

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**INSTITUTIONAL CONFLICTS OF
INTEREST AT NIH GRANTEES**



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Inspector General

January 2011
OEI-03-09-00480



OBJECTIVES

1. To determine whether National Institutes of Health (NIH) grantee institutions have written policies and procedures to address institutional financial interests and conflicts of interest.
2. To determine whether grantee institutions had financial interests and financial conflicts of interest related to NIH research grants in fiscal year (FY) 2008.

BACKGROUND

Grantee institutions consist of universities, medical schools, and other research institutions (e.g., private or nonprofit research organizations) receiving research grants from NIH. An institutional conflict may arise when an institution's own financial interests (e.g., royalties, equity, stockholdings, and gifts) or those of its senior officials pose a risk of undue influence on decisions involving the institution's research.

Pursuant to Federal regulations, each grantee institution receiving NIH funds must have a written policy for identifying researchers' financial conflicts of interest (hereinafter referred to as conflicts) and ensuring that conflicts are managed, reduced, or eliminated. These regulations do not apply to institutions' conflicts. The Public Health Service (PHS) Act directed the establishment of regulations that would protect PHS-funded research (i.e., NIH grant research) from bias resulting from conflicts of both researchers and entities (i.e., grantee institutions). However, there are currently no Federal requirements to define, identify, report, and manage actual or potential institutional conflicts. Therefore, NIH lacks information on the number of institutional conflicts at its grantee institutions and the impact these conflicts may have on NIH-sponsored research.

We surveyed 250 grantee institutions to determine whether they have any policies and procedures regarding institutional financial interests and conflicts. We requested information on any institutional financial interests related to NIH grants awarded in FY 2008. A total of 156 grantee institutions responded, for a response rate of 62 percent.

FINDINGS

Although not required for institutional financial interests, 70 of 156 responding NIH grantee institutions have written policies and procedures addressing institutional interests.

Fifty-nine of the seventy institutions use a variety of definitions for what constitutes an institutional financial interest. Policies and procedures for some institutions relate only to financial interests held by the institutions themselves, others consider the interests of both the institutions and their employees/officials, and still others relate only to the interests of institutional employees/officials.

The number of definitions used by institutions for institutional financial interests ranged from one to eight. The average number of definitions was five. The three most common definitions are (1) an institutional official's individual financial interests, (2) equity held by the institution in publicly held entities, and (3) equity held by the institution in nonpublicly held entities.

Although not required for institutional conflicts, 69 of 156 responding NIH grantee institutions have written policies and procedures addressing institutional conflicts.

Fifty-nine of these institutions have defined, in writing, what constitutes an institutional conflict. These institutions typically defined institutional conflicts as financial interests that could affect the research, decisionmaking, loyalty, or objectivity of either the institution or individuals.

Fifty-three of the sixty-nine institutions have implemented a process to determine whether an institutional financial interest creates an institutional conflict. Their processes generally involve notifying an institutional official and/or committee regarding the financial interests. The official and/or committee then determines whether the financial interest is an institutional conflict.

Eighteen NIH grantee institutions identified 38 institutional conflicts.

Twenty-one of one-hundred fifty-six institutions identified institutional financial interests. Of those, almost all identified the financial interests as institutional conflicts. Eighteen of the twenty-one institutions identified at least 38 institutional conflicts related to NIH research grants in FY 2008. Institutions that have written policies and procedures were more likely to identify conflicts (15 of 69 institutions) compared to those that do not (3 of 87 institutions). The most common type of institutional conflict was institutions' holding equity in

nonpublicly held companies. For institutions that identified institutional conflicts, the strategy most often used to address them was disclosure.

RECOMMENDATION

NIH is the primary Federal agency responsible for conducting and supporting medical research. It is vital to public health and safety that this research be free from bias. Federal regulations establish standards to ensure that the design, conduct, and reporting of federally funded research will not be biased by any conflicting financial interest of a researcher. Currently, no Federal regulations require grantee institutions to identify and report institutional conflicts to NIH. Therefore, NIH lacks information on the number of institutional conflicts that exist among its grantee institutions and the impact these conflicts may have on NIH-sponsored research.

We continue to recommend that NIH require grantee institutions to identify, report, and address institutional conflicts in a consistent and uniform manner to NIH. It is important that NIH know of the existence of institutional conflicts so it can ensure that the related research is free from any intended or unintended bias.

Therefore, we recommend that NIH:

Promulgate regulations that address institutional financial conflicts of interest. Until regulations are promulgated, NIH should encourage grantee institutions to develop policies and procedures regarding institutional financial interests and conflicts.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

NIH stated that it is reviewing public comments to finalize regulations regarding financial conflicts of interest and, therefore, it neither concurs nor nonconcurrs with our recommendation. Instead, NIH stated it will take the Office of Inspector General's (OIG) recommendation into consideration as it considers future actions on extramural financial conflicts of interest.

OIG understands that NIH is engaged in the rulemaking process regarding financial conflicts of interest. However, in the May 21, 2010, Notice of Proposed Rulemaking regarding financial conflicts of interest, NIH proposed regulatory changes that focus only on

researchers' conflicts. The proposed regulations do not address institutional conflicts. Therefore, OIG continues to recommend that NIH include institutional conflicts in regulations addressing financial conflicts of interest.

