Magazine on the NIH and foreign influences on research integrity.

**Why are the NIH and the FBI so concerned?**

During a hearing of a Senate panel that oversees the NIH budget, Senator Roy Blunt (R–MO), asked NIH Director Frances Collins “..about NIH’s ongoing efforts to ensure that grantees are complying with agency rules on disclosing foreign ties, protecting the confidentiality of peer review, and handling intellectual property. ‘Something that the research community needs to take more seriously,’ Blunt said in his opening remarks, is ‘that foreign governments are initiating systematic ways to influence our research and frankly to take advantage of our research by stealing it.’ Blunt mentioned China in particular, which he said has a ‘government program to recruit NIH-funded researchers’ to set up shadow labs in China and steal U.S. intellectual property and confidential grant information. ‘I think NIH has to be sure that the research community is fully aware of the threats and more importantly, how to combat those threats,’ Blunt said.” Click [here](#) for the full Science Magazine article.

This communications focuses on the NIH definition of foreign involvement and how to report foreign involvement on your NIH grant application and after your grant is underway. It does not replace the NIH application instructions so be sure to read those when completing.

**“If I don’t pay for it, does it actually happen?” What is Foreign Involvement?**

A common misconception is that foreign involvement only occurs when there is a subaward to a foreign institution. The actual definition (in section 1.2) from the NIH Grants Policy Statement (NIHGPS) is much broader:
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:

- 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.

**How do I report foreign involvement to the NIH?**

There are 3 ways to do.

1. Reporting in Competitive Grant Application
2. Reporting in Annual Research Performance Progress Report (RPPR)
3. Prior Approval Request

1. Reporting in Competitive Grant Application

   **Other Project Information Page**
   
   Whenever there is Foreign Involvement as defined above, question 6 in the Other Project Information Page must be answered “yes.”
   
   Depending on the type of foreign involvement, there are numerous other places where this information may also be disclosed.

   **Performance Sites Tab**
   The Project/Performance Site Location(s) Form is used for all grant applications. It is used to report the primary location and any other locations at which the project will be performed. Include foreign site/s if appropriate.

   **Senior/ Key Personnel Form**
   Unless otherwise specified in a FOA, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, **whether or not salaries are requested**. **Consultants should be included in this “Senior/Key Person Profile (Expanded)” Form if they meet this definition.** List individuals that meet the definition of
senior/key regardless of what organization they work for.

- **Budget tab**
  Subaward form, if appropriate.

- **Budget Justification**
  List all personnel whether paid or not salaries are requested.
  For non modular grants, explain foreign travel. Include the purpose, destination, dates of travel (if known), and the number of individuals for each trip. If the dates of travel are not known, specify the estimated length of trip (e.g., 3 days).

- **Research Plan > Consortium / Contractual (i.e, subawards) if appropriate**
  Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

- **Biosketches for Senior/ Key Personnel**, if appropriate
  We will review this section in detail in a future Helpful Hints on the topic. The NIH instructions are [here](#).

- **Progress Report Publication List**, if appropriate
  A “Progress Report Publication List” attachment is required only if the type of application is renewal. List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. The NIH instructions are [here](#).

2. Reporting in Annual Research Performance Progress Report (RPPR)

Please see the sections below. The NIH RPPR instructions are [here](#).

- **Special Reporting Requirements - Section G**

  G.9 Foreign component. Provide the organization name, country, and description of each foreign component.

  Depending on the type of foreign involvement there are numerous other places where this information may also be disclosed.

- **Products section - Section C**

  This section allows agencies to assess and report both publications and other products to Congress, communities of interest, and the public.

  C.1 – Publications
  Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph, preprint) during the reporting period resulting directly from the award?
• **Participants - Section D**
  This section allows the agency to know who has worked on the project to gauge and report performance in promoting partnerships and collaborations.
  
  D.1 What individuals have worked on the project?
  
  Provide or update the 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

  Is the individual’s primary affiliation with a foreign organization? Y/N

• **Impact - Section E**
  This section will be used to describe ways in which the work, findings, and specific products of the project have had an impact during this reporting period.

  E. 4 - What dollar amount of the award’s budget is being spent in foreign country(ies)? If more than one foreign country identify the distribution between the foreign countries.

• **Special Reporting Requirements - Section G**
  
  G.8 Project/Performance Sites.
  
  If there are changes to the project/performance site(s) displayed, edit as appropriate.

3. Prior Approval Request - What if foreign involvement was not included in the competitive NIH application or a subsequent RPPR and I’m adding later on?

  This prior approval request follows the standard process as explained in this GCO prior approval guidance document. The PI sends the request to the GCO and the GCO reviews and endorses it.

We plan on posting this communication series on foreign influence and disclosure to the NIH on the GCO webpage. In the meantime, if you need any former communications, please do contact me.

