

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**NATIONAL INSTITUTES OF
HEALTH'S HANDLING OF
ALLEGATIONS CONCERNING
CONFLICT OF INTEREST AND
ETHICS VIOLATIONS**



Daniel R. Levinson
Inspector General

October 2008
OEI-03-07-00220

Office of Inspector General

<http://oig.hhs.gov>

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OBJECTIVE

1. To determine the number and nature of allegations related to conflicts of interest and ethics violations received by the National Institutes of Health (NIH) between January 1, 2006, and June 30, 2007.
2. To determine the final resolution of these allegations.
3. To determine how different Institutes and offices at NIH handle allegations of conflicts of interest and ethical misconduct.

BACKGROUND

Congress, the Office of Government Ethics, and the Department of Health and Human Services (HHS) have promulgated conflict-of-interest statutes and ethics regulations to help ensure that Federal employees are not compromised by conflicts of interest when performing their official duties. Although NIH employees are permitted to perform outside activities with non-Federal entities, they may not undertake activities that might cause actual or perceived conflicts of interest.

The NIH ethics program is composed of the NIH Ethics Office within the Office of the Director and ethics offices within each of the Institutes and Centers (Institutes) at NIH. The ethics program encompasses all of NIH's approximately 18,000 employees.

The NIH Ethics Office was established to provide guidance and advice to the ethics offices within each Institute and to the NIH community as a whole. In addition, the HHS Office of the General Counsel (OGC) maintains an ethics division at NIH to provide advice on ethics issues and the interpretation of HHS regulations.

NIH staff members are responsible for reporting employee activities that they believe are criminal or improper. The HHS Office of Inspector General (OIG) handles allegations of criminal offenses, including violations of conflict-of-interest statutes. NIH's Office of Management Assessment (OMA) handles allegations of noncriminal employee misconduct and conflicts of interest related to NIH programs and activities.

We reviewed all documentation that we received from NIH pertaining to allegations of violations of conflict-of-interest statutes and violations of

ethics regulations. The allegations were received by NIH from January 1, 2006, to June 30, 2007. We surveyed 31 Deputy Ethics Counselors at the Institutes. We also interviewed relevant staff in OMA, the NIH Ethics Office, and OGC Ethics Division to determine what role each plays in the handling of allegations. As part of our interview protocol, we collected any relevant documentation or operating procedures that these offices maintain.

FINDINGS

The most common allegations involved National Institutes of Health employees not completing required ethics training or ethics forms.

We received documentation from NIH for 565 allegations related to conflicts of interest and/or ethics violations. NIH determined that 542 of the allegations were substantiated and 23 were unsubstantiated. The majority of substantiated allegations (296 allegations) were related to employees not completing required ethics training. The second most common substantiated allegation (194 allegations) was related to employees not completing required ethics forms.

The majority of allegations were resolved within the National Institutes of Health; however, for one-third of allegations, no final resolution was documented. NIH resolved 60 percent of substantiated allegations internally and forwarded another 7 percent to OIG for possible investigation. The majority of allegations were resolved by having the employees complete the required ethics training or forms. NIH did not provide documentation regarding its final resolutions for 33 percent of substantiated allegations. The absence of documentation does not necessarily mean that the allegation was not resolved. However, without complete documentation, it is impossible to determine whether and how these allegations were resolved, including whether they were handled appropriately and consistently.

The majority of Institutes do not have written procedures regarding how to handle allegations and do not handle allegations uniformly.

The majority of Institutes do not have Institute-specific policies or procedures for reviewing allegations regarding violations of the conflict-of-interest statutes and ethics regulations. Institutes reported that when handling an allegation, they do not uniformly confer with the NIH Ethics Office, the OGC Ethics Division, or OMA. For example, eight Institutes reported that they would contact any of the three offices for guidance when reviewing allegations. Another 15 Institutes

E X E C U T I V E S U M M A R Y

reported that they would seek assistance from only one or two of the offices. The remaining Institutes did not specifically report conferring with any of the three offices. With regard to criminal allegations, most Institutes rely on the NIH Ethics Office, the OGC Ethics Division, or OMA to refer these allegations to OIG. However, several Institutes make referrals directly to OIG.

Coordination among the Ethics Office, the Office of Management Assessment, and the Office of the General Counsel Ethics Division occurs but is not formalized in a written policy. During interviews with staff at the NIH Ethics Office, OMA, and the OGC Ethics Division, it was clear that they understand their own roles and responsibilities with regard to handling allegations. However, although OMA has written policies and procedures in place to handle allegations, the NIH Ethics Office and the OGC Ethics Division do not. In addition, none of the offices have written procedures outlining the coordination between the three offices.

RECOMMENDATIONS

NIH employees have a responsibility to avoid the appearance of impropriety, which can undermine public confidence in the scientific integrity of NIH's research program. Consequently, NIH has a responsibility to ensure that its employees abide by Federal statutes and regulations regarding ethics and conflicts of interest. Violations of these statutes and regulations could jeopardize the scientific integrity of NIH's research programs.