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OBJECTIVES

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2. To determine whether grantee institutions had financial interests and financial conflicts of interest related to NIH research grants in fiscal year (FY) 2008.

BACKGROUND

Grantee institutions consist of universities, medical schools, and other research institutions (e.g., private or nonprofit research organizations) receiving research grants from NIH. Pursuant to Federal regulations, each institution receiving NIH funds must have a written policy for (1) identifying investigators' (hereinafter referred to as researchers) financial conflicts of interest (hereinafter referred to as conflicts) and (2) ensuring that conflicts are managed, reduced, or eliminated.^{1, 2} The purpose of these regulations is to promote objectivity in research by establishing standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of research funded under NIH grants will be biased by any conflicting financial interest of a researcher.

Conflicts can also exist for the institutions themselves. An institution's financial interests (e.g., royalties, equity, stockholdings, and gifts) or those of its senior officials can become institutional conflicts when the financial interests pose a risk of undue influence on decisions involving the institution's research.³ There are no Federal regulations for defining, identifying, reporting, and managing institutional conflicts. Prior research has shown that not all medical schools have policies regarding institutional financial interests and conflicts.⁴

¹ 42 CFR pt. 50, subpart F. This regulation covers Public Health Service (PHS) grants and NIH is the largest agency within PHS.

² The term "researcher" includes the principal researcher or any other person who is responsible for the design, conduct, or reporting of research funded by NIH.

³ Institute of Medicine of the National Academies, *Conflict of Interest in Medical Research, Education, and Practice*, ch. 8, April 21, 2009.

⁴ Ehringhaus, S., et al., "Responses of Medical Schools to Institutional Conflicts of Interest," *Journal of the American Medical Association*, February 13, 2008.

NIH Grants

NIH is the primary Federal agency responsible for conducting and supporting medical research. Organized into 27 Institutes and Centers, NIH receives billions of dollars annually to support its mission. In FY 2010, NIH's budget totaled over \$31.2 billion. More than 80 percent of this amount was distributed through almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 institutions across the country and around the world.⁵

Impact of the Bayh-Dole Act

In 1980, the Patent and Trademark Act Amendments (P.L. 96-517), commonly known as the Bayh-Dole Act, was enacted to facilitate the transfer of technology from grantee institutions to private industry. The Bayh-Dole Act has encouraged the commercialization of federally funded inventions but has also increased financial ties between grantee institutions and private industry.

The Bayh-Dole Act allows grantee institutions to retain title to inventions developed through federally funded research. If institutions elect to retain title to inventions, they can license them to private businesses or companies. Companies can then develop these inventions into commercial products that benefit the public. These inventions have provided institutions with millions of dollars in royalties and equity.⁶ Commercial products developed as a result of NIH-funded research include prescription drugs and other health care products.

Requirements for Grantee Institutions Regarding Researcher Conflicts

Federal regulation establishes standards to ensure that the design, conduct, or reporting of research funded under NIH grants will not be biased by researchers' conflicts.⁷ Each institution receiving NIH funds must have a written policy for identifying researchers' conflicts and ensuring that conflicts are identified, managed, reduced, or eliminated.⁸

Each grantee institution must collect from each researcher a listing of his/her known significant financial interests that would reasonably

⁵ NIH budget information. Accessed at <http://www.nih.gov/about/budget.htm> on April 15, 2010.

⁶ *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests Are Protected*, July 2001. Accessed at <http://www.nih.gov/news/070101wyden.htm> on April 15, 2010.

⁷ 42 CFR pt. 50, subpart F.

⁸ 42 CFR § 50.604.

appear to be affected by the research. Federal regulation (42 CFR § 50.605(a)) provides that a conflict exists when a designated official at the institution reasonably determines that a researcher's significant financial interest could directly and significantly affect the design, conduct, or reporting of NIH-funded research. If a researcher conflict exists, it must be reported to NIH. The institution must also manage, reduce, or eliminate the researcher conflict.

Lack of Requirements for Grantee Institutions Regarding Institutional Conflicts

For institutional financial interests, there are no Federal regulations for defining, identifying, reporting, or managing conflicts. Grantee institutions are not required to have policies that address either institutional financial interests or conflicts. However, section 493A of the PHS Act directed the Secretary of Health & Human Services (HHS) to establish regulations that would protect PHS-funded research (i.e., NIH grant research) from bias resulting from conflicts of both researchers and entities (i.e., grantee institutions).⁹ In the July 1995 final rule that promulgated Federal regulations for researchers' conflicts (42 CFR pt. 50, subpart F), NIH stated that the issue of institutional conflicts would be considered separately from researchers' conflicts. Currently, no Federal regulation addresses institutional conflicts.

On May 8, 2009, NIH issued an Advance Notice of Proposed Rulemaking (ANPRM) to gain public input on whether modifications are needed to 42 CFR pt. 50, subpart F. NIH invited public comments on all aspects of potential regulation in this area, including broadening the regulations to address institutional conflicts.¹⁰ Taking public comments regarding the ANPRM into consideration, on May 21, 2010, NIH issued a Notice of Proposed Rulemaking (NPRM). In the NPRM, NIH proposed new requirements to strengthen the reporting and management of researcher conflicts. However, the regulations were not broadened to include institutional conflicts. NIH believed that further consideration was necessary before regulations could be formulated that would address institutional conflicts in the same comprehensive manner as the proposed regulations regarding researcher conflicts.¹¹

⁹ The Secretary of HHS delegated authority to NIH to promulgate Federal regulations.

