

April 2007

# NIH CONFLICT OF INTEREST

## Recusal Policies for Senior Employees Need Clarification





Highlights of [GAO-07-319](#), a report to congressional requesters

## Why GAO Did This Study

To safeguard the integrity of National Institutes of Health (NIH) research, government employees who have significant decision-making responsibilities and peer reviewers who evaluate the scientific and technical merit of research funding requests should be free from conflicts of interest. One method to resolve a conflict of interest is recusal, which is accomplished by not participating in work that will affect a personal interest or involves a personal relationship. GAO reported on (1) how NIH informs senior employees about recusal and what the requirements are for them to notify supervisors, and (2) how NIH informs peer reviewers about recusal and how NIH monitors their compliance with recusals. GAO reviewed relevant NIH policy manual chapters and NIH guidance and interviewed NIH officials. GAO selected NIH's National Cancer Institute and National Institute of Allergy and Infectious Diseases for the review because they have the largest budgets at NIH.

## What GAO Recommends

GAO recommends that NIH expeditiously clarify its policies with regard to written recusals and supervisor notification related to senior employees' use of recusal to resolve conflicts of interest. HHS, on behalf of NIH, concurred with GAO's recommendation and plans to revise and reissue relevant portions of its policy manual within 6 months.

[www.gao.gov/cgi-bin/getrpt?GAO-07-319](http://www.gao.gov/cgi-bin/getrpt?GAO-07-319).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Cynthia A. Bascetta at (202) 512-7101 or [bascettac@gao.gov](mailto:bascettac@gao.gov).

# NIH CONFLICT OF INTEREST

## Recusal Policies for Senior Employees Need Clarification

### What GAO Found

NIH has provided several methods to inform senior employees about recusal as a remedy to conflicts of interest, such as annual ethics training. However, NIH has not established clear recusal policies for senior employees, as the NIH policy manual is contradictory on whether senior employees must recuse in writing and notify their supervisors of their recusals. For example, the policy manual contains contradictory directions on how employees seeking nongovernment employment are to recuse. One section states that the employee "must" put the recusal in writing and that his or her supervisor "should" be notified, while another section states that the recusal "may" be done in writing and that the supervisor "must" be notified if the recusal is not written. Moreover, the two definitions of recusal in the policy manual imply that the employee must put a recusal into writing but do not explicitly require such action, and neither definition requires that the employee's supervisor be notified of the recusal. Senior employees who consult the policy manual may or may not put their recusals in writing and may or may not notify their supervisors, depending on what section of the policy manual they consult.

NIH provides written and oral methods for informing peer reviewers about recusal and for monitoring compliance with recusals. In the NIH policy manual and guidance, NIH states that peer reviewers must be informed about NIH conflict of interest regulations and policies, which include information pertaining to recusal. The policy manual refers to a form that describes situations that may constitute conflicts of interest and the need to recuse in those situations. The Scientific Review Administrators (SRAs)—NIH employees who manage the scientific review group (SRG), or peer review meeting—are also instructed to give oral guidance on the NIH conflict of interest policy to peer reviewers, according to NIH guidance. The NIH policy manual states that the SRA is responsible for overseeing the SRG meeting to ensure fair and unbiased evaluations of research funding requests, and that peer reviewers must certify in writing after the meeting that they have executed their recusals.

GAO concludes that, although the NIH policy manual and guidance describe how peer reviewers are to be informed about and comply with recusals, the lack of clear recusal policies for senior employees results in a vulnerability in the management of one part of NIH's conflict of interest policies.

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## Abbreviations

DAEO	Designated Agency Ethics Official
DEC	Deputy Ethics Counselor
FACA	Federal Advisory Committee Act
HHS	Department of Health and Human Services
NCI	National Cancer Institute
NEO	National Institutes of Health Ethics Office
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
OER	Office of Extramural Research
OGE	Office of Government Ethics
R&D	research and development
SGE	special government employee
SRA	Scientific Review Administrator
SRG	Scientific Review Group

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United States Government Accountability Office  
Washington, DC 20548

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April 30, 2007

The Honorable Joe Barton  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Ed Whitfield  
Ranking Member  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
House of Representatives

The National Institutes of Health (NIH), a part of the Department of Health and Human Services (HHS), is the primary federal agency for supporting medical research. In fiscal year 2005, NIH awarded approximately 85 percent of its \$28 billion budget through awards of grants and research and development (R&D) contracts to researchers at universities, medical schools, and other research institutions. NIH senior employees, such as the NIH director and the directors of NIH's 27 institutes and centers, provide leadership for NIH scientific research priorities and programs and have significant decision-making responsibilities. Peer reviewers, who are generally outside scientific experts from academia, also play significant roles in advising NIH research and programs through the scientific and technical review of requests for research funding. There is a potential for conflicts of interest to occur when senior employees or peer reviewers have personal or financial interests that could impair their judgment in carrying out their NIH responsibilities. Identifying and addressing conflicts of interest among senior employees and peer reviewers helps to safeguard public funds and the integrity of NIH-funded research.

Under federal ethics laws and regulations, employees and peer reviewers are responsible for identifying and appropriately resolving their conflicts of interest. Federal criminal law on conflict of interest prohibits government employees from participating personally and substantially in a particular matter in which they have a financial interest, if the matter will

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have a direct and predictable effect on that interest.<sup>1</sup> Federal regulations also provide that an employee should not participate in a matter when there is an appearance of a conflict of interest such that a reasonable person with knowledge of the relevant facts would question the employee's impartiality in the matter.<sup>2</sup> HHS regulations prohibit peer reviewers from reviewing requests for research funding with which they have conflicts of interest or which present an appearance of a conflict.<sup>3</sup> One method an employee or peer reviewer may use to resolve a conflict of interest or the appearance of a conflict is recusal.<sup>4</sup> According to federal regulations, recusal is the responsibility of the employee or peer reviewer and is accomplished by the employee or peer reviewer not participating in the matter affected by the conflict of interest.<sup>5</sup> Additionally, an employee may also notify his or her supervisor about the recusal to help ensure that the matter affected by the conflict of interest is not presented to the recused employee.

In response to concerns about ethics at NIH raised by congressional committees and in the media, the agency created the NIH Blue Ribbon Panel on Conflict of Interest Policies to assess the status of conflict of

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<sup>1</sup>See 18 U.S.C. § 208(a). Participation is also prohibited when the financial interest is held by a person or organization that is closely related to the employee, namely, (1) the employee's spouse; (2) the employee's minor child; (3) the employee's general partner; (4) an organization in which the employee serves as officer, director, trustee, partner, or employee; or (5) a person or organization with which the employee is negotiating for prospective employment or has an arrangement for prospective employment. These interests are often referred to as "imputed interests."