Because NIH is organized as various components, including Institutes, NIH's ethics program is composed of various offices that work to handle allegations of conflict of interest and ethics violations. To maintain consistency in how allegations are handled, we recommend that NIH:

Develop a formal, written policy outlining how allegations of conflicts of interest and ethics violations are to be handled among the Institutes' ethics offices, the National Institutes of Health Ethics Office, the Office of the General Counsel Ethics Division, and the Office of Management Assessment.

Ensure that documentation detailing how allegations are ultimately resolved is maintained.

AGENCY COMMENTS

NIH concurred with our recommendations, stating that as of August 15, 2008, the recommendations were implemented as a new chapter in the “NIH Policy Manual.” However, NIH noted that our finding related to employees not completing required ethics forms was misleading because it did not provide as context the number of employees required to take the training. The official draft report shared with NIH did note in the background, as does this final report, that NIH’s ethics program encompasses approximately 18,000 employees.

▶ T A B L E O F C O N T E N T S

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS 9

 Most allegations involved NIH employees not completing
 required ethics training or ethics forms..... 9

 One-third of allegations did not have documented resolutions... 10

 The majority of Institutes do not have written procedures
 regarding how to handle allegations 13

 Coordination among internal offices occurs but is not
 formalized in a written policy..... 15

RECOMMENDATIONS 17

 Agency Comments..... 18

APPENDIXES 19

 A: Types and Number of Allegations Related to Conflict
 of Interest and Ethics Violations Between January 1, 2006,
 and June 30, 2007..... 19

 B: Agency Comments..... 21

ACKNOWLEDGMENTS 24

OBJECTIVE

1. To determine the number and nature of allegations related to conflicts of interest and ethics violations received by the National Institutes of Health (NIH) between January 1, 2006, and June 30, 2007.
2. To determine the final resolution of these allegations.
3. To determine how different Institutes and offices at NIH handle allegations of conflicts of interest and ethical misconduct.

BACKGROUND

NIH, located within the Department of Health and Human Services (HHS), is the primary Federal agency responsible for conducting and supporting medical research. Organized into 27 Institutes and Centers, NIH spends billions of dollars annually to support its mission. In fiscal year 2007, the total NIH appropriation was over \$29.2 billion. Much of this funding is distributed through almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions across the country and around the world.¹

One of NIH's stated goals is to "exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science."² Maintaining this scientific integrity involves avoiding conflicts of interest in which employees' performance of official duties might be affected by outside financial interests, such as stock holdings or employment activities with non-Federal entities. Although NIH employees are permitted to interact with non-Federal entities to perform certain outside activities that are crucial to maintaining technical proficiency, professional licenses, and academic credentials, they may not undertake activities that might cause actual or perceived conflicts of interest. Because NIH employees hold positions of trust, even the appearance of conflicts of interest can undermine the public's confidence.

¹ NIH. "NIH Budget." Available online at www.nih.gov/about/budget.htm. Accessed on July 3, 2008.

² NIH. "About NIH." Available online at www.nih.gov/about. Accessed on July 3, 2008.

Conflict of Interest

Congress has imposed prohibitions to help ensure that Federal employees are not compromised by conflicts of interest when performing their official duties. For example, 18 U.S.C. § 208 prohibits employees from participating in official matters in which they and certain others with whom they have relationships (such as spouses, dependent children, and outside employers) have a financial interest. A related statute, 18 U.S.C. § 209, prohibits Federal employees from receiving any salary, or contribution to or supplementation of salary, from any source other than the United States as compensation for services as a Government employee (such as receiving an honorarium for giving an official speech). Violations of these two statutes are considered criminal offenses.

The Office of Government Ethics exercises leadership to prevent conflicts of interest on the part of executive branch employees. In 1992, the Office of Government Ethics promulgated Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR pt. 2635), which included prohibitions against engaging in conflicting outside activities. In 1996, the Supplemental Standards of Ethical Conduct for Employees of HHS (Supplemental Standards), which prohibited all HHS employees from engaging in compensated outside activities involving HHS-funded grants, contracts, cooperative agreements, and cooperative research and development agreements, was issued.

The Supplemental Standards were revised in August 2005, when additional prohibitions on outside activities were imposed. These prohibitions prevented NIH employees from engaging in outside activities with substantially affected organizations, supported research institutions, and health care providers or insurers. The revisions also included additional prohibitions on financial holdings for senior NIH employees, such that these employees and their spouses and minor children must divest all holdings in substantially affected organizations in excess of \$15,000 per company.

NIH monitors outside activities and financial interests of its employees by reviewing the following forms:

- *Request for Approval of Outside Activity (HHS-520)*. This form is required for certain outside activity requests. It contains information on the employee's position; the nature of the outside activity; the length of time over which the outside activity will be

performed; and the method of compensation, if any, for the outside activity.