¹⁰ 74 Fed. Reg. 21610, 21612 (May 8, 2009).

¹¹ 75 Fed. Reg. 28688, 28700 (May 21, 2010).

Recommendations From HHS Regarding Financial Interests Related to Human Subjects Research

In a guidance document finalized in May 5, 2004, HHS' Office for Human Research Protections recommended 12 actions for grantee institutions to consider when handling financial interests in research involving human subjects.¹² Two of the recommended actions included (1) "establishing the independence of institutional responsibility for research activities from the management of the institution's financial interests" and (2) "establishing policies regarding the types of financial relationships that may be held by parties involved in the research and circumstances under which those financial relationships and interests may or may not be held."

Recommendations From the Institute of Medicine Regarding Institutional Conflicts

Institutional conflicts have prompted discussion and recommendations from industry and the research community. In an April 2009 report by the Institute of Medicine (IOM), the Committee on Conflict of Interest in Medical Research, Education, and Practice (Committee) presented challenges with managing institutional conflicts and provided recommendations to handle such challenges.¹³

According to the Committee, institutional conflicts arise when an institution's own financial interests pose risks of undue influence on decisions involving the institution's primary interests. For example, conflicts may arise when an institution receives gifts or grants from companies to develop clinical practice guidelines related to the companies' products.¹⁴ In addition, research conducted at the institution could affect the value of the institution's patents or its equity positions or options in biotechnology, pharmaceutical, or medical device companies.¹⁵

In addition, the IOM report highlighted that in an American Association of Medical Colleges' survey of its members conducted in 2006, only 38 percent of the respondents reported having a policy that applied to

¹² HHS, Office for Human Research Protections, *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*. Accessed at <http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf> on April 15, 2010.

¹³ Institute of Medicine of the National Academies, loc. cit.

¹⁴ A clinical practice guideline is a document that provides criteria regarding diagnosis, management, and treatment in specific areas of health care.

¹⁵ Institute of Medicine of the National Academies, loc. cit.

their institutions' financial interests, although another 37 percent reported that they were developing such a policy.

The Committee directed recommendations to NIH and grantee institutions. The Committee recommended that NIH extend Federal regulations to cover institutional conflicts as well as researchers' conflicts by developing rules governing institutional conflicts for grantee institutions. The Committee suggested that these rules require institutions to report identified institutional conflicts and the steps that have been taken to eliminate or manage such conflicts to NIH.

The Committee recommended to institutions that the assessment of institutional conflicts fall to their governing boards (e.g., board of trustees). Specifically, the governing boards should establish standing committees on institutional conflicts that are composed of members without conflicts relevant to the activities of the institution and at least one member who is not a board member, an employee, or an officer of the institution. Such standing committees would be at a greater distance from the daily pressures of decisionmaking that senior officials face. They would also have access to comprehensive information about the finances of the institutions to better resolve disputes regarding conflicts.

Related Studies by the Office of Inspector General

In a January 2008 report, the Office of Inspector General (OIG) found that NIH relies on grantee institutions to ensure compliance with Federal financial conflict-of-interest regulations rather than directly overseeing or reviewing their management of researchers' conflicts.¹⁶

In a November 2009 report, OIG reviewed 184 financial conflict-of-interest reports for researchers that were received by NIH from grantee institutions during FY 2006.¹⁷ OIG found vulnerabilities in institutions' identification, management, and oversight of conflicts. OIG also found vulnerabilities related to institutional financial interests. The potential for financial gain can pose an institutional conflict when an institution licenses technology/intellectual property for the purposes of commercialization. Therefore, one of our

¹⁶ HHS, OIG, *National Institutes of Health: Conflicts of Interest in Extramural Research*, OEI-03-06-00460, January 2008.

¹⁷ HHS, OIG, *How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health*, OEI-03-07-00700, November 2009.

recommendations called for NIH to develop regulations that address institutional conflicts.

METHODOLOGY

Sample Design

We determined from a data file found on NIH's Web site that 2,648 grantee institutions received grant money in FY 2008.¹⁸ We excluded any institutions located outside the United States (we included all 50 States and the District of Columbia). We also excluded institutions that received only training grants.¹⁹ Finally, we excluded any institutions for which NIH's data listed grant award amounts of \$1 or less.²⁰ After the exclusions, we determined that 2,321 grantee institutions received research grants in FY 2008.

We requested from NIH a list of financial conflict-of-interest reports for researchers submitted by grantee institutions during FY 2008. We asked for this information to ensure that we were including in our sample a representative number of those institutions that submitted reports for researchers to NIH. Based on the information provided by NIH, we determined that 64 institutions reported at least 1 researcher conflict to NIH in FY 2008 and 2,257 institutions did not report any conflicts.

We selected a stratified random sample of 250 institutions to survey as shown in Table 1. Stratum 1 contains all of the institutions that reported at least one researcher conflict in FY 2008. Stratum 2 contains all of the institutions that did not report any researcher conflicts.

