NIH Policy Manual

2400-01 - Introduction to Government Ethics at the NIH

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Transmittal Notice

1. **Explanation of Material Transmitted:** This new chapter introduces the NIH Ethics Manual issued in the 2400 series of NIH Manual. This introductory chapters provides information relevant to all chapters in the 2400 series and includes corresponding authorities, definitions, records retention, and management control information. It incorporates some information from the obsolete chapters , NIH Manuals 2300-735-1 and 2300-735-4, regarding interactions with outside organizations. Additional new chapters in the 2400 series will be issued in the coming months.
2. **Filing Instructions:**

   Remove: NIH Manual Chapter 2300-735-1 and 2300-735-4.
   Insert: NIH Manual 2400-01 dated 06/18/08.

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.
- On-line information, enter this URL: http://oma.od.nih.gov/manualchapters/

A. Purpose

This Ethics Manual for the National Institutes of Health (NIH), in the US Department of Health and Human Services (HHS), provides the policies and guidelines based on Federal laws and government-wide and agency-specific regulations which govern the activities of NIH staff, including financial disclosure and various activities with outside organizations, e.g., outside activities, gift exceptions (awards, honorary degree), and seeking outside employment. Other activities for which no NIH implementation policy is required, e.g., post-employment restrictions and political activities, have fact sheets on the NIH Ethics Program web site. This Manual replaces the information in two separate manual chapters noted above, which are now obsolete.

To ensure the integrity of the Federal Government, a comprehensive set of statutes and regulations govern the personal relationships and official interactions Federal employees may

have with certain persons and entities in a variety of circumstances (see “Authorities” below). Statutes include the Ethics in Government Act (as amended) and several laws under the heading of conflict of interest statutes. The regulations issued by the Office of Government Ethics (OGE) provide guidance on implementing the statutes, including instructions for the various ethics activities required in an agency’s ethics program. In addition, HHS Supplemental Regulations add policies specific to HHS employees.

Several functions are required in the NIH Ethics Program: financial disclosure reporting systems, advance approval of outside activities, advance approval of permitted gift exceptions (i.e., awards, honorary degrees, sponsored travel), procurement integrity enforcement, foreign activity screening, enforcement and advice based on all of the applicable rules, conflicts resolution, education and training, and prevention of conflicts for members of the advisory committees. This manual interprets and is intended to be used in conjunction with the statutes and regulations, and the HHS Supplemental Standards of Ethical Conduct (5 CFR 5501) and HHS Supplemental Financial Disclosure Requirements (5 CFR 5502), to implement and maintain a viable and visible ethics program at the National Institutes of Health, including the central NIH Ethics Office (NEO) and the programs within each Institute and Center (IC).

B. Coverage

The NIH Ethics Manual applies to all Civil Service and Commissioned Corps employees (also referred to as FTEs), including employees in the General Schedule, Federal Wage System, Senior Executive/Scientific Service, Senior Biomedical Research Service, and Senior Level/Senior Technical. Coverage also extends to employees appointed under Title 42, and persons working at NIH under Intergovernmental Personnel Act (IPA) assignments, both detailees and appointees. However, IPA detailees are not subject to all provisions of the HHS Supplemental Standards of Ethical Conduct (i.e., part-time detailees do not have to relinquish their HHS-funded grants at their home institution). Both IPA appointees and detailees are covered by the statutes and the executive branch-wide Standards of Ethical Conduct.

Persons who are not NIH employees but who work at the NIH (also referred to as non-FTEs), including National Research Council Research Associates, Guest Researchers, Special Volunteers, Scientist Emeriti, Intramural Research Training Award (IRTA) Program Trainees, and National Research Service Awardees at the NIH are not subject to the requirements of this Manual, though other laws and regulations may apply. Although they are not employees, their work at the NIH may appear to conflict with their personal financial interests. Therefore, any involvement with an outside organization must be discussed first with the supervisor or other individual to whom they report, to ensure that there are no conflicts with the work being performed at NIH. The supervisor, in consultation with the IC Ethics Office if necessary, will determine whether the NIH duties must be modified to avoid conflicting with the individual’s outside interests. In addition, trainees can be required through their training agreements to adhere to the standards and provisions set forth in this manual.

Individuals working at the NIH under a contract are not covered by this Manual, though are covered by any standards of conduct which are included in their contracts, i.e., maintaining confidentiality of Government information. By virtue of their position with the Government,

contract personnel are prohibited from disclosing confidential information.

Visiting Program staff (all visa holders) are covered by specific chapters, e.g., receipt of awards from outside organizations, but not covered by other chapters. Some visa holders may not engage in any work other than that approved under their visa. Visiting Program staff should talk to the Deputy Ethics Counselor (DEC), Ethics Coordinator (EC), or ethics specialist in their respective Institute or Center (IC).