- *Supplemental Information to the HHS-520 (NIH-2657)*. Outside activities involving consulting for industry, legal consulting/testimony, and professional practice by NIH employees require the submission of this form.
- *Annual Report of Outside Activity (HHS-521)*. NIH employees who conduct outside activities are also required to file this annual report of outside activities for the previous calendar year by February 28.
- *Public Financial Disclosure Report (SF-278)* and *Confidential Financial Disclosure Report (OGE-450)*. Office of Government Ethics regulations outline which executive branch officials are required to file these forms.
- *Confidential Report of Financial Interests in Substantially Affected Organizations for Employees of the NIH (HHS-717-1)*. Under the revised HHS Supplemental Standards of Ethical Conduct, NIH employees who file public or confidential financial disclosure forms and clinical researchers must disclose the amounts that they invest in substantially affected organizations on this form.³

Ethics Program at the National Institutes of Health

The ethics programs of HHS agencies, including NIH, are coordinated by the Designated Agency Ethics Official, who also serves as the Department's Associate General Counsel for Ethics. The Designated Agency Ethics Official appoints Deputy Ethics Counselors in each agency, issues policies and procedures for the HHS ethics program, establishes ethics training for the Deputy Ethics Counselors and HHS employees, and conducts periodic site reviews of agencies' ethics programs.

The Deputy Director of NIH serves as the Deputy Ethics Counselor for all of NIH and the NIH Ethics Office assists the NIH Deputy Ethics Counselor in overseeing the NIH ethics program. The ethics program encompasses all of NIH's approximately 18,000 employees. NIH requires more than one-third of these employees to submit financial disclosure forms on an annual basis.

³ The HHS-717-1 used to be referred to as the HHS-716. For the purposes of this report, the HHS-716 and HHS-717-1 constitute the same form.

The NIH Ethics Office was established to provide guidance and advice to the ethics offices within each Institute and Center and to the NIH community as a whole. It also serves as the ethics office for senior NIH employees and Office of the Director employees and, as such, provides guidance and advice to these employees. It also assists with the formal and informal training of Institute officials.

Each Institute's and Center's ethics office at NIH is also managed by a Deputy Ethics Counselor. In addition, the Office of Director, the Office of Research Facilities, and the Office of Research Services (both located within the Office of Director) each have their own Deputy Ethics Counselors as well. Hereafter we will use the term "Institute" to represent all Institutes, Centers, and offices. Each Deputy Ethics Counselor is responsible for the overall coordination and management of that Institute's ethics program. Deputy Ethics Counselors review NIH staff financial disclosure forms and requests to engage in activities with outside organizations. Some of these forms are also initially reviewed by the employee's supervisor. Deputy Ethics Counselors can approve and disapprove outside activity requests based on the requests' compliance with current ethics regulations and policies. Institutes may also have their own Ethics Coordinators, who provide administrative and program support for the Institutes' ethics programs.

The HHS Office of the General Counsel (OGC) maintains an ethics division at NIH. The OGC Ethics Division functions as the NIH liaison to the Office of Government Ethics and provides advice on ethics issues, such as conflicts of interest, financial disclosures, and ethics training materials.

The NIH Office of Management Assessment (OMA) also has a responsibility regarding the ethics program at NIH. It is responsible for reviewing allegations referred to its office. OMA does not have any other ethics functions.

Policy and Procedures for Reporting Allegations of Misconduct

All NIH employees, including management and supervisory personnel, are responsible for reporting allegations of noncriminal misconduct to the appropriate supervisor, to a higher level management official within the organization, or to OMA. According to Chapter 1754 of the "NIH Policy Manual," OMA is responsible for reviewing allegations of noncriminal employee misconduct and conflicts of interest.

All NIH employees also have the responsibility for reporting employee activities that they believe are criminal. According to the "NIH Policy

Manual,” every employee, supervisor, and management official should report any allegation of criminal offense to the Office of Inspector General (OIG) for possible investigation.⁴ Depending on its assessment of the allegation, OIG may decide to conduct an investigation or to refer the allegation to OMA for administrative action.

NIH employees may confer with OMA at any time for advice and to determine whether allegations are criminal in nature. OMA does not have authority to investigate allegations involving criminal offenses by NIH employees.

Reviews of National Institutes of Health’s Ethics Program

Multiple reviews conducted in recent years have highlighted the weaknesses of the NIH ethics program. The Office of Government Ethics has conducted five reviews since 1987. These reviews reported problems with the outside activity review process. In 2004, the most recent review, the Office of Government Ethics reported that “. . . NIH has had a permissive culture on matters relating to outside compensation for more than a decade.” It also noted that there is confusion at NIH as to who is responsible for the ethics program. According to the report, this results from having OGC ethics staff at NIH as well as a separate NIH Ethics Office.

In response to conflict of interest concerns, NIH convened a Blue Ribbon Panel on Conflict-of-Interest Policies in 2004. The panel concluded that “the many hiring authorities used by NIH, combined with different regulatory and statutory requirements regarding financial disclosure, create a patchwork of policies and procedures that could easily lead to misunderstandings.”⁵ The panel’s recommendations helped in the development of revised Supplemental Standards, which were published in 2005. New provisions were added specifically for NIH employees.

In 2005, OIG published a report entitled “Outside Activities of Senior-Level NIH Employees” (OEI-01-04-00150) that assessed NIH’s process for reviewing outside activity requests between 2001 and 2003. The study found that limited information submitted by employees and inadequacies in the review process inhibit NIH’s ability to effectively review outside activity requests. OIG recommended that NIH improve

⁴ “NIH Policy Manual,” Chapter 1754, Reporting Allegations of Criminal Offenses, Misuse of Grant and Contract Funds, or Improper Conduct by an NIH Employee.