¹⁸ NIH, *Aggregate Data 2008*. Accessed at <http://report.nih.gov/award/trends/AggregateData.cfm?Year=2008> on August 5, 2009.

¹⁹ Training grants are designed to support the research training of scientists for careers in the biomedical and behavioral sciences, as well as to help professional schools establish, expand, or improve programs of continuing professional education.

²⁰ After the initial exclusions, five institutions were listed in NIH's file as having received \$1 in grant awards.

Table 1: Sample of Grantee Institutions

Stratum	Description of Stratum	Number of Grantee Institutions in Population	Number of Grantee Institutions in Sample	Number of Grantee Institutions That Responded to Survey	Response Rate
1	Grantee institutions that submitted a researcher financial conflict-of-interest report to NIH in FY 2008	64	64	52	81%
2	Grantee institutions that did not submit a researcher financial conflict-of-interest report to NIH in FY 2008	2,257	186	104	56%
Total		2,321	250	156	62%

Source: OIG analysis of NIH data and OIG sample response rate, March 2010.

We made at least three attempts by email to request responses from nonresponding grantee institutions. A total of 156 institutions responded, for an overall response rate of 62 percent. However, based on the overall response rate and the difference in response rates for Stratum 1 (81 percent) and Stratum 2 (56 percent), we did not project our findings to the population of 2,321 NIH grantee institutions. Instead, we have provided simple unweighted frequencies for our findings. Appendix A provides both overall totals and totals by stratum for the main findings in this report.

Data Collection

We collected our data between November 2009 and January 2010. We surveyed the sampled institutions to determine whether they have developed any policies and procedures regarding institutionally held financial interests and conflicts. We asked whether grantee institutions included in their policies and procedures any of the recommendations from HHS’ Office for Human Research Protections or IOM regarding institutionally held financial interests or conflicts.

We asked the institutions whether they had institutional financial interests related to any NIH grants awarded in FY 2008. We requested information about whether the institutional financial interests were determined to be conflicts by institutions. We also asked for information on how these conflicts were addressed.

Data Analysis

From the survey data, we determined the frequency of responses to closed-ended survey questions. We also reviewed and categorized responses to open-ended survey questions that were related to institutions' definitions, policies, and procedures regarding institutionally held financial interests and institutional conflicts. For these analyses we have provided, when applicable, both the overall totals and totals for each stratum.

Limitations

Because of the overall 62-percent response rate and the large difference in response rates between the two strata, the data in our findings represent only the information for responding grantee institutions. It is possible that the data would have changed if the response rate had been higher, especially for Stratum 2 (grantee institutions that did not submit a researcher financial conflict-of-interest report to NIH in FY 2008).

All of the information in the findings section of this report was self-reported by grantee institutions. We did not collect supporting documentation from them.

Standards

This study was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

► FINDINGS

Although not required for institutional financial interests, 70 of 156 responding NIH grantee institutions have written policies and procedures addressing institutional interests

Grantee institutions can acquire financial interests related to NIH-funded research at their institutions. These financial interests can include royalties,

equity, stockholdings, and corporate gifts. Currently, no Federal regulations require grantee institutions to have policies and procedures that address institutional financial interests.

Seventy of the one hundred fifty-six grantee institutions that responded to our survey have written policies and procedures regarding institutional financial interests. Institutions that reported a researcher conflict to NIH in FY 2008 (Stratum 1) were more likely to have written policies and procedures. Table 2 shows the number of institutions with such written policies and procedures.

Table 2: Number of Grantee Institutions That Have Written Policies and Procedures Regarding Institutional Financial Interests

Stratum	Description of Stratum	Number of Grantee Institutions	Percentage of Respondents in Stratum With Written Policies and Procedures
1 (n=52)	Grantee institutions that submitted a researcher financial conflict-of-interest report to NIH in FY 2008	37	71%
2 (n=104)	Grantee institutions that did not submit a researcher financial conflict-of-interest report to NIH in FY 2008	33	32%
Total		70	45%

Source: OIG analysis of grantee institution survey responses, March 2010.

Fifty-nine of the seventy grantee institutions with written policies and procedures regarding institutional financial interests have defined, in writing, what constitutes an institutional financial interest

The 59 institutions use a variety of specific definitions for what constitutes an institutional financial interest. Policies and procedures for some institutions relate only to financial interests held by the institutions themselves, others consider the interests of both the institutions and their employees/officials, and still others relate only to the interests of institutional employees/officials.

The number of definitions used by institutions for institutional financial interests ranged from one to eight. The average number of definitions used by grantee institutions was five. The three most common

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definitions were (1) an institutional official's individual financial interests, (2) equity held by the institution in publicly held entities, and (3) equity held by the institution in nonpublicly held entities. Table 3 shows the number of grantee institutions with written policies and procedures that use the different definitions of financial interests.

Table 3: Number of Grantee Institutions With Written Policies and Procedures Using Various Definitions of Institutional Financial Interests

Institution Defined Financial Interest As:	Number of Grantee Institutions in Stratum 1	Number of Grantee Institutions in Stratum 2	Total Number of Grantee Institutions ¹
Institutional officials' individual financial interests	30	20	50
Equity in publicly held companies	29	19	48
Equity in nonpublicly held companies	28	19	47
Royalties resulting from federally funded research	19	18	37
Royalties resulting from nonfederally funded research	20	16	36
Gifts from research sponsors	17	19	36
Payments from research sponsors for reaching designated milestones in a course of a study	12	18	30
Other (e.g., intellectual property)	5	7	12

Source: OIG analysis of grantee institution survey responses, March 2010.