<sup>2</sup>See 5 C.F.R. § 2635.502(a) (2006).

<sup>3</sup>See 42 C.F.R. § 52h.5 (2006). These regulations define a conflict of interest as a situation in which a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal. An appearance of a conflict occurs when the financial interest of the reviewer or a close relative or professional associate of the reviewer would cause a reasonable person to question the reviewer's impartiality if he or she were to participate in the review. See 42 C.F.R. § 52h.2 (2006).

<sup>4</sup>Recusal is called disqualification in the ethics regulations that apply to the executive branch. The other three methods for resolving a conflict of interest are waivers, authorizations, and divestiture. Waivers permit employees or peer reviewers to participate in the matter in spite of a conflict. Authorizations permit employees to participate in the matter in spite of a conflict. Divestiture, which is not used by peer reviewers, typically involves selling the financial holdings that pose the conflict.

<sup>5</sup>See, for example, 5 C.F.R. § 2635.402(c) (2006) and 42 C.F.R. § 52h.5 (2006).

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interest policies and procedures.<sup>6</sup> The panel issued a report in 2004 with 18 recommendations for improving NIH conflict of interest policies and procedures for employees, including one recommendation that employees be required to submit recusals in writing to their supervisors.<sup>7</sup> Also in response to congressional concerns, the NIH Director stated, in a May 2004 prepared statement for a subcommittee of the House Committee on Energy and Commerce, that NIH would require a uniform policy for employees to notify relevant personnel of recusals and would establish a new process for monitoring employees' recusals.<sup>8</sup>

In light of these congressional concerns, you asked us to examine issues related to conflicts of interest at NIH. We report on (1) how NIH informs senior employees about recusal and what the requirements are for them to notify supervisors, and (2) how NIH informs peer reviewers about recusal and how NIH monitors their compliance with recusals.

Our work is based on our review of written materials and interviews in NIH's Office of the Director—the agency's central office—and in 2 of NIH's 27 institutes and centers.<sup>9</sup> We selected the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID) for our review because they have the largest budgets among all NIH institutes.<sup>10</sup>

To report on how NIH informs senior employees about recusal and what the requirements are for them to notify supervisors, we reviewed relevant chapters of the NIH policy manual. We also reviewed NIH ethics training

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<sup>6</sup>Also in response to media reports and congressional hearings, in August 2005 HHS issued revised regulations that focus on outside activities, awards, prohibited financial interests, and financial reporting requirements. See 5 C.F.R. Parts 5501 and 5502 (2006).

<sup>7</sup>National Institutes of Health, Working Group of the Advisory Committee to the Director, *Report of the National Institutes of Health Blue Ribbon Panel on Conflict of Interest Policies* (June 22, 2004). Accessed on February 6, 2007, at [http://www.nih.gov/about/ethics\\_COI\\_panelreport.htm](http://www.nih.gov/about/ethics_COI_panelreport.htm).

<sup>8</sup>See *NIH Ethics Concerns: Consulting Arrangements and Outside Awards: Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 108th Cong. (2004) 24 (statement of Elias A. Zerhouni, Director, National Institutes of Health).

<sup>9</sup>Throughout the report, we use the term institute to refer to an institute or center.

<sup>10</sup>NCI and NIAID also have the largest budgets among all institutes for awards of grants and R&D contracts.

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materials for 2005 and 2006 and NIH guidance on identifying conflicts of interest. We used the definition of “senior employee” that is found in the HHS supplemental ethics regulations.<sup>11</sup> Under this definition, NIH senior employees are the Director and Deputy Director; members of the senior staff within the Office of the Director who report directly to the Director; the institutes’ Directors, Deputy Directors, Scientific Directors, and Clinical Directors; Extramural Program Officials who report directly to an institute Director; and any employee of equivalent levels of decision-making responsibility who is designated as a senior employee by either the HHS Designated Agency Ethics Official (DAEO)<sup>12</sup> or the NIH Director in consultation with the HHS DAEO.<sup>13</sup> We did not include two senior employees—the NIH Director and the NCI Director—in our review. The individuals who hold these positions are appointed by the President, and the HHS DAEO, rather than an NIH ethics official, serves as their ethics officer. We interviewed ethics officials who provide advice and counseling to senior employees, including the Director, NIH Ethics Office; the HHS DAEO; the HHS DAEO’s representative on the NIH campus; the NIH Deputy Ethics Counselor (DEC); and the NCI and NIAID DECs.

To report on how NIH informs peer reviewers about recusal and how NIH monitors their compliance with recusals, we reviewed relevant NIH policy manual chapters and guidance for peer reviewers. We interviewed officials in the NIH Office of Extramural Research, which is responsible for developing NIH peer review policies. We also interviewed officials at NCI and NIAID who are responsible for the peer review process at those institutes.

Our review focused on recusal; we did not review the other remedies to a conflict of interest, which are waivers, authorizations, and divestiture. Our scope of review included recusals that senior employees or peer reviewers communicate to NIH officials; it was not possible to identify recusals by senior employees or peer reviewers who did not disclose their recusals to NIH officials. We also examined only the recusal processes in place for senior employees’ and peer reviewers’ recusals; we did not examine

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<sup>11</sup>See 5 C.F.R. § 5501.110(b)(1) (2006). This section prohibits senior employees at NIH from having certain financial interests.

<sup>12</sup>The DAEO is the individual selected by the Secretary of HHS to coordinate its ethics program.

<sup>13</sup>There are 9 senior employees at NIAID, 14 senior employees at NCI, and 16 senior employees in the Office of the Director.

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whether these processes were followed or specific instances of recusal for individual senior employees or peer reviewers. Furthermore, for peer reviewers we reviewed recusals related to the scientific peer review process for grant applications and R&D contract proposals, which is carried out by scientific review groups (SRGs) composed of peer reviewers who are primarily nonfederal scientists selected for membership based on their current research areas and depth of scientific expertise.<sup>14</sup> Finally, our findings from interviews with NCI and NIAID officials cannot be generalized to other institutes at NIH. We conducted our work from March 2006 through April 2007 in accordance with generally accepted government auditing standards.