Parts of this manual also apply to Special Government Employees (SGE) who work 130 days or less during a service year. SGEs may contact their DEC, EC, the Committee Management Officer in their IC, or the program staff responsible for their NIH work for additional information. SGEs may also wish to review the the NIH Manual Chapter 1810 pertaining to conflicts of interests for SGEs. This chapter is available on the NIH manual chapter web site at NIH Manual Chapter 1810.

See also the "Coverage" section of each chapter where additional criteria relevant to employee coverage for that chapter is provided, when applicable.

C. Resources

In addition to this manual, employees may contact the following individuals or web sites for assistance regarding compliance with applicable statutes and regulations, topic-specific information, forms, and other information such as the process for requesting approval, dealing with conflicts of interests, and other ethics issues.

1. Institute/Center (IC) Deputy Ethics Counselor (DEC): http://ethics.od.nih.gov/decs.pdf
2. IC Ethics Coordinators (EC) and ethics specialists: http://ethics.od.nih.gov/coord.pdf
3. NIH Ethics Office staff (names/phone number on the web list of Coordinators, above)
4. NIH Ethics Program web site: http://ethics.od.nih.gov/
5. HHS Office of the General Counsel, Ethics Division (OGC/ED), staff in the NIH office and web site: http://intranet.hhs.gov/ogc/hhsethics/ (HHS access only)

DECs and ECs are encouraged to first contact staff in the NIH Ethics Office for assistance. DECs and ECs may also contact staff in the HHS Office of the General Counsel, Ethics Division, satellite office at the NIH, whose names and contact information are available on the DEC list on the NIH Ethics Program web site.

D. Authorities and References

The following authorities provide the basis for the NIH Ethics Program policies as provided in the chapters of this Ethics Manual. Most are available electronically from the 'Policies' page on the NIH Ethics Program web site. http://ethics.od.nih.gov/policies.htm

1. United States Constitution (especially Article I, Section 9, Clause 8, the "Emoluments Clause")
2. Ethics in Government Act of 1978, as amended (P.L. 95-521, codified at 5 USC Appendix) by the Ethics Reform Act of 1989 (P.L. 101-194)

3. Executive Order 12674 as amended by Executive Order 12731 (October 17, 1990)
4. Foreign Gifts and Decorations Act (5 United States Code 7342)
5. Conflict of Interest Statutes:

    a. 18 USC § 201, Bribery of public officials and witnesses
    b. 18 USC § 202, Definitions
    c. 18 USC § 203,Compensation to Members of Congress, officers, and others in matters affecting the Government
    d. 18 USC § 204, Practice is US Claims Court or the US Court of Appeals for the Federal Circuit by Members of Congress
    e. 18 USC § 205, Activities of officers and employees in claims against and other matters affecting the Government
    f. 18 USC § 206, Exemption of retired officers of the uniformed services
    g. 18 USC § 207, Restrictions on former officers, employees, and selected officials of the executive and legislative branches
    h. 18 USC § 208, Acts affecting a personal financial interest
    i. 18 USC § 209, Salary of Government officials and employees payable only by United States
    j. 18 USC § 216, Penalties and injunctions

6. Hatch Act: 5 USC §§ 7321-7326, and 5 CFR Parts 733 and 734
7. Anti-Lobbying Act: 18 USC § 1913
8. Office of Government Ethics Regulations

    a. 5 CFR § 2634, Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture
    b. 5 CFR § 2635, Standards of Ethical Conduct for Employees of the Executive Branch
    c. 5 CFR § 2636, Limitations on Outside Earned Income, Employment and Affiliations for Certain Noncareer Employees
    d. 5 CFR § 2637, Regulations Concerning Post Employment Conflict of Interest (unless superseded by subsequent rule)
    e. 5 CFR § 2638, Office of Government Ethics and Executive Agency Ethics Program Responsibilities
    f. 5 CFR § 2640, Interpretation, Exemptions and Waiver Guidance Concerning 18 USC § 208 (Acts Affecting a Personal Financial Interest)
    g. 5 CFR § 2641, Post-employment Conflict of Interest Restrictions