¹ The total number of institutions with a written definition of an institutional financial interest equals 59. The number of institutions in this column does not equal 59 because some institutions established more than 1 definition.

Most of the 70 grantee institutions with written policies and procedures reported that they had incorporated recommendations from the HHS Guidance Document

Sixty-two of the seventy institutions stated that they have incorporated recommendations from the HHS Guidance Document into their policies and procedures. The Guidance Document, issued by HHS's Office of Human Research Protections, outlines 12 recommended actions that grantee institutions engaged in human subject research should consider to help ensure that financial interests do not compromise the rights and welfare of human research subjects.

The most common recommendation that institutions reported including was establishing conflict-of-interest committees or identifying other bodies or persons and procedures to deal with individuals' or institutional financial interests in research. The recommendation incorporated least often was to allow independent organizations to hold

or administer the institution’s financial interest. Appendix B contains the number of institutions that incorporated each recommendation.

Although not required for institutional conflicts, 69 of 156 responding NIH grantee institutions have written policies and procedures addressing institutional conflicts

Institutional conflicts arise when a grantee institution’s own financial interests or those of its senior officials pose risks of undue influence on decisions involving the institution’s research.²¹ For

example, an institutional conflict exists if the outcome of research conducted at a grantee institution could affect the value of the institution’s equity in a particular company. Currently, there are no Federal requirements that grantee institutions have policies and procedures to address institutional conflicts.

Beyond policies and procedures to address institutional financial interests, grantee institutions also have policies and procedures specifying how to handle instances in which those interests pose an actual conflict with research activities. Sixty-nine institutions have written policies and procedures regarding institutional financial conflicts. A total of 78 institutions have not developed written policies and procedures for either institutional financial interests or conflicts.²² Again, institutions that reported a researcher conflict to NIH in FY 2008 (Stratum 1) were more likely to have written policies and procedures regarding institutional conflicts. Table 4 shows the number of institutions with written policies and procedures for institutional conflicts.

²¹ Institute of Medicine of the National Academies, loc. cit.

²² Sixty-one grantee institutions have written policies and procedures for both institutional financial interests and conflicts, nine institutions have policies and procedures for only institutional financial interests, and eight institutions have policies and procedures for only institutional conflicts.

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Table 4: Number of Grantee Institutions That Have Written Policies and Procedures Regarding Institutional Conflicts

Stratum	Description of Stratum	Number of Grantee Institutions	Percentage of Respondents
1 (n=52)	Grantee institutions that submitted a researcher financial conflict-of-interest report to NIH in FY 2008	37	71%
2 (n=104)	Grantee institutions that did not submit a researcher financial conflict-of-interest report to NIH in FY 2008	32	31%
Total		69	44%

Source: OIG analysis of grantee institution survey responses, March 2010.

Fifty-nine of the sixty-nine grantee institutions with written policies and procedures regarding institutional conflicts have defined, in writing, what constitutes an institutional conflict

The 59 institutions typically defined institutional conflicts as financial interests that could affect the research, decisionmaking, loyalty, or objectivity of either the institution or individuals. Some institutions determined that institutional conflicts exist when financial interests are of a certain type or reach a certain threshold amount (e.g., \$100,000 or 5-percent equity holding).

Fifty-three of the sixty-nine grantee institutions with written policies and procedures have implemented a process to determine whether an institutional financial interest creates an institutional conflict

These 53 institutions' processes generally involved notifying an institutional official and/or committee regarding the financial interests. The official and/or committee then determines whether the financial interest is an institutional conflict. Some of these officials/committees also review institutional equity holdings and/or license/royalty agreements to determine whether they are institutional conflicts.

Forty of the sixty-nine grantee institutions with written policies and procedures regarding institutional conflicts have a committee that reviews institutional conflicts

All of the committees among these 40 grantee institutions have the authority to determine whether institutional financial interests are institutional conflicts. All but two of the committees have the additional authority to determine how the conflicts will be addressed. Nineteen of

these committees are separate entities from the committees responsible for reviewing researchers' conflicts at the institutions.

In its April 2009 report, IOM recommended that grantee institutions handle challenges in managing institutional conflicts by implementing standing committees to assess the conflicts. As recommended by IOM, 15 of the 69 institutions have boards of trustees (or an equivalent governing body) that have established their own standing committees on institutional conflicts. Seven institutions also have at least one outside member of their committees who is not a board member, an employee, or an officer of the institutions. Five of these committees submit annual reports to the boards of trustees regarding institutional conflicts, which are made public.

**Eighteen NIH grantee institutions identified
38 institutional conflicts**

Twenty-one of one hundred fifty-six grantee institutions identified institutional

financial interests. Almost all of those 21 identified the financial interests as institutional conflicts.

