

INTRODUCTION: SCHOOL OF MEDICINE GUIDANCE FOR RESPONDING TO RECENTLY EMPHASIZED NIH/PHS REQUIREMENTS FOR DISCLOSURE OF FOREIGN RELATIONSHIPS AND INTERACTIONS (e.g. “FOREIGN COMPONENT” and OTHER FOREIGN INTERACTIONS)

- 1) **WHAT IS THE DEFINITION OF A “FOREIGN COMPONENT”?**
- 2) **DOES A FOREIGN COMPONENT REQUIRE PRIOR NIH APPROVAL?**
- 3) **WHEN SHOULD YOUR FOREIGN TRAVEL BE INCLUDED AS A “FOREIGN COMPONENT”?**
- 4) **WHAT, WHEN, AND WHERE DO I DISCLOSE MY “FOREIGN COMPONENTS” OR MY OTHER FOREIGN INTERACTIONS RELATED TO MY NIH/PHS FUNDED RESEARCH?**
 - A. **“FOREIGN COMPONENTS”**
 - B. **OTHER FOREIGN INTERACTIONS**
- 5) **WHAT INFORMATION RELATED TO MY “FOREIGN COMPONENTS” OR OTHER FOREIGN INTERACTIONS SHOULD BE INCLUDED IN MY NIH/PHS “OTHER SUPPORT” PAGE?**
- 6) **WHAT ARE MY FINANCIAL CONFLICT OF INTEREST DISCLOSURE REQUIREMENTS?**
- 7) **WHO CAN I CONTACT FOR GUIDANCE ON NIH/PHS REQUIREMENTS FOR DISCLOSURE OF MY FOREIGN RELATIONSHIPS/INTERACTIONS AND/OR MY FOREIGN COMPONENT?**
- 8) **SOME RELEVANT NIH FAQs AND OTHER EXAMPLES**

INTRODUCTION: GUIDANCE ON NIH/PHS REQUIREMENTS FOR DISCLOSURE OF “FOREIGN COMPONENTS,” OTHER SUPPORT, AND CONFLICTS OF INTERESTS RELATED TO ACTIVITIES OUTSIDE THE U.S.

This advisory information is intended to guide NIH and PHS investigators at Stanford on what, when, and where activities outside of the U.S. must be disclosed to Stanford and also to NIH/PHS. This guidance explains three requirements: (1) Foreign Component, (2) Other Support, and (3) Conflicts of Interest and Commitment.

To further assist investigators, the School of Medicine provides personalized [School of Medicine Guidance on NIH/PHS Reporting Requirements](#) for disclosure of foreign relationships and interactions and the determination of “Foreign Component”. This support aims to help investigators and staff with the review of their foreign interactions as they relate to NIH/PHS research projects to identify and determine potential need for disclosure.

1) WHAT IS THE DEFINITION OF A “FOREIGN COMPONENT”?

Per [NIH Grants Policy Statement](#), a recent [NIH Guide Memo](#), and other relevant sources, the definition of “foreign component” is outlined below:

A foreign component is defined as “[t]he 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.

Foreign travel for consultation is not considered a foreign component.” (Emphasis added above.)

According to the NIH Guide Memo referenced above that was issued as a reminder to the research community on July 10, 2019, “If a recipient determines that **a portion of the project will be conducted outside of the U.S.**, the recipient then will need to determine if the activities are considered **significant**. If **both criteria** are met, **then there is a “foreign component”**.”

To aid the determination as to what may be considered **significant** in your “foreign component” determination, click on the [NIH FAQs](#). In addition, if needed you can request [School of Medicine Guidance on NIH/PHS Reporting Requirements](#) for assistance with the assessment of significant scientific element/authorship and/or extensive travel (*see Section 8 in this document*).

2) DOES A FOREIGN COMPONENT REQUIRE PRIOR NIH APPROVAL?