9. General Records Schedule 25: Ethics Program Records (April 2003)
10. Department of Health and Human Services (HHS) Regulations, Manuals, and Instructions:

    a. 45 CFR § 73, Standards of Conduct, Employee Responsibilities and Conduct (Residual Standards, those sections not superseded by the HHS Supplemental Standards of Ethical Conduct)

b. 5 CFR Part 5501, Supplemental Standards of Ethical Conduct for Employees of HHS
c. 5 CFR Part 5502, Supplemental Financial Disclosure Requirements for Employees of HHS
d. Designated Agency Ethics Official (DAEO) Instruction No. 98-1, November 20, 1998: Exemption from Prior Approval for Letters to the Editor(s) of Newspapers and Other Periodicals
e. DAEO Instruction 98-02, December 2, 1998: Exemption from Prior Approval for Service as Officer, Board Member of Condominium, Homeowners, or similar group
f. DAEO Supplemental Instruction No. 99-1, December 21, 1999: Exempts political activities from the prior approval requirement
g. Memo from HHS Designated Agency Ethics Official to HHS Deputy Ethics Counselors and Ethics Contacts: Internal Agency Procedures or Processes for Reviewing HHS-520 Outside Activity Request Forms, dated January 27, 2004
h. DAEO Instruction 06-1, January 5, 2006: Implementation of forms HHS-520 Request for Approval of Outside Activity and HHS-521 Annual Report of Outside Activity
i. Memo from Designated Agency Ethics Official to HHS Employees, July 30, 2007: Ethics Rules Pertaining to Employment and Activities Outside of Your HHS Employment
j. DAEO Instruction 06-2, December 14, 2006: Confidential Financial Disclosure System Procedures for HHS
k. DAEO Instruction 07-1, March 7, 2007: HHS Form 717-1 Confidential Report of Financial Interests in Substantially Affected Organizations for Employees of the NIH
l. DAEO Instruction 07-2, May 23, 2007: Public Financial Disclosure System Procedures for HHS
m. HHS Chapter 20-25, General Administration Manual: Foreign Gifts and Decorations

11. NIH Delegations of Authority, Ethics: The HHS Designated Agency Ethics Official (DAEO) delegates authority to implement the ethics program at NIH to an NIH Deputy Ethics Counselor (DEC). All further redelegations of authority within NIH, including delegations within ICs, must be consistent with and reflect any limitations associated with the original delegation, HHS General Administration Manual, Chapter 8-100, and applicable NIH policies set forth in NIH MC 1130, Delegations of Authority (pending release). Ethics delegations are addressed to individuals, not positions.

    See also the Ethics section of the NIH Delegation of Authority web site, accessible only to those on the NIH network: http://www.delegations.nih.gov/
12. NIH Ethics Training Policy, dated April 2, 1998
13. NIH Policy Memo: Changes in the NIH Ethics Program, dated January 18, 2004
14. NIH Policy Memo: Changes to Outside Activity and Award Approval Process, dated February 6, 2004

15. NIH Policy Memo: Supervisory Review of Outside Activity Requests, dated February 16, 2004

E. Responsibilities

All NIH employees have a responsibility to be knowledgeable about the government ethics and conduct-related statutes and regulations and how they may affect them individually. In addition, the various offices and positions associated with the overall government-wide ethics program have specific responsibilities.

1. **HHS Designated Agency Ethics Official (DAEO)/Associate General Counsel for Ethics**

    a. The Associate General Counsel for Ethics in the HHS Office of the General Counsel is appointed by the Secretary, HHS, to serve as the DAEO. The DAEO is responsible for the implementation and enforcement of the ethics program throughout HHS.
    b. The DAEO supports the NIH ethics program by maintaining an office at NIH (OGC/E) staffed by attorneys (NIH Ethics Counsel) who:

        i. provide guidance and advice to the NIH, the NIH Ethics Office, NIH ethics officials, and employees regarding the interpretation and application of all conflict of interest laws and standards of ethical conduct issues;
        ii. function as the NIH liaison to the Office of Government Ethics and, in relation to government ethics matters, the Department of Justice, and as a liaison with the Office of the Inspector General;
        iii. provide advice and assistance in developing policies compatible with existing ethics regulations and statutes; and
        iv. act as the DAEO's representative in relation to government-ethics authorities the exercise of which are reserved to the DAEO.

    c. The DAEO issues HHS policies, procedures, and announcements regarding the implementation of the ethics program.
    d. The DAEO exercises general oversight regarding the ethics program and conducts periodic program reviews of all agency components.
    e. In consultation with the head of each operating or staff division, the DAEO appoints Deputy Ethics Counselors (DEC) in each area across HHS.
    f. The DAEO prescribes the content of required ethics training for HHS employees and provides and coordinates training for NIH ethics officials on all government ethics issues.

