International Engagement Series (Foreign Influence in Research)

NIH Disclosure Requirements

Lynn Hudachek

Associate Director, Division of Sponsored Programs

https://dsp.research.uiowa.edu/

NIH@uiowa.edu

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Agenda

Disclose foreign components/involvement of NIH funded research on:

- **Proposals**

- **Other Support (JIT)**

- **Progress Reports (RPPR)**

Sponsor Disclosure Requirements

-Many sponsors have unique requirements for reporting foreign interests and international collaborations.

-Always check general requirements for the sponsoring agency and requirements related to the specific funding announcement, notice of award, or contract.

NIH Definitions

NIH definitions:

https://grants.nih.gov/grants/glossary.htm#ForeignComponent

NIH Grants Policy Statement:
https://grants.nih.gov/policy/nihgps/index.htm

See section 16: Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components

NIH definition of Foreign Component

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.

Foreign travel for consultation is not considered a foreign component.

NIH Proposals

RR Other Project Information Form:

From SF424 Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide.html

6.a. Does this project involve activities outside of the United States or partnerships with inter-national collaborators?

→ Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check "Yes" or "No."

→ 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. See NIH Glossary for a definition of a foreign component.

NIH Proposals

RR Other Project Information Form:

From SF424 Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide.html

→ **6.b. If yes, identify countries:**

This field is required if you answered "Yes" to Question 6. Enter the countries with which international cooperative activities are planned.

You may use abbreviations. Your entry is limited to 55 characters.

→ **6.c. Optional Explanation:**

This field is optional. Enter an explanation for involvement with outside entities. Your entry is limited to 55 characters.

NIH Proposals

RR Other Project Information Form:

6.a. * Does this project involve activities outside the U.S. or partnership with International Collaborators? ○ Yes ◉ No

6.b. If yes, identify countries:

6.c. Optional Explanation:

NIH Proposals

RR Other Project Information Form:

From SF424 Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide.html

→ **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."

NIH Proposals

RR Project Performance Sites Location Form:

From SF424 Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide.html

→ Use this "Project/Performance Site Location 1" block to provide information on performance sites in addition to the Primary Performance Site listed above, if applicable. Include any VA facilities and **foreign sites**.

NIH Proposals

Consortium Budget Justification (modular budget):

From SF424 Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide.html

→ List the individuals/organizations with whom consortium or contractual arrangements have been made and indicate whether the collaborating institution is **foreign** or domestic.

→ Additional justification should include explanations for any variations in the number of modules requested annually. Also, this section should describe any direct costs that were excluded from the total direct costs (such as equipment, tuition remission) and any work being conducted off-site, **especially if it involves a foreign study site** or an off-site F&A rate.

NIH Proposals

Human Subjects & Clinical Trials Information:

From SF424 Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide.html

→ **3. Enrollment Location Type (Domestic/Foreign)**

Select whether the participants described in the IER are based at a U.S. (Domestic) or at a non-U.S. (Foreign) site. Participants at U.S. and non-U.S. sites must be reported separately (i.e., on separate IERs), even if it is for the same study.

NIH Proposals

PHS 398 Research Plan Form:

From SF424 Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide.html

6. Select Agent Research - Provide the registration status of all entities* where select agent(s) will be used.

If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.

9. Letters of Support - Letters should stipulate expectations for co-authorship, and whether cell lines, samples, or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only

NIH Post-Submission/Pre-Award

→ **Just in Time (JIT) -** allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. The standard application elements include **other support** information (both active and pending) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement. Other program-specific information may also be requested using this procedure.

