

**United States Public Health Service
Technology Transfer Manual
Chapter No. 104**

PHS Technology Transfer Conflict of Interest Guidelines

A. PURPOSE

This Manual Chapter sets forth guidelines to follow for applying Federal Government conflict of interest statutes and regulations to specific technology transfer activities. The guidelines are based on current statutes and regulations. Advice, guidance, and interpretation on issues arising under this Chapter are issued from the Office of the General Counsel, Ethics Division, and the Deputy Ethics Counselors at the appropriate PHS operating components.

B. BACKGROUND

The Stevenson-Wydler Technology Innovation Act, as amended by the Federal Technology Transfer Act of 1986 and subsequent public laws, encourages private sector commercialization of Federally-developed inventions. This is accomplished, in part, by authorizing Federal employees to engage in a variety of technology transfer-related activities as part of their Government duties, including collaborating with private sector entities to make and improve inventions for which the United States Government has patent rights. In addition, with appropriate approval, Federal employees may engage in outside activities, which are by definition personal to the employee. Both kinds of activities may raise questions under conflict of interest statutes and regulations, which generally prohibit employees from using their Government positions for private gain and from having employment and financial interests with entities that may be affected by the exercise of their Government duties. Thus, these guidelines have been developed to assist the Government employees involved in technology transfer activities to assess the appropriateness of these activities under applicable conflict of interest statutes and regulations.

C. DEFINITIONS

1. **“Authorization under Section 502”** means an authorization to engage in an official duty activity notwithstanding the fact that the employee has a situation that creates an appearance of a conflict of interest under 5 CFR Part 2635.502. This authorization is obtained by contacting the Deputy Ethics Counselor at the appropriate PHS operating component.
2. **“Covered relationship”** means:
 - a. any business, contractual, or other financial relationship that involves other than a routine consumer transaction that the employee has or seeks with any person; (Whether a “business relationship” exists with parent companies or subsidiary companies of an entity with which the employee has a business relationship is determined case by case based upon the degree of financial control or involvement the parent or subsidiary has with the entity with which the employee has a business relationship);

- b. a relationship with any person with whom the employee's spouse, parent, or dependent child is, to the employee's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;
 - c. a relationship with any person for whom the employee has, within the last year, served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee;
 - d. a relationship with an organization, other than a political party, in which the employee is an active participant, as for example, if it involves service in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, or participation in directing the activities of the organization. In other cases, significant time devoted to promoting specific programs of the organization, including coordination of fund-raising efforts, is an indication of active participation. Payment of dues or the donation or solicitation of financial support does not, in itself, constitute active participation; or,
 - e. the relationship between an employee and a person who is a member of the employee's household or an employee's close relationship with a relative.
3. **“Conflict of interest waiver”** means an individual waiver, as authorized under 18 U.S.C. § 208(b)(1), available to an employee based on a determination by the employee's appointing authority that the financial interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee. (See Appendix A for further information.)
4. **“CRADA”** means a cooperative research and development agreement authorized under the Stevenson-Wydler Technology Innovation Act, as amended.
5. **"Diversified Mutual Fund"** means the fund does not have a policy of concentrating its investments in an industry, business, country other than the United States, or single state within the United States. *For example, Fidelity Blue Chip Growth is a diversified mutual fund. However, Fidelity Select-Biotechnology is not a diversified mutual fund because its holdings are concentrated in the biotechnology industry. Fidelity Select -Biotechnology is considered a sector fund.* Whether a mutual fund meets this standard may be determined by checking the fund's prospectus or by calling a broker or the manager of the fund. The Office of Government Ethics (OGE) has exempted, by regulation, diversified mutual funds from the conflict of interest provisions.
6. **“Employment”** means service as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee.
7. **“Federal Employee”** means an employee of the Federal Government, including a special Government employee (an employee performing temporary duties who serves for a period not to exceed 130 days in any consecutive 365 day period). Contractors or employees of contractors, including contractor laboratories, are not Federal employees.