2. **NIH Deputy Ethics Counselor (DEC):** The NIH Deputy Ethics Counselor (DEC) will:

    a. establish NIH policies and procedures to implement the Government-wide and HHS Supplemental Standards of Ethical Conduct in consultation with the DAEO and NIH Ethics Counsel;

b. grant exceptions to NIH program or policy requirements otherwise consistent with government-wide and HHS requirements when justified by special circumstances;
c. serve as DEC to review and make final decisions for all ethics requests for the NIH Office of the Director (OD) staff; and
d. serve as DEC to review and make final decisions for all ethics requests for NIH Senior staff, IC Deputy Ethics Counselors, and for Outside Activities and Awards reviewed by the NIH Ethics Advisory Committee (NEAC).

3. **Chief NIH Ethics Officer (CNEO)/Director, NIH Ethics Office (DNEO):** For all of NIH, CNEO/DNEO will:

a. provide oversight and leadership for the NIH Ethics Program;
b. provide assistance to IC DECs, ECs, and other managers and supervisors on all aspects of the NIH Ethics Program including advice, resources, information, training, and other consultation as needed;
c. advise the Director, NIH, the NIH DEC, and other top management officials of new trends, developments, activities or practices that may raise ethical conduct concerns for NIH employees;
d. manage financial disclosure and other ethics requests from NIH Senior employees and DECs, maintaining the official files and requesting forms and information as required;
e. maintain the NIH Ethics Program web site, on-line annual ethics training modules, new employee ethics orientation module, and computer-based tracking systems;
f. conduct post audit reviews consistent with NIH Management Control guidelines;
g. provide informal or formal training for IC ethics officials as needed to enhance their knowledge and skills in the ethics arena;
h. represent the NIH at HHS, government-wide, and private sector ethics meetings, conferences, seminars, or other gatherings; and
i. manage the ethics program in the NIH Office of the Director (OD), serving as the Ethics Coordinator for the OD to provide all ethics services to OD staff, including distributing and tracking financial disclosure reports, providing advice, processing requests, providing and tracking required training, and maintaining the files for OD.

4. **NIH Ethics Advisory Committee (NEAC):** The NEAC will serve as an advisory body to the NIH DEC, and will review those proposed activities under its jurisdiction, as defined in NIH Manual Chapter 2400-06, NIH Ethics Advisory Committee (pending release).
5. **Institute/Center (IC) Directors:** Within their respective ICs, the Directors will:

a. provide adequate staffing and resources to maintain a viable ethics program within their ICs; and
b. provide obvious leadership and support of the ethics program to staff in their ICs.

6. **IC Deputy Ethics Counselors (DECs):** Within their respective ICs, DECs will maintain their own level of ethics knowledge and competence to:

    a. coordinate and manage Institute and Center (IC) ethics programs, including financial disclosure, outside activities, education and training, advice, conflicts resolution, procurement integrity enforcement, sponsored travel, awards, honorary degrees, widely attended gatherings, other gifts, and other ethics-related activities;
    b. provide advice to IC managers and employees regarding the application of the conflict of interest statutes, the Standards of Ethical Conduct, the HHS Supplemental Standards, and NIH policies;
    c. review all ethics requests for conformance with regulations and policies and approve or disapprove requests as needed (including but not limited to: outside activities, official duty activities, awards from outside organizations, honorary degrees, recusals, waivers, widely attended gathering exceptions, authorizations, sponsored travel, activities with foreign entities, and other ethics requests);
    d. oversee the public, confidential and supplemental financial disclosure reporting systems, and review and certify reports as required by statute and regulation;
    e. assure the maintenance of all records associated with IC employee ethics matters;
    f. provide Procurement Integrity Act advice when requested;
    g. respond in a timely manner to requests for information from the NIH Ethics Office, OGC/E, or the NIH Ethics Counsel, e.g., the annual agency ethics questionnaire, requests from Congress, Freedom of Information requests, annual training plan, and other requests; and
    h. provide input to the NIH Ethics Office to facilitate the NIH Ethics Program.

7. **IC Ethics Coordinators/Specialists:** Within their respective ICs, the coordinators/ specialists will maintain their own level of ethics knowledge and competence to:

    a. serve as the primary point of contact for the exchange of information on activities with outside organizations and other ethics issues;
    b. provide administrative and/or program support for IC Ethics Programs as defined by their Directors and/or DECs.

8. **Supervisors:** Within their respective areas of authority, supervisors will:

    a. acquire a working knowledge of the statutes, regulations, policies, and procedures regarding ethical conduct;
    b. help employees understand and comply with these requirements;
    c. ensure that job applicants are fully aware of outside activity and other ethics requirements and, if appropriate, resolve any conflicts before employment with the assistance of the IC DEC, the NIH Ethics Office and the NIH Ethics Counsel;
    d. review requests for outside work and official duty activities, and either approve those within their authority or make recommendations on the disposition of requests for those that must be approved by their DEC; and

e. obtain assistance from their DEC or ethics coordinator/specialist to fulfill these responsibilities.