⁵ “Report of the National Institutes of Health, Blue Ribbon Panel on Conflict-of-Interest Policies,” June 22, 2004, p. 21.

the quality and extent of information collected for outside activities and address the inadequacies in the review process for outside activities. NIH concurred with the findings and recommendations of the report. NIH noted that it had already taken many steps to address the vulnerabilities identified in the report and had further initiatives planned.⁶

METHODOLOGY

Scope

This study is limited to allegations provided by NIH that relate to violations of conflict of interest statutes and violations of ethics regulations (hereafter referred to as allegations).⁷ We limited our review of allegations to those made during the 18-month period between January 1, 2006, and June 30, 2007. To assess the handling of these allegations by NIH, we focused our review on the NIH Ethics office, OMA, the OGC Ethics Division at NIH, the Institutes, and Deputy Ethics Counselors.

Data Sources and Data Collection

We requested all documentation pertaining to allegations. We requested that the documentation include:

- (1) Allegations received by NIH (including the Institutes, the NIH Ethics Office, and OMA) and the OGC Ethics Division at NIH during the 18-month period between January 1, 2006, and June 30, 2007. Allegations included any evidence of noncompliance that Deputy Ethics Counselors found in the course of their ethics work and that involved clear, intentional, and preexisting or ongoing noncompliance.
- (2) Any letters, e-mails, memorandums, records of phone conversations, or other materials relevant to the allegations.

⁶ During its review, OIG also found that two outside activities may have violated HHS supplemental regulations, which prohibit employees from providing consultative or professional services for compensation to assist in the preparation of any grant application intended for submission to HHS. These two cases were referred to NIH for further review. NIH agreed that the cases appeared to violate HHS supplemental regulations and the outside activities should not have been approved.

⁷ Conflict-of-interest statutes are established in 18 U.S.C. §§ 208 and 209. Ethics regulations are established in Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture; Standards of Ethical Conduct for Employees of the Executive Branch; and Supplemental Standards of Ethical Conduct and Financial Disclosure Requirements for Employees of HHS (5 CFR pts. 2634, 2635, 5501, and 5502).

We also conducted structured interviews with relevant staff in OMA, the NIH Ethics Office, and the OGC Ethics Division to determine what role each office plays in the handling of allegations. Our questions covered topics such as roles and responsibilities in the ethics program, policies and procedures for handling allegations, coordination among the different offices within NIH when handling allegations, and training and outreach efforts. We conducted these interviews onsite at NIH. As part of our interview protocol, we collected any relevant documentation or operating procedures that these officials maintained.

Additionally, we sent a survey to the Deputy Ethics Counselors for NIH and the Institutes.⁸ All of the Deputy Ethics Counselors responded to our survey, for a total of 31 survey responses.

Our questions covered topics such as each Institute's policies and procedures for how employees report allegations; the Deputy Ethics Counselors' understanding of the roles of OMA, the NIH Ethics Office, and the OGC Ethics Division; the circumstances under which allegations are referred to the appropriate NIH offices and the referral policies and procedures; the Institute's procedures for determining when disciplinary action is necessary; and the Institute's outreach and training regarding the reporting of allegations.

Data Analysis

We used a standard protocol to extract information from the documentation. From the information, we determined the number, nature, and final resolutions of the allegations. Some of the documentation we received involved allegations that related to multiple violations and/or instances of misconduct. For these allegations, each violation and/or instance of misconduct was counted separately. If the same type of allegation was made against a particular employee during different periods of time, the allegations were counted separately as well. If duplicate documentation regarding an allegation was received by more than one NIH office or Institute, the allegation was counted only once.

From the survey data, we determined the frequency of responses to closed-ended survey questions and reviewed and categorized responses to open-ended survey questions.

⁸ The NIH Deputy Ethics Counselor serves as the Deputy Ethics Counselor for NIH's senior employees.

I N T R O D U C T I O N

Standards

This study was conducted in accordance with the “Quality Standards for Inspections” issued by the President’s Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

► FINDINGS

The most common allegations involved National Institutes of Health employees not completing required ethics training or ethics forms

We received documentation from NIH for 565 allegations related to conflicts of interest and/or ethics violations between January 1, 2006,

and June 30, 2007. According to the documentation, NIH determined that 542 of the allegations were substantiated and 23 were unsubstantiated.

Table 1 below shows the categories and numbers of allegations received by NIH. Appendix A provides more details on the specific types and numbers of allegations.

For the 542 substantiated allegations, the majority (296) involved employees' failure to complete required ethics training. All of these allegations came from two Institutes. One Institute had 279 allegations and the other Institute had 17.

Table 1. Number of Allegations Related to Conflicts of Interest and Ethics Violations by NIH Employees Between January 1, 2006, and July 30, 2007			
Category of Allegations	Number of Unsubstantiated Allegations	Number of Substantiated Allegations	Total Number of Allegations
Failure To Complete Required Ethics Training	13	296	309
Failure To Complete Required Ethics Forms	2	194	196
Violations Related to Outside Activities/Outside Entities	4	18	22
Violations Related to Conflict of Interest Statutes	0	15	15
Other	2	10	12
Misuse of Position	2	9	11
Total	23	542	565

Source: OIG analysis of NIH allegation documents.