Yes. You may not perform a significant scientific element or segment of a NIH-funded project outside the U.S. without prior NIH approval. Per [NIH Grants Policy Statement 8.1.2.10](#) “Adding a foreign component under a grant to a domestic or foreign organization requires NIH **prior approval.**”

3) WHEN SHOULD FOREIGN TRAVEL BE INCLUDED AS A “FOREIGN COMPONENT”?

The NIH definition of “foreign component” states that “extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities” is a “foreign component”. Note that NIH defines a “foreign component” as a **significant** scientific element or segment of your NIH project (so if the extensive travel for data collection and other activities described above is not part of your NIH project, it would not be a Foreign Component). NIH has not defined “extensive” or “significant,” but you should err on the side of disclosure. If needed, you can request [School of Medicine Guidance on NIH/PHS Reporting Requirements](#) for assistance with the assessment of what is extensive travel (*see Section 7 below for guidance on how to request assistance*).

In contrast, if the travel is for work associated with your grant and is performed on U.S. soil, but there is a non-U.S. resource that supports the travel, this travel is not a “foreign component”. However, it needs to be reported on your Other Support page.

Note: See *Section 5* for more information on Other Support requirements. Detailed instructions for completing your Other Support page and a sample Other Support page can be also be found in *Section 8* of this website.

4) WHAT, WHEN, AND WHERE DO I DISCLOSE MY “FOREIGN COMPONENTS” OR MY OTHER FOREIGN INTERACTIONS RELATED TO MY NIH/PHS FUNDED RESEARCH?

There are 2 categories of foreign relationships related to your NIH/PHS research funding that need to be considered and evaluated as to whether they meet NIH/PHS requirements for disclosure:

- The first is “foreign component” which is defined as “significant scientific element or segment of a project outside of the United States” (*see full definition in Section 1 on this website*).
- The second type of foreign interactions or affiliations that need to be reported are those that don't meet the NIH/PHS definition of “foreign component,” i.e., they are not a significant part of an NIH-funded project that is performed in a foreign jurisdiction, but are related to your research activities or role as a research scientist or academic. These reports are made as part of “other support” information and they must be disclosed before a grant is awarded and at least annually thereafter.

Below provides an outline of the disclosure requirements for what, where, and when you must disclose information regarding these 2 categories of foreign engagement. When in doubt, report.

A. DISCLOSING “FOREIGN COMPONENTS”

I. **Competitive Proposal (New, Renewal, Resubmission, or Supplement)**

When developing the application for your competitive NIH grant proposal (New, Renewal, Resubmission, and Supplement Applications) in ASSIST, note the following sections of the application that need to disclose “foreign components” (Note: RPPR submissions (progress reports) are addressed separately below):

- **Biosketch in your grant application**

Disclose joint publications with a foreign collaborator that meet the above definition of a Foreign Component. That is, a significant [see NIH Grants Policy Statement 1.2]. (if unsure about the significance of the relationship you can request [*School of Medicine Guidance on NIH/PHS Reporting Requirements*](#))

Under “Positions and Honors” on the NIH Biosketch format page, include any 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).

Refer to <https://grants.nih.gov/grants/forms/biosketch.htm> for the NIH instructions for Biosketch.

- **Budget and Budget Justification in your grant application**

Significant relationships with foreign institutions, organizations, or companies where there is work that will be performed or resources that will be provided at a foreign location should be budgeted as Subawards. This requires detailed budget, budget justification, scope of work, and signed commitment form (OSR Form 33) from the participating institution, organization or company.

Consultants/collaborators (paid or unpaid) who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested, should be identified in the budget and their role explained in the budget justification.

- **Foreign Component Section of the grant application**

Check “yes” to question #6 in Section G220 of the ASSIST application when this project involves activities, resources, or extensive travel outside of the United States or partnerships with international collaborators taking place outside the United States (*see the full definition of Foreign Component outlined above in Section I*).

List all foreign positions and scientific appointments held by Principal Investigator or key personnel **that are relevant to the application** including affiliations with foreign entities or governments. This includes titled academic, professional, institutional appointments, or foreign talent programs whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

If you have checked "Yes" to Question 6, you must include a "Foreign Justification" attachment in Field 12, Other Attachments. Describe special resources or characteristics

of the research project (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."