Eighteen of the twenty-one institutions identified at least 38 institutional conflicts related to NIH research grants in FY 2008.²³ The remaining three institutions that identified financial interests did not determine them to be conflicts. Of the 18 grantee institutions that identified institutional conflicts, 15 had written policies and procedures regarding institutional conflicts. The remaining three institutions did not have written policies and procedures. Therefore, our findings show that institutions with written policies and procedures were more likely to identify conflicts (15 of 69 institutions) than those without written policies and procedures (3 of 87 institutions). Table 5 shows the number of institutions per stratum that identified conflicts.

²³ Three of the eighteen grantee institutions reported that they had at least one institutional conflict, but could not provide a specific number.

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Table 5: Number of Grantee Institutions That Reported Identifying Institutional Conflicts

Stratum	Description of Stratum	Number of Grantee Institutions With Institutional Conflicts	Number of These Grantee Institutions With Written Policies and Procedures
1	Grantee institutions that submitted a researcher financial conflict-of-interest report to NIH in FY 2008	14	13
2	Grantee institutions that did not submit a researcher financial conflict-of-interest report to NIH in FY 2008	4	2
Total		18	15

Source: OIG analysis of grantee institution survey responses, March 2010.

Grantee institutions tended to have the same conflicts as their researchers. This is important because, in essence, institutions are overseeing researchers' conflicts when they themselves have the same potential conflict. At 17 of the 18 institutions, researchers who worked on the grant(s) had the same types of conflict(s) as the institutions. For example, at one institution, both the institution and the researcher held equity in the same nonpublicly held company.

The most common type of institutional conflict was grantee institutions' holding equity in nonpublicly held companies

The 18 institutions that had institutional conflicts identified different types of conflicts. The two most common types were holding equity in nonpublicly held companies and receiving royalties resulting from federally funded research. Table 6 shows the types of institutional conflicts per stratum that were reported by institutions in FY 2008 and the number of institutions reporting each type.

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Table 6: Number of Grantee Institutions With Different Types of Institutional Conflicts Reported Between October 1, 2007, and September 30, 2008

Type of Institutional Conflicts	Number of Grantee Institutions in Stratum 1 Reporting Type of Conflict	Number of Grantee Institutions in Stratum 2 Reporting Type of Conflict	Total Number of Grantee Institutions Reporting Type of Conflict ¹
Equity in nonpublicly held companies	9	2	11
Royalties resulting from federally funded research	8	2	10
Institutional officials' individual financial interests	4	1	5
Royalties resulting from nonfederally funded research	3	0	3
Equity in publicly held companies	2	0	2
Unspecified royalties	1	0	1
Not specified/other	1	1	2

Source: OIG analysis of grantee institution survey responses, March 2010.

¹ Eighteen institutions identified thirty-eight institutional conflicts. The number of institutions in this column does not equal 18 because some institutions had more than 1 type of conflict. The number of conflicts in the column does not equal 38 because, for example, some institutions reported that a conflict involved both equity and royalties.

Grantee institutions reported having various strategies available to address their institutional conflicts

Pursuant to Federal regulation, grantee institutions must ensure that researchers' conflicts will be managed, reduced, or eliminated.

Although no such requirement exists for addressing institutional conflicts, 98 of 156 institutions reported that they had strategies to ensure that institutional conflicts do not bias research. The five most commonly reported strategies were (1) ensuring an open exchange of research results through publication and/or presentations, (2) disclosing the institutional conflict during the informed consent process for human subjects, (3) formally recusing the official who has a conflict from the chain of authority over the project and communicating the recusal to the official's superior and colleagues, (4) notifying the Institutional Review Board²⁴ regarding the institutional conflict, and (5) ensuring that adequate peer review of research is performed by the institution. Appendix C contains the number of institutions per stratum that use these and other strategies.

²⁴ Institutional review boards ensure the rights and safety of people participating in clinical trials.

F I N D I N G S

Grantee institutions that identified institutional conflicts most often used disclosure to address them

For the 18 institutions that identified institutional conflicts, the 2 methods most often used to address conflicts were (1) disclosing them during the informed consent process for research involving human subjects and (2) notifying the Institutional Review Board regarding the conflicts. The next two strategies most commonly used were disclosing the institutional conflicts in public presentations and publications and ensuring that adequate peer review of research was performed by the institution.

NIH is the primary Federal agency responsible for conducting and supporting medical research. It is vital to public health and safety that this research be free from bias. Federal regulations establish standards to ensure that the design, conduct, and reporting of federally funded research will not be biased by a researcher's conflict. The PHS Act directed the establishment of regulations that would protect PHS-funded research (i.e., NIH grant research) from bias resulting from conflicts of both researchers and entities (i.e., grantee institutions). However, there are currently no Federal requirements to identify and report institutional conflicts to NIH. Therefore, NIH lacks information on the number of institutional conflicts that exist among its grantee institutions and the impact these conflicts may have on NIH-sponsored research.

Our review shows that institutional conflicts do exist at grantee institutions. Eighteen of the one hundred fifty-six institutions that responded to our survey identified institutional conflicts related to their NIH grants in FY 2008. We found that the institutions with written policies and procedures regarding institutional conflicts were more likely to identify conflicts. However, because half of the responding institutions have no written policies and procedures, it is impossible to know how many additional institutions would have identified institutional conflicts if they had policies and procedures.