F I N D I N G S

The second most common substantiated allegation was related to employees not completing required ethics forms.⁹ We reviewed documentation for 194 of these allegations at 15 Institutes. These allegations included: (1) failing to file required forms (162 allegations), (2) filing required forms in an incomplete manner (26 allegations), and (3) filing required forms in an untimely manner (6 allegations).

Of the 162 substantiated allegations related to failure to file required forms, 65 percent involved financial disclosure forms (OGE-450, SF-278, HHS-717-1, and/or an unspecified financial disclosure form). The remaining 35 percent were related to failure to file an outside activity form (HHS-520, HHS-521, and/or NIH-2657) or Section 502 authorization request.

There were 52 substantiated allegations that were not related to ethics training or ethics forms. Eighteen of these allegations involved violations related to outside activities or outside entities. Examples of this type of allegation include employees conducting prohibited outside activities or holding prohibited financial interests in outside entities. Another 15 allegations were potential criminal violations of conflict-of-interest statutes. Ten allegations involved other issues, such as employees using Government resources for personal use. The remaining nine allegations were related to employees inappropriately using their official titles or inappropriately using their authority in the workplace.

The majority of allegations were resolved within the National Institutes of Health; however, for one-third of allegations, no final resolution was documented

NIH provided documentation that detailed how it resolved 60 percent of substantiated allegations (326) internally and referred another 7 percent (39) to OIG. For the remaining 33 percent of

⁹ Required forms include the HHS-520, HHS-521, NIH-2657, SF-278, OGE-450, and HHS-717-1. We received one allegation related to an employee not filing a Section 502 authorization request. This permits an employee who knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of the employee's household, or who knows that a person or entity with which the employee has a covered relationship is or represents a party to such matter, to participate in the matter because the interest of the Government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations (5 CFR § 2635.502).

F I N D I N G S

allegations (177), NIH did not provide documentation about how it resolved the allegations. Table 2 below shows how the 542 substantiated allegations were handled.

Table 2. Final Resolutions of Allegations Related to Conflicts of Interest and Ethics Violations by NIH Employees Between January 1, 2006, and July 30, 2007

Category of Allegations	Number of Substantiated Allegations Resolved by NIH	Number of Substantiated Allegations Referred to OIG	Number of Substantiated Allegations Without Documented Resolution	Number of Substantiated Allegations
Failure To Complete Required Ethics Training	196	0	100	296
Failure To Complete Required Ethics Forms	116	12	66	194
Violations Related to Outside Activities/Outside Entities	5	11	2	18
Violations Related to Conflict of Interest Statutes	1	14	0	15
Other	4	1	5	10
Misuse of Position	4	1	4	9
Total	326	39	177	542

Source: OIG analysis of NIH allegation documents.

Sixty percent of allegations were resolved internally within the National Institutes of Health

Because most of the 326 substantiated allegations that were resolved by NIH involved violations of ethics training and form requirements, NIH resolved these violations by having employees complete the required training or forms.

For 195 of the 296 substantiated allegations involving ethics training, NIH provided documentation to show that the employees had eventually completed the required training. For one additional allegation, NIH provided documentation that the employee no longer worked at NIH.

Of the 194 substantiated allegations concerning required ethics forms, NIH resolved 116 using a number of approaches. It resolved 101 by

having the employees submit the missing required forms and/or missing information. NIH resolved another 10 ethics form allegations by: suspending administrative actions (leave requests, travel requests, and bonuses) for five employees until ethics forms were completed; directing two employees to cease conducting the outside activities; placing a letter regarding the violation in one employee's personnel file; failing to approve an employee's late HHS-520 request; and having one employee resign from his/her position at NIH.¹⁰ For five allegations related to the untimely filing of paperwork, the employees were counseled as to the importance of submitting paperwork on time.

NIH resolved 14 of the 52 substantiated allegations not related to ethics training or forms. NIH resolved these 14 allegations using a number of different methods. These methods included: removing an employee from NIH employment, restricting an employee's use of Government property, and having an employee return travel expenses to the outside entity that paid for them.

Seven percent of allegations involved potential criminal violations and were referred to the Office of Inspector General for possible investigation

Because NIH does not have authority to investigate allegations involving criminal offenses, it forwarded 39 potentially criminal allegations to OIG for possible investigation. Fourteen of the fifteen allegations related to potential criminal violations of conflict-of-interest statutes were included in this group.

One allegation involving a potential violation of 18 U.S.C. § 208 was not referred to OIG. This allegation involved an employee who was working on an NIH-funded research project and whose spouse was listed as a contractor on the same project. This allegation was not forwarded to OIG because it was resolved internally by removing the employee from the NIH research project.

The 39 allegations involved potential violations of conflict-of-interest statutes, as well as violations of other ethics regulations. Examples of the potential criminal allegations include employee(s) who:

- served as a director of a company that submitted an application for an exclusive license to develop and commercialize a drug privately while participating as an NIH employee in research and data collection for the same drug,

¹⁰ Other allegations led to the employee's resignation.

F I N D I N G S

- influenced the award of a contract to a university from which the employee is on a leave of absence,
- improperly acted as a consultant for pharmaceutical companies,
- used position and influence to encourage an NIH Board of Scientific Directors to deny funding to an intramural research program investigating a drug because of the employee's financial ties with a pharmaceutical company developing a competing drug,
- conducted prohibited outside activities, and
- accepted compensation from prohibited outside entities.

