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NIH Issues New Guidance on “Other Support” and “Foreign Components” in Funded Research

In the wake of ongoing concerns expressed about “foreign influence” in U.S.-funded research activities, the National Institutes of Health (NIH) last week released a series of documents addressing disclosures of “foreign components,” “other support” and affiliations in grant applications and reports. Collectively, these documents include an overview blog from the NIH Deputy Director for Extramural Research, a Guide Notice entitled “*Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components*” and a number of Frequently Asked Questions (FAQs).

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Presented as “clarifications” of long-standing policies, they are important and valuable tools for applicants and awardees to understand better the NIH’s thinking on these issues. However, some of the information contained will sound new and may raise concerns or operational challenges. Universities, academic medical centers and other entities that receive any NIH research funding should review these documents carefully. Recipients of research funding from other agencies, e.g., from the National Science Foundation, may want to examine these documents also, as they likely are predictive of how other federal agencies may interpret their own related regulations.

Following are highlights and some examples of the questions that arise from the guidances.

Other Support

The NIH’s Grants Policy Statement (GPS) at section 2.5.1 defines the “other support” that must be disclosed to NIH as part of initial grant reporting (*i.e.*, Just-in-Time) or ongoing grant reporting. The new Guide Notice emphasizes 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.” In detailing this further, among other clarifications, the NIH explains in the Guide Notice that disclosure must include:

- All positions and appointments held by senior/key personnel relevant to an application, including domestic or foreign, full or part time, paid or unpaid, adjunct, visiting, or honorary.
- All resources for senior/key personnel, regardless 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.”
- All current projects and activities for senior/key personnel, including “in-kind (e.g. office/laboratory space, equipment, supplies, employees)” and “foreign financial support, research or laboratory personnel, lab space, scientific materials, selection to a foreign ‘talents’ or similar-type program....”

NIH’s FAQs add that other support disclosures must include, for example, all: (1) lab space, materials, staff, travel and living expenses for appointments, paid or unpaid, at foreign universities (FAQ3); (2) outside consulting and teaching activities, whether paid or unpaid, that relate to research activities or expertise (FAQ6); and (3) start-up packages for investigators and research grants (FAQ5).

In applying NIH’s thinking to real-world settings, a number of question arise regarding the vast scope of “other support” that must be reported under a literal reading of the guidance. For example, the guidance indicates that all foreign relationships, appointments and even compensation arrangements in support of the senior/key personnel’s research

represent “other support” that must be reported. How to distinguish this other support from, for example, personal consulting income may be less than clear under this new guidance. Similarly, start-up packages can include direct funding, space, general funding, salary, compensation and more. Disclosing all of these sources of support is not necessarily relevant to the question of whether there are one or more foreign sources of support, which appears to be the agency’s primary goal. Nonetheless, it appears to be required for all senior/key personnel, regardless of whether they are employed by the prime awardee. Furthermore, while this information would not be distributed to peer reviewers, as it would need to be provided only for funded or likely-to-be-funded projects at Just-in-Time, compiling and disclosing extensive details on specific financial plans may create an undue burden on awardees and may threaten the personal privacy interests of senior/key personnel. We understand from NIH sources that actual dollar amounts of start up packages are not expected to be reported, but this may require additional clarification from NIH.

Foreign Components

International collaboration is a mainstay of scientific progress, and federal funders like NIH support it, subject to certain limitations and disclosure. If individual funding opportunity announcements permit foreign components, and if applicants disclose their foreign component plans in the application, then NIH may approve a “foreign component” of the project. A foreign component can also be added during the performance of the award by obtaining NIH’s prior approval.

NIH defines a foreign component in the GPS at section 1.2 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.”

Last week’s guidance documents emphasize how geography is a critical element to distinguishing foreign components from other support. The agency offers a formula for assessment: first, determine if any activities will be performed outside of the U.S., and, second, determine if those activities are significant. If so, prior authorization is required to add them as foreign components.

By contrast, if all research activities for a project occur in the U.S., but an investigator or researcher receives support from outside the U.S., either for that project or others, then it must be disclosed as “other support.” This means that NIH would not typically regard a visiting researcher with a salary paid by her foreign institution to be a “foreign component” requiring prior approval if she works in a laboratory in the U.S. on an NIH-supported project. However, her service would likely be considered “other support” for the senior/key personnel and would be reportable to NIH as such.

Financial Conflict of Interest

The agency’s new guidance documents do not elaborate on its financial conflict of interest regulation, found at 42 CFR Part 50, Subpart F, except to emphasize that investigators must report all sources of income to their institutions and that these duties to disclose income related to one’s primary appointment are distinct from, and in addition to, the other support and foreign component disclosures that must be made to the NIH.

Implications

It remains to be seen how much this new guidance will allay concerns about how the government is examining and accounting for possible undue foreign influence in federally-funded research.

It is important at this time in history that attention continue to be paid to the many valuable contributions of foreign and non-native scientists working in the United States and foreign collaborators working to advance U.S.-funded research activities around the globe. NIH has continued to emphasize this, noting again in the Open Mike blog describing this new guidance that the “overwhelming majority of researchers participating in NIH grants, whether U.S. or foreign-born, are honest contributors to the advancement of knowledge that benefits us all.” This bears repeating, especially as methods for accurate and proper reporting of foreign ties are implemented and refined.

Additionally last week, the White House's Office of Science and Technology Policy hosted a high-level, intergovernmental leadership meeting focused, among other issues, on "undue foreign influence" in research and developing further guidance, including possibly standardizing conflict of interest and commitment disclosure requirements and enforcement. Engaging the academic and research communities is expected to be a key element of this process over time.

The new documents for review are:

- [*Clarifying Long-Standing NIH Policies on Disclosing Other Support*](#), NIH Open Mike Blog (July 11, 2019)
- [*Reminders of NIH Policies on Other Support and on Policies Related to Financial Conflicts of Interest and Foreign Components*](#), NOT-0D-19-114 (July 10, 2019)
- [*Frequently Asked Questions--Other Support and Foreign Components*](#) (July 3, 2019).

Information on the White House Office of Science and Technology Policy activities may be found [here](#).