8. **“Financial Interest”** means any current or contingent ownership interest, including salaries, stocks *and stock options (whether in publicly traded or non-publicly traded companies)*, consultant agreements, patent rights, and license agreements. Royalty payments received by Government employee-inventors from Government inventions are considered to be financial interests for the purposes of conflict of interest considerations. However, OGE has exempted these interests by regulation. The exemption would permit a scientist to work on a Government invention licensed to a CRADA partner. **The exemption does not permit that scientist to act as the final authorizing official approving such a CRADA. Compliance with the terms of this exemption is deemed a determination that there is not even an appearance of a conflict of interest.**

Patent rights held in a personal capacity, such as those waived by the Government to the Government employee-inventor, are personal financial interests. **Personal patent rights are not covered by the OGE exemption.**

9. **“Invention”** means any discovery that is or may be patentable or otherwise protected under Title 35 of the United States Code or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act.
10. **“Member of the employee’s household”** has the same meaning OGE, through case-by-case interpretations, gives to that term as it is used in 5 CFR Part 2635. OGE has stated that the term is to be construed broadly to include a college student who lives in his parents’ home only between semesters, but does not include a guest who visits briefly, as for a month.
11. **“Outside employment”** and **“outside activities”** mean private, non-Governmental activities of a Government employee.
12. **“Recent former employer”** means any person for whom the employee has, within the last year, served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee.

D. POLICY

It is the policy of the PHS that all technology transfer activities will be carried out consistent with applicable conflict of interest statutes and regulations. As required by those laws, a Federal employee may not participate in an official Government capacity on a particular matter that will have a direct and predictable effect on the financial interests of the employee (the employee's spouse, minor child, or the employee’s outside employer). A Federal employee may not participate in an official capacity in a particular matter involving specific parties in which a person with whom the employee has a covered business or personal relationship is a party or represents a party. An employee may not use his or her public office for private gain or engage in outside activities that conflict with his or her Government responsibilities. Finally, no employee of the Federal government may represent a party (other than him or herself or immediate family) before any agency of the Federal government.

E. GUIDELINES

1. Potential conflicts of interest and their resolution

a. Potential Conflicts of Interest

Participating in the development or negotiation of a CRADA, working on a CRADA or participating in the commercialization of an invention for the government is considered part of the involved Federal employee's official Government duties. The following situations, which represent private interests of the involved Federal employee, create a potential conflict of interest for an employee who participates in such CRADA activities or the development or commercialization of an invention for the Government:

- (1) **Stock or other equity or financial interests** owned by the employee (or the employee's spouse or minor child) in a company which is a party to a CRADA or otherwise has financial interests in a Government-owned invention with which the employee is involved as part of Government duties;
- (2) **Outside employment or former outside employment** within one year by the employee (or the employee's spouse or minor child) with a party to a CRADA or an entity which otherwise has financial interests in a Government-owned invention with which the employee is involved as part of Government duties;
- (3) **Patent interest, a license, or other intellectual property interest** held personally by the employee (or the employee's spouse or minor child), such as personal U.S. or foreign patent rights in an invention with continuing involvement by the employee as part of Government duties in the subject matter of the invention;
- (4) **Business relationships or outside activities** by the employee with an entity that is a party to the CRADA, or which otherwise has financial interests in a Government-owned invention with which the employee is involved as part of Government duties;
- (5) **Participation** by a recent former employer, relative with whom the employee has a close personal relationship, a member of the employee's household or the employer or future employer of a spouse, parent, or dependent child, in a CRADA or other agreement regarding a Government-owned invention with which the employee is involved as part of Government duties.

b. Resolving potential conflicts of interest

Before participating in the development or negotiation of a CRADA, or in the development or commercialization of an invention as part of his or her Government duties, an employee shall consult with his or her ethics official at the appropriate PHS component to determine

whether a conflict of interest is likely to arise, and to resolve the potential conflict of interest as indicated below:

(1) **Stock Holdings**

An employee should seriously consider the consequences of holding stock or other equity or financial interests in a company that is a party to the CRADA or that otherwise has financial interests in the CRADA or a Government invention (or an employee who has a spouse or minor child who has a financial interest in such a company). An employee who holds such interests shall:

- (a) **obtain a conflict of interest waiver** for the financial interest of the employee, the employee's spouse or minor child; or
- (b) **divest the financial interest** of the employee, employee's spouse or minor child; or
- (c) **disqualify himself or herself** from participating in further work on the CRADA or the invention; or,
- (d) *participate in the CRADA only if you hold publicly traded stock of \$5,000 or less (cumulative total of the holdings of the employee, spouse and minor children) prior to the employee's involvement in the CRADA and sell or give a broker a standing order in writing to sell any value over \$5,000. **NOTE: Notwithstanding the \$5,000 exemption, an agency may prohibit or restrict an individual employee from acquiring or holding a financial interest based on the agency's determination that the holding of such interests constitutes a substantial conflict of interest. In addition, other Federal laws and regulations may prohibit an employee from purchasing or holding stock.***

EXAMPLES:

A CDC employee owns \$10,000 of stock in a publicly traded company which owns a cruise ship. The ship is being investigated by the CDC for potential health problems. Before the employee may be assigned to work on, or supervise work on the investigation, he or she must either sell the stock to \$5,000 or less, or obtain a conflict of interest waiver.

