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

Rev. 8/17/22
# National Institutes of Health (NIH) and Foreign Influences on Research Integrity

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I. Background

During a 2019 hearing of a Senate panel that oversees the National Institutes of Health (NIH) budget, Senator Roy Blunt (R–MO), asked former 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 additional information and review the NIH Inquiries into Foreign Affiliations, Research Support, and Award Components Ropes & Gray teleconference slides.

The NIH has partnered with the Federal Bureau of Investigation (FBI) to investigate possible foreign interference with the integrity of federally-funded biomedical research and has contacted research institutions across the country regarding undisclosed relations with foreign entities.

The NIH has identified the following potential deficiencies in an investigator’s disclosure:

- Undisclosed dual appointments with foreign universities or institutes
- Undisclosed foreign grant support
- Undisclosed foreign components (e.g., foreign co-authors listed on publications of research supported by NIH

Although disclosures are the area in which institutions’ own obligations under federal funding requirements are most likely to be affected, NIH’s concerns are broader than disclosure failures and include the following:

- Operation of “shadow labs” in foreign countries, creating plausible claim that work generating intellectual property (IP) occurred outside the U.S.
- Theft of biomedical IP from confidential grant applications under review by NIH or from research supported by NIH.
- Breach of confidentiality in NIH peer review of grant applications to influence NIH award decisions.

Depending on the severity and duration of the noncompliance, NIH may decide to take one or more actions. This includes 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.

Mount Sinai investigators must disclose all forms of other support and financial interest including support from foreign governments or other foreign entities. Please refer to each section of this document for additional information. The terms “foreign component” and “foreign involvement” are used interchangeably.
II. Foreign Components

A common misconception is that foreign involvement only occurs when there is a subaward to a foreign institution.

The definition 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:

- Involvement of human subjects or animals,
- Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or
- 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.

Foreign involvement is disclosed in these activities and NIH documentation:

- Publications and other documents when acknowledging NIH support (i.e., co-authorship with investigators at a foreign site)
- Grant Applications (Competitive or Non-Competitive) and Prior Approval Requests
- Biosketch
- Other Support
- Conflicts of Interests Reporting and Foreign Travel Request
III. Publications and Other Documents: 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 instructions, please refer to the NIH webpage “Communicating and Acknowledging Federal Funding” and review this FAQ “Should I cite my NIH grant when I publish?”

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 even if the publication is not arising from the award. 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 is an issue when the 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?”
IV. Competitive Grant Applications

Depending on the type of foreign involvement, there are different sections where this information may also be disclosed in a competitive application (e.g., new, competitive renewals, resubmission).

A. Other Project Information Page: Required
Whenever there is foreign involvement, question 6 in the Other Project Information Page must be answered “Yes.” Remember that if you are including a letter of support from a foreign collaborator, the answer should be “Yes.”

Below is a screenshot of the Other Project Information page as a S2S submission through InfoEd.

Below are additional instructions from the NIH SF 424 Guide. The NIH SF424 includes additional instructions for fellowships and multi-project applications.

B. Performance Sites Tab, if appropriate
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.

Below is a screenshot of the Other Project Information page as a S2S submission through InfoEd.
Below are additional instructions from the NIH SF424 Guide. Refer to NIH SF424 Guide for additional instructions.

C. Senior/Key Personnel Form, if appropriate
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.

If you are working with foreign consultants and other significant contributors, choose "External Consultant” and add the appropriate designation.

If you are working with subawards, please review the personnel data entry instructions in Policy on Subawards: ISMMS as the Prime Institution.
D. Budget Tab

1. Consultant Services
   For non-modular grants, please choose Consultant Costs if appropriate. See the budget justification section below for more information.

2. Travel
   For non-modular grants, please choose Foreign Travel Costs if appropriate. See the budget justification section below for more information.

3. Subawards
   Complete the subaward budget form, if appropriate. If you are working with subawards, please review the budget data entry instructions in Policy on Subawards: ISMMS as the Prime Institution.