Sincerely, Allison Gottlieb

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PLEASE DO NOT REPLY DIRECTLY TO THIS MESSAGE.
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You are currently subscribed as: allison.gottlieb@mssm.edu. Visit the Research Portal Getting Started page and enter this email address under Research Listserv to update your subscription preferences at any time within the MSHS firewall.
Dear Faculty and Staff,

Pursuant to the email communications that the GCO sent on 4/4/19 entitled “NIH - Foreign Influences on Research Integrity”, we are following up and providing more specific information on disclosing foreign affiliations and best practices.

This third communications focuses on the NIH Biosketch, particularly the “Positions and Honors” section, section B.

The NIH Biosketch is submitted to the NIH for all senior/key personnel and other significant contributors in the competitive grant application. Biosketches are also included in the Research Performance Progress Report (RPPR) when there are new senior/key personnel and other significant contributors.

NIH Instructions - Positions and Honors – Section B

Complete instructions and sample biosketches can be found here.

List in chronological order the positions you've held that are relevant to this application, concluding with your present position. High school students and undergraduates may include any previous positions. For individuals who are not currently located at the applicant organization, include the expected position at the applicant organization and the expected start date.

List any relevant academic and professional achievements and honors. In particular:

- Students, postdoctorates, and junior faculty should include scholarships, traineeships, fellowships, and development awards, as applicable.
- Clinicians should include information on any clinical licensures and specialty board certifications that they have achieved.

GCO FAQs - Determining Which Positions and Honors to Include

FAQ # 1
Q: Do I only include paid positions on my biosketch?
A: No, include the positions, whether or not they are salaried, that are relevant to your grant application.
FAQ # 2
Q: Work on this project will be conducted at another institution at which I have an appointment. Do I need to include that appointment?
A: Yes, this is relevant to your grant application.

FAQ # 3
Q: I have an appointment in China at China’s Best Medical College restricted to teaching and mentoring. I plan to offer graduate students there the opportunity to travel to New York and do their theses at Mount Sinai working on this grant. Do I need to include this appointment on my Biosketch?
A: Yes, this is relevant to your application.

FAQ # 4
Q: I have an appointment at Moscow State University in Russia restricted to teaching and mentoring. I am mentoring a student there on her graduate thesis. The thesis topic is unrelated to my grant application. I don’t plan to involve her or any future Moscow State students in my NIH funded research. Do I need to include that appointment on my biosketch?
A: No, this is not relevant to your grant application.

We plan on posting this communication series on foreign influence and disclosure to the NIH on the GCO webpage. In the meantime, if you need any former communications, please do contact me.

Sincerely, Allison Gottlieb
Dear Faculty and Staff,

In light of the Faculty Handbook update from June 2019 regarding the de minimis amount for reporting reimbursed or sponsored travel, we are updating this communications.

Please see ISMMS Faculty Handbook > Financial Conflicts of Interest in Research > What Must Be Disclosed? section for more information.

FAQ # 3 below has been updated to reflect that there is no minimum amount to be reported.

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Dear Faculty and Staff,

Pursuant to the email communications that the GCO sent on 4/4/19 entitled “NIH - Foreign Influences on Research Integrity,” we are following up and providing more specific information on disclosing foreign affiliations and best practices.

On August 25, 2011, the U.S. Department of Health and Human Services (HHS) issued a final rule in the Federal Register on Financial Conflict of Interest Regulations (FCOIR)- Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors.

This fourth communications focuses on the reporting of foreign travel as per the FCOIR and NIH policy. Below is a series of FAQs on reporting foreign travel.

GCO FAQs on Reporting Foreign Travel

FAQ # 1
Q: Is it true that I must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to my institutional responsibilities?
A: Yes, that is true. (Source: final rule)

FAQ # 2
Q: How about if my spouse is reimbursed for travel by a foreign entity? Does that need to be reported?
A: Yes, spouses and dependent children are subject to the Final Rule FCOI regulation. (Source: final rule)

FAQ #3
Q: What is the minimum amount to be reported?
A: Mount Sinai’s policy is that there is no minimum amount. (Source: ISMMS Faculty Handbook > Financial Conflicts of Interest in Research > What Must Be Disclosed?)

FAQ #4
Q: Where do I report reimbursed or sponsored travel?
A: Disclose this on the Annual Conflict of Interest form which can be amended throughout the year. Specifically refer to this section of the form. (Source: final rule) Section VIII. Federally- Funded Research (Federal Requirement)
If you traveled during [year of annual form], was your travel paid by any entity other than Mount Sinai? You may also chose to report the travel prospectively if you know in advance that it will be occurring.

FAQ #5
Q: Are there any exceptions?
A: Yes, travel paid for by federal, state or local governments, institutions of higher education, academic teaching hospitals, medical centers or research institutes are excluded from reporting.