*An NIH employee is assigned to conduct a review of contract proposals under the Small Business Innovation Research Program. **NOTE: The \$5,000 exemption does not apply to non-publicly traded stocks or stock options. The employee holds \$4,000 worth of stock options (not publicly traded) in a start-up biotechnology company that intends to submit a proposal. Before participating in the review, the employee must completely divest of the options or obtain a conflict of interest waiver.***

An NIH employee is assigned to conduct a review of contract proposals under the Small Business Innovation Research Program. The employee holds \$5,000 worth of stock in a publicly traded start-up biotechnology company that intends to submit a

proposal. Because of the sensitivity of the review, the difficulty of reassigning the review to another employee, and the extent to which the award of a contract would affect the employee's financial interest, NIH determines that the stock holdings constitute a substantial conflict of interest and orders the employee to divest of the stock prior to participating in the review.

An employee is the principal investigator (PI) in a CRADA between the NIH and a publicly traded company. The initial research results (not yet published) are promising. The PI cannot purchase stock in the company because of the prohibition against engaging in a financial transaction using nonpublic information.

(2) **Outside Employment**

An employee who has outside employment or former outside employment within one year with an entity that is developing or engaged in a CRADA with the NIH or which otherwise has financial interests in a Government-owned invention may not engage in official duties related to the CRADA or the invention, including negotiation or research. He or she must:

- (a) **resign from the outside position and seek approval for further participation as indicated under 5 CFR 2635.502, despite the appearance of a conflict; or**
- (b) **disqualify himself or herself from participating in development or negotiation activities or further work on the CRADA or the invention; and,**
- (c) **either wait one year before participating in development or negotiation activities or further work on the CRADA or invention or get authorization under section 502 for a shorter period of time.**

EXAMPLE 1:

An employee of the Centers for Disease Control and Prevention (CDC) is consulting with a company as an approved outside activity. The employee and the company wish to begin negotiating a CRADA to expand on ideas developed during the consultancy. The employee must either disqualify himself from participating in the negotiation of the CRADA (as well as the subsequent conduct of the research under the CRADA); **terminate the outside activity** and wait one year to begin negotiating the CRADA and conducting research under the CRADA; or **terminate the outside activity** and obtain an authorization under section 2635.502 to begin the negotiation and conduct the research within a shorter period of time.

EXAMPLE 2:

An employee of the NIH teaches a survey course on genetics at the University of Maryland as an approved outside activity. He or she is assigned by his or her supervisor to work on a CRADA project with the University to develop genetic tests which may eventually be useful in AIDS research.

The employee must disqualify himself or herself from participating in the project or must resign from the outside position and seek an authorization under section 2635.502.

(3) Outside Employment With A Company Holding a License in a Government-Owned Invention

An employee who receives royalty payments from a Government invention which is licensed to an outside company may, under certain circumstances, engage in outside employment with that same company. OTT and TDC handle the licensing of such inventions without the participation of the inventor. The licensing agreement typically does not contain any official obligations on the part of the inventor with respect to the company. The outside employment must be unrelated to the invention. If the employee is permitted to do the outside work, then the employee will be disqualified from acting officially on matters affecting the company (e.g., a CRADA).

EXAMPLES:

The Government licenses an employee invention to ABC Drug Company (ABC). The employee-inventor is assigned to provide technical assistance to ABC regarding the invention. The employee is prohibited from engaging in outside employment with ABC.

The Government licenses an employee invention to Drugs-R-Us (D-R-U). The employee-inventor is invited by D-R-U to do outside consulting based on an expertise unrelated to the invention. If it is anticipated that D-R-U will seek a CRADA to further develop the invention, the employee may be prohibited from engaging in the outside activity if that employee will be working on that CRADA.

