CODE OF FEDERAL REGULATIONS

TITLE 5

CHAPTER XLV – DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 5501 -- SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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§ 5501.101 General.

(a) *Purpose.* The regulations in this part apply to employees of the Department of Health and Human Services (HHS) and supplement the Standards of Ethical Conduct for Employees of the Executive Branch contained in 5 CFR part 2635. In addition to 5 CFR part 2635 and this part, employees are required to comply with implementing guidance and procedures issued by HHS components in accordance with 5 CFR 2635.105(c). Employees are also subject to the executive branch-wide financial disclosure regulations at 5 CFR part 2634, the Employee Responsibilities and Conduct regulations at 5 CFR part 735, and the HHS regulations regarding conduct at 45 CFR part 73.

(b) *Applicability.* The regulations in this part apply to individuals who are “employees” within the meaning of 5 CFR 2635.102(h). The regulations thus apply to special Government employees, except to the extent they are specifically excluded from certain provisions, and to uniformed service officers in the Public Health Service Commissioned Corps on active duty.

(c) *Definitions.* Unless a term is otherwise defined in this part, the definitions set forth in 5 CFR parts 2635 and 2640 apply to terms in this part. In addition, for purposes of this part:

(1) *Federally recognized Indian tribe or Alaska Native village or regional or village corporation* means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act, 43 U.S.C. 1601 *et seq.,* which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(2) *Significantly regulated organization* means an organization for which the sales of products regulated by the Food and Drug Administration (FDA) constitute ten percent or more of annual gross sales in the organization's previous fiscal year; where an organization does not have a record of sales of FDA-regulated products, it will be deemed to be significantly regulated if its operations are predominately in fields regulated by FDA, or if its research, development, or other business activities are reasonably expected to result in the development of products that are regulated by FDA.

§ 5501.102 Designation of HHS components as separate agencies.

(a) *Separate agency components of HHS.* Pursuant to 5 CFR 2635.203(a), each of the twelve components of HHS listed below is designated as an agency separate from each of the other eleven listed components and, for employees of that component, as an agency distinct from the remainder of HHS. However, the components listed below are not deemed to be separate agencies for purposes of applying any provision of 5 CFR part 2635 or this part to employees of the remainder of HHS:

(1) Administration on Aging;
(2) Administration for Children and Families;
(3) Agency for Healthcare Research and Quality;
(4) Agency for Toxic Substances and Disease Registry;
(5) Centers for Disease Control and Prevention;
(6) Centers for Medicare and Medicaid Services;
(7) Food and Drug Administration;
(8) Health Resources and Services Administration;
(9) Indian Health Service;
(10) National Institutes of Health;
(11) Program Support Center; and
(12) Substance Abuse and Mental Health Services Administration.

(b) *Definitions*–

(1) *Employee of a component* includes, in addition to employees actually within a component, an employee of the Office of the General Counsel whose regularly assigned duties and responsibilities principally involve the provision of legal services to the relevant component with respect to substantive programmatic issues.

(2) Remainder of HHS means employees in the Office of the Secretary and Staff Divisions, employees of the Office of the General Counsel with Department-wide responsibility, and any HHS employee not in one of the 12 components designated as separate agencies in paragraph (a) of this section.

(c) *Applicability of separate agency designations.* The designations in paragraph (a) of this section identify an employee's "agency" for purposes of:

(1) Determining when a person is a prohibited source within the meaning of 5 CFR 2635.203(d) for purposes of applying:

(i) The regulations at subpart B of 5 CFR part 2635 governing gifts from outside sources; and

(ii) The regulations at § 5501.106 requiring prior approval of outside employment and other outside activities; and

(iii) The regulations at § 5501.111 governing the receipt of awards by employees of the National Institutes of Health; and

(2) Determining whether teaching, speaking or writing relates to the employee's official duties within the meaning of 5 CFR 2635.807(a)(2)(i).

§ 5501.103 Gifts from federally recognized Indian tribes or Alaska Native villages or regional or village corporations.