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## Results in Brief

NIH has provided several methods to inform senior employees about recusal as a remedy to conflicts of interest, such as annual ethics training. However, NIH has not established clear recusal policies for senior employees, as the NIH policy manual is contradictory on whether senior employees must recuse in writing and notify their supervisors of their recusals. For example, the policy manual contains contradictory directions on how employees seeking nongovernment employment are to recuse. One section states that the employee “must” put the recusal in writing and that his or her supervisor “should” be notified, while another section states that the recusal “may” be done in writing and that the supervisor “must” be notified if the recusal is not written. Moreover, the two definitions of recusal in the policy manual imply that the employee must put a recusal into writing but do not explicitly require such action, and neither definition requires that the employee’s supervisor be notified of the recusal. These inconsistencies raise questions as to which sections of the manual are to be followed. Senior employees who consult the policy manual may or may not put their recusals in writing and may or may not

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<sup>14</sup>Unlike many other federal agencies, NIH does not appoint the members of these SRGs as Special Government Employees (SGEs). HHS regulations state that no more than one-quarter of the members of an SRG may be full-time federal employees. *See* 42 C.F.R. § 52h.4(c) (2006). However, according to NIH, membership on SRGs has been only about 1 percent full-time federal employees since the inception of NIH’s peer review process approximately 50 years ago. NIH also conducts a subsequent review of grant applications that is carried out by different advisory committees that comprise both scientific and lay members chosen for their expertise, interest, or activity in matters related to health and disease. Most of these committee members are appointed as SGEs, who are subject to less restrictive conflict of interest prohibitions than regular federal employees and to different rules than those applicable to NIH peer reviewers.

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notify their supervisors, depending on what chapter and section of the policy manual they consult.

NIH provides written and oral methods for informing peer reviewers about recusal and for monitoring compliance with recusals. In the NIH policy manual and guidance, NIH states that peer reviewers must be informed about NIH conflict of interest regulations and policies, which include information pertaining to recusal. The policy manual refers to a form that describes situations that may constitute conflicts of interest and the need to recuse in those situations. NCI and NIAID officials told us that peer reviewers are provided with this form before the SRG meets. In addition, the Scientific Review Administrators (SRAs)—NIH employees who manage the SRGs—are instructed to give oral guidance on the NIH conflict of interest policy to peer reviewers prior to the first meeting of the SRG, according to NIH's SRA handbook. The NIH policy manual states that the SRA is responsible for overseeing the SRG meeting to ensure fair and unbiased evaluations of applications and proposals. Peer reviewers must certify in writing after the meeting that they have executed their recusals, according to NIH policy.

To address the inconsistencies in the policy manual related to senior employees' notification of recusals and ensure that NIH helps its senior employees fulfill their responsibilities related to recusal, we recommend that the Director of NIH expeditiously clarify NIH policies with regard to written recusals and supervisor notification related to senior employees' use of recusal to resolve conflicts of interest. In commenting on a draft of this report on behalf of NIH, HHS concurred with our recommendation and said it plans to revise and reissue relevant portions of its policy manual within 6 months. NIH also provided technical comments that we incorporated as appropriate.

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## Background

One of the ways that NIH assists its employees, including senior employees, in avoiding and preventing conflicts of interest is through its ethics program. NIH ethics officials assist senior employees in examining potential conflicts of interest between senior employees' myriad and changing job responsibilities and their professional and financial outside activities and interests. Peer reviewers at NIH are subject to HHS regulations governing conflict of interest and recusal. To manage conflicts of interest that may arise in the course of the peer review process, NIH officials provide ethics guidance and advice to peer reviewers.

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## The NIH Ethics Program and the Office of Extramural Research

All executive branch agencies, including HHS, are required to have an ethics program and a DAEO who is tasked with coordinating and managing the agency's ethics program.<sup>15</sup> HHS has established a decentralized ethics program, allowing all agencies within HHS to administer their own distinct programs. The NIH Ethics Office (NEO) administers the NIH ethics program and provides leadership, guidance, and advice to the NIH community. The NEO is headed by the NIH DEC and is located in the Office of the Director. In addition, the NEO also serves as the ethics office for all senior employees and for employees in the Office of the Director. In addition to the NEO, each institute has its own ethics office. Each institute's ethics office is headed by an institute DEC who can provide ethics advice and counseling to institute employees. The HHS DAEO has delegated most of his responsibility for ethics matters at NIH to the NIH DEC and to the institute DECs.<sup>16</sup> There is also a representative of the HHS DAEO located on the NIH campus. The HHS DAEO serves as the agency's primary liaison to the Office of Government Ethics (OGE), an independent executive branch agency that oversees ethics programs at all executive branch agencies and advises agencies on many ethics issues.

While the NEO administers the ethics program for senior employees, the NIH Office of Extramural Research (OER) develops NIH peer review policy, including policy regarding conflicts of interest. The OER is located within the Office of the Director. NIAID and NCI each have a Division of Extramural Activities that implements, and provides information about, peer review in the institute.

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## NIH Senior Employees and Conflict of Interest Regulations

OGE promulgates regulations relating to conflicts of interest and remedies for conflicts of interest for all employees in executive branch agencies. In addition to OGE regulations, HHS has issued supplemental conflict of interest regulations specific to its agencies.<sup>17</sup> According to OGE and HHS supplemental regulations, as described below, conflicts of interest may generally arise because of an NIH employee's (1) financial holdings,

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<sup>15</sup>See 5 C.F.R. Part 2638, Subpart B (2006).

<sup>16</sup>The DAEO has retained his responsibility for the ethics actions involving the NIH Director, who is a presidential appointee confirmed by the Senate. The DAEO also has responsibility for the ethics actions involving the NCI Director, who is a presidential appointee.

<sup>17</sup>See 5 C.F.R. Parts 5501 and 5502 (2006).