Thirty-three percent of allegations had no documented final resolution

NIH did not provide documentation showing its final resolution of 177 substantiated allegations. The absence of documentation does not necessarily mean that the allegations were not resolved. However, without complete documentation, it is impossible to determine whether and how these allegations were resolved, including whether they were handled appropriately and consistently.

We could not determine whether ethics training was completed for the 100 allegations related to employees not completing the required training. For 66 allegations related to employees not completing required ethics forms, there was no documentation to show that the required forms and/or missing information were submitted. We could not determine the final resolution of 11 allegations related to other types of violations, such as employees inappropriately using their official titles and using Government resources for personal use.

The majority of Institutes do not have written procedures regarding how to handle allegations and do not handle allegations uniformly

Twenty of thirty-one Institutes do not have written procedures for reviewing allegations regarding violations of the conflict-of-interest statutes and ethics regulations. Although 11 Institutes reported that they have written procedures, the documentation we reviewed indicated that these were not Institute-specific procedures that detailed a review process. Rather, the Institutes were referring to more general policies or procedures established by NIH, OIG, or Federal regulation.

When reviewing allegations, Institutes consult with or receive guidance from different offices

Some Institutes reported that they do not uniformly confer with the NIH Ethics Office, the OGC Ethics Division, or OMA. For example, eight Institutes reported that they would contact any of the three offices for guidance when reviewing allegations. Six Institutes stated that they would contact either the NIH Ethics Office or the OGC Ethics Division for guidance regarding how to proceed with an allegation. Another five Institutes reported contacting either the NIH Ethics Office or OMA when reviewing an allegation. Three Institutes reported contacting only the NIH Ethics Office, and one reported contacting only OMA.

In contrast, some other Institutes did not cite any of the three offices when describing how they review allegations. Three Institutes stated that they follow NIH policies and procedures in reviewing allegations. Another five Institutes reported that they review relevant documents and facts, but did not specifically state that they confer with the NIH Ethics Office, the OGC Ethics Division, or OMA.

Several Institutes refer allegations of criminal offenses directly to the Office of Inspector General, but most rely on other National Institutes of Health offices to make the referral

As stated in the “NIH Policy Manual,” Chapter 1754, “. . . every employee, supervisor, and management official shall report any allegations of criminal offenses to the OIG. . . .” This would include violations of the financial conflict of interest statutes (18 U.S.C. §§ 208 and 209). We found that the majority of Institutes work with the NIH Ethics Office, the OGC Ethics Division, or OMA before referring criminal allegations to OIG. Seventeen Institutes forward criminal allegations to the NIH Ethics Office, the OGC Ethics Division, or OMA; these Institutes rely on these offices to refer the allegation to OIG if they believe it is warranted. Eight Institutes reported that they refer allegations of criminal offenses directly to OIG only after consultation with the NIH Ethics Office, the OGC Ethics Division, or OMA.

Other Institutes reported that they would forward criminal allegations directly to OIG. Three Institutes reported that they follow the procedures outlined in the “NIH Policy Manual,” Chapter 1754, to determine when and how to refer allegations to OIG. Two Institutes did not specifically mention involving the NIH Ethics Office, the OGC Ethics Division, or OMA in the referral process, but reported that they refer allegations of criminal offenses directly to OIG. The remaining

Institute did not respond to our question regarding referral procedures to OIG.

The majority of Institutes refer allegations of noncriminal offenses to the Office of Management Assessment

According to the “NIH Policy Manual,” allegations of improper employee conduct, such as violations of standards of conduct, shall be reported to OMA. Eighteen of the thirty-one Institutes reported that they refer allegations of noncriminal violations of the regulations directly to OMA. An additional seven Institutes stated that they refer allegations requiring further investigation to OMA. Three Institutes stated that the nature of the allegation would determine whether they refer allegations to OMA. One Institute replied that referrals would not be made directly to OMA, but did not elaborate further. Two Institutes did not provide a response to our question regarding referral to OMA.

Coordination among the Ethics Office, the Office of Management Assessment, and the Office of the General Counsel Ethics Division occurs but is not formalized in a written policy

From interviews with staff at the NIH Ethics Office, OMA, and the OGC Ethics Division, it was clear that they understand their own roles and

responsibilities with regard to handling allegations. They reported that OMA is responsible for reviewing reported allegations, the OGC Ethics Division provides legal advice and guidance, and the NIH Ethics Office maintains the role of ethics policy expert. Because the three offices have distinct roles and responsibilities, they work together as necessary to handle allegations. However, this coordination is not outlined in a written policy. If staff were to change, this coordination might not occur because there are no policies in place to guide new staff.

All three offices encourage employees to report allegations. Although employees can report allegations to any of the three offices, the OGC Ethics Division and the NIH Ethics Office understand that OMA is responsible for case development. The NIH Ethics Office reported that, for tracking purposes, it forwards to OMA allegations that need further investigation or need to be referred to OIG. If the NIH Ethics Office needs help in determining whether an allegation is criminal, it will seek assistance from the OGC Ethics Division. If an allegation is reported to the OGC Ethics Division, it consults with the Designated Agency Ethics Official to determine whether the allegation should be referred to OMA

F I N D I N G S

or directly to OIG. The OGC Ethics Division reported that, as a matter of courtesy, it informs OMA if an allegation is referred to OIG.