(a) *Tribal or Alaska Native gifts.* In addition to the gifts which come within the exceptions set forth in 5 CFR 2635.204, and subject to all provisions of 5 CFR 2635.201 through 2635.205, an employee may accept unsolicited gifts of native artwork, crafts, or other items representative of traditional native culture from federally recognized Indian tribes or Alaska Native villages or regional or village corporations, provided that the aggregate market value of individual gifts received from any one tribe or village under the authority of this paragraph shall not exceed $200 in a calendar year.

(b) *Limitations on use of exception.* If the donor is a tribe or village that has interests that may be substantially affected by the performance or nonperformance of an employee's official duties, the employee may accept the gifts authorized by paragraph (a) of this section only where there is a written finding by the agency designee that acceptance of the gift is in the agency's interest and will not violate any of the limitations on the use of exceptions contained in 5 CFR 2635.202(c).

§ 5501.104 Prohibited financial interests applicable to employees of the Food and Drug Administration.

(a) *General prohibition.* Except as permitted by paragraph (b) of this section, no employee or spouse or minor child of an employee, other than a special Government employee or the spouse or minor child of a special Government employee, of the Food and Drug Administration shall have a financial interest in a significantly regulated organization.

(b) *Exceptions.* Notwithstanding the prohibition in paragraph (a) of this section:

(1) An employee or spouse or minor child of an employee may have a financial interest, such as a pension or other employee benefit, arising from employment with a significantly regulated organization.

NOTE TO PARAGRAPH(b)(1): FDA employees who file public or confidential financial disclosure reports pursuant to 5 CFR part 2634, as opposed to spouses and minor children of such employees, are generally prohibited under § 5501.106(c)(3) from engaging in current employment with a significantly regulated organization.

(2) An employee who is not required to file a public or confidential financial disclosure report pursuant to 5 CFR part 2634, or the spouse or minor child of such employee, may hold a financial interest in a significantly regulated organization if:

(i) The total cost or value, measured at the time of acquisition, of the combined interests of the employee and the employee's spouse and minor children in the regulated 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 (the phrase "time of acquisition" shall mean the date on which the employee actually acquired the financial interest–or on which the financial interest became imputed to the employee under 18 U.S.C. 208–whether by purchase, gift, bequest, marriage, or otherwise, except that with respect to a financial interest that was acquired prior to the employee's entrance on duty

as an employee of the Food and Drug Administration, the "time of acquisition" shall be deemed to be the date on which the employee entered on duty);

(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 significantly regulated organizations account for less than 50 percent of the total value of the combined investment portfolios of the employee and the employee's spouse and minor children.

(3) An employee or spouse or minor child of an employee may have an interest in a significantly regulated 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 significantly regulated organizations, if the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund.

(4) In cases involving exceptional circumstances, the Commissioner or the Commissioner's designee may grant a written exception to permit an employee, or the spouse or minor child of an employee, to hold a financial interest in a significantly regulated organization based upon a determination that the application of the prohibition in paragraph (a) 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.

NOTE TO PARAGRAPH (b): 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 of part 2635 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.

(c) *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 (a) 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 § 5502.106(c) of this chapter is due.

§ 5501.105 Exemption for otherwise disqualifying financial interests derived from Indian or Alaska Native birthrights.

(a) Under 18 U.S.C. 208(b)(4), an employee who otherwise would be disqualified may participate in a particular matter where the otherwise disqualifying financial interest that would be affected results solely from the interest of the employee, or the employee's spouse or minor child, in birthrights:

(1) In an Indian tribe, band, nation, or other organized group or community, including any Alaska Native village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act, which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians;

(2) In an Indian allotment the title to which is held in trust by the United States or which is inalienable by the allottee without the consent of the United States; or

(3) In an Indian claims fund held in trust or administered by the United States.

(b) The exemption described in paragraph (a) of this section applies only if the particular matter does not involve the Indian allotment or claims fund or the Indian tribe, band, nation, organized group or community, or Alaska Native village