

NIH POLICY MANUAL
2400-04 Managing Conflicts of Interests and the Introduction of Bias

Issuing Office: NIH Ethics Office 301-402-6628
Release Date: 06/18/08

1. **Explanation of Material Transmitted:** This new chapter implements the rules that NIH employees are subject to regarding managing conflict of interest and avoiding bias in the conduct of official duties. This chapter is part of the new NIH Ethics Manual (in the 2400 series of the NIH Manual). It incorporates some information from the obsolete NIH Manual 2300-735-4.

2. **Filing Instructions:**

Insert: NIH Manual Chapter 2400-04 dated 06/18/08

Remove: NIH Manual Chapters 2300-735-1 and 2300-735-4

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-4606.
- Online information, enter this URL: <http://www1.od.nih.gov/oma/manualchapters/>

MANAGING CONFLICTS OF INTERESTS AND THE INTRODUCTION OF BIAS

2400-04 Managing Conflicts of Interests and the Introduction of Bias

- A. Purpose
- B. Real Conflicts of Interests
 1. Description of a Real Conflict
 2. Examples of Real Conflicts
- C. Appearances of Conflicts of Interests
 1. Description of an Apparent Conflict
 2. Examples of Apparent Conflicts of Interests
- D. Managing the Introduction of Bias from Professional Activities with Outside Organizations
- E. Mechanisms to Resolve Real and Apparent Conflicts of Interests
 1. Regulatory Exemptions
 2. Recusal/Disqualification
 3. Waiver of the Conflict
 4. Authorization to Participate
 5. Resignation
 6. Divestiture
 7. Blind Trusts
- F. NIH Policy
- G. Availability of Forms
- H. Confidentiality of Documents/Release of Information
- I. Additional Information

MANAGING CONFLICTS OF INTERESTS AND THE INTRODUCTION OF BIAS

- A. PURPOSE:** The National Institutes of Health (NIH), in the US Department of Health and Human Services (HHS), supports employee participation in activities involving outside organizations. However, some activities raise concerns about real or apparent conflicts of interests (COIs). Government ethics rules prohibit employees from participating in any activities that conflict with, or appear to conflict with, their official duties. Employees must refrain from participating in official decisions which affect their own financial interests, or the financial interests of certain other individuals, organizations, or entities. There are two types of conflicts, real and apparent, and as to each there are policies and procedures to follow to resolve a conflict to enable an employee to continue activities in an appropriate manner whenever possible.

This chapter discusses appropriate use of waivers, authorizations, disqualification (also referred to as recusals), and other mechanisms to resolve conflicts of interests. It also provides guidance on how to manage the introduction of bias that may result from engaging in professional activities as part of your official duties. Case studies of extramural situations are provided to give examples of the proper handling of such bias. For employee coverage, authorities and references, records retention, and management controls, see NIH Manual 2400-01 Introduction to Government Ethics at the NIH.

B. REAL CONFLICTS OF INTERESTS:

- 1. Description of a Real Conflict:** A real, or actual, conflict of interest arises when an employee is assigned official responsibilities in a particular matter that will directly and predictably affect the employee's personal financial interests or the interests of other specific persons. The persons whose interests are attributed to the employee (these interests are also referred to as imputed interests) are detailed in a statute, 18 USC § 208, and include the following:
 - the employee's spouse;
 - the employee's minor child(ren);
 - the employee's general partner in an outside business endeavor;
 - an organization the Federal employee serves as officer, director, trustee, general partner, or employee; and
 - any organization or person with whom the employee is negotiating for or has an arrangement concerning prospective employment.

For purposes of the statute, the financial interests of these persons are treated as if they are the employee's own financial interests.

When an employee has a real conflict of interest in an assigned matter, the employee may not participate in that matter as a federal employee without first resolving the conflict. Conflicts are resolved through waiver, disqualification (also called recusal), or divestiture. (These mechanisms are fully discussed below.) The [Deputy Ethics Counselor](http://ethics.od.nih.gov/decs.pdf) (DEC) (<http://ethics.od.nih.gov/decs.pdf>) or other Institute/Center (IC) [Ethics Office](http://ethics.od.nih.gov/coord.pdf) staff (<http://ethics.od.nih.gov/coord.pdf>) will review the situation with the employee and determine which of the resolution mechanisms are available to resolve the conflict. Conflicts of interest must be resolved to the satisfaction of the DEC before an employee may participate in any official matter that will affect his or her personal or imputed financial interests.