OMA follows a standard procedure for handling allegations as they are received.¹¹ However, these procedures do not address OMA's coordination with either the NIH Ethics Office or the OGC Ethics Division. OMA reported that it seeks advice from the OGC Ethics Division and the NIH Ethics Office when necessary. If OMA needs legal advice regarding an allegation or clarification of whether an allegation is within the purview of OIG, it contacts the OGC Ethics Division and requests a written legal opinion. If OMA has a policy question regarding an allegation, it consults the NIH Ethics Office.

Unlike OMA, the OGC Ethics Division and the NIH Ethics Office do not have written policies for handling allegations. They also do not have any written procedures outlining coordination among the three offices. The NIH Ethics Office is currently developing a policy to help employees determine where allegations should be reported and to provide some general guidance for managers and employees.

¹¹ OMA is currently in the process of revising its internal manual, which outlines the case review policies and procedures.

NIH employees have a responsibility to avoid the appearance of impropriety, which can undermine public confidence in the scientific integrity of NIH's research program. Consequently, NIH has a responsibility to ensure that its employees abide by Federal statutes and regulations regarding ethics and conflicts of interest. Violations of these statutes and regulations could jeopardize the scientific integrity of NIH's research programs.

Because NIH is organized as various components, including Institutes, NIH's ethics program is composed of various offices that work to handle allegations of conflict of interest and ethics violations. To maintain consistency in how allegations are handled at NIH, we recommend that NIH:

Develop a Formal, Written Policy Outlining How Allegations of Conflicts of Interest and Ethics Violations Are to be Handled Among the Institutes' Ethics Offices, the National Institutes of Health Ethics Office, the Office of the General Counsel Ethics Division, and the Office of Management Assessment

This policy should outline:

- when managers and Deputy Ethics Counselors should report allegations and to which office they should report them;
- which office should handle questions regarding allegations; as part of this clarification, NIH may want to designate a single, centralized office for allegation intake;
- how the Deputy Ethics Counselors, NIH Ethics Office, the OGC Ethics Division, and OMA coordinate and share information regarding an allegation;
- how much factfinding/case development should be conducted by each office regarding an allegation; and
- the definitions of criminal and noncriminal allegations.

Ensure That Documentation Detailing How Allegations Are Ultimately Resolved Is Maintained

Because we found no documented resolutions for one-third of substantiated allegations, we believe that NIH should require all of its

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

offices to maintain complete documentation regarding how they resolve allegations about ethics and conflicts of interest.

AGENCY COMMENTS

NIH concurred with our recommendations, stating that as of August 15, 2008, the recommendations were implemented as a new chapter in the “NIH Policy Manual.” This new chapter is entitled “Managing Employee Non-Compliance with Government Ethics Requirements.” However, NIH noted that our finding related to employees not completing required ethics forms was misleading because it did not provide as context the number of employees required to take the training. NIH stated that its policy requires all employees to complete ethics training. In contrast, Federal regulation requires only those who file public and confidential financial disclosure forms to complete annual ethics training. Therefore, NIH reported that ethics training noncompliance would be less than 2 percent of the total population of approximately 18,000 NIH employees required to take the training. The official draft report shared with NIH did note in the background, as does this final report, that NIH’s ethics program encompasses approximately 18,000 employees.

The full text of NIH’s comments is presented in Appendix B.

➤ A P P E N D I X A

Types and Number of Allegations Related to Conflicts of Interest and Ethics Violations Between January 1, 2006, and June 30, 2007					
Category of Allegations	Specific Type of Allegation	Number of Substantiated Allegations	Number of Unsubstantiated Allegations	Total Number of Allegations	
Failure To Complete Required Ethics Training (Total = 309)	NA	296	13	309	
Failure To Complete Required Ethics Forms (Total = 196)	Failure To File Paperwork (Total = 164)	Failure To File the OGE-450	62	0	62
		Failure To File the HHS-520	45	1	46
		Failure To File the HHS-717-1	38	1	39
		Failure To File the HHS-521	10	0	10
		Failure To File the SF-278	4	0	4
		Failure To File an Unspecified Financial Disclosure Form	1	0	1
		Failure To File a Section 502 Authorization Request ¹	1	0	1
		Failure To File the NIH-2657	1	0	1
	Filing Incomplete Paperwork (Total = 26)	Filing an Incomplete HHS-717-1	21	0	21
		Filing an Incomplete HHS-520	2	0	2
		Filing an Incomplete SF-278	2	0	2
		Filing an Incomplete NIH-2657	1	0	1
	Untimely Filing of Paperwork (Total = 6)	Untimely Filing of the HHS-520	6	0	6
	Violations Related to Outside Activities/Outside Entities (Total = 22)	Conducting a Prohibited Outside Activity	5	3	8
		Financial Interest in Outside Entity Influencing Professional Decisions	3	0	3
Holding Prohibited Financial Interests in Outside Entities		3	0	3	
Inappropriately Accepting Reimbursement of Travel Expenses From Outside Entity		3	0	3	
Accepting Prohibited Compensation From Outside Entities		1	1	2	
Comingling Outside Activities With Official Duties		1	0	1	
Conducting an Outside Activity as an Official Duty Without Approval		1	0	1	
Asking Outside Entity To Donate Honoraria to Private Foundation		1	0	1	