E. Budget Justification

1. Personnel
   Justify all personnel whether or not salaries are requested.

2. Consultant Services
   For non-modular grants, please note the instructions excerpted from the NIH SF424 Guide > Budget > Other Direct Costs > Consultant Services.

3. Consultant Services:
   List the total funds requested for all consultant services. Identify the following items in Section L, Budget Justification, as applicable:
   - each consultant, the services he/she will perform, total number of days, travel costs, and the total estimated costs;
   - the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements;
   - consulting physicians in connection with patient care; and
   - persons who are confirmed to serve on external monitoring boards or advisory committees to the project. Describe the services to be performed.
3. Travel
For non-modular grants, please note the instructions excerpted from the NIH SF424 Guide > Budget Justification > Travel.

F. Consortium / Contractual Arrangements (i.e., subawards) if appropriate
If you are working with subawards, please review the Contractual / Consortium plan in GCO’s Policy on Subawards: ISMMS as the Prime Institution. Upload information in the PHS 398 Research Plan > Consortium/ Contractual Arrangements section.

G. Biosketches for Senior/Key Personnel, if appropriate
Please review the Biosketch section of this document.
V. Annual Research Performance Progress Report (RPPR)

Depending on the type of foreign involvement, there are numerous other places where this information may also be disclosed in the non-competitive application known as the NIH’s Annual Research Performance Report.

The NIH RPPR instructions are [here](#) and excerpted below.

A. Special Reporting Requirements: Required — Section G.9 of NIH Application

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

B. Participants — Section D of NIH Application

This section allows the agency to know who has worked on the project to gauge and report performance in promoting partnerships and collaborations.

6.4 Section D — Participants

The RPPR Section D. 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 (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 person months, rounded to the nearest one-tenth (Calendar, Academic, Summer) that the individual worked on the project.

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

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. Select the Add Participant button to add the data to the table.
D. Impact – Section E of NIH Application

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.

E. 8 Project/Performance Sites.
If there are changes to the project/performance site(s) displayed, edit as appropriate.
VI. Prior Approval Requests

If foreign involvement was not disclosed in the competitive NIH application or a subsequent Research Performance Progress Report, please submit a prior approval request as per the standard process described in the NIH Prior Approval Requirements and Rebudgeting Policy.

Submit the information below to the GCO or use the NIH Foreign Component Prior Approval Form. The GCO will review and submit the information or form to the National Institutes of Health Institute or Center (NIH I/C) for prior approval.

1. Primary Institution Name and Address
   Icahn School of Medicine at Mount Sinai (ISMMS)
   1 Gustave L. Levy Place, Box 1075
   New York, NY 10029
2. ISMMS Principal Investigator Name
3. Project Number

Foreign Component Information
4. Institution Name: Investigator must be affiliated with this institution. If investigator is not affiliated with an Institution, please leave blank and use the “other” section for additional clarification.
5. Country in which research will be conducted
6. Names of Foreign Component Collaborating Investigators
7. Foreign Component Address: Provide as much detail as possible.
8. Collaborating Investigator Telephone Number
9. Collaborating Investigator E-mail Address

The information requested is regarding the research conducted at the foreign component. Do not include information about studies performed in the U.S. or at another site.

10. AIDS Related? Y/N
11. Involves Biodefense? Y/N
12. Description of Activities to be Conducted at the Foreign Component:
   Describe the activities to be conducted at the foreign component written for a lay audience. The NIH I/C is responsible for approving this activity.
13. Total Amount Requested
   If appropriate, add total requested amount.
14. Budget: Attach or State None
   If appropriate, attach a budget which includes the total costs per year at the foreign component.

Vertebrate Animals
Include the following information if vertebrate animals are involved at the foreign component:

15. Vertebrate Animals? Y/N
16. For experiments involving animals, please identify the type of animal being used, how many animals, and a brief description of what will be done to them?