MANAGING CONFLICTS OF INTERESTS AND THE INTRODUCTION OF BIAS

2. **Examples of Real Conflicts:** The following examples are not exhaustive, but can be used to help identify situations where a conflict of interest would exist.

Example 1: The spouse of an extramural program official, e.g., Health Scientist Administrator (HSA), who manages a grant portfolio works at a local university. Since the spouse's income is imputed to the employee, that is, treated as if it were the employee's own financial interest, the employee may not be involved in official particular matters which affect that local university's ability or willingness to pay the spouse's salary or benefits or that will otherwise affect the spouse's financial interests unless the conflict is appropriately resolved (see mechanisms to manage, below).

Example 2: An employee holds stock in a pharmaceutical company, valued above the amount defined in the regulation as being the amount below which a conflict cannot arise (the de minimis level). Stock ownership constitutes a financial interest in the company. An employee who owns stock in a company may not engage in any official particular matter that will affect the employee's interest in that company unless the conflict is resolved.

Example 3: An administrative officer (AO) has an approved outside job working in an office furniture store, and the AO is considered an employee of the furniture store (rather than an independent consultant). The AO's IC is planning to renovate and expects to submit a large furniture purchase. The AO's outside employer submits a bid. The AO cannot officially participate in this particular procurement because it will affect the financial interests of his/her outside employer unless the conflict is appropriately managed.

Example 4: An employee may not personally participate in official matters affecting an outside organization with which the employee is negotiating future employment, or already has an arrangement in place for future employment, unless that conflict is appropriately resolved.

C. APPEARANCES OF CONFLICTS OF INTERESTS:

1. **Description of an Apparent Conflict:** As discussed above, interests of parties identified in the statute (18 USC § 208) result in a real conflict if a matter to which an employee is assigned could affect those interests. The appearance of a conflict of interest arises where an employee is assigned to participate in an official duty matter where an organization with which the employee has a covered relationship is or represents a party to that matter, or where the matter is likely to affect the interests of a household member, and there are circumstances that would cause a reasonable person with knowledge of the relevant facts to question the employee's impartiality in the official matter. The regulation (5 CFR § 2635.502) provides that employees have covered relationships with:

- Members of their households and relatives with whom they are deemed to have close personal relationships;
- Persons or organizations with whom they have or seek a business, contractual or other financial relationship other than a routine consumer transaction;

MANAGING CONFLICTS OF INTERESTS AND THE INTRODUCTION OF BIAS

- Persons or organizations for whom their spouses, parents or dependent children are, to their knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee;
- Persons or organizations for whom they have, within the last year, served as an officer, director, trustee, general partner, agency, attorney, consultant, contractor or employee; or
- An organization in which they are an active participant (e.g., serves as a committee chair, spokesperson, promotes the organization, coordinates fund-raising events).

When an appearance of a conflict of interest arises under 5 CFR § 2635.502, the employee may not participate unless an authorization is issued to permit him or her to participate in the government matter even though the appearance of a conflict exists. The IC DEC must find that, in light of all relevant circumstances, the Government's interest in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations.

2. **Examples of Apparent Conflicts of Interest:** The following examples are not exhaustive but can be help identify situations where the appearance of a conflict of interest would exist.

Example 1: An IC is planning a renovation, including new carpet and furniture. The brother of the AO working on the procurement owns a carpet store and submits a bid. The AO has an appearance of a conflict of interest because of the family relationship. The AO may not continue working on the procurement unless the apparent conflict is resolved.

Example 2: An employee ended an outside activity six months ago. That employee may not participate in an official matter where the previous employer is a party during the one-year 'cooling off' period (recusal time) following the end of an outside activity unless the apparent conflict is resolved through authorization.