Follow the instructions outlined in [SF424 Guidelines](#).

II. Just-in-Time Process

For those proposal applications that are being considered for funding, applicants will receive a notification from NIH (primarily by e-mail) when [Just-in-Time](#) information is required. This procedure allows certain elements of an application to be submitted later in the application process. The standard Just-in-Time application elements include the submission of up to date Other Support information (both active and pending) for all senior/key personnel. See guidelines outlined under Other Support on this website for more information on foreign collaborations, resources, or interactions that must be disclosed.

Note: See *Section 5 below* for more information on Other Support requirements. Detailed instructions for completing your Other Support and a sample Other Support page can be also be found in *Section 8 below* of this website.

III. Research Performance Progress Report (RPPR) Process

NIH grants require an annual **Research Performance Progress Report** (RPPR). The RPPR is submitted through eRA Commons. Below are the reminders on where foreign component need to be disclosed in this annual update report:

Provide updated Other Support for the Principal Investigator and Key Personnel (*see Other Support guidelines in Section 5 of this website for more information on foreign collaborations, resources, or interactions that must be disclosed*).

Check “yes” to section G9 Foreign Component and provide a list of those foreign interactions **that are relevant** to this grant and meet the definition of a “foreign component” (*see Section 1 of this website for the complete definition*). This list will be a restatement of previously disclosed “foreign components” that were approved by NIH/PHS.

Follow RPPR instructions at https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf

IV. Requirements for disclosing a *NEW* “foreign component” related to my NIH funding

- Note that **prior approval** from NIH is **required** before adding a new “foreign component.”
- [NIH Grants Policy Statement 8.1.2](#), Prior Approval Requirements.
If a recipient determines that a portion of the funded project will now need to be conducted outside of the U.S., the recipient then will need to determine if the activities are considered **significant** as outlined in the “Foreign Component” definition on this website. If both criteria are met, then there is a “foreign

component” and **prior NIH approval is required** before performing any such activity.

To submit a prior approval request to the NIH, contact your Institutional Official (Research Process Manager) in the [Research Management Group \(RMG\)](#).

B. DISCLOSING OTHER FOREIGN INTERACTIONS

If an activity does not meet the definition of “foreign component” because all research is being conducted within the United States, but there is a non-U.S. resources (space, equipment, materials, etc) or funding that supports the research of an investigator and/or researcher being conducted in the U.S., it must still be reported as “**Other Support**” on your grant (*see more information on the requirements for Other Support in Section 5 of this website below*).

For example, if a PD/PI of an NIH-funded grant has a collaborator outside of the U.S. who performs experiments in support of the PD/PI’s NIH-funded project, this would constitute a “foreign component”, regardless of whether the foreign collaborator receives funding from the PD/PI’s grant. However, additional funding that came from a foreign source for the NIH-supported research of a PD/PI at a U.S. institution would not constitute a “foreign component” **but would necessitate reporting as “Other Support”** (*see detailed Other Support Instructions and a Sample Other Support Page in Section 5 of this website*).

I. Competitive Proposal (New, Renewal, Resubmission)

Biosketch in your grant application

Under “Positions and Honors” on the NIH Biosketch format page, include any 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).

Refer to <https://grants.nih.gov/grants/forms/biosketch.htm> for the NIH instructions for Biosketch.

Budget Justification in your grant application

Many of our faculty will not know, for example, if visiting foreign scholars/students will be working on the research proposed until the grant is awarded. However, if you know at the time of proposal submission that a visiting foreign scholar/student will be participating in that specific research proposal, the scholar or student should be referenced in the budget and budget justification section. Name the scholar or student in the budget with no request for salary or benefits. In the budget justification, also indicate which foreign institution is providing support for the scholar/student.

Note: visiting foreign scholars/students must also be referenced in the PI’s Other Support at the Just-in-Time submission process.