(4) Patent Rights

An employee with personal patent rights, a license, or other intellectual property interests in the subject matter of a CRADA or non-CRADA invention or an employee with a spouse or minor child who has such an interest shall:

- (a) obtain a conflict of interest waiver for the interest; or
- (b) divest the interest; or
- (c) disqualify himself or herself from participating in further official work on the CRADA, the invention, or research directly involving the subject matter as determined by the IC ethics officer; or,
- (d) if a member of the employee's household has such an interest, the employee shall obtain an authorization under section 2635.502 or disqualify himself or herself from participating.

Note that this prohibition does not apply when an employee is an inventor on patent rights, a license, or other intellectual property rights held by the Government. This prohibition applies only to such rights held in a personal capacity by the inventor, such as when the Government has waived its intellectual property rights to the employee-inventor.

EXAMPLE:

The Food and Drug Administration (FDA) has obtained the domestic patent rights to a novel compound developed by an FDA employee as part of her Government duties. FDA elects not to pursue foreign patent rights to the invention, and assigns the rights back to the employee-inventor under the Federal Technology Transfer Act. Thus, the FDA holds U.S. rights and the employee-inventor personally holds foreign rights.

FDA proposes that the employee-inventor continue working on the invention to improve it. Improvements will benefit both FDA and the employee, as a private patent rights holder. However, because this would constitute a private interest in official Government duties, the employee-inventor may not work on improvements unless he or she obtains a waiver under 18 U.S.C. 208.

(5) Outside Business Relationships and Activities

An employee who has or is seeking a business relationship with, or who is actively participating in the activities of, an entity that is a party to a CRADA with the employee's agency or which otherwise has financial interests in a Government-owned invention with which the employee is involved as part of Government duties shall:

- (a) **obtain an authorization** that his or her participation in the CRADA or on the invention is in the agency's interests and outweighs the concern that a reasonable person may question the integrity of the agency's programs; or
- (b) **discontinue the outside business** relationship or participation in entity's activities and wait one year before working on the CRADA; or
- (c) **disqualify himself or herself** from participating in further work on the CRADA or the invention.

EXAMPLE:

An employee of the CDC is the **chair of a committee** of a professional association which has frequently taken public positions on public policy issues relating to scientific ethics. The employee has been assigned to work on a controversial research matter with a company under a CRADA. The professional association has adopted a position opposing the research. The employee is not required to disqualify himself from working on the CRADA, because the organization is not a party to the CRADA. However, **the employee's supervisor may exercise managerial prerogative** and take into account the employee's outside activities when making the assignment and may limit the employee's outside activities.

If the organization in which the employee is a **committee chair** is a trade association composed of companies, one of which is a party to the CRADA, disqualification or authorization would be required.

(6) Participation by a Recent Former Employer, Member of the Employee's Household, Relative with Whom the Employee has a Close Personal Relationship, or Employer of a Spouse, Parent, or Dependent Child

An employee shall receive agency authorization before participating in a CRADA or other activity concerning an invention, if the activity may affect the financial interests of a member of his or her household or if any of the following persons or entities is or represents a party to the matter:

- (a) a relative with whom the employee has a close personal relationship or a member of the employee's household;
- (b) an entity with whom the employee's spouse, parent, or dependent child has or is seeking outside employment; or
- (c) an entity with whom the employee had been employed during the past year.

Authorization shall be based on a determination that the employee's participation in the CRADA or the invention is in the agency's interests and outweighs the concern that a reasonable person may question the integrity of the agency's programs.

EXAMPLE:

An employee's spouse is seeking employment with a pharmaceutical company that has a license agreement regarding an invention the employee is developing as part of his or her official Government duties. The employee must discontinue participating in the development of the invention unless he first receives authorization under 5 CFR 2635.502 that the importance of his participation to the Government outweighs the potential for an appearance of impartiality. If the spouse works for the company, the employee needs to obtain a conflict of interest waiver or an authorization before he or she could continue to work on the invention.

(7) Seeking Employment

An employee who is seeking employment with a party to a CRADA must:

- (a) disqualify himself or herself from any further participation; or,
- (b) obtain a conflict of interest waiver.

2. Prohibitions

a. Use of Nonpublic Information

An employee may not:

- (1) disclose non-public information obtained through Government employment, except as authorized by PHS policies and practices; or
- (2) use such information for the private financial gain of himself or herself or another, including use of the information in making investment decisions.

EXAMPLE 1:

A Government scientist who is working under a CRADA in the field of polymers has had access to information that has not previously been disclosed, including trade secrets of certain polymer manufacturers. The scientist may not tell others about these matters, except as authorized to conduct his or her Government duties.