- D. **MANAGING THE INTRODUCTION OF BIAS FROM PROFESSIONAL ACTIVITIES WITH OUTSIDE ORGANIZATIONS:** In addition, NIH management exercises inherent authority to assign work in a manner that protects the perceived integrity of NIH programs and operations. NIH staff often engage in professional activities that involve outside entities or organizations and these activities are often part of the employee's official duties. Examples of professional activities are scientific collaborations, co-authorship of a paper, and certain editorial positions. This section assumes that none of these official duty assignments create a real or apparent financial conflict of interest as discussed above, or if such a conflict did arise, it was resolved.

In ensuring the integrity of NIH programs, it is essential to ensure that employees are free from conflicts of interest and apparent conflicts, as discussed above, and that an employee's official professional activities cannot be perceived as biasing NIH decisions or actions. Perceptions of bias may arise when an employee stands to benefit professionally from a particular research outcome, collaboration, or service that results from an official duty. It might occur when an employee has multiple assigned official duties that involve a particular outside organization or person, or when an employee has assigned official duties involving different entities or investigators who view themselves as competitors. Note that most conflicts between two official duty assignments can be managed by the supervisor and employee as opposed to a personal

MANAGING CONFLICTS OF INTERESTS AND THE INTRODUCTION OF BIAS

(financial) conflict or apparent conflict which often requires the help of the IC ethics office to resolve.

The ability of an employee to participate in professional activities is dependent on the nature of the activity, whether the professional activity may introduce or appear to introduce bias towards other official duty assignments, and whether the resulting bias or perception of bias can be appropriately managed or mitigated. This policy requires the NIH staff member to personally consider whether a conflict exists with respect to professional activities and other official duty activities. The NIH employee is responsible for: 1) identifying any real or apparent source of bias that may arise from official duty interactions with organizations with which they have professional interests or relationships; 2) resolving the identified conflicts with the help of his/her supervisor (and the Deputy Ethics Counselor (DEC) if necessary); and 3) securing approval from the appropriate source, if required, prior to entering into such an activity.

The [Official Duty Activity](http://ethics.od.nih.gov/topics/ODA/2-ODA-Chart.pdf) [http://ethics.od.nih.gov/topics/ODA/2-ODA-Chart.pdf] chart, available on the NIH Ethics Program web site, is to be used as guidance in managing professional activities and official duties. The chart lists examples of many different official duty activities in which NIH staff might engage with an outside organization. This chart allows NIH staff to identify professional activities, understand who should be approving such activities, what conflicts or biases may arise as a result of the activity, and how those should be managed. Most of these activities only require supervisory approval. Such approval may be given after any self-identified conflict that would arise from a personal outside interest or relationship has been resolved with the help of the supervisor (and IC DEC, if necessary).

In addition, case studies are available that illustrate scenarios where professional activities and official duties may conflict or lead to bias and how they can be resolved. See the [Official Duty Activity](http://ethics.od.nih.gov/topics/Official.htm) topic page. [http://ethics.od.nih.gov/topics/Official.htm]

E. MECHANISMS TO RESOLVE REAL AND APPARENT CONFLICTS OF INTERESTS

- 1. Regulatory Exemptions:** The regulations (5 CFR Part 2640) implementing the conflict of interest statute (18 USC § 208) describe several types of financial interests where particular interests are too remote or too inconsequential to affect the integrity of the services of our employees. These **regulatory exemptions** exist to permit the affected employees to participate without any further actions. Those employees required to file a Public or Confidential financial disclosure report must still report these holdings on their financial disclosure report, even if they think that one of the regulatory exemptions removes their conflict. The DEC will make the final determination whether a regulatory exemption applies. See details on the NIH Ethics Program web site, on the Topics/Financial Disclosure page. [Note: The regulatory exemptions have no effect on financial disclosure reporting and/or other approval requirements.]
- 2. Recusal/Disqualification:** Employees are responsible for identifying any situation that could pose a real or apparent conflict and to discuss it with their supervisor and/or IC Ethics Office staff before taking any action or otherwise participating in any way in the matter. If the analysis and consideration demonstrates that a conflict of interest or impartiality problem exists and that recusal is required, the supervisor accepts responsibility for handling the

MANAGING CONFLICTS OF INTERESTS AND THE INTRODUCTION OF BIAS

official matters which could affect the employee's conflicting interest. (For some employees (e.g., IC Directors), an NIH official other than the supervisor will accept responsibility for the matter. Regardless, the official must be at a higher organizational level than the employee.) The supervisor may reassign or keep that responsibility. The employee must inform those who need to know about the reassignment or conflict or are affected by the decision, including his or her supervisor, so the employee is not inappropriately involved in the official matter. The employee then is never to be consulted about the matter. Nor may the employee seek information about any matters from which s/he is or should be recused.