Just-in-Time Process

For those proposal applications that are being considered for funding, applicants will receive a notification from NIH (primarily by e-mail) when [Just-in-Time](#) information is needed. This procedure allows certain elements of an application to be submitted later in the application process. The standard Just-in-Time application elements include the submission of up to date

Other Support information (both active and pending) for all senior/key personnel. See guidelines outlined under Other Support on this website for more information on foreign collaborations, resources, or interactions that must be disclosed.

Note: See *Section 5* for more information on Other Support requirements. Detailed instructions for completing your Other Support page and a sample Other Support page can be also be found in *Section 8* of this website.

II. Research Performance Progress Report (RPPR) Process

NIH grants require an annual **Research Performance Progress Report** (RPPR). The RPPR is submitted through eRA Commons. Provide updated Other Support for the Principal Investigator and Key Personnel.

Note: See *Section 5 below* for more information on Other Support requirements. Detailed instructions for completing your Other Support and a sample Other Support page can be also be found in *Section 8 below* of this website.

5) WHAT INFORMATION SHOULD BE INCLUDED IN YOUR OTHER SUPPORT?

NIH/PHS reminds applicants and recipients that other support includes ***all resources both domestic and foreign made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value.*** This includes resources and/or financial support from all foreign entities, including but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.).

Some examples of other support include, but are not limited to:

- **Positions:** List all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application including affiliations with foreign entities or governments. Information to provide 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). *Provide information on any financial remuneration received.*
- **Resources:** Report all resources provided by a domestic or foreign entity that contribute to the scientific development or execution of a project in a substantive, measurable way, even if the support received is only in-kind (e.g. office/laboratory space, equipment, supplies, employees). All research resources including, but not limited to, foreign financial support, research or laboratory personnel, lab space, scientific materials, selection to a foreign “talents” or similar-type program, or other foreign or domestic support must be reported. *Note: you don’t need to assign a dollar value to the resource for the purposes of listing in your other support.*
- **Materials:** Provision of high-value materials not freely available (e.g., biologics, chemical, model systems, technology, etc.). *Note: you don’t need to assign a dollar value to the resource for the purposes of listing in your other support.*

- Lab Personnel: Identify personnel (primarily visiting scholars/students) working in a researcher’s lab who are supported by a domestic or foreign entity either through salary, stipend, or receipt of living or travel expenses.
Note: you don’t need to assign a dollar value to the compensation for the purposes of listing in your other support.
- Other: List selection to a foreign “talents” or similar-type program, or other foreign or domestic support

Note: Detailed instructions for completing your Other Support page and a sample Other Support page can be found in *Section 8* of this website.

6) WHAT ARE THE FINANCIAL CONFLICT OF INTEREST REQUIREMENTS?

In compliance with PHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F, Objectivity of Research), investigators are required to report to Stanford University all personal financial sources of income and associated duties associated therein that are related to their institutional responsibilities on the Financial Conflict on the [Outside Professional Activities Certification System \(OPACS\) web site](#).

As described in [NOT-OD-18-160](#) , the NIH issued a reminder to the research community of their obligation to disclose financial interests and **specifically called out financial interests received from foreign entities**. Federal regulations require researchers who receive funding from the Public Health services (PHS), inclusive of subawards or agencies who have adopted the PHS financial conflict of interest regulations, to disclose certain financial interests. Stanford’s policy on disclosing of financial interests can be found [here](#). This requirement is in addition to other disclosures required by the NIH.

7) WHO CAN I CONTACT FOR ASSISTANCE WITH DETERMINATION OF DISCLOSURE REQUIREMENTS OF MY FOREIGN RELATIONSHIPS/ INTERACTIONS AND/OR MY FOREIGN COMPONENT?

You can request assistance of the [School of Medicine Guidance on NIH/PHS Reporting Requirements](#) support with the review and assessment of your foreign interactions and Foreign Component to determine the requirement for disclosure to the NIH funded research project as defined by NIH.

8) NIH FAQs AND OTHER EXAMPLES

For more information, please visit NIH FAQs: [Other Support and Foreign Components](#)

[NIH Other Support Page Instructions](#)

[Sample NIH Other Support Page](#)