Human Subjects
Include the following information if human subjects are involved at the foreign component:

17. Human Subjects? Y/N
18. If Yes to Human Subjects, either state “pending approval” or include an FWA (Federal-Wide Assurance) # as appropriate.
   If there is no information about Approval status, then there may be a hold on approval.
19. Does the research at the foreign component meet the NIH definition of a Clinical Trial? Y/N
20. Involves Stem Cells? Y/N
21. Number of subjects
22. Demographics:
   Include age-range, gender, inclusion of special populations such as pregnant women, etc.
23. How will the subjects be recruited?
24. Will informed consent be obtained? Y/N
25. What will the subject participation entail?
26. If subjects are to be interviewed, where, how long, and how many times?
27. How long they will participate?
28. How will subject confidentiality be protected?
29. If samples are to be obtained, samples of what and how often?
30. Other: Provide any additional information.
VII. Biosketch

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.

Complete instructions and sample biosketches can be found here.

NIH Instructions – Positions, Scientific Appointments, and Honors – Section B

List in reverse chronological order all current positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary). 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

1. Q: Do I only include paid positions on my biosketch?

   A: No, include all current positions and scientific appointments, whether or not they are salaried. See the NIH Biosketch Section B Instructions for complete information.

2. Q: Work on this project will be conducted at another institution at which I have an appointment. Do I need to include this appointment?

   A: Yes, include this appointment on your biosketch.

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 to do their theses at Mount Sinai working on this grant. Do I need to include this appointment on my Biosketch?

   A: Yes, include this appointment on your biosketch.

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 this appointment on my biosketch?

   A: Yes, include this appointment on your biosketch.
VIII. Other Support

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) and RPPR processes. Other Support includes all resources made available to a researcher in support of and/or related to all of their research endeavors.

- This includes resources and/or financial support from all foreign and domestic entities that are available to the researcher.
- This is regardless of whether or not they have monetary value.
- This is regardless of whether they are based at the institution the researcher identifies for the current grant.

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

If an investigator has a foreign appointment and/or employment or an unpaid appointment with a foreign institution, the NIH also requires copies of contracts/agreements including foreign sponsored project agreements to be submitted with the Other Support page. Provide all foreign contracts/agreements/sponsored project agreements in the original foreign language in advance to the designated GCO Grants Specialist. Please review the Other Support Instructions for additional information.

If you have a foreign appointment please review the Multiple Research Appointment section of the Other Support Instructions regarding reporting effort.

In addition to the Other Support Instructions, the GCO has numerous resources and training sessions for the preparation of the Other Support page that can assist investigators with foreign appointments, such as the Other Support Template and the Other Support Checklist and GCO’s Other Support Class Series. Please visit the GCO’s Application Information page > NIH – NSF Biosketch and Other Support Info for more information.

GCO FAQs

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 GCO’s OS Instructions re: reporting global effort on multiple research appointments.

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 GCO’s Other Support Instructions for information on reporting global effort on multiple research appointments.

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.
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.

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.
IX. Conflicts of Interest and Reporting Foreign Travel

Background
The U.S. Department of Health and Human Services (HHS) issued a final rule August 25, 2011 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.

Please refer to the ISMMS Faculty Handbook > Financial Conflicts of Interest in Research > What Must Be Disclosed? for a faculty member’s obligations.

The GCO is providing FAQs on reporting foreign travel and including the NIH’s FAQs below.

GCO FAQs
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)

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)

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?)

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.

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.

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)

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
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)
X. 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)**
  - Biosketch: Who Must Submit
  - Biosketch and Other Support FAQs
  - Other Support: List of Most Common Errors
  - Other Support Instructions
  - Other Support Training: GCO 400-series

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

XI. Highlights of Significant Changes from Previous Versions

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<tr>
<th>Section</th>
<th>Description of Change</th>
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<tr>
<td>8/17/2022</td>
<td>- Updated and newly organized Foreign Component, Biosketch, Other Support and Component Prior Approval sections. &lt;br&gt; - Reorganized all sections &lt;br&gt; - Removed information about original GCO Helpful Hints communication columns &lt;br&gt; - Added NIH instructions in the Competitive Grant Application and RPPR sections.</td>
</tr>
<tr>
<td>6/29/2019</td>
<td>Reorganization of material and updated to adhere to NOT-OD-21-073</td>
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