

Report on Research Compliance Volume 16, Number 11. November 01, 2019

RRC E-Alerts: October 3, 2019

By Theresa Defino

OIG: NIH Has Improved FCOI Reporting, Oversight, But Must Do More

In a series of recently released reports focusing on possible threats from foreign influences in U.S.-funded research, the HHS Office of Inspector General (OIG) has disclosed data on how many NIH-supported investigators reported financial conflicts of interest (FCOIs). A second report found that not all institutions are posting their FCOI policies online as required. In one report, OIG concluded that NIH has “made substantial strides in reviewing each reported FCOI for completeness and compliance, as well as to ensure the reasonableness of institutions’ management plans,” but it “found inconsistencies in the depth of its oversight reviews.”

OIG also noted that NIH “was unable to identify FCOIs involving foreign interests” because HHS currently doesn’t “require institutions to indicate whether an investigator’s FCOI involves an entity (e.g., a company, university, or government) that is based outside the United States. NIH has no plans to require institutions to designate—when reporting their investigators’ FCOIs—whether those FCOIs involve foreign entities. Instead, NIH is collecting information regarding investigators’ foreign associations through a clarification of its requirements for pre-award reporting,” OIG said.

According to data OIG said has not previously been revealed, 2,755 FCOIs were reported to NIH in fiscal year (FY) 2018; these came from 202 institutions and represent 3% of awards (out of a possible universe of 2,064 institutions and 55,597 awards). The most commonly reported FCOIs were equity interests (49%), payment for services (24%), and intellectual property rights from another entity (8%). By far, the National Cancer Institute had the highest number of FCOIs reported to it in FY 2018—676, involving 96 institutions and 409 awards. Second was the National Heart, Lung, and Blood Institute, with 344 reported FCOIs involving 75 institutions and 213 awards, followed by the National Institute of Allergy and Infectious Disease, which had 301 FCOIs involving 67 institutions and 191 awards. “We recommend that NIH (1) perform periodic quality assurance reviews of the FCOI information in its online system to ensure the adequacy of its oversight, and (2) use information regarding foreign affiliations and support that it collects during the pre-award reporting process to decide whether to revise its FCOI review process to address concerns regarding foreign threats,” OIG said. “NIH concurred with both recommendations.”

The second report concluded that 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.” Among a sample of nearly 2,000 institutions with NIH awards in FY 2018, more than half failed to post their FCOI policies online as required, the report found. OIG “determined that 1,013 of the 1,776 [sampled] institutions with a web presence did not have FCOI policies posted on their websites as required by 42 C.F.R. § 50.604(a).” A further sample of 90 “that had websites but did not have posted FCOI policies” showed 41 that “either did not have FCOI policies or did not respond to our requests that they provide policies.” OIG recommended that NIH “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.” Moreover, OIG said NIH should “implement procedures to ensure that all institutions required to have FCOI policies actually have FCOI policies.”

OIG added that, “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.” In its response, NIH “noted that the 1,013 institutions...account for less than 4 percent of NIH grant awards and less than 5 percent of research funding.” NIH agreed with OIG’s overall recommendations, saying it would provide OIG with a “detailed corrective action plan in our six-month response.”

[Link to report with FCOI data](#)

[Link to report addressing posting of FCOI policies](#)

This document is only available to subscribers. Please log in or purchase access.

[Purchase Login](#)