EXAMPLE 2:

An employee-inventor has reviewed an exclusive license agreement involving her invention that was negotiated and executed by the agency with a biotechnology company. The employee-inventor knows confidential terms of the license, such as the royalty rates and fields of use. The scientist may not tell anyone about these matters, except as authorized to conduct his or her Government duties.

b. Representational Activities Before the United States Government

An employee may not represent another party (except a spouse, child, or parent) before any Federal agency or court on a matter in which the United States is a party or has an interest. An employee may not communicate with the Federal Government to obtain patent rights, a license, or other intellectual property interests on behalf of a corporation or an individual (other than himself or herself, a spouse, child, or parent), including a CRADA collaborator, **EXCEPT** to provide factual information at the request of the Government or if such communications are required in the course of the employee's official duties. *Merely being named as an inventor in a patent application does not constitute a prohibited communication.*

EXAMPLE 1:

A Government researcher works with a private sector company, as an outside activity, to develop an improved light bulb. For the Government, the employee's duties are confined to biotechnology issues and are unrelated to electronics. The company has asked the employee to attend a meeting with the Patent and Trademark Office (PTO) and serve as an advocate in support of a patent application on its behalf. Because he is prohibited from representing another before a Federal agency, the Government researcher may not serve as an advocate on behalf of the company.

However, if the PTO requests factual information of the employee, he or she may provide such information. If the employee was seeking the patent for himself or herself, he or she could submit the application.

EXAMPLE 2:

A Government researcher is negotiating the research plan of a proposed CRADA as part of his or her official duties. The CRADA collaborator has applied to the NIH Office of Technology Transfer to license background patent rights important to the commercialization of the CRADA research. The researcher may not represent the collaborator to the OTT or advocate on its behalf to the OUT. The researcher may provide factual information at the request of OUT about the research.

EXAMPLE 3:

NCI's Cancer Therapy Evaluation Program (CTEP) uses extramural CRADAs for clinical development of new treatment agents for cancer. CTEP always files an IND application for studies conducted under these CRADAs. A CTEP investigator's communications with the FDA on an agent submitted by a drug company under such a CRADA are not prohibited.

c. Negotiations for Future Employment

An employee may negotiate employment with a party to a CRADA or an entity that has an interest in an invention on which he or she is working, but upon initiation of any approach to the CRADA partner for the purpose of negotiating employment, the employee must immediately disqualify himself or herself from further participation on the CRADA or the invention, unless he or she obtains a conflict of interest waiver.

EXAMPLE:

An agency scientist has been working with a company under a CRADA, and the president of the company asks the scientist if he or she would consider going to work for the company. If he or she is interested in pursuing employment negotiations with the company, the scientist must immediately discontinue working on the CRADA for the Government.

3. Impartiality Concerns for Employees with Extramural Funding Responsibilities

Advisory opinions from OGE state that an employee's official duty with respect to an outside organization may create the appearance of giving preferential treatment, loss of impartiality, or using public office for private gain if that employee has certain other official duties affecting that same organization.

EXAMPLE:

An extramural scientist who serves as a PI on a CRADA with Eli Lilly should be disqualified from making funding decisions with respect to Eli Lilly. The employee's impartiality may be

questioned if that employee awarded funding to a company with which he or she is currently collaborating.

F. REFERENCES

The following legal provisions are relevant to the sections of the Manual Chapter as identified.

Section B. Background

15 U.S.C. §§ 3701-3714, the Stevenson-Wydler Technology Innovation Act as amended by the Federal Technology Transfer Act of 1986 and subsequent laws encourages private sector commercialization of Federally-developed inventions.

Section D. Policy

1. Restrictions on Government Activities by Federal Officials

a. General ethics restriction

18 U.S.C. §§ 201-209, criminal conflict of interest statutes; 5 CFR Part 2635, Standards of Ethical Conduct for Employees of the Executive Branch.

b. Stock holdings

18 U.S.C. § 208(a) prohibits an employee from participating in matters that will have a direct and predictable effect on the employee's financial interests, the financial interests of the employee's spouse, minor child, partner, or organization which the employee serves or is seeking to serve.

18 U.S.C. § 208(b) authorizes a conflict of interest waiver by an agency for a financial interest that is not so substantial as to be likely to affect the integrity of the employee's duties to the Government.