9. **Employees:** Employees are at all times responsible for complying with the statutes, the OGE Standards of Ethical Conduct and the HHS Supplemental Standards; avoiding conflicts of interest; and refraining from participation in any activities that conflict or appear to conflict with their official duties. Because failure to observe these requirements may be cause for disciplinary or legal action, NIH provides extensive guidance and assistance to employees so that their participation in official duty activities will be positive and rewarding experiences free of any complications or problems, and so that employees understand the requirements for all actions governed by the ethics statutes and regulations, for example, filing financial disclosure reports and completing the required ethics training. Employees will:

    a. acquire a working knowledge sufficient to comply with the conflict of interest statutes, the Government-wide Standards of Ethical Conduct, HHS Supplemental Standards, and NIH policies regarding activities with outside organizations;
    b. obtain advice from supervisors and their IC ethics staff when needed;
    c. submit requests for activities with outside organizations for review and approval sufficiently in advance of the activity to permit adequate review time;
    d. provide all information needed by higher level officials to make well-informed decisions about the approval of requests to engage in activities with outside organizations;
    e. file timely financial disclosure reports if designated as a filer; and
    f. complete annual ethics training when notified.

F. Definitions

Many terms used in the ethics statutes and regulations and in this manual are legal terms. Therefore, they are very specific and important in determining the nature and appropriateness of activities governed by the applicable statutes and regulations.

1. **Actual Conflict of Interest:** An actual conflict of interest arises when an employee has (or would have) official responsibilities that will directly and predictably affect an employee's personal or imputed interest in or with an outside organization, as defined by the statute at 18 United States Code (USC) Section 208. Imputed interests for purposes of this statute include those of the: spouse; dependent children; an entity by which the Federal employee is also employed; an entity which the employee serves as an office, trustee, or member of the board of directors. The employee who personally and substantially participates in a matter involving or affecting his/her own interest or those of any of these other persons or entities outlined in the statute likely violates that criminal statute (18 USC 208). See "Financial Interest" (#9) below.
2. **Appearance of a Conflict of Interest:** An appearance of a conflict of interest arises when an employee is involved in a particular matter involving specific outside parties (including individuals or corporate entities) and the circumstances are such that a

reasonable person with knowledge of the relevant facts would question the employee's impartiality in the matter. This may occur when the matter is likely to have a direct and predictable effect on a member of the employee's household or involves the people or entities as outlined in 5 CFR § 2635.502 of the Standards of Ethical Conduct for Employees of the Executive Branch. Under the regulation, an employee has a covered relationship with, among others, the following: a person or organization with whom s/he seeks a business or financial relationship; a close relative; an entity that employs the employee's spouse, parent, or dependent child; an organization in which the employee's spouse serves as an officer, director, or other position; or an organization where the employee is an active participant. In order to participate in an official decision or action affecting any of these individuals or entities, the employee must have an authorization prior to any participation.

3. **Authorization:** An authorization is a written mechanism used to resolve an appearance of a conflict of interest under 5 C.F.R. § 2635.502. An authorization reflects the agency's consideration of the circumstances and determination to permit the employee to participate in a particular official duty activity concerning an outside organization despite the appearance of a conflict of interest with that outside organization or person (see Appearance of a Conflict of Interest, above). In making this determination, the agency designee concludes that the need for the employee's official participation outweighs the concern that a reasonable person with knowledge of the relevant facts might question the employee's impartiality or the integrity of the agency's programs and operations.
4. **Cooling-Off Period:** The 'cooling-off period' is the time during which an employee must sometimes be disqualified from conducting any official activity which involves or affects an outside entity in order to comply with ethics regulations. (See #7, Recusal, below.)

    a. Outside Activities: For one year following the end of the outside activity, employees may not officially interact with the outside entity absent an authorization. The cooling off period also applies to interactions with former employers (5 CFR § 2635.502).
    b. **Extraordinary Severance Pay:** In some cases, when a former employer decides to give an extraordinary severance payment (greater than $10,000) to an employee after learning that the employee may accept or has accepted a Government position, there is a two-year cooling-off period beginning the date the payment was received (5 CFR § 2635.503). This provision may not apply if the severance pay was part of an established program of compensation or benefits, or if there is a history of similar payments being made to others not entering into Federal service. In addition, under certain circumstances, this cooling-off period may be waived by the Secretary, HHS. Discuss specific situations with your DEC or EC.
    c. **Official Duty Activities:** There is no cooling-off period following the termination of an official duty activity with an outside organization. The employee and the DEC must, however, carefully review the circumstances and the appearance of using public office for private gain if an employee ends an official duty activity with an outside organization and immediately requests

permission to initiate an outside activity with that same organization.

d. **Awards:** When an employee is offered an award which requires advance approval via the request for approval of an award form, the employee is recused from all official matters which affect the donor organization immediately, until one year following receipt of the award.
e. **Honorary Degrees:** When an employee is offered an honorary degree, that employee is immediately recused from all official matters involving the degree granting institution, until receipt of the honorary degree. No further cooling off period following receipt is required.