→ **Other Support**

Other support, as described in the NIH Grants Policy Statement (GPS) Section 2.5.1, includes all resources, regardless of whether or not they have monetary value, available in direct support of an individual's research endeavors

NIH Post-Submission/Pre-Award

→ **Other Support**

[FAQs on Other Support and Foreign Components](#)

∨ A. Other Support

∨ B. Foreign Components

∨ C. Financial Conflict of Interest (FCOI)

NOT-OD-19-114 - NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html

NIH Post-Submission/Pre-Award

→ **Other Support Cont'd**

NOT-OD-19-114 - NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components

- NIH reminds applicants and recipients that other support includes *all* resources 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 and regardless of whether they are based at the institution the researcher identifies for the current grant. This includes resource and/or financial support from all foreign and domestic 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.).

NIH Award

Upon Receipt of Funding *review* the:

- Grant Notice of Award,
- Cooperative Agreement,
- Contract, or
- Subaward Agreement

NIH Post-Award

→ **Research Performance Progress Report (RPPR)**: https://grants.nih.gov/grants/rppr/index.htm

→ **RPPR FAQs**: https://grants.nih.gov/faqs#/research-performance-progress-report.htm?anchor=header11194

NIH Post-Award

→ **RPPRs cont'd**:

→ **Section D. Participants**

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.

→ **D.2.c Changes in other support**

Has there been a change in the active other support of senior/key personnel since the last reporting period?

If yes, upload active other support for senior/key personnel whose support has changed and indicate what the change has been. List the award for which the progress report is being submitted and include the effort that will be devoted in the next reporting period.

NIH Post-Award

→**RPPRs cont'd**

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

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

Report only cumulative first-tier subawards dollars by country. Do not report foreign travel, purchases, etc., unless part of a first-tier subaward to a foreign country.

NIH Post-Award

RPPRs cont'd:

G.9 Foreign component.

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

Planned Inclusion Enrollment Report Fields

Foreign/Domestic

This field indicates whether the IDR involves participants from a non-US site (i.e., foreign) or a US site (i.e., domestic).

Sponsor Disclosure Requirements

-Protecting U.S. Biomedical Intellectual Innovation -
https://grants.nih.gov/policy/protecting-innovation.htm

- Requirements for Disclosure of Other Support, Foreign Relationships and Activities, as well as Conflicts of Interest (See Table 1)

Examples of What to Disclose to NIH about Senior/Key Personnel on Applications and Awards:*

Table 1: Recipients Must Report**

Type of Activity	Report in Biosketch / Application	Report as Foreign Component in Application	Obtain Prior Approval and Report as Foreign Component in RPPR	Report as Other Support (JIT)	Report as Other Support (RPPR)	Review for potential FCOI
All positions and affiliations, including volunteer positions, relevant to the application	✓					✓ If personal payments to the individual
Relevant appointments at foreign institutions – even if labeled as "guest," "adjunct," "honorary," with or without salary support	✓					✓ If personal payments to the individual

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NIH Changes Coming Soon

→ **Biosketch**:

→ **Updating Section B.** to include relevant appointments at foreign institutions – even if labeled as "guest," adjunct," "honorary," with or without salary support

→ **Removing Section D**. Research Support section (will be asked for at JIT)

NIH Changes Coming Soon

Other Support:

→ Aligning with National Science Foundation's new Other Support Format. Common data elements.

→ New format with instructions and definitions.

→ NIH Commitment Transparency: Part I of II
https://www.youtube.com/watch?v=vsThTKXy2ls&feature=youtu.be

→ NIH Commitment Transparency: Part II of II
https://www.youtube.com/watch?v=HcMt_KBAIHg

Resources

-International Engagement website includes additional links and resources

-NIH Virtual Seminar on Program Funding and Grants Administration: https://nihvirtualseminar2020.vfairs.com/

- Keynote with Dr. Michael Lauer, NIH Deputy Director for Extramural Research, 1:00 PM – 1:45 PM EDT , Tuesday, October 27th

- Current Issues at NIH: Grants Policy Updates

- Open Mike with Dr. Michael Lauer

Contact DSP

nih@uiowa.edu (shared e-mailbox for all NIH/PHS communications that's triaged by DSP NIH reviewers)

#319-335-2123 – DSP main telephone number

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