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(2) outside activities, (3) pursuit or negotiation of nonfederal employment, or (4) receipt of awards and honorary degrees.<sup>18</sup>

- **Financial holdings:** Generally, under federal law and OGE regulations, an employee may not participate personally and substantially in a particular matter in which the employee has a financial interest if participation in the matter will have a direct and predictable effect on that interest.<sup>19</sup> Although this standard calls for a case-by-case analysis of an employee's interests, OGE regulations also allow agencies to prohibit ownership of certain kinds of financial holdings by regulation.<sup>20</sup> HHS supplemental regulations state that NIH senior employees generally may not have holdings in a substantially affected organization. However, holdings of \$15,000 or less are generally permitted.<sup>21</sup> Substantially affected organizations generally include organizations such as biotechnology or pharmaceutical companies and medical device manufacturers, and organizations significantly involved in those industries through research, development, or manufacturing.<sup>22</sup> The HHS supplemental regulations state that when a senior employee is permitted to retain a financial interest, that employee is generally obligated to recuse from any particular matter that would affect that interest.<sup>23</sup>

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<sup>18</sup>In addition to those situations in which an actual conflict of interest may arise, OGE regulations state that executive branch employees must take appropriate steps to avoid the appearance of a loss of impartiality in the performance of their official duties. *See* 5 C.F.R. § 2635.501 (2006). For example, such appearance problems may arise when the employee knows that a particular matter is likely to have a direct and predictable effect on the financial interest of a member of the employee's household. *See* 5 C.F.R. § 2635.502(a) (2006).

<sup>19</sup>This prohibition also applies to instances in which the financial interest is held by a person whose interests are imputed to the employee. *See* 18 U.S.C. § 208(a) (2006); 5 C.F.R. § 2635.402(a) (2006).

<sup>20</sup>*See* 5 C.F.R. § 2635.403 (2006). These regulations must be based on the agency's determination that the holdings would cause a reasonable person to question the impartiality and objectivity with which agency programs are administered.

<sup>21</sup>This rule also applies to the spouses and minor children of the senior employees. *See* 5 C.F.R. § 5501.110 (2006). The regulation provides for other exceptions to this rule, including for interests held in pension plans or other employee benefits and publicly available mutual funds.

<sup>22</sup>*See* 5 C.F.R. § 5501.109(b)(10) (2006).

<sup>23</sup>*See* 5 C.F.R. § 5501.110(d) (2006). Recusal is not required when the value of the interest is less than the thresholds for regulatory exemptions established by OGE in its executive branch regulations at 5 C.F.R. § 2640.202 (2006).

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- **Outside activities:** OGE and HHS supplemental regulations generally prohibit employees from engaging in outside employment or other outside activities that conflict with their official duties.<sup>24</sup> The OGE regulations contain many exceptions, particularly in the areas of speaking, teaching, and writing. OGE also allows agencies to prohibit participation in or require prior approval of outside activities.<sup>25</sup> HHS supplemental regulations prohibit NIH employees from participating in certain outside activities (such as teaching, speaking, writing, or editing for compensation) with any substantially affected organization, a supported research institution, or a health care provider or insurer.<sup>26</sup> In addition, the HHS regulations require NIH employees to apply for advance approval of certain outside activities, such as editing a journal or book that relates to the employee's official duties.<sup>27</sup> According to the OGE regulations, even when an outside activity is permitted, participation in that activity may require an employee to recuse from matters involving or affecting the employee's interest in the outside entity or employer to avoid conflicts of interest.<sup>28</sup>
  - **Pursuit or negotiation of nonfederal employment:** According to OGE regulations, a conflict may arise when an employee seeks or negotiates for nonfederal employment with an organization whose financial interests would be affected by the employee's actions as a government employee.<sup>29</sup> Generally, OGE regulations require an employee to recuse from particular matters that would have a direct and predictable effect on a prospective employer.<sup>30</sup> However, an employee may receive a waiver or authorization to participate in the matter.<sup>31</sup> In addition, an agency may determine that an

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<sup>24</sup>See 5 C.F.R. Part 2635, Subpart H (2006).

<sup>25</sup>See 5 C.F.R. §§ 2635.802(a); 2635.803 (2006).

<sup>26</sup>See 5 C.F.R. § 5501.109(c) (2006). There are several exceptions to the general prohibition, including one for the authorship of writings subjected to scientific peer review or a substantially equivalent editorial review process.

<sup>27</sup>See 5 C.F.R. § 5501.106(d) (2006). The regulation states that approval may only be given if the activity is not expected to involve conduct prohibited by statute or federal regulation, including the OGE regulations.

<sup>28</sup>See 5 C.F.R. § 2635.802 (2006).

<sup>29</sup>There are no HHS supplemental regulations on seeking or negotiating outside employment.

<sup>30</sup>See 5 C.F.R. § 2635.602 (2006).

<sup>31</sup>Whether a waiver or an authorization must be sought depends on whether the employee is merely seeking employment or has begun to negotiate for employment. See 5 C.F.R. §§ 2635.605 and 2635.606 (2006).

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employee must recuse for a certain period of time after negotiations that did not result in employment have concluded.<sup>32</sup> Finally, according to the Procurement Integrity Act, if an employee who is participating in an agency procurement initiates contact with or is contacted by the contractor regarding employment with the contractor, then the employee must report the contact in writing to his or her supervisor and to the DAEO or the DAEO's designee. The employee must then either reject the employment or recuse from further participation in the procurement.<sup>33</sup>

- **Receipt of awards and honorary degrees:** OGE regulations permit federal employees to accept awards with a value of less than \$200 if the donor does not have interests that may be substantially affected by the employee's duties.<sup>34</sup> Awards from such donors with values greater than \$200 may be accepted only with the approval of an agency ethics official.<sup>35</sup> An employee may also accept an honorary degree with written permission from an agency ethics official.<sup>36</sup> The HHS supplemental regulations require NIH employees to obtain advance approval for any award, regardless of value.<sup>37</sup> Further, the HHS regulations generally prohibit employees from accepting an award with a value greater than \$200 if the employee has official responsibility over matters affecting the donor of the award.<sup>38</sup> However, an exception can be made for an award that would further an agency interest because it confers an exceptionally high honor in the fields

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<sup>32</sup>This decision to require the recusal for a certain period of time after negotiations have ended is made based on an assessment of whether the employee's participation in the matter would create an appearance of a conflict. *See* 5 C.F.R. § 2635.606(b) (2006).

<sup>33</sup>*See* 41 U.S.C. § 423(c).

<sup>34</sup>*See* 5 C.F.R. § 2635.204(d)(1) (2006). The award must be given for meritorious public service or achievement. The rule governing the acceptance of awards is an exception to the general gifts rule. For the purposes of this report, we use the term award to refer specifically to gifts given as awards or given incident to awards.

<sup>35</sup>All awards consisting of cash or investment interests, regardless of value, must be approved by an agency ethics official prior to acceptance by the employee.

<sup>36</sup>*See* 5 C.F.R. § 2635.204(d)(2) (2006).

<sup>37</sup>*See* 5 C.F.R. § 5501.111(c)(2) (2006). The HHS supplemental regulations do not address honorary degrees.

