

Rounds program conducted by an accredited educational institution offering instruction in the life sciences, such as a medical school or school of public health, or by an affiliated teaching hospital, provided that:

(A) The employee's presentation includes an interactive component, such as visiting patients or discussing individual clinical cases, or interacting for educational purposes with undergraduates, graduates, or post-graduate students and fellows, in addition to any lecture;

(B) The audience is composed primarily of faculty and students or trainees registered in a biomedical or health-related program of studies; and

(C) A substantially affected organization or a speakers' bureau affiliated with a substantially affected organization does not sponsor or underwrite the costs of the Grand Rounds program or the employee's presentation, except pursuant to an unrestricted educational grant.

(viii) *Grant or scientific review committee.* An employee may serve on a grant or scientific review committee for a supported research institution or a health care provider or insurer, provided that:

(A) The members of the grant or scientific review committee are not selected or paid for their service by a substantially affected organization;

(B) The grant award or program in relation to which the recommendation of the grant or scientific review committee is sought is not funded under a grant, cooperative agreement, or research and development contract from, conducted pursuant to a cooperative research and development agreement (CRADA) with, or aided under another funding mechanism by, the NIH; and

(C) If the service is performed for compensation, the service does not entail prohibited assistance in the preparation of documents intended for submission to HHS within the meaning of §5501.106(c)(1), and the grant award or program in relation to which the recommendation of the grant or scientific review committee is sought is not an HHS-funded activity described in §5501.106(c)(2).

[70 FR 5560, Feb. 3, 2005, as amended at 70 FR 51569, Aug. 31, 2005]

§5501.110 Prohibited financial interests applicable to senior employees of the National Institutes of Health.

(a) *Applicability.* This section does not apply to special Government employees or the spouse or minor children of a special Government employee.

(b) *Definitions.* For purposes of this section:

(1) *Senior employee* means the Director and the Deputy Director of the National Institutes of Health; members of the senior staff within the Office of the Director who report directly to the NIH Director; the Directors, the Deputy Directors, Scientific Directors, and Clinical Directors of each Institute and Center within NIH; Extramural Program Officials who report directly to an Institute or Center Director; and any employee of equivalent levels of decision-making responsibility who is designated as a senior employee by the designated agency ethics official or the NIH Director, in consultation with the designated agency ethics official.

(2) *Substantially affected organization* has the meaning set forth in §5501.109(b)(10).

(c) *Prohibition applicable to senior employees.* Except as permitted by paragraph (d) of this section, a senior employee or the spouse or minor child of such senior employee shall not have a financial interest in a substantially affected organization.

(d) *Exceptions for certain financial interests.* Notwithstanding the prohibition in paragraph (c) of this section:

(1) *Pension or other employee benefit.* A senior employee or spouse or minor child of a senior employee may have a financial interest, such as a pension or other employee benefit, arising from employment with a substantially affected organization.

NOTE TO PARAGRAPH (d)(1): NIH employees, as opposed to spouses and minor children of employees, are generally prohibited under §5501.109 from engaging in current employment with a substantially affected organization.

(2) *De minimis holdings.* A senior employee or spouse or minor child of a senior employee may have a financial interest in a substantially affected organization if:

(i) The aggregate market value of the combined interests of the senior employee and the senior employee's spouse and minor children in any one substantially affected organization is equal to or less than the *de minimis* exemption limit for matters involving parties established by 5 CFR 2640.202(a) or \$15,000, whichever is greater;

(ii) The holding, if it represents an equity interest, constitutes less than 1 percent of the total outstanding equity of the organization; and

(iii) The total holdings in substantially affected organizations and sector mutual funds that, in the literature they distribute to prospective and current investors or participants, state the objective or practice of concentrating their investments in the securities of substantially affected organizations account for less than 50 percent of the total value of the combined investment portfolios of the senior employee and the senior employee's spouse and minor children.

(3) *Diversified mutual funds.* A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a publicly traded or publicly available investment fund (e.g., a mutual fund), or a widely held pension or similar fund, which, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in substantially affected organizations, if the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund.

(4) *Exceptional circumstances.* In cases involving exceptional circumstances, the NIH Director or the NIH Director's designee, with the approval of the designated agency ethics official or his designee, may grant a written exception to permit a senior employee, or the spouse or minor child of a senior employee, or a class of such individuals, to hold a financial interest in a substantially affected organization based upon a determination that the application of the prohibition in paragraph (c) of this section is not necessary to ensure public confidence in the impartiality or objectivity with

which HHS programs are administered or to avoid a violation of part 2635 of this title.