Even institutions with policies and procedures differed in how they defined and addressed institutional financial interests and conflicts related to research. Therefore, we continue to recommend that NIH require institutions to identify, report, and address institutional conflicts in a consistent and uniform manner. It is important that NIH know of the existence of institutional conflicts so it can ensure that research is free from any intended or unintended bias.

Therefore, as in our previous report, we recommend that NIH:

Promulgate regulations that address institutional financial conflicts of interest

We recommend that the regulations include the following:

- the definition of an institutional financial conflict of interest;

R E C O M M E N D A T I O N

- a requirement that grantee institutions have written policies regarding the identification and oversight of institutional financial conflicts of interest;
- the elements required in an institution's policy regarding institutional financial conflicts of interest (such as the identification and management of conflicts);
- a requirement that institutions report institutional conflicts to NIH, including reporting the details regarding the nature and management of such conflicts; these details should include the value of the financial interest, a description of how the financial interest relates to the research, a description of how the institutional conflict will be managed, and a description of how the management of the institutional conflict will ensure objectivity in the research; and
- guidance on how institutional conflicts should be identified, managed, reduced, or eliminated.

Until regulations are promulgated, NIH should encourage grantee institutions to develop policies and procedures regarding institutional financial interests and conflicts.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

NIH agreed that institutional conflict of interest is a significant and timely topic worthy of serious consideration. NIH stated that it is reviewing public comments to finalize regulations regarding financial conflicts of interest and, therefore, it neither concurs nor nonconcurrs with our recommendation. Instead, NIH stated it will take OIG's recommendation into consideration as it considers future actions on extramural financial conflicts of interest. NIH also made several technical comments on the report, and OIG has made changes to the report based on these comments where appropriate.

OIG understands that NIH is engaged in the rulemaking process regarding financial conflicts of interest. However, in the May 21, 2010, Notice of Proposed Rulemaking regarding financial conflicts of interest, NIH proposed regulatory changes that focus only on researchers' conflicts. The proposed regulations do not address institutional conflicts. Therefore, OIG continues to recommend that

R E C O M M E N D A T I O N

NIH include institutional conflicts in regulations addressing financial conflicts of interest. The full text of NIH's comments is provided in Appendix D.

▶ A P P E N D I X ~ A

Table A-1: Results by Stratum for Grantee Institutions With Written Policies and Procedures Regarding Institutional Financial Interests and Institutional Conflicts

	Number of Grantee Institutions in Stratum 1	Number of Grantee Institutions in Stratum 2	Total Number of Grantee Institutions
Number of grantee institutions that have written policies and procedures regarding institutional financial interests	37	33	70
Number of institutions that have defined, in writing, what constitutes an institutional financial interest	32	27	59
Number of grantee institutions that have written policies and procedures regarding institutional conflicts	37	32	69
Number of institutions that have defined, in writing, what constitutes an institutional conflict	35	24	59
Number of institutions that have implemented a process to determine whether an institutional financial interest creates an institutional conflict	31	22	53
Number of institutions that have a committee that reviews institutional conflicts	26	14	40
Number of institutions whose committees have the authority to determine whether institutional financial interests are institutional conflicts	26	14	40
Number of institutions whose committees have the authority to determine how institutional conflicts will be addressed	24	14	38
Number of institutions whose committees are separate entities from the committees responsible for reviewing researchers' conflicts	12	7	19
Number of institutions whose boards of trustees (or equivalent governing bodies) have also established their own standing committees on institutional conflicts as recommended by the Institute of Medicine	9	6	15

Source: Office of Inspector General analysis of grantee institution survey responses, March 2010.

▶ A P P E N D I X ~ B

Table B-1: Number of Grantee Institutions That Reported Incorporating Recommended Actions From Departmental Guidance in Written Policies and Procedures Regarding Institutional Financial Interests

Recommendation	Number of Grantee Institutions in Stratum 1	Number of Grantee Institutions in Stratum 2	Total Number of Grantee Institutions ¹
Establish conflict-of-interest committees or identify other bodies or persons and procedures to deal with individual or institutional financial interests in research or verify the absence of such interests and address institutional financial interests in research	35	20	55
Establish criteria to determine what constitutes an institutional financial conflict, including identifying leadership positions for which the individual's financial interests are such that they may need to be treated as institutional financial interests	32	20	52
Determine whether particular individuals should report financial interests to the conflict-of-interest committee (individuals could include Institutional Review Board members and staff, appropriate officials of the institutions, and researchers)	34	17	51
Establish policies on providing information, recommendations, or findings from conflict-of-interest committee deliberations to Institutional Review Boards	29	16	45
Establish the independence of institutional responsibility for research activities from the management of the institution's financial interests	26	17	43
Establish policies regarding the types of financial relationships that may be held by parties involved in the research and circumstances under which those relationships and interests may or may not be held	25	18	43
Establish clear channels of communication between conflict-of-interest committees and Institutional Review Boards	29	13	42
Establish measures to foster the independence of Institutional Review Boards and conflict-of-interest committees	28	14	42
Establish procedures for disclosures of institutional financial relationships to conflict-of-interest committees	25	16	41
Provide training to appropriate individuals regarding financial interest requirements	27	11	38
Include individuals from outside the institution in the review and oversight of financial interests in research	23	10	33
Use independent organizations to hold or administer the institution's financial interest	12	4	16

Source: Office of Inspector General analysis of grantee institution survey responses, March 2010.