When IC Ethics Offices become aware of circumstances that could pose a real or apparent conflict for employees, DEC's will issue cautionary notes to the employees to inform them when disqualification is or may be necessary based on their duties, financial interests, and other known relationships. Such cautionary notes must be updated annually, or sooner when appropriate, and are based on the ethics records (e.g., financial disclosure reports, and outside activity and award request forms) contained in the employee's files. Employees are required to review, correct and acknowledge receipt of such notes. Employees who give no information to the IC Ethics Office, i.e., they are not required to file an ethics form, or the forms they do file contain no information suggesting that a conflict currently exists or may arise in the future, will not receive a cautionary note. Regardless of whether a note is issued, IC Ethics Offices can be consulted at any time to discuss whether a recusal is needed for a particular situation.

- 3. Waiver of the Conflict:** A waiver may be used for **resolving a real conflict of interest** under the criminal statute (18 USC § 208). The waiver may be issued to resolve conflicts that arise when an employee's personal or imputed financial interest will be affected by the matter, when the interest is determined in consultation with IC ethics officials and the NIH Ethics Counsel not to be so substantial as to be deemed likely to affect the integrity of the employee's service in conducting his or her official responsibilities.

Waivers must be issued in writing and must address all issues prescribed by the Office of Government Ethics (OGE), as outlined in the template provided on the NIH Ethics Program web site, on the Forms page. All waivers issued under the authority of 18 USC § 208(b)(1) (i.e. the authority generally used in relation to FTEs) must be reviewed and cleared by the NIH Ethics Counsel prior to issuance.

A waiver of the provisions of 18 USC § 208 (the criminal conflict of interest statute) must be obtained from the employee's appointing authority/official, who is the only person with legal authority to approve the waiver. Generally the IC Director will be the employee's appointing authority, though the IC Director may redelegate the authority to the DEC, or some other official. The delegation must be in writing and maintained in the ethics files. The IC may determine the internal format for routing the waiver, i.e., whether the waiver memo is completed by the employee and sent through the supervisor to the appointing authority, or from the DEC to the appointing authority on behalf of the employee. Waivers are approved on a case-by-case basis. Waivers can be recommended by the Deputy Ethics Counselor (DEC) when the DEC and IC Director are not the same person. If the DEC and appointing official are the same person, the waiver can be from the individual requesting the waiver or from a supervisor. In either case, the format and content remain the same.

MANAGING CONFLICTS OF INTERESTS AND THE INTRODUCTION OF BIAS

A special circumstance that causes a conflict of interest arises when an employee serves as an officer or member of a board of directors or similar position for an outside organization as part of his or her official duties. As a matter of law, such service involves a fiduciary responsibility. If such service is provided as part of one's official duties, there is a conflict between the employee's responsibilities to the Government and responsibilities to the outside organization. This conflict can be resolved with a waiver if the employee's service in that capacity further the agency mission. See the waiver template on the NIH Ethics Program web site, on the Forms page, for guidance on preparing the waiver memo for this situation.