<sup>38</sup>*See* 5 C.F.R. § 5501.111(c)(1) (2006). Awards of cash or investment interests are prohibited under these circumstances regardless of value.

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of medicine or scientific research.<sup>39</sup> According to the HHS supplemental regulations, when any award is approved, the employee must recuse from any particular matter in which the donor is a party for 1 year following receipt of the award.<sup>40</sup>

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## Peer Reviewers at NIH and Conflict of Interest Regulations

NIH uses a peer review process to evaluate the scientific and technical merit of grant applications and R&D contract proposals.<sup>41</sup> These evaluations are conducted by peer reviewers in SRGs, which can include standing committees and special emphasis panels.<sup>42</sup> Standing committees generally meet three times per year and have as many as 16 to 20 members, who usually serve for a term of 4 years. Special emphasis panels are not standing but instead are convened on an as-needed basis. NIAID convenes about 120 special emphasis panels per year, and NCI convenes about 50 to 75 special emphasis panels per year. In the SRG meeting, applications with the highest merit, and all proposals, are discussed and scored by the peer reviewers. Consistent with the Federal Advisory Committee Act (FACA), NIH policy designates a Scientific Review Administrator (SRA) to manage the SRG meeting.<sup>43</sup> A non-NIH scientist also chairs each SRG meeting.

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<sup>39</sup>See 5 C.F.R. § 5501.111(d). In addition, it must be determined that the award would be otherwise permissible under the OGE regulations and that the application of the prohibition is not necessary to ensure public confidence in the impartiality or objectivity with which NIH programs are administered or to avoid a violation of the OGE regulations.

<sup>40</sup>See 5 C.F.R. § 5501.112 (2006). An authorization to participate may be granted under 5 C.F.R. § 2635.502(d) (2006).

<sup>41</sup>Peer review of grant applications and R&D contract proposals is required by statute. See 42 U.S.C. § 289a. Grants are awarded to institutions on behalf of a principal investigator to facilitate the pursuit of a scientific objective when the idea for the research is initiated by the investigator and the institute anticipates no substantial involvement. R&D contracts are awarded to procure specific activities for scientific inquiries in particular areas of R&D needed by NIH.

<sup>42</sup>SRGs for solicited grant applications and R&D contract proposals are conducted in the institutes. Specifically, the majority of scientist-initiated grant applications are reviewed by NIH's Center for Scientific Review, whereas applications that are submitted in response to an institute-initiated request for applications are generally reviewed by that institute. R&D contract proposals are reviewed by the institute that requested the proposals for that individual contract.

<sup>43</sup>FACA requires agencies to designate a federal officer or employee to chair or attend every meeting of each advisory committee it convenes. Committee meetings may not be held without the advance approval of the designated official. See 5 U.S.C. app., § 10(e),(f).

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HHS regulations govern the procedures for selecting peer reviewers and contain a section on conflict of interest.<sup>44</sup> According to the regulations, conflicts of interest may arise because of peer reviewers' financial interests, employment, or professional relationships. Conflicts occur when a peer reviewer or his or her close relative or professional associate<sup>45</sup>

- has or could receive a direct financial benefit of any amount deriving from an application or proposal;
- has or could receive a financial benefit over \$10,000 from an institution, offeror, or principal investigator named in an application or proposal;<sup>46</sup> or
- is currently employed or negotiating for employment with an institution, offeror, or principal investigator named in the application or proposal.<sup>47</sup>

The HHS regulations provide two possible remedies for conflicts of interest—recusals and waivers. If a recusal is used, then the peer reviewer for an NIH SRG does not evaluate the application or applications with which there is a conflict. If a waiver is used, then the peer reviewer may

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<sup>44</sup>See 42 C.F.R. Part 52h (2006).

<sup>45</sup>Close relative means the peer reviewer's parent, spouse, child, or domestic partner. Professional associate means a colleague, scientific mentor, or student with whom the peer reviewer is currently conducting research or other significant professional activities or with whom the peer reviewer has conducted such activities within 3 years of the date of the SRG meeting. 42 C.F.R. §§ 52h.2(e) and (m) (2006).

<sup>46</sup>A principal investigator oversees the scientific and technical aspects of the grant and manages the day-to-day research funded by the grant. An offeror is the organization submitting a proposal for an R&D contract.

<sup>47</sup>The regulation allows for a determination that there is no conflict of interest in situations where the components of a large or multicomponent organization are sufficiently independent so as to be considered separate organizations. In these situations, the reviewer would be allowed to consider an application or proposal from a separate component, provided that he or she has no responsibilities at the institution that would significantly affect that component. 42 C.F.R. § 52h.5(b)(1) (2006).

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participate in the review of the application despite the conflict.<sup>48</sup> Waivers of conflicts are allowed when the NIH Director or his designee determines that there are no other practical means of securing appropriate expert advice and that the conflict is not so substantial as to be likely to affect the integrity of the advice of the reviewer.<sup>49</sup>

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## NIH Informs Senior Employees about Recusal through Several Methods; However, Its Policy Requirements for Notification of Supervisors Are Unclear

NIH has provided several methods to inform senior employees about recusal as a remedy to conflicts of interest, such as annual ethics training. However, NIH has not established clear recusal policies for senior employees, as the NIH policy manual is contradictory on whether senior employees must recuse in writing and notify their supervisors of their recusals. For example, the policy manual contains contradictory directions on how employees seeking nongovernment employment are to recuse. One section states that the employee “must” put the recusal in writing and that his or her supervisor “should” be notified, while another section states that a recusal “may” be done in writing and that the supervisor “must” be notified if the recusal is not written. The two definitions of recusal in the policy manual imply that the employee must put the recusal into writing but do not explicitly require such action, and neither definition requires that the employee’s supervisor be notified of the recusal.

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<sup>48</sup>The rules of recusal for grant applications differ from the rules of recusal for R&D contract proposals. For grant applications, peer reviewers who have a conflict with an application must recuse from, or obtain a waiver for, the application with which they have a conflict of interest. *See* 42 C.F.R. § 52h.5(b) (2006). Therefore, a reviewer who has recused from one application is allowed to review and score the other applications in the group. For R&D contract proposals, a peer reviewer who has a conflict with one proposal must recuse from the review of all proposals for the same contract, unless the NIH Director grants a waiver to allow the peer reviewer to recuse from the proposal with which he has a conflict and to review the other proposals in the group. The waiver is based on a determination that there is no other qualified reviewer available with the reviewer’s expertise and that expertise is essential to ensure a competent and fair review. *See* 42 C.F.R. § 52h.5(b)(3) (2006) .