FAQ #6
Q: Those are pretty broad exceptions. If all of my travel is paid for by institutions of higher education, academic teaching hospitals, medical centers or research institutes, may I ignore these regulations?
A: There is an exception to the exception. This exclusion does not apply to foreign institutions. Do report sponsored travel paid for by any foreign source including institutions of higher education, academic teaching hospitals, medical centers or research institutes. (Source: NIH Notice NOT-OD-18-160)

FAQ #7
Q: What if I fail to report my sponsored travel? How will anyone know?
A: If it is unintentional, please do report immediately. Please be aware that the FBI is tracking who is leaving and returning to the US by air, what class ticket they have and who paid for that ticket. They are sharing that information with the NIH. (Source: Ropes and Gray Webinar on “NIH Inquiries into Foreign Affiliations, Research Support, and Award Components” March 25, 2019 Teleconference Replay / Presentation Slides)

NIH FAQs on FCOIR
Select NIH FAQs are included below.

- Does an Investigator need to disclose all reimbursed or sponsored travel, no matter the dollar level, if it is reimbursed or sponsored by sources other than those excluded from disclosure (i.e., Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education)?
- What about payments to or assets held by my spouse or dependent children?
Must these financial interests to be disclosed?

- Is an Investigator required to disclose all financial interests received from a foreign Institution of higher education or the government of another country? (Institution and Investigator)

We plan on posting this communication series on foreign influence and disclosure to the NIH on the GCO webpage. In the meantime, if you need any former communications, please do contact me.

Sincerely, Allison Gottlieb

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Dear Faculty and Staff,

Pursuant to the email communications that the GCO sent on 4/4/19 entitled “NIH - Foreign Influences on Research Integrity,” we are following up and providing more specific information on disclosing foreign affiliations and best practices.

This fifth communications focuses on the NIH Other Support page.

The NIH requests Other Support pages for each senior/key personnel designated in an application (i.e., investigator) as part of the Just In Time (JIT) process. Both active and pending support is included. GCO’s guidance document on preparing a JIT Other Support page can be found here.

The NIH also requests Other Support pages for each senior/key personnel, active support only, when there are certain changes in the active support. GCO’s guidance document on preparing an RPPR Other Support page can be found here.

Let’s review the NIH definition of Other Support and see how to apply it to situations when an investigator has a foreign affiliation or award.

NIH Other Support Definition
excerpted from 2.5.1 of the NIH Grants Policy Statement (NIHGPS)

Other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual’s research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards.

Training awards, prizes or gifts do not need to be included.

GCO FAQs

FAQ # 1
Q: I have a dual appointment with the University of Ontario. I am a PI on a grant for the Canadian Institutes of Health there. Do I need to include this on my Other Support page?
A: Yes, this financial resource directly supports your research endeavors. It is necessary to include this award on your Other Support page. Please include sections
labeled Icahn School of Medicine at Mount Sinai and University of Ontario under both the awarded and pending portions of your Other Support page and list this grant in the appropriate spot. See section VIII in GCO’s OS guidance documents JIT I RPPR for instructions on reporting global effort on multiple research appointments.

FAQ # 2
Q: I am an Adjunct Professor at Fudan University. I am listed as a Co-Investigator on a Chinese National Science Foundation award held by that University. I do not personally receive any compensation, but the grant pays for technicians’ salaries and the supplies for the aim that I work on when visiting Fudan. Do I need to include this award on my Other Support page?
A: Yes, this financial resource directly supports your research endeavors. It is necessary to include this appointment on your Other Support page. Please include sections labeled Icahn School of Medicine at Mount Sinai and Fudan University under both the awarded and pending portions of your other support and list this grant in the appropriate spot. See section VIII in GCO’s OS guidance documents JIT I RPPR for instructions on reporting global effort on multiple research appointments.

FAQ # 3
Q: I was awarded a postdoctoral fellowship from the Onassis Foundation in Greece. A stipend is paid directly to me. Do I need to include this award on my Other Support page?
A: Yes, this financial resource directly supports your research endeavors. It is necessary to include this appointment on your Other Support page.

FAQ # 4
Q: I am a Pulmonologist and I do consulting work for Teva Pharmaceuticals in Israel in their asthma program. On behalf of Teva, I consult on the development of a monoclonal antibody that specifically targets IL-5 in order to interrupt its production. My research at Sinai focuses on treating respiratory disorders. Do I need to include my consulting position on my Other Support page?
A: No, this consultancy does not support your research endeavors. It is not necessary to include this activity on your Other Support page. However, don’t forget to include this consulting work on your annual Conflict of Interest Disclosure.

FAQ # 5
Q: I just won a Nobel Prize from Karolinska Institute! Do I need to include this award on my Other Support page?
A: First off, congratulations! It is not necessary to include this award on your Other Support page because prizes are specifically excluded as per the other support guidelines.

We plan on posting this communication series on foreign influence and disclosure to the NIH on the GCO webpage. In the meantime, if you need any former communications, please do contact me.

Sincerely, Allison Gottlieb

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