

# NIH issues long-awaited guidance on other support, foreign components, and financial conflicts of interest

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On 10 July 2019 the National Institutes of Health (NIH) issued its long-awaited guidance addressing grantee disclosure obligations related to researchers' activities outside the United States. The NIH notice is presented as a "remind[er]" and explicitly states that "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."<sup>1</sup> However, when read in conjunction with the accompanying FAQs<sup>2</sup>, this "clarification" is effectively a significant expansion of grantee reporting obligations and will likely pose considerable compliance challenges and risks going forward.

## Background

On 23 August 2018 NIH Director Dr. Francis Collins issued a statement highlighting risks associated with the loss of intellectual property generated with NIH assistance and the integrity of the peer review process used to evaluate grant proposals. Since then, NIH has placed substantial emphasis on ensuring that its grantees, and their researchers, adequately report foreign affiliations and financial support. In addition, NIH has engaged in substantial oversight activity that has taken the form of letters to dozens of institutions suggesting that they have not properly disclosed the foreign ties of certain researchers and, in some cases, referrals to the Department of Health and Human Services Office of Inspector General and the Federal Bureau of Investigation. There are also active investigations being conducted under the False Claims Act focused on the alleged nondisclosure of foreign affiliations and or support.

This oversight activity has taken place under a set of definitions, requirements, and guidance that were not necessarily wholly aligned with NIH's current expectations. That gap between existing requirements and NIH's current expectations has proven extraordinarily challenging for institutions to navigate. The NIH notice and the FAQs, while providing some clarity in the areas of other support, foreign components, and financial conflicts of interest, raise additional questions and will likely test the ability of grantee institutions to meet NIH's expectations.

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<sup>1</sup> NIH Notice NOT-OD-19-114, [available here](#)

<sup>2</sup> NIH grants and funding FAQs, [available here](#)

## Other support

The NIH Grants Policy Statement defines "other support" as including "all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts."<sup>3</sup> Although that is a broad definition, NIH grantees have often taken the position that financial support that does not have a defined scope of work or time commitment is not reportable. For example, many institutions have long taken the view that a lab startup package that is essentially discretionary funding for an investigator is not reportable as other support. The NIH notice, and its related FAQs, have clarified some open issues around other support but have done so in a way that will be viewed by the research community as substantially expanding disclosure obligations. Among the areas that NIH now expects to be disclosed as other support are the following:

- Unpaid appointments that provide access to lab space, research materials, and staff.
- Startup packages.
- Domestic research collaborations with scientists whose work is supported by an institution that is not the NIH grantee.
- Consulting that is in "any way" related to a faculty member's research endeavors.
- Research conducted outside of a faculty member's appointment period, i.e., during summer months by a nine-month faculty member.
- Participation in a "talent" program.

There are multiple issues addressed in the notice and FAQs that continue preexisting uncertainty or introduce new questions. For example, the FAQs state that when evaluating other support submissions, NIH will consider whether "[o]nly funds necessary to the approved project are included in the award."<sup>4</sup> The meaning of that is open to interpretation but it is a broader review than just seeking to identify various forms of overlap and suggests the possibility of funding reductions tied to disclosed other support. Another area that remains unclear is when to report positions and scientific appointments at other institutions given that the NIH notice still refers to "relevant" appointments. In light of NIH's recent oversight activity that has consistently asked about foreign appointments, it is uncertain how much stock one should place on the word "relevant" and whether NIH really means "all." NIH has also included a statement in the notice that substantive, post-award, changes to other support are subject to NIH's prior approval requirements. It is uncertain how that prior approval requirement will work in conjunction with existing obligations to provide updates through annual progress reports.

## Foreign components

NIH continues to define a "foreign component" as follows:

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

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<sup>3</sup> NIH Grants Policy Statement at I-31 (Oct. 2018 ed.), [available here](#)

<sup>4</sup> NIH FAQ A.2., [available here](#)

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.
- Receipt of financial support or resources from a foreign entity.

Foreign travel for consultation is not considered a foreign component.<sup>5</sup>

From a compliance perspective, NIH has recently been aggressively pursuing instances of potentially undisclosed foreign components, in part based on its review of published articles that acknowledge support from both NIH and one or more foreign sources. This focused oversight activity has resulted in a considerable amount of uncertainty in terms of what exactly constitutes a foreign component. For example, there has been uncertainty around whether hosting a visiting fellow who works exclusively in a U.S. lab on an NIH project but whose salary is paid by a foreign government creates a foreign component. NIH has explained that fact pattern would generally not constitute a foreign component. Likewise, NIH has explained that, in general, work performed in the United States will not be considered a foreign component. The FAQs, however, implicitly recognize the continued nuances surrounding what constitutes a foreign component through their repeated use of the word "generally," and encouraging communication with NIH grants officers.

### **Financial conflicts of interest**

The NIH notice underscores that financial interests received from foreign institutions of higher education or foreign governments must be reported by investigators through the institutional financial conflict of interest process and, when necessary, to NIH. This is further clarification that certain exclusions outlined in the Public Health Service financial conflict of interest regulations are limited to domestic institutions of higher learning and U.S. governmental entities.

### **Key takeaways**

Although pitched as a clarification, the new guidance is going to result in significant changes in terms of how NIH grantees handle disclosure of research activities outside of the United States. Grantees will find that more information will need to be collected from researchers and other staff and, once collected, will need to make its way into required disclosure forms. These heightened disclosure requirements are already posing operational challenges. As a result, many grantees have started taking a holistic look at all of the existing institutional functions that may already have, or could obtain, relevant information. Often, these efforts have resulted in requesting additional information, adjusting information collection methods, and/or taking steps to improve intra-institutional communication around foreign activities.

From a compliance and exposure standpoint, such work is increasingly important. The FAQs explain that failure to meet other support requirements may result in NIH "withdrawing approval of the Program Director/Principal Investigator or other researchers contributing to the NIH award, imposing specific award conditions, disallowing costs, withholding future awards including the possibility of suspending or terminating the award."<sup>6</sup> Perhaps even more significant from an institutional perspective is the possibility for False Claims Act enforcement related to

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<sup>5</sup> NIH Grants Policy Statement at I-22 (Oct. 2018 ed.), [available here](#)

<sup>6</sup> NIH FAQ A.8., [available here](#)

inaccurate or incomplete other support disclosures. Either the government or a relator could advance a theory that NIH (or another sponsor) would not have made a grant award if it had full insight into the investigator's activities outside the United States. Under such a fraud in the inducement theory, the damages could be the full value of the award or awards received by the institution, plus applicable multipliers and penalties.

Because it is unlikely that the emphasis on activities outside the United States – or the related enforcement activity – will end any time soon, institutions should consider taking a hard look at the procedures and business processes applicable to NIH's reporting requirements and assess whether they are adequate to meet current expectations.

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