<sup>49</sup>42 C.F.R. § 52h.5(b)(4) (2006). In comparison, waivers are permitted for an appearance of a conflict when the NIH Director or his designee determines that it would be difficult or impractical to carry out the review otherwise and that the integrity of the review process would not be impaired by the peer reviewer’s participation. 42 C.F.R. § 52h.5(c) (2006).

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## NIH Informs Senior Employees about Recusal through Several Methods

NIH informs senior employees about recusal through several methods, including annual ethics training, preemployment financial disclosure review, and information on various ethics forms that are completed for certain new financial interests and outside activities as they arise. NIH is required by regulation to conduct annual ethics training that includes certain topics, such as the Standards of Ethical Conduct for Employees of the Executive Branch.<sup>50</sup> The agency may supplement the training to cover additional topics as needed each year. For example, the 2005 training not only provided a high-level summary of the Standards of Ethical Conduct for Employees of the Executive Branch and ethics principles, but also described what constitutes a conflict of interest related to outside activities, awards, and prohibited financial interests. These additional topics were the focus of the HHS supplemental ethics regulations revised in August 2005. The 2005 training also noted that recusal may be used in cases of conflicts arising from the acceptance of an award or from financial interests and that recusal involves nonparticipation in official duties related to the particular matter. However, it did not discuss the use of recusal as a remedy for conflicts arising from outside activities. The 2006 training noted that recusal may be used to remedy conflicts arising from seeking employment, after receiving an award from an outside organization, and in any situation where an employee's impartiality would be questioned. In addition to the annual ethics training for all employees, staff with supervisory responsibilities, which includes most senior employees, completed an ethics training module for supervisors in 2005, according to a NEO official. This training module described how to screen employees' financial disclosures related to substantially affected organizations for potential conflicts of interest and how to evaluate whether recusals are an appropriate remedy to resolve the conflicts.<sup>51</sup>

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<sup>50</sup>See 5 C.F.R. Part 2638, Subpart G (2006), for the requirements related to agency ethics training programs. According to the regulations, certain federal employees, such as those who are required to file public or confidential financial disclosure reports, are required to receive annual ethics training. Since 2004, NIH has required that all NIH employees receive annual ethics training, according to NIH ethics officials.

<sup>51</sup>NIH also requires all new employees to receive initial ethics training, according to NIH ethics officials. The training we reviewed consists of an overview of the Standards of Ethical Conduct for Employees of the Executive Branch and an ethics orientation module. Both the overview and the ethics orientation module state that recusal may be used in cases of conflicts arising from financial interests, seeking employment, and outside activities, and that recusal involves nonparticipation in official duties related to the particular matter.

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The preemployment financial disclosure review is another method of informing senior employees about recusal. In the review, required by HHS since October 2004, HHS guidance states that NIH ethics officials inform prospective NIH senior employees about the ethics laws and regulations they will be subject to as federal employees and discuss the remedies for conflicts of interest, including recusal. NIH ethics officials are to review the prospective senior employees' outside activities and financial holdings before the prospective senior employees make final decisions about employment. If an actual or apparent conflict of interest is identified through this process, the prospective senior employee is required to agree to resolve the conflict, which may include using recusal. NIH provides a standard ethics agreement form on which the prospective senior employee describes specific actions to be taken to execute the recusal and indicates the duration of the recusal in the recusal section of the form.

NIH also informs senior employees about recusal through information presented on several other ethics forms that senior employees complete for certain new financial interests and outside activities as they arise. Certain ethics forms—specifically the “Confidential Report of Financial Interests in Substantially Affected Organizations for Employees of the National Institutes of Health” (HHS Form 717-1),<sup>52</sup> the “Request for Approval of Outside Activity” (HHS Form 520),<sup>53</sup> and the “Annual Report of Outside Activity” (HHS Form 521)<sup>54</sup>—provide detailed summaries of

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<sup>52</sup>This form is used to fulfill the requirement in the HHS supplemental regulations that certain NIH employees, including all senior employees, file supplemental disclosures of their financial interests in substantially affected organizations. 5 C.F.R. § 5502.107(c) (2006). Employees must disclose these interests upon beginning employment with NIH, and within 30 days of acquiring any additional interests during their employment.

<sup>53</sup>Employees use this form to comply with the HHS supplemental regulation requiring approval of certain outside activities, 5 C.F.R. § 5501.106(d) (2006).

<sup>54</sup>Employees use this form to comply with the HHS supplemental regulation requiring an annual supplemental report on any activities for which prior approval has been obtained or is required. 5 C.F.R. § 5502.102 (2006). This form must be reviewed by the employee's supervisor, in consultation with a DEC or other ethics official, to make sure the employee has complied with applicable ethics laws and regulations and to determine whether approval of the activities listed should be continued or canceled.

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conflict of interest regulations and recusal.<sup>55</sup> For example, all of these forms notify employees that they must refrain entirely and absolutely from participating personally and substantially in a government matter that affects their own financial interest or that of an outside employer, and HHS Form 520 lists examples of official duties from which an employee might be required to recuse. These forms also state that employees must refrain from participating in all parts of their official duties that are in conflict with any financial interests or outside activities. In addition, HHS Form 717-1 includes a space for the employee to describe a recusal, including naming another employee to whom the official duties are transferred. By signing the forms, employees certify that they have read and understand the summaries provided on the forms and that any statements they have made on the forms, such as recusal statements, are correct. Finally, senior employees may also seek individual advice and counseling from the DEC and supervisors about recusal as a resolution to an identified conflict of interest, according to NIH ethics officials.<sup>56</sup>

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### NIH Policy Manual Is Contradictory on Whether Written Recusals and Notification of Supervisors Are Required

The NIH policy manual is contradictory on whether senior employees must recuse in writing and notify their supervisors of their recusals. For example, with respect to employees seeking nongovernment employment,<sup>57</sup> one section of the manual chapter “Avoiding Conflicts of Interest” states that an employee must submit a recusal statement to the person responsible for the employee’s assignment. However, the same section also states that recusal is “accomplished by not participating in the

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<sup>55</sup>In addition, two other forms—the “Public Financial Disclosure Report” (Form 278) and the “Confidential Financial Disclosure Report” (OGE 450)—do not specifically include information about conflicts of interest and recusals but when completed may disclose information about financial interests that allows for identification of potential conflicts of interest. These forms were developed by OGE based on their regulations implementing provisions of the Ethics in Government Act, which required a public annual financial reporting system for certain high-level federal employees and authorized a confidential annual financial reporting system for other employees, as OGE deems appropriate. *See* 5 U.S.C. app. §§ 101; 107 and 5 C.F.R. Part 2634 (2006).