(5) *Technology transfer.* A senior employee may have a financial interest in connection with the development and commercialization of invention rights obtained by the employee pursuant to Executive Order 10096, 15 U.S.C. 3710d, or implementing regulations.

(6) *Sector mutual funds.* (i) A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a sector mutual fund that, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in the biomedical science, pharmaceutical, medical device, biotechnology, or health industry sectors.

(ii) A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a sector mutual fund that, in the literature it distributes to prospective and current investors or participants, states the objective or practice of concentrating its investments in the securities of substantially affected organizations provided that:

(A) The aggregate market value of the combined ownership interests of the senior employee and the senior employee's spouse and minor children in such sector funds is equal to or less than the *de minimis* exemption limit for sector mutual funds established by 5 CFR 2640.201(b)(2)(i) or \$50,000, whichever is greater; and

(B) The total holdings in substantially affected organizations and in sector mutual funds that, in the literature they distribute to prospective and current investors or participants, state the objective or practice of concentrating their investments in the securities of substantially affected organizations account for less than 50 percent of the total value of the combined investment portfolios of the senior employee and the senior employee's spouse and minor children.

NOTE TO PARAGRAPH (d): With respect to any excepted financial interest, employees are reminded of their obligations under 5

CFR part 2635, and specifically their obligation under subpart D to disqualify themselves from participating in any particular matter in which they, their spouses or minor children have a financial interest arising from publicly traded securities that exceeds the *de minimis* thresholds specified in the regulatory exemption at 5 CFR 2640.202 or from non-publicly traded securities that are not covered by the regulatory exemption. Furthermore, the agency may prohibit or restrict an individual employee from acquiring or holding any financial interest or a class of financial interests based on the agency's determination that the interest creates a substantial conflict with the employee's duties, within the meaning of 5 CFR 2635.403.

(e) *Reporting and divestiture.* For purposes of determining the divestiture period specified in 5 CFR 2635.403(d), as applied to financial interests prohibited under paragraph (c) of this section, the "date divestiture is first directed" means the date on which the new entrant public or confidential financial disclosure report required by part 2634 of this title or any report required by §5502.107(c) of this chapter is due.

[70 FR 5562, Feb. 3, 2005, as amended at 70 FR 51571, Aug. 31, 2005]

§5501.111 Awards tendered to employees of the National Institutes of Health.

(a) *Applicability.* This section does not apply to special Government employees.

(b) *Definitions.* For purposes of this section, official responsibility has the meaning set forth in 18 U.S.C. 202(b).

(c) *Additional limitations on awards to employees of the National Institutes of Health.* The following limitations shall apply to the acceptance by an employee of an award pursuant to 5 CFR 2635.204(d):

(1) *Limitations applicable to employees with official responsibility for matters affecting an award donor.* An employee shall not accept a gift with an aggregate market value of more than \$200, or that is cash or an investment interest, that is an award or incident to an award from a person, organization, or other donor that:

(i) Is seeking official action from the employee, any subordinate of the employee, or any agency component or subcomponent under the employee's official responsibility;

(ii) Does business or seeks to do business with any agency component or subcomponent under the employee's official responsibility;

(iii) Conducts activities substantially affected by the programs, policies, or operations of any agency component or subcomponent under the employee's official responsibility; or

(iv) Is an organization a majority of whose members are described in paragraphs (c)(1)(i) through (iii) of this section.

(2) *Prior approval of awards*—(i) No employee shall accept an award under 5 CFR 2635.204(d) or this section unless the receipt thereof has been approved in writing in advance in accordance with procedures specified by the designated agency ethics official, or with the concurrence of the designated agency ethics official, the NIH Director or the NIH Director's designee.

(ii) Approval shall be granted only upon a determination that acceptance of the award is not prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part.

NOTE TO PARAGRAPH (c): In some circumstances cash and other things of value provided in connection with the provision of personal services, including speaking or writing, may be compensation, not a gift. Other ethics rules governing outside activities may restrict receipt of such compensation. See, for example, 5 CFR 2635.807.

(d) *Exception.* Notwithstanding the prohibition in paragraph (c)(1) of this section, the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director), with the approval of the designated agency ethics official, may grant a written exception to permit an employee to accept an award otherwise prohibited by this section under the following conditions:

(1) There is a determination by the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director) that acceptance of the gift will further an agency interest because it confers an exceptionally high honor in the fields of medicine or scientific research. The following criteria will be considered in making such a determination:

(i) The identity of the awarding organization;