

## Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components

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Notice Number: NOT-OD-19-114

### Key Dates

Release Date: July 10, 2019

### Related Announcements

None

### Issued by

OFFICE OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH (OD)

### Purpose

The intent of this notice is to remind the extramural community about the need to report foreign activities through documentation of other support, foreign components, and financial conflict of interest to prevent scientific, budgetary, or commitment overlap. NIH has long required full transparency for all research activities both domestic and foreign and does not consider these clarifications to be changes in policy. The requirements referenced in this Notice, along with the other obligations in the NIH Grants Policy Statement (NIHGPS) and other terms and conditions of award, are instrumental to achieving the mutual goal of NIH and the extramural community, to protect the integrity of biomedical research.

### Background

On August 23, 2018, the NIH Director issued a [statement](#) regarding the protection of the integrity of biomedical research conducted in the United States, and convened a working group of the Advisory Committee to the NIH Director to review this issue. NIH recognizes the importance of international collaborations for scientific advances. By clarifying NIH expectations for other support reporting, NIH seeks to improve the reporting of all sources of research support, financial interests and affiliations, both foreign and domestic, and to continue to support properly reported international collaborative research.

The NIHGPS, [2.5.1](#), states that 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 to ensure no scientific, budgetary or commitment overlap.

### Other Support

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 applicants must:

1. 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. 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).

2. Report all resources and other support for all individuals designated in an application as senior/key personnel – including for the program director/principal investigator (PD/PI) and for other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation. Information must be provided about all current support for ongoing projects, irrespective of whether such support is provided through the applicant organization, through another domestic or foreign organization, or is provided directly to an individual that supports the senior/key personnel’s research efforts.

3. Report all current projects and activities that involve senior/key personnel, 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.

4. Provide the total award amount for the entire award period covered (including facilities and administrative costs), as well as the number of person-months (or partial person-months) per year to be devoted to the project by the senior/key personnel involved.

All pending support at the time of application submission and prior to award must be reported using “Just-in-Time Procedures” by providing all information indicated above. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award, including “Other Support” changes that must be assessed for budgetary or scientific overlap. Further, if other support, as described as above, is obtained after the initial NIH award period, from any source either through the institution or directly to senior/key personnel, the details must be disclosed in the annual research performance progress report (RPPR). Post-award, recipients must address any substantive changes by submitting a prior approval request to NIH in accordance with the NIHGPS section on “Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award.”

## **Foreign Components**

NIH requires recipients to determine whether activities it supports include a foreign component, defined as: The existence of any “significant scientific element or segment of a project” outside of the United States, in other words

1. performance of work by a researcher or recipient in a foreign location, whether or not NIH grant funds are expended and/or

2. performance of work by a researcher in a foreign location employed or paid for by a foreign organization, whether or not NIH grant funds are expended.

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 aide with what may be considered significant, click on the FAQ link below. The addition of a foreign component to an ongoing NIH grant continues to require NIH prior approval, as outlined in the NIHGPS, [Section 8.1.2](#), Prior Approval Requirements.

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. resource that supports the research of an investigator and/or researcher, it must be reported as other support.

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. Additional funding 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.

## Financial Conflict of Interest

This notice also reminds the extramural community of the requirements in 42 CFR Part 50, Subpart F, Objectivity of Research. This regulation, also known as the FCOI regulation, specifies the minimum requirements for investigators to disclose to their institution their significant financial interests. As outlined previously in [NOT-OD-18-160](#), the requirement to disclose includes financial interests received from a foreign entity. This requirement is distinct and in addition to the reporting of other support and foreign components to the NIH.

The FCOI regulation acknowledges that an applicant/recipient's policy on financial conflicts of interest may have standards that are more stringent than those in the regulation, e.g., that require a more extensive disclosure of financial interests, in which case the [institution](#) shall adhere to its policy and shall provide FCOI reports to NIH regarding identified financial conflicts of interest in accordance with its own standards and with the protocol specified in the regulation.

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

#### Inquiries

Please direct all inquiries to:

Office of Policy for Extramural Research Administration  
Division of Grants Compliance Oversight  
Telephone: 301-435-0949  
Email: [grantscompliance@od.nih.gov](mailto:grantscompliance@od.nih.gov)

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