4. **Authorization to Participate:** An authorization may be used to resolve the appearance of a conflict of interest under the regulation (5 CFR §2635.502). The authorization permits (or authorizes) the employee to participate in the official matters with the particular outside organization, despite the appearance of a conflict of interest. The IC may determine the internal recommendation and approval process, i.e., completed by the employee and routed through the supervisor to the DEC, or prepared by the DEC to the employee. Although no particular written or formal form is required, documentation reflecting the agency designee's consideration of the regulatory considerations should be maintained in the employee's ethics file. A sample template is provided on the NIH Ethics Program web site, on the Forms page.
 5. **Resignation:** Occasionally, it may be necessary for an employee to resign from an outside activity in order to resolve a conflict with his/her official responsibilities. The employee must send a resignation letter to the outside entity with a copy to the DEC. The one-year cooling off period following an outside activity remains in place so a decision is necessary whether the employee will remain disqualified from matters where the outside organization is a party for one year from the date of resignation, or grant an authorization to the employee to allow his or her participation despite the recent association with the outside entity. It is also possible that an employee prefers to resign from the Federal Government and keep his/her outside interest, which then resolves the conflict of interest for that individual.
 6. **Divestiture:** Occasionally, it may be necessary for an employee to divest of a particular conflicting financial interest (sell, gift, or otherwise permanently give up the conflicting interest). When the DEC determines that divestiture is necessary and capital gains tax would be owed due to the resulting sale, the employee may request a Certificate of Divestiture (CD) to defer the requirement to pay such tax when the interests are divested. The CD must be obtained **prior to the sale**. [Additional details about CDs](http://ethics.od.nih.gov/topics/divest.htm) are available on the NIH Ethics Program web site at: <http://ethics.od.nih.gov/topics/divest.htm>
 7. **Blind Trust:** This mechanism to resolve a conflict is rarely used. It is an expensive legal process handled by the Office of Government Ethics. The DEC will contact the HHS Office of the General Counsel, Ethics Division, and the Office of Government Ethics if this option appears to be necessary.
- F. **NIH POLICY:** In addition to the policies stated in the descriptions of the mechanisms to resolve conflicts of interest above, the following specific policies will prevent conflicts for the employee and for the NIH.

MANAGING CONFLICTS OF INTERESTS AND THE INTRODUCTION OF BIAS

1. **Outside Activities:** Except in extenuating circumstances, an employee will not be granted a waiver or authorization to initiate an outside activity with an organization with which the employee has an official relationship.
2. **Sponsored Travel:** ICs should not accept sponsored travel for employees where they have certain official relationships, e.g., the offering organization is in the grant portfolio of an extramural Health Scientist Administrator (HSA), supplies a drug for a clinical trial the employee conducts, or is a Cooperative Research and Development Agreement (CRADA) or Materials Transfer Agreement (MTA)-CRADA partner with the employee (unless the travel was explicitly negotiated as part of the CRADA contract). In addition, sponsored travel may not be accepted by the NIH if the employee is traveling to explore potential collaborative activities with the organization, or if the employee has conducted an approved outside activity with the organization less than 12 months ago. Although official travel is governed by the regulations from the General Services Administration and sponsored travel is a gift to the NIH not to the individual, it is important to consider the potential conflicts of interest for the employee and the NIH associated with accepting sponsored travel from an outside organization.
3. **Negotiating Employment:** An employee who wishes to negotiate employment with an outside organization with which the employee also has an official relationship must disqualify him/herself from the matters that would affect the interests of the prospective employer.

G. AVAILABILITY OF FORMS: Sample waiver, authorization, and recusal memos are available from each IC's Ethics Office and on the NIH Ethics Program web site at:

<http://ethics.od.nih.gov/forms.htm>

H. CONFIDENTIALITY OF DOCUMENTS/RELEASE OF INFORMATION: Waivers, authorizations, recusals and other documents are maintained in a secure area with other ethics documents, in accordance with the instructions in NIH Manual 2400-01 Introduction to Government Ethics at the NIH. The DEC is responsible for maintenance of the ethics files. Waivers, recusals and authorizations may sometimes be released in response to a Freedom of Information Act (FOIA) request. If a request is received, contact the FOIA officer and the NIH Ethics Office for assistance.

I. ADDITIONAL INFORMATION: For additional information or answers to your questions, contact your IC's Deputy Ethics Counselor or Ethics Coordinator, whose names are listed on the NIH Ethics Program web site, or review the topics on the web site. <http://ethics.od.nih.gov/>

Additional information may also be obtained from the NIH Ethics Office (301-402-6628).

See the introductory chapter NIH Manual Chapter 2400-01, Introduction to Government Ethics at the NIH (6/18/08) for information regarding relevant Authorities and References (Section D), Records Retention and Disposal (Section H), and Management Controls (Section I).