5. "Dependent" vs. "Minor" Child: The terms "minor child" and "dependent child" are used in various sections of law and regulation and, accordingly, throughout this chapter. For these purposes, a "dependent child" is any person claimed as such for income tax purposes. Whether a child is a 'minor child' is a question of state law.
6. **Direct and Predictable Effect:** The term "direct and predictable effect" refers to the impact a government matter may have on a financial interest. A direct effect may exist if there is a close causal link between any decision or action to be taken in the particular matter and any expected affect the matter may have on the financial interest. An effect may be direct even though it does not occur immediately. A particular matter will have a predictable effect if there is a real possibility that the matter will affect the financial interest. It is not necessary to know the magnitude of the gain or loss as the dollar amount is irrelevant. A particular matter will not have a direct effect on a financial interest, however, if the chain of events expected to affect the matter is contingent upon the occurrence of other events that are speculative or that are independent of and unrelated to the matter.
7. **Disqualification or Recusal:** To disqualify (also called recuse) is to remove oneself from official participation in a matter which could affect one's personal or imputed financial interest or where an appearance of conflict would arise.
8. **Fiduciary Duty:** A fiduciary duty or responsibility is a legal obligation to act in the best interests of another party. For example, a board member of a corporation has a fiduciary duty to the shareholders, an attorney has a fiduciary duty to a client, a trustee has a fiduciary responsibility to the trust, or a business owner has a fiduciary responsibility to him/herself and the business. A fiduciary obligation exists whenever special trust and confidence is placed, by law, in a person who is relied upon to exercise his/her discretion or expertise in acting for the client, company, etc. Fiduciary duties typically involve the internal business, management, or personnel activities of the organization and are not limited to financial matters.
9. **Financial Interest:** A financial interest is any potential for gain or loss. A financial interest may arise from service as an officer, employee, trustee, or general partner (such as from an outside activity). Such interests include, but are not limited to, stock interests, bank accounts, mutual funds, sector funds, consulting relationships, sources of salaries, and leave of absence agreements. The monetary interest may be present or future (future royalties and patent rights, return to a position with former employer). A financial interest may also arise from service on the Board of Directors of an outside organization or from financial interests of a general partner or organization in which the employee has a financial interest, such as an interest in an organization with which the

employee is seeking employment.

10. **Health Care Provider and Insurer** [5 CFR § 5501.109(b)(8)] means:

    a. a hospital, clinic, skilled nursing facility, rehabilitation facility, durable medical equipment supplier, home health agency, hospice program, or other provider of health care items and services; or
    b. a health maintenance organization, managed care organization, or other entity licensed as a risk-bearing entity eligible to offer health insurance or benefits coverage.

11. **Negotiation:** Negotiation is a means of discussion or communication with another person, or that person's agent or intermediary, mutually conducted with a view toward reaching an agreement, such as negotiating for employment. The term is not limited to discussions of specific terms and conditions, but may involve generalities.
12. **Official Duty Activities:** In this Manual, #39;official duty activities#39; refers to approved activities with an outside organization carried out by an employee as part of his/her official Government duties and responsibilities because the activities relate to his/her official responsibilities. An activity is considered related to official duties if:

    a. the employee was invited to perform the activity primarily because of the employee's official position;
    b. it deals with any matter to which the employee is presently assigned, or was assigned to in the past, even if it was publicly disclosed;
    c. it deals with any ongoing or announced policy, program or operation of the NIH or HHS;
    d. the invitation or offer of compensation is extended by a source who has interests that could substantially be affected by the performance or non-performance of the employee's official duties; and/or
    e. the activity advances the agency mission.

    Employees already receive a salary for completing their official responsibilities so they cannot accept additional compensation from the outside organization. Travel expenses may be paid by NIH or accepted by the NIH via the HHS-348 sponsored travel mechanism. Some examples of official duty activities may include serving as a peer reviewer of manuscripts submitted to scientific journals or serving as a Federal liaison to an outside organization.

13. **Outside Activities:** Outside activities are outside work, separate from official responsibilities. An outside activity involves engaging in providing a service to or a function for an outside organization, with or without pay or other compensation. Outside activities may not conflict with an employee's official duties or work schedule.