A P P E N D I X ~ A

Category of Allegations	Specific Type of Allegation	Number of Substantiated Allegations	Number of Unsubstantiated Allegations	Total Number of Allegations
Violations Related to Conflict of Interest Statutes (Total = 15)	Violation of 18 U.S.C. § 208	13	0	13
	Violation of 18 U.S.C. § 209	1	0	1
	Violation of 18 U.S.C. § 205 ²	1	0	1
Other (Total = 12)	Using Government Resources for Personal Use	6	0	6
	Misuse of Federal Funds by Not Complying With Government Travel Rules	0	1	1
	Supervisory Failure Regarding Ethics Duties	1	0	1
	Overuse of Vendor	1	0	1
	Improper Purchase of Government Equipment	1	0	1
	Violation of Employment Law	1	0	1
	NIH Staff Denying Funding to Outside Entity	0	1	1
Misuse of Position (Total = 11)	Inappropriate Use of Official Title	7	2	9
	Inappropriate Use of Authority	2	0	2
Total		542	23	565

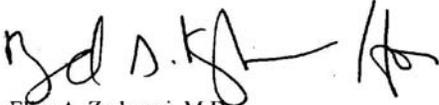
Source: Office of Inspector General analysis of National Institutes of Health allegations documents.

¹This permits an employee who knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of the employee's household, or who knows that a person or entity with which the employee has a covered relationship is or represents a party to such matter, to participate in the matter because the interest of the Government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations (5 CFR § 2635.502).

²18 U.S.C. § 205 prohibits employees from representing the interests of an outside entity before a Government agency.

▶ A P P E N D I X ~ B

Agency Comments

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Public Health Service
		National Institutes of Health Bethesda, Maryland 20892
AUG 25 2008		
TO:	Daniel R. Levinson Inspector General, HHS	
FROM:	Director, NIH	
SUBJECT:	Comments on the Draft Report, <i>National Institutes of Health's Handling of Allegations Concerning Conflicts of Interest and Ethics Violations</i> (OEI-03-07-00220)	
<p>The National Institutes of Health (NIH) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report entitled, <i>National Institutes of Health's Handling of Allegations Concerning Conflicts of Interest and Ethics Violations</i>, OEI-03-07-00220.</p>		
<p>We concur with the report's two recommendations, which we have already fully implemented when we published policy that incorporates both recommendations. Please see the attached page for our expanded comments.</p>		
<p>Should you or your staff have any questions, please call Ms. Holli Beckerman Jaffe, in the NIH Ethics Office, at 301-594-9555.</p>		
<p>Again, thank you for the opportunity to comment.</p>		
 Elias A. Zerhouni, M.D.		
<p>Attachment</p>		

**Comments from the National Institutes of Health on Office of Inspector General
Draft Report, *National Institutes of Health's Handling of Allegations Concerning
Conflicts of Interest and Ethics Violations (OEI-03-07-00220)***

The NIH concurs with the report's two recommendations. These recommendations were already fully implemented in the NIH Manual Chapter 2400-08, published on August 15, 2008.

OIG Recommendation

Develop a formal, written policy outlining how allegations of conflicts of interest and ethics violations are to be handled among the Institutes' ethics offices, the NIH Ethics Office, the Office of the General Counsel Ethics Division, and the Office of Management Assessment.

NIH Response

NIH concurs with this recommendation. The new Manual Chapter outlines how allegations of conflicts of interest and ethics violations are to be handled among the Institutes' ethics offices, the NIH Ethics Office (NEO), the Office of the General Counsel Ethics Division (OGC), and the Office of Management Assessment.

OIG Recommendation

Ensure that documentation detailing how allegations are ultimately resolved is maintained.

NIH Response

NIH concurs with this recommendation. The new NIH Manual Chapter 2400-08, "Managing Employee Non-Compliance with Government Ethics Requirements," requires that NIH Deputy Ethics Counselors report annually to the NEO and OGC the number and types of referrals to supervisors during the previous calendar year.

Additional NIH Comment

The data reported in Table 1, which cites 309 cases of NIH employees who failed to complete required ethics training, is misleading. The report omits the number of NIH employees who were required to take training and thus gives no context to the finding.

The Government-wide regulations at 5 CFR 2638.704 and 2638.705 require only those employees who must file annual financial disclosure forms (SF 278 and OGE 450) to take annual ethics training. However, NIH policy goes far beyond the Government-wide regulations and requires all of its approximately 18,000 employees to take the training, not just the approximately 6,000 employees who file SF 278 and OGE 450 forms. In

fact, if the OIG measured the 309 cases of noncompliance against the total population at NIH that year, noncompliance would drop to less than 2 percent (309 out of 18,000).

A clear explanation of how NIH goes far and above Federal Government requirements for annual ethics training would make the report more balanced and fair.

8/25/08



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 Diane Epstein and Maria Johnson; central office staff who contributed include Ayana Everett and Rita Wurm.