¹ The total number of institutions that reported incorporating recommendations equals 62. The number of institutions in this column does not equal 62 because some institutions incorporated more than 1 recommendation.

➤ A P P E N D I X ~ C

Table C-1: Methods Employed by Grantee Institutions To Manage, Reduce, or Eliminate Institutional Conflicts

Methods	Number of Grantee Institutions in Stratum 1	Number of Grantee Institutions in Stratum 2	Number of Grantee Institutions ¹
Ensuring open exchange of research results through publications and/or presentations	30	40	70
Disclosure of institutional conflicts during the informed consent process for research subjects	31	24	55
Where the institutional conflict involves senior officials, formal recusal of the conflicted officials from the chain of authority over the research and communication of the recusal arrangement to the officials' superiors and colleagues	37	17	54
Notification of the Institutional Review Boards regarding institutional conflicts	31	22	53
Ensuring that adequate peer review of research is performed by the institution	18	34	52
Disclosure of the institutional conflicts in public presentations and publications	25	25	50
Where the institutional conflict involves a senior official, designation of a "safe haven" (e.g., a nonconflicted senior individual) with whom researchers can address institutional-conflict-related concerns	32	15	47
Monitoring the use of institution facilities or prohibiting the use of institution facilities/resources to further the interests of companies connected to institutional conflicts	24	19	43
Ensuring that no technology/intellectual property is inappropriately shared with companies connected to institutional conflicts	19	23	42
External monitoring of research studies	20	19	39
Prohibiting outside companies related to institutional conflicts from sponsoring research associated with the conflicts or requiring approval for outside companies to sponsor research	17	17	34
Preapproving/overseeing purchases of goods/services from companies connected to institutional conflicts	17	16	33
Elimination of the institutional conflict	18	15	33
Disclosure of the institutional conflicts to other researchers and/or centers in a multicenter trial	11	10	21
Additional internal monitoring of research studies	3	0	3
Prohibiting clinical research at the grantee institutions	2	0	2

Source: Office of Inspector General analysis of grantee institution survey responses, March 2010.

¹ The total number of institutions equals 156. The number of institutions in this column does not equal 156 because some institutions use more than 1 method for managing, reducing, and/or eliminating institutional conflicts.

▶ A P P E N D I X ~ D

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

NOV 2 2010

TO: Stuart Wright
Deputy Inspector General for Inspection and Evaluations, HHS

FROM: Director, NIH

SUBJECT: National Institutes of Health Comments on the Draft Office of Inspector
General Report: *Institutional Conflicts of Interest at NIH Grantees*
(OEI-03-09-00480)

Attached are our general and technical comments on the draft Office of Inspector General report, entitled *Institutional Conflicts of Interest at NIH Grantees* (OEI-03-09-00480).

We appreciate the opportunity to review and comment on this important topic. Should you have questions or concerns regarding our comments, please contact Mary Anne Mazzarino in the Office of Management Assessment at 301-496-2461.

/s/

Francis S. Collins, M.D., Ph.D.

Attachments

**GENERAL COMMENTS OF THE NATIONAL INSTITUTES OF HEALTH ON THE
OFFICE OF INSPECTOR GENERAL DRAFT REPORT, ENTITLED *INSTITUTIONAL
CONFLICTS OF INTEREST AT NIH GRANTEES (OEI-03-09-00480)***

The National Institutes of Health (NIH) appreciates the review conducted by the Office of Inspector General (OIG) and the opportunity to provide comments on this draft report. We respectfully submit the following general comments. Technical comments are contained in a separate attachment.

We found this report informative, being interested to learn that close to half of the respondents to the OIG's sample already have written policies on institutional conflicts of interest in place at their institutions. We are aware that many of the professional societies, such as the Association of American Medical Colleges, the Association of American Universities, and the Council on Governmental Relations, among others, have developed guidance and encouraged members to adopt institutional conflict of interest policies. There also have been numerous articles on the topic appearing in publications such as the *New England Journal of Medicine* and the *Journal of Law, Medicine & Ethics*. This information is consistent with the OIG's findings that the extramural research community has taken steps to implement policies. Moreover, this supports NIH's specific requests for public comments on this important topic.

OIG Recommendation: NIH should promulgate regulations that address institutional financial conflicts of interest.

NIH Response: We agree institutional conflict of interest is a significant and timely topic worthy of serious consideration. For this reason, we requested public comments on institutional conflict of interest in the Advanced Notice of Proposed Rulemaking of May 2009 and in the Notice of Proposed Rulemaking of May 2010 on the "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors."

However, at this time, particularly as we are in the process of reviewing public comments to finalize the regulations, the NIH neither concurs or nonconcur with the OIG recommendation that NIH promulgate regulations that address institutional financial conflicts of interest. As we stated in our notices to the public referenced above, institutional conflict of interest is a highly complex issue that affects a wide array of recipient institutions that receive awards from across the Federal Government, as well as from a variety of other sources. Therefore, we will take the OIG's recommendation into consideration as we consider future actions on extramural financial conflict of interest.



A C K N O W L E D G M E N T S

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General.

Tanaz Dutia served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Emily Multari; central office staff who contributed include Heather Barton.

Office of Inspector General

<http://oig.hhs.gov>

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