



January 31, 2011

HHS OIG Recommends New Federal Regulations to Govern NIH Grantee Institutions

According to OIG, NIH lacks information on institutional conflicts and the impact these conflicts may have on NIH-sponsored research

Summary

The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) recently issued a report finding that:

- There are no Federal requirements that grantee institutions identify, report, and manage actual or potential institutional conflicts.
- The National Institute of Health (NIH) should require grantee institutions to identify, report, and address institutional conflicts in a consistent and uniform manner.
- It is important that NIH know of the existence of such conflicts so it can ensure that research conducted by grantee institutions is free from any intended or unintended bias.

Alert - Potential Implications of OIG Report

- Some grantee institutions have been the subject of Congressional oversight regarding financial conflicts of interest. The OIG report may prompt Congress to investigate grantee institutions and their financial interests and conflicts of interest.
- Grantee institutions should take the prudent step of adopting appropriate written policies and procedures to address institutional financial interests and real or potential conflicts in a consistent and uniform manner.
- Grantee institutions should be prepared to file comments if/when the NIH issues a notice of proposed rulemaking in response to the OIG's recommendations.

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Report on Institutional Conflicts of Interest at NIH Grantees

On January 10, 2011, the OIG released a report on institutional conflicts of interest at NIH grantees.ⁱ Grantee institutions include universities, medical schools, and other research institutions (*e.g.* private or nonprofit research organizations) that receive research grants from NIH. The OIG recommended that NIH promulgate regulations that address institutional financial conflicts of interest. Section 493A of the Public Health Service (PHS) Act already directs the Secretary of HHS to establish regulations that would protect PHS funded research, of which NIH grants are a significant part, from bias resulting from conflicts of interest of both researchers and entities (*i.e.* grantee institutions). Accordingly, Federal regulations were implemented that require these institutions to have a written policy for (1) identifying investigators/researchers' conflicts of interest; and (2) ensuring that conflicts are managed, reduced, or eliminated.ⁱⁱ In promulgating the relevant Federal regulations, NIH stated in the July 1995 final rule that institutional conflicts would be treated separately from investigators/researchers' conflicts. Since that time, neither HHS nor NIH have promulgated Federal regulations for defining, identifying, reporting, or managing institutional conflicts of interest.

The OIG surveyed 250 NIH grantee institutions to determine (1) whether NIH grantee institutions have written policies and procedures to address institutional financial interests and conflicts of interest; and (2) whether grantee institutions had financial interests and financial conflicts of interest related to NIH. An institution is deemed to have a conflict of interest when its financial interests, resulting from royalties, equity, stockholdings, grants, or gifts pose a risk of undue influence on decisions involving the institutions' research. Additionally, if an institution's senior officials have financial interests that relate to the institution's research, these interests are viewed as creating potential conflicts as well.

OIG Findings and Recommendations

Less than half of responding grantee institutions (70 of 156) have written policies and procedures addressing institutional financial interests.

- According to the OIG, some responding grantee institutions reported that their policies only govern the financial interests (including equity interests) held by the institution, others consider the interests of both the institution and their employees/officials, and some only consider the interests of individual employees/officials.

Less than half of responding NIH grantee institutions (69 of 156) have written policies and procedures addressing institutional conflicts of interest.

- According to the OIG, ten of the institutions with written policies had not defined what constitutes an institutional conflict and of those that did, the definitions varied. The OIG notes that several grantee institutions with written policies had not developed a process for determining whether an institution's financial interests actually created an institutional conflict.

Less than a fifth of responding grantee institutions (21 of 156) identified an institutional financial interest.

- Grantee institutions with written policies and procedures were more likely to identify conflicts (15 of 69) compared to those that do not (3 of 87 institutions).



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- Holding equity in non-publicly held companies was the most commonly cited conflict and disclosure was most commonly used to address the conflict.
- Among the 18 institutions that actually identified conflicts, 17 had the identical conflicts as the researchers (*e.g.*, holding equity in a non-public company).

The OIG concluded that the NIH lacks information on the number of institutional conflicts among its grantee institutions and the impact these conflicts may have on NIH-sponsored research; thus, OIG recommended promulgating regulations requiring policies to address institutional financial conflicts of interest.

- The NIH agreed that institutional conflicts of interest is a topic “worthy of serious consideration” and noted it was already in the process of reviewing public comments to finalize regulations regarding financial conflicts of interest. The OIG countered that NIH’s current proposed regulatory changes focused only on researchers’ conflicts—not institutional conflicts.

Potential for Congressional Oversight and Implications for Grantee Institutions

- The OIG’s findings may prompt inquiries from some members of Congress to grantee institutions and/or to the NIH to promulgate regulations that address institutional financial conflicts of interest.
- In particular, Senator Grassley has embarked on a series of investigations and industry-wide surveys related to conflicts of interest in the health care field. Though Senator Grassley is no longer the Ranking Member of the Senate Finance Committee (SFC), he is now Ranking Member of the Senate Judiciary Committee and he says he will continue to conduct oversight of healthcare issues.ⁱⁱⁱ
- Likewise, SFC Chairman Max Baucus, who joined Sen. Grassley on several such investigations, has shown a willingness to continue conducting aggressive oversight.
- In the House, where the Republican majority now controls the oversight committees, the conduct of oversight is not viewed as a partisan issue due to the risk of improper influence on decisions involving NIH research and funding of the agency’s research.
- Grantee institutions should be prepared to respond to requests for detailed information about their policies and procedures for identifying and managing institutional conflicts of interest, their rationale, if no written policies have been developed, and their stance on potential future regulations.

King & Spalding will continue to monitor the response to the OIG’s Report, as well as further congressional oversight of financial conflicts of interest in the health care field. Please contact us with any questions or if we can assist with targeted analysis of institutional financial interests and conflicts of interest, with congressional inquiries, or with preparing agency comments.

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This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.

ⁱ Dep't of Health and Human Services, Office of Inspector General, OEI-03-09-00480, Institutional Conflicts of Interest at NIH Grantees (January 2011), <http://oig.hhs.gov/oei/reports/oei-03-09-00480.asp>

ⁱⁱ 42 C.F.R. § 50, subpart F.

ⁱⁱⁱ Ed Tibbets, *Grassley to become top Republican on Judiciary Committee*, Sioux City Journal, Nov. 12, 2010, http://www.siouxcityjournal.com/news/state-and-regional/iowa/article_950070e0-aaa2-5c8a-8ae7-f5a8cbdae3de.html