    Examples of outside activities **requiring advance approval** include: serving as an officer of an outside organization; consulting; writing an article for publication in a professional/scientific journal; working as a physician or other health care professional. Activities which **do not require advance approval** include retail clerk or similar

activities, as outlined in the HHS Supplemental Standards of Ethical Conduct (5 CFR § 5501.106).

14. **Particular Matter:** A particular matter is a government matter that involves deliberation, decision, or action that is focused upon the interests of specific persons, or upon a discrete and identifiable class of persons. A particular matter does not need to involve formal parties and may include governmental action such as legislation or policy-making that is narrowly focused on the interests of a discrete and identifiable person or class of persons, e.g., one specific university system. It does not include general policy or other discussions that affect a large class of persons or entities, e.g., all universities as a whole.
15. **Personal and Substantial Participation:** Personal participation means the employee is directly involved in the matter or actively supervises someone actively involved in the matter. Substantial participation means that the employee's involvement is of significance to the matter. Participation may be substantial even though it does not determine the outcome of a particular matter. For example, an employee involved in multiple discussions and planning sessions for a particular program initiative may be personally and substantially involved, even if the final decision is not made during the employee's actual participation. Clerical functions such as typing, though possibly time-consuming, are not considered personal and substantial participation.
16. **Prohibited Source:** Employees are subject to restrictions on accepting gifts from entities that are considered prohibited sources. Prohibited source means any person or entity who:

    a. is seeking official action by the employee's agency; or
    b. does business or seeks to do business with the employee's agency; or
    c. conducts activities regulated by the employee's agency; or
    d. has interests that may be substantially affected by performance or nonperformance of the employee's official duties; or
    e. is an organization, a majority of whose members meet any of the above criteria.

17. **Substantially Affected Organization (SAO):** [5 CFR § 5501.109(b)(10)] means any of the following entities:

    a. biotech, device, and pharmaceutical companies, and others significantly involved (directly or indirectly through subsidiaries) in the research, development or manu-facture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products;
    b. any organization a majority of whose members are such entities; and
    c. other entities identified as substantially affected by the work of the NIH by the HHS Designated Agency Ethics Official (DAEO) or by the NIH in consultation with the DAEO.

18. **Supported Research Institution (SRI)** [5 CFR 5501.109(b)(11)] means any educational institution or non-profit independent research institute which:

a. is, or within the last year was, an applicant, recipient, or partner on an NIH grant, cooperative agreement, or Research and Development contract; or
b. is, or within the last year, proposed or was a partner on a Cooperative Research and Development Agreement (CRADA) with the NIH; or
c. is any organization a majority of whose members are such entities.

19. **Waiver:** A waiver is a written determination used to resolve a real conflict of interest under the statute (18 USC § 208). The employee's appointing authority or delegate may, in consultation with NIH Ethics Counsel, issue a waiver to permit an employee's official participation in a matter that would affect a personal or imputed financial interest, but where that interest is not so substantial as to be deemed likely to affect the integrity of the employee's service to the Government.

G. Violations

If it appears that an employee has engaged in an activity in violation of the criminal statutes or regulations, it is the responsibility of the supervisor, management, and/or ethics staff to report the alleged violation. Because this action may result in future investigations and prosecution, DECs and ECs are encouraged to consult with staff in the NIH Ethics Office or NIH Ethics Counsel in connection with reporting alleged violations. For details, see NIH Manual Chapter 2400-08 Referring Employees Non-Compliant With Government Ethics Requirements (pending release). See also NIH Manual 1754, Reporting Allegations of Criminal Offenses, Misuse of NIH Grant & Contract Funds, or Improper Conduct by an NIH Employee.

H. Records Retention and Disposal

All records (e-mail and non-e-mail) pertaining to this Manual must be retained and disposed of under the authority of NIH Manual Chapter 1743, "Keeping and Destroying Records," and Government-wide General Records Schedule 25 covering ethics program records. Note that some records may need to be held longer than the time frame indicated if they are still current, e.g., policies. In addition, if files are stored electronically, originally submitted forms, reports and requests must continue to be held for the full required time period, though can be stored off site as long as they are immediately available electronically (e.g., scanned).

1. **Six-year retention cycle:** DECs must retain the ethics forms and records noted below for a minimum of six years after the termination of the activity except that documents needed in an on-going investigation will be retained past the 6-year time frame until no longer needed in the investigation. To determine which reports should be destroyed, subtract six from the current year. Everything filed prior to that resulting year number is destroyed. For example, 2008 minus 6 = 2002. Therefore, everything filed prior to 2002 is destroyed, including financial disclosure reports filed in 2002 or earlier, outside activities which ended in 2002 or earlier, and other activities which ended in 2002 or earlier.

