

# Higher Education Alert

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## NIH Continues to Focus on Foreign Influence Issues: Updated Biosketch & Other Support Disclosure Forms

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### Key Points

- Notice reflects NIH's continued concerns regarding foreign influence and imposes significant new compliance obligations on both grantees and individual researchers.
- Obligates grantees to provide NIH with copies of researcher agreements with institutions located outside the U.S. and requires researchers to individually certify the accuracy of information provided to NIH.

Effective May 25, 2021, universities and research institutions will be required to use updated Biographical Sketch and Other Support forms in National Institutes of Health (NIH) applications and Research Performance Progress Reports (RPRRs). Please [click here](#) to read the entire notice. NIH explains that the intent of the changes is “to support the need for applicants and recipients to provide full transparency and disclosure of all research activities, foreign and domestic.” Although the updated forms are in some ways directionally consistent with NIH's recent disclosure expectations and guidance, they impose some potentially significant compliance burdens and risks on institutions and individual researchers.

Items in the updated forms to note include:

- A requirement to include in Other Support submissions that reflect “foreign activities and resources,” copies of contracts, grants or other documents “specific to senior/key personnel appointments or employment with a foreign institution.”
- A mandatory disclosure obligation to correct any failure to disclose.
- An effort to clarify what type of consulting constitutes Other Support.
- More fulsome Biographical Sketch information.
- A requirement that individual researchers personally certify the accuracy of their Other Support information.
- Although not in the Notice, a change to the Other Support instructions requiring the disclosure of support completed within the past three years.

**Contact Information**  
If you have any questions  
concerning this update, please  
contact:

**Michael J. Vernick**  
Partner  
mvernick@akingump.com  
Washington, D.C.  
+1 202.887.4460

The notice explains that the updated forms will be required for all submissions made on or after May 25, 2021.

## Key Changes

### Requirement to Include Contracts and Other Documents

When assessing questions of foreign influence, NIH has consistently expected grantees to obtain, (if necessary) translate and provide copies of all relevant contracts, grants and other documents. To date, however, there has been no formal requirement that the U.S. grantee do so. The Notice changes that by stating that if an Other Support disclosure includes:

“foreign activities and resources, recipients are required to submit copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution as supporting documentation. If they are not in English, recipients must provide translated copies.”

This requirement is likely to create multiple risk areas. Perhaps most significant is that it creates at least an implicit obligation on the grantee to review the documents to ensure that they are being accurately represented in the Other Support disclosure. As discussed below, the researcher will now be required to certify as to the accuracy of the Other Support information but there remains risk for the grantee because it too is responsible for the accuracy of materials included in grant applications and progress reports. To that point, not reviewing the documents to ensure the accuracy of the Other Support disclosure could be viewed by enforcement authorities as recklessness actionable under the False Claims Act.

In addition to legal risk, having to review these documents would place a significant administrative burden on grantee institutions. At a basic level, there would be questions of bandwidth for research administration teams often already stretched thin. In addition, grantees would have to make decisions about the scope of any review. For example, should it be limited to issues directly relevant to Other Support, such as funding amount and effort commitment, or would/should it be broader, i.e., potentially problematic intellectual property terms? Having access to, and reviewing, documents may also raise faculty confidentiality concerns that have would to be navigated.

From a purely practical perspective, translating documents can be a time consuming and expensive process. NIH’s FAQs say that NIH will accept machine translations but it remains to be seen whether those will be accurate enough for NIH to, for example, assess scientific overlap across grants.

### Mandatory Disclosure

Another significant new risk area is what NIH refers to as the “[i]mmediate notification of undisclosed Other Support” relevant to an active grant. In practice, when a grantee identifies a past non-disclosure, the grantee must provide “updated” information to the cognizant Grants Management Specialist “as soon it becomes known.” Notably, in contrast to the NIH language, the National Science Foundation implemented a similar mandatory disclosure requirement last fall that affords the grantee 30 calendar days to inform NSF after identifying the undisclosed information.

How NIH, and perhaps enforcement authorities, interpret and synthesize the terms “immediate” and “as soon as it becomes known” is uncertain and raises the possibility that grantees will face scrutiny around the timeliness of a correcting disclosure, and/or whether a grantee’s decision not to update prior submissions was sound. Questions of this nature are more than hypothetical. For example, it is not uncommon to identify, or have someone bring forward, a screen shot from a website, a news article or some other “evidence” suggesting possible participation in a talent program, service on a grant from a non-U.S. sponsor, or an affiliation with an institution outside the U.S. At what point the grantee “knows” there was a non-disclosure can often be open to reasonable debate. Likewise, there could well be fundamental questions of whether an activity or resource must be disclosed at all, as well as questions of materiality.

### **Reportable Consulting**

Throughout this period of increased emphasis on foreign influence, NIH has given somewhat mixed signals in terms of what types of consulting activities constitute reportable Other Support. This is an important issue for researchers and grantees because of the amount of consulting faculty engaging in, and the widely varying, activities that fall under the consulting umbrella. The Notice draws a line between those consulting activities that involve “conducting research,” which are reportable, and those do not and therefore need not be reported. Of course, what constitutes “conducting research” is a gray area that may well generate numerous difficult questions from faculty members and hard decisions for grantees.

### **New Biosketch Instructions**

The Notice imposes new, more stringent, requirements regarding information to be included in a researcher’s Biosketch. Specifically, NIH has revised the “Positions and Honors” section to now include “Scientific Appointments” and requires researchers to list:

“all positions and scientific appointments both domestic and foreign, 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).”

The instructions are generally consistent with other guidance NIH has put out recently but nonetheless underscores the emphasis NIH is placing on being informed of all of a researcher’s scientific appointments. Although the Notice uses the phrase “all positions and scientific appointments,” there is likely going to continue to be debate about what constitutes a “scientific appointment.”

### **Individual Researcher Certification**

From the perspective of individual researchers, the Notice effects a significant change, namely a new requirement that Other Support forms must be specifically certified as accurate by the individual whose information is being presented. In light of the continuing stream of indictments and prosecutions related to non-disclosure of activities outside the U.S., this new requirement further raises the stakes for individual researchers. They will now be forced to make a specific representation of accuracy that will provide a new basis for civil and/or criminal exposure.

## **Providing Completed Other Support**

For submissions made on or after May 25, disclosures will be required to include Other Support completed within the past three years. This obligation will increase risk for both individual researchers and grantees because it effectively creates a mechanism through which NIH will be able to detect past non-disclosures and perhaps initiate enforcement activities.

## **Takeaways**

Overall, the Notice reflects NIH's continued concerns regarding foreign influence and imposes some significant new obligations on both grantees and individual researchers. The clear takeaway is that grantee institutions should continue working to enhance their compliance policies, procedures, and practices in the foreign influence area. This work could include a comprehensive assessment considering, among other areas, ways to leverage existing data within the grantee institution, breaking down silos that limit information sharing, IT solutions and development and implementation of new policies and standard operating procedures for key units. Grantees may also want to consider developing a "Toolkit" specifically focused on managing the obligation to provide contracts, grants and other documents to NIH as part of an Other Support submission.

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