<sup>56</sup>A NEO official told us that the NIH DEC is the official ethics officer of record for all NIH senior employees and signs senior employees’ ethics forms, except for those of the NIH Director and the NCI Director, who are presidential appointees. The HHS DAEO serves as the ethics officer for these appointees.

<sup>57</sup>This includes but is not limited to services as an officer, director, employee, agent, attorney, consultant, contractor, general partner, or trustee. *See* 5 C.F.R. § 2635.603(a) (2006).

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particular matter,”<sup>58</sup> which could lead the reader to assume that there are no other requirements. Further, a section in the manual chapter “Outside Work and Related Activities with Outside Organizations” on employees seeking nongovernment employment states that the notice of recusal “must be in writing” and that the employee’s supervisor “should” be notified of the recusal.<sup>59</sup> In contrast, another section of the same chapter states that a recusal “may be done either in writing or simply by the employee withdrawing from participation” in the particular matter but that employees who do not recuse in writing “must” notify their supervisors of their recusal.<sup>60</sup> These inconsistencies raise questions as to which sections of the manual are to be followed.

Moreover, neither definition of recusal in the policy manual provides clear guidance. Both imply that the employee must put a recusal into writing but do not explicitly require that action, and neither definition requires that the employee’s supervisor be notified of the recusal.<sup>61</sup> The definition of recusal in the chapter “Avoiding Conflicts of Interest” states that the recused employee “signs a written statement” reflecting the scope of the recusal and the nature of the conflicting interest or activity,<sup>62</sup> and the definition of recusal in the chapter “Outside Work and Related Activities with Outside Organizations” states that recusal is a “written statement used to resolve an apparent or actual conflict of interest.”<sup>63</sup>

NIH ethics officials, who may be contacted by senior employees for guidance, provided varying responses on whether recusals must be put in writing and whether supervisors must be notified. The DECAs we interviewed generally stated that in practice senior employees either put

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<sup>58</sup>See *National Institutes of Health Policy Manual*, Chapter 2300-735-1—Avoiding Conflicts of Interest (June 19, 1998), p. 12.

<sup>59</sup>*National Institutes of Health Policy Manual*, Chapter 2300-735-4—Outside Work and Related Activities with Outside Organizations, February 17, 1998, Appendix 4, p. 3.

<sup>60</sup>*Ibid.*, pp. 1-2.

<sup>61</sup>NIH also makes available on its Web site two templates that senior employees may use to write a recusal memorandum. One recusal memorandum template is for institute directors, and the other template is for all other NIH employees. Although these templates allow for notification of supervisors, employees are not required to use these templates.

<sup>62</sup>*National Institutes of Health Policy Manual*, Chapter 2300-735-1—Avoiding Conflicts of Interest, p. 7.

<sup>63</sup>*National Institutes of Health Policy Manual*, Chapter 2300-735-4—Outside Work and Related Activities with Outside Organizations, p. 4.

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recusals in writing, or were advised to do so, and notified their supervisors of their recusals. However, other ethics officials at NIH and HHS each correctly stated that OGE's regulations do not require written recusal, and the HHS ethics official stated that employees meet the legal obligation for recusal by not participating in the particular matter.<sup>64</sup> As a result, a senior employee seeking clarity from an NIH ethics official could receive varying directions about how to recuse.

NIH officials provided us with a draft paragraph in October 2006 that would require employees to put recusals in writing and notify their supervisors. The officials expect the paragraph will be included in the forthcoming revision to the policy manual. However, as of February 2007 this revision to the policy manual had not been issued and NIH officials reported that they did not know when it would be issued. Furthermore, it is not clear to what extent this revision will address the inconsistencies we identified in different chapters of the manual.

NIH ethics officials said that although they may be notified of a recusal they were not involved in monitoring compliance with it. A NEO official told us that monitoring compliance with recusals was a management responsibility, because recusals relate to official duties of the recused employee and it is the supervisor, rather than the ethics officials, who has access to information about official duties. The NEO official told us that she did not know whether supervisors are trained or instructed on monitoring compliance with their employees' recusals. Our review of the 2005 and 2006 annual ethics training materials found that neither set of materials contained instructions for supervisors to monitor compliance with recusals.

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<sup>64</sup>OGE regulations state that recusal is accomplished by not participating in the particular matter. See, for example, 5 C.F.R. § 2635.402(c) (2006). Written recusal is not required by the regulation, with some exceptions that apply to the NIH Director, who is nominated by the President and confirmed by the Senate and is under an ethics agreement. The regulations further state that the employee "should notify the person responsible for his assignment" about a recusal and that the employee "may" make "appropriate oral or written notification" to coworkers. Several other federal agencies, such as the Department of Defense and the Department of Energy, have promulgated supplemental regulations approved by OGE that require employees to provide written notice of recusals in certain situations. Additionally, the Procurement Integrity Act requires written recusals resulting from a government employee's contacts regarding employment with a bidder or offeror in a contract exceeding the simplified acquisition threshold (most contracts greater than \$100,000). *See* 41 U.S.C. § 423(c).

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## NIH Provides Written and Oral Methods for Informing Peer Reviewers about Recusal and for Monitoring Compliance with Recusals

In the NIH policy manual and guidance, NIH states that peer reviewers must be informed about recusal and describes how compliance with such recusals is to be monitored. According to NCI and NIAID officials, prior to the SRG meeting peer reviewers are given a form, referred to in the policy manual, that describes situations that may constitute conflicts of interest and the need to recuse in those situations. In addition, peer reviewers are to receive oral instruction on the NIH conflict of interest policy from SRAs at the beginning of each SRG meeting, according to NIH's SRA handbook. The NIH policy manual states that SRAs are required to oversee the SRG meeting to ensure fair and unbiased evaluations of grant applications and R&D contract proposals. The NIH policy manual also requires peer reviewers to certify in writing after the SRG meeting that they have recused.