Disposition: Destroy (burn or shred) when 6 years old.

Documents covered by the 6-year retention cycle: Maintain the following records for six (6) years:

a. Financial disclosure, both public (SF 278) and confidential (OGE 450, 450A).
b. Records relating to the Standards of Ethical Conduct, the Supplemental Standards. the criminal conflict of interest statutes, or executive orders, e.g., Outside Activity forms, Official Duty Activity requests, honorary degrees, awards, recusals, waivers, authorizations, advice, training certificates.
c. Ethics agreements.
d. Referrals and notifications to the Inspector General, Department of Justice, or the Office of Government Ethics (OGE).
e. Ethics program procedure files, e.g., policies and procedures, hold longer than 6 years if not superseded (i.e., hold 6 years or until superseded or obsolete, which ever is later)
f. Ethics program review files, e.g., the report from the OGE following their review of the NIH/IC Ethics Programs (see #3 below).

2. **Three-year retention cycle:** Records relating to routine application of settled legal standards, as noted below, are destroyed after three (3) years. Subtract three from the current year and destroy forms for activities in all years prior to the remainder. For example, 2008 - 3 = 2005; destroy WAG forms for activities prior to 2005, unless needed for an ongoing investigation.

   Disposition: Destroy (burn or shred) when 3 years old.

   Documents covered by the 3-year retention cycle: Maintain the following records for three (3) years:

   a. Widely Attended Gathering (WAG) approval forms.
   b. Annual agency ethics program questionnaire submitted to HHS for submission to the OGE (see #3 below)
   c. Sponsored travel requests and related files (HHS 348) (see #3 below)

3. **One-year retention cycle:** The following files may be destroyed after one year.

   a. Background information used to prepare the annual agency ethics questionnaire, and agency responses and follow-up letters following receipt of the OGE report (see 2b above).
   b. Semiannual Expense Report on sponsored travel which is submitted to OGE (see 2c above).

4. **No retention time frame, destroy when superseded or obsolete:** Policy chapters are retained until superseded, though for future investigations, it is useful to maintain copies of the previous policies. Training materials, such as handouts, may be retained until superseded or obsolete. Training certificates are covered by the 6-year retention

cycle, above.

5. **Electronic Files:** Electronic records such as word processing files and electronic mail are covered by other items in the General Record Schedule, and may be deleted 180 days after the official record keeping copy is made, e.g., after the file is finalized and printed.
6. **NIH e-mail messages:** NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

   All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are sometimes retained for significant periods of time, e-mail messages and attachments may be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls

The purpose of the NIH Ethics Manual is to assure that all employees are aware of and abide by the conflict of interest statutes, the applicable regulations, and HHS and NIH policy regarding conflicts of interests.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter: NIH Ethics Office
2. Through this issuance, the NIH Ethics Office, Office of the Director, NIH is accountable for the method used to ensure that management controls are implemented and working.
3. Frequency of Review: On-going review.
4. Method of Review: The NIH Ethics Office will initiate and lead reviews as deemed necessary.
5. Other Reviews: The HHS Office of the General Counsel, Ethics Division (OGC/ED) at NIH will be consulted as needed to determine the legal correctness of actions taken under the Standards of Ethical Conduct for Employees of the Executive Branch issued by the Office of Government Ethics and the criminal conflict of interest statutes. These reviews will be performed on a case by case basis, as needed.
6. The Office of Government Ethics (OGE) conducts periodic audits of the NIH ethics program including the legal correctness and propriety of outside work and other activities with outside organizations, financial disclosure, and other related topics.

7. Finally, each IC has a DEC who is responsible for reviewing and approving or disapproving all ethics activity requests of the employees of their respective organizations. Input from one or more of these sources often leads to the formulation of agency wide policy and/or training efforts to improve the NIH Ethics Program as well as the adequacy and propriety of outside activities engaged in by NIH personnel.
8. Review Reports are sent to the NIH Deputy Director, the NIH Deputy Ethics Counselor, the Deputy Director for Management, OGC/E, and the Deputy Ethics Counselor in the audited IC(s). Reports should indicate that controls are in place and working well or indicate any internal management control issues that should be brought to attention of the report recipient(s).

J. Additional Information

Since the operating procedures and practices of employees participating in activities with outside organization differs from one IC to another, employees should direct their questions to their IC DEC or EC. The names and phone numbers of ethics staff can be obtained by calling the Executive Office of your IC or by checking the NIH Ethics Program web site: http://ethics.od.nih.gov/

Additional information regarding NIH policies and procedures for ethics activities is available from the NIH Ethics Office at 301-402-6628.