5 CFR 2634.1002 permits, in limited circumstances, an employee to seek a certificate of divestiture which would defer payment of taxes on capital gains received when an employee sells a financial interest because of a conflict of interest.

5 CFR 2635.402 cross-references 18 U.S.C. § 208 and provides interpretive regulations relating to the prohibition on participation in matters affecting an employee's financial interests.

5 CFR 2635.502(a) prohibits an employee from participating in particular matters involving specific parties likely to affect the financial interests of a person with whom the employee has certain personal or business relationships.

5 CFR 2635.502(d) authorizes an exception to the prohibition on participation in a matter affecting the financial interests of a person with whom the employee has certain personal or

business relationships upon a determination that the interest of the agency in the employee's participation outweighs the potential of an appearance of impartiality.

c. Outside employment

18 U.S.C. § 208(a) prohibits an employee from participating in matters that will have a direct and predictable effect on the financial interests of an employee's general partner or an organization in which the employee is serving or seeking to serve as an officer, director, trustee, general partner, or employee.

d. Patent rights

18 U.S.C. § 208(a) prohibits an employee from participating in matters that will have a direct and predictable effect on the employee's financial interests or the financial interests of the employee's spouse or minor child.

18 U.S.C. § 208(b) authorizes a conflict of interest waiver by an agency for a financial interest that is not so substantial as to be likely to affect the integrity of the employee's duties to the Government.

5 CFR 2635.402 cross-references 18 U.S.C. § 208 and provides interpretive regulations relating to the prohibition on participation in matters affecting an employee's financial interests.

5 CFR 2635.502(a) prohibits an employee from participating in particular matters involving specific parties likely to affect the financial interests of a person with whom the employee has certain personal or business relationships.

5 CFR 2635.502(d) authorizes an exception to the prohibition on participation in a matter affecting the financial interests of a person with whom the employee has certain personal or business relationships upon a determination that the interest of the agency in the employee's participation outweighs the potential of an appearance of impartiality.

15 U.S.C. § 3710c(a) authorizes an employee to receive the first \$2,000, and thereafter payments of not less than 15 percent of the royalties the Government receives from the commercialization of an invention developed by the employee.

15 U.S.C. § 3710d authorizes an employee to obtain patent rights to an invention developed as part of Government duties if the United States Government does not obtain a patent or take action to commercialize the invention; such patent rights would create a potential conflict of interest which should be resolved as set forth in these guidelines.

e. Outside business and personal relationships

5 CFR 2635.502(a) and (b)(1)(i) and (v) prohibit an employee from participating in a particular matter involving specific parties if one of the parties is (or is represented by) a person with whom the employee has or seeks a business, contractual, or other financial relationship that

involves other than a routine commercial transaction or an organization in which the employee is an active participant. This prohibition applies for one year, unless authorization under this section for a shorter period is obtained.

5 CFR 2635.502(d) authorizes an exception to the prohibition on participation in a matter in which one of the parties is a business associate or organization in which the employee actively participates upon a determination that the interest of the agency in the employee's participation outweighs the potential of an appearance of impartiality.

f. Participation by a recent former employer, member of employee's household, relative with a close personal relationship with the employee, or employer of a spouse, parent or dependent child

5 CFR 2635.502(a) and (b)(1)(ii), (iii), and (iv) prohibit an employee from participating in a particular matter involving specific parties if the matter may affect the financial interests of a member of his or her household or if one of the parties is (or is represented by) a member of the employee's household; a relative with whom the employee has a close personal relationship; a person for whom the employee's spouse, parent, or dependent child is serving, or seeking to serve, as an officer director, trustee, general partner, agent, attorney, consultant, contractor, or employee; or a person for whom the employee has, within the last year, served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor, or employee.

5 CFR 2635.502(d) authorizes an exception to the prohibition on participation in a matter in which one of the parties is (or is represented by) a close relative, a member of the employee's household, employer of certain relatives, or former employer upon a determination that the interest of the agency in the employee's participation outweighs the potential of an appearance of impartiality.

Section 2. Restrictions on Investments and Private Activities of Federal Officials

1. General rule

5 CFR 2635.702 prohibits an employee from using public office for private gain.

5 CFR 2635.802 prohibits an employee from engaging in outside employment or outside activities that conflict with the employee's official Government duties.

2. Acquiring financial interests

5 CFR 2635.402 prohibits an employee from acquiring or holding a financial interest that is prohibited by agency regulation or by a determination that the interest will create a substantial conflict with the employee's duties.