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## NIH Provides Written and Oral Methods for Informing Peer Reviewers about Recusal

The NIH policy manual and guidance provide written and oral methods for informing peer reviewers about recusal, including guidance on a form. The NIH policy manual states that peer reviewers must be informed about NIH conflict of interest regulations and policies, which include information pertaining to recusal. The policy manual refers to the form, "NIH Conflict of Interest, Confidentiality and Non-Disclosure Rules: Information for Reviewers of Grant Applications and R&D Contract Proposals," that describes situations that may constitute conflicts of interest and the need to recuse in these situations, and states that it is the responsibility of the peer reviewer to notify the SRA of any potential conflict of interest. This form is provided to all peer reviewers prior to each SRG meeting, according to NCI and NIAID officials. A NIAID official told us that after a notification of a potential conflict of interest, the SRA follows up with the peer reviewer to discuss whether a conflict exists.<sup>65</sup> In addition, peer reviewers are to receive oral instruction on the NIH conflict of interest policy from SRAs at the beginning of each SRG meeting, according to NIH's SRA handbook. NCI and NIAID also send written review guides to peer reviewers prior to each SRG meeting, according to NCI and NIAID officials. These guides include sections describing circumstances in which peer reviewers may encounter conflicts of interest and describe the NIH policy that requires peer reviewers to leave the room in order to execute recusals during the SRG meeting.

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<sup>65</sup>HHS regulations allow the SRA to determine whether a peer reviewer has a conflict of interest with an application or proposal. *See* 42 C.F.R. § 52h.2(q) (2006).

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## NIH Policy and Guidance Provide for Monitoring Compliance with Recusals through Required Certification Forms and Oversight at SRG Meetings

The NIH policy manual requires peer reviewers to sign an “NIH Pre-Review Certification Form” before each SRG meeting. This form instructs peer reviewers to list the grant applications or R&D contract proposals with which they have a conflict and to certify that they will not review these applications or proposals.<sup>66</sup> NIH policy also requires peer reviewers to sign an “NIH Post-Review Certification Form” to certify that they recused from discussion of any application or proposal with which they had a conflict. NIH policy requires the SRA and his or her staff to compile an SRG file that contains the pre- and postreview certification forms. NCI and NIAID officials told us that their institutes maintain these SRG files.

The NIH policy manual states that SRAs are required to oversee the SRG meeting to ensure fair and unbiased evaluations of grant applications and R&D contract proposals. According to NCI and NIAID officials, the SRA is responsible for ensuring that the peer reviewer leaves the room to execute his or her recusal. The SRA handbook states that the SRA or the chair of the SRG should ask peer reviewers to leave the room during discussion of the application or proposal with which they have a conflict. The SRA’s assistant is to tell the peer reviewers when to return to the meeting, according to the SRA handbook.

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## Conclusions

The NIH policy manual and guidance describe how peer reviewers are to be informed about and comply with recusal, but NIH has not established clear recusal policies for senior employees. The statements in the NIH policy manual regarding whether employees’ recusals must be put in writing and whether supervisors must be notified are unclear, and, regarding recusals associated with seeking nongovernment employment, contradictory. Senior employees who consult the policy manual may or may not put their recusals in writing and may or may not notify their supervisors, depending on what chapter and section of the policy manual they consult. Therefore, it is unclear what actions NIH wants senior employees to take regarding notifications of recusals.

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<sup>66</sup> Reviewers with no stated conflicts must also certify to that fact on the form. NCI and NIAID officials told us that peer reviewers with conflicts of interest generally do not receive documents related to applications with which they have a conflict, or if they have received them are instructed to destroy those documents.

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Although recusal is only one resolution to conflicts of interest, it constitutes an important component of NIH's overall framework for managing conflicts of interest and ensuring the integrity of NIH-funded research. Clear policies and guidance for senior employees' recusals are particularly important because senior employees serve in positions of leadership. NIH has undertaken a number of activities to improve its policies and processes related to conflicts of interest, such as requiring a preemployment financial disclosure review for prospective senior employees and implementing the revised HHS supplemental regulations through the annual ethics training and ethics forms. Nevertheless, the lack of clear recusal policies for senior employees results in a vulnerability in the management of one part of NIH's conflict of interest policies.

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## Recommendation

To address the inconsistencies in the policy manual related to senior employees' notification of recusals and ensure that NIH helps its senior employees fulfill their responsibilities related to recusal, we recommend that the Director of NIH expeditiously clarify NIH policies with regard to written recusals and supervisor notification related to senior employees' use of recusal to resolve conflicts of interest.

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## Agency Comments

On behalf of NIH, HHS provided us with comments on a draft of this report, which we have reprinted in appendix I. In its comments, HHS agreed with our recommendation and said it plans to revise and reissue relevant portions of its policy manual within 6 months. NIH also provided technical comments, which we have incorporated as appropriate.

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As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies of this report to the Director of the National Institutes of Health and other interested parties. We will also provide copies to others on request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

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If you or your staffs have any questions about this report, please contact me at (202) 512-7101 or [bascettac@gao.gov](mailto:bascettac@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix II.



Cynthia A. Bascetta  
Director, Health Care

# Appendix I: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary  
for Legislation

Washington, D.C. 20201

APR 11 2007

Ms. Cynthia A. Bascetta  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street, NW  
Washington, DC 20548

Dear Ms. Bascetta:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "NIH Conflict of Interest: Recusal Policies for Senior Employees Need Clarification" (GAO-07-319), before its publication.

The report notes that the current NIH manual chapter contains inconsistencies regarding the procedures senior employees should follow to document their need to recuse from a matter and recommends that we expeditiously clarify our policies on written recusals and supervisor notification. We concur and will work quickly to clarify our policies by revising and reissuing the relevant portions of the manual chapter. We expect to complete this task as soon as possible and certainly within six months.

We are committed to providing consistent and clear guidance to our employees on the situations that require them to recuse from official duty matters because of a conflict of interest and on the procedures they should follow.

The Department has provided several technical comments directly to your staff.

The Department appreciates the opportunity to review and comment on this draft.

Sincerely,

A handwritten signature in cursive script, appearing to read "R. Ventimiglia".

A small, stylized handwritten mark or signature, possibly initials.

Vincent J. Ventimiglia  
Assistant Secretary for Legislation

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# Appendix II: GAO Contact and Staff Acknowledgments

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## GAO Contact

Cynthia A. Bascetta, (202) 512-7101

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## Acknowledgments

In addition to the contact named above, Linda Kohn, Assistant Director; Lori Fritz; Adrienne Griffin; Roseanne Price; and Ann Tynan made key contributions to this report.

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