

Report in Brief

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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

News reports have raised concerns about foreign threats to the United States biomedical research enterprise. In a letter to institutes receiving National Institutes of Health (NIH) funding, the Director of NIH highlighted concerns about diversion of intellectual property; sharing of confidential information from grant applications; and the failure by some NIH-funded researchers to report substantial financial support from other organizations, including foreign governments.

Our objective was to determine whether NIH has policies, procedures, and controls in place for helping to ensure that institutions report all sources of research support, financial interests, and affiliations.

How OIG Did This Review

We reviewed the 2011 financial conflict of interest (FCOI) regulations and the NIH Grants Policy Statement to identify any FCOI requirements with which institutions must comply during the grant period and any NIH oversight responsibilities to monitor institutions during the grant period. We obtained an understanding of NIH's FCOI compliance program and analyzed the results of reviews conducted after the implementation of the 2011 FCOI regulations.

We reviewed institutions that were required to maintain FCOI policies and that received NIH grants in fiscal year 2018 to determine whether they had publicly accessible FCOI policies.

The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place for Helping To Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations

What OIG Found

NIH has limited policies, procedures, and controls in place for helping to ensure that institutions report all sources of research support, financial interests, and affiliations. Of the 1,875 institutions that received NIH funding in fiscal year 2018 and were required to have FCOI policies, 1,013 did not have FCOI policies posted on their websites. Of the 90 institutions in our sample that had websites but did not have posted FCOI policies, 41 either did not have FCOI policies or did not respond to our requests that they provide policies. Of the 10 institutions in our sample that did not have websites, 3 did not have FCOI policies, and 1 did not respond to our request that it provide its policy. In addition, not all NIH-funded investigators may be aware that they are required to disclose significant financial interests to their institutions, and some institutions stated that they were not aware of their responsibility to create and maintain FCOI policies.

What OIG Recommends and NIH Comments

We recommend that NIH (1) ensure that the 1,013 institutions we identified as not having FCOI policies on their website post those policies as required, (2) enhance its FCOI monitoring program to ensure that institutions resolve identified deficiencies and to review all grantee websites to ensure that FCOI policies are publicly accessible, and (3) implement procedures to ensure that all institutions required to have FCOI policies actually have FCOI policies.

In written comments on our draft report, NIH concurred with our recommendations but stated that we conflated reporting requirements for research support and affiliations with reporting requirements for FCOIs. NIH also noted that the 1,013 institutions we identified that did not have an FCOI policy on their websites account for less than 4 percent of NIH grant awards and less than 5 percent of research funding.

We maintain that the facts of our report are valid; we reviewed NIH policies with regard to significant financial interests resulting from research support and affiliations. Additionally, although the institutions we identified that did not have an FCOI policy posted on a publicly accessible webpage represent only a small percentage of the overall dollar amount, they still represent a risk because the size of an institution or the amount of funding received does not lessen the possibility that an FCOI may go unreported.