5 CFR 2640.202(a) provides a \$5,000 de minimis exemption for participating in particular matters involving specific parties. The \$5,000 must be in securities, which are publicly traded,

and the aggregate market value of these securities owned by the employee, his or her spouse, and his or her minor children must not exceed \$5,000.

3. Engaging in outside employment or outside activities

5 CFR 2635.802 prohibits an employee from engaging in outside employment or outside activities that conflict with the employee's duties, including an activity that is prohibited by statute or agency supplemental regulation or that would require the employee's disqualification from matters central or critical to the performance of the employee's duties.

4. Use of nonpublic information

5 CFR 2635.703 prohibits an employee from engaging in a financial transaction using nonpublic information or allowing the improper use of such information to further a private interest.

18 U.S.C. § 1905, the Trade Secrets Act, prohibits disclosure by Federal employees of information obtained in the course of official duties which relates to trade secrets, processes, operations, style of work or apparatus.

5. Representational activities before the United States Government

18 U.S.C. §§ 203 and 205 prohibit an employee from representing others before a Federal agency or court in which the United States is a party or has an interest.

6. Negotiations for future employment

18 U.S.C. § 208(a) prohibits an employee from participating in matters that will have a direct and predictable effect on the financial interest of an entity with which the employee is negotiating for employment or has an arrangement regarding future employment. 18 U.S.C. § 208(b) authorizes a conflict of interest waiver by an agency for a financial interest that is not so substantial as to be likely to affect the integrity of the employee's duties to the Government.

5 CFR 2635.602 prohibits an employee from participating in a matter likely to affect the financial interests of a person for whom the employee is seeking future employment.

5 CFR 2635.605(b) authorizes an agency to permit participation with a waiver by an employee in a matter affecting a person with whom the employee is seeking future employment upon a determination that the financial interest is not so substantial as to be likely to affect the integrity of the employee's duties to the Government.

G. EFFECTIVE DATE

The guidelines set forth in this Manual Chapter are effective immediately.

H. ADDITIONAL INFORMATION

For further information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057. Questions on particular factual situations may be directed to the Deputy Ethics Counselor at the appropriate PHS operating component or the Office of the General Counsel, Ethics Division.

Appendix A

CONFLICT OF INTEREST WAIVER

PURPOSE

An employee must obtain a conflict of interest waiver before participating in a matter affecting the employee's financial interests or the financial interests of the employee's spouse, minor child, general partner, organization in which the employee is serving as an officer, director, trustee, general partner, or employee, or any person or organization with whom the employee is negotiating or has any arrangement concerning prospective employment. An individual waiver can be issued only if the employee's appointing authority determines that the employee's financial interest in the matter is not so substantial as to be likely to affect the integrity of the employee's services.

Criteria Indicating a Waiver of a Conflicting Financial Interest Under 18 U.S.C. § 208(b)(1) may be appropriate

1. Nature and Extent of Financial Interest

- a. The nature of the financial interest is such that its effect on the services to be expected of the employee is uncertain or limited. Normally, an employment relationship creates stronger and more permanent ties than stock ownership or other types of investment relationships.
- b. The value of the financial interest is limited or speculative or represents an insignificant portion of the employee's net worth.

2. Nature of Services to be Provided by the Employee

- a. The employee's actions are subject to review and oversight and the services do not involve final decision-making authority on a grant, contract, regulatory decision, or other matter that will directly and predictably affect the financial interest.
- b. The Government requires the services of the employee and those services are of significant value to the Government. Additionally, the employee is uniquely qualified to provide those services.
- c. The services are advisory or relate to general matters that would have a speculative or uncertain effect on the financial interest attributable to the employee.

- d. The employee has significant professional or other reasons for providing the services to the Government without regard to any potential effect on the financial interest.
- e. Any adjustments that could be made in the employee's duties that would reduce or eliminate any questions about the integrity of the employee's services.

3. Nature of the Agency's Mission

Issuance of the waiver is consistent with the mission of the agency and is not likely to undermine public confidence in the agency's activities, particularly if the agency has regulatory or enforcement responsibilities.

4. Public Interest

Issuance of the waiver is in the general public interest, i.e., the employee is uniquely qualified to perform the work and the nature of the work is of significant public concern.

NOTE: The personal integrity of the employee is not an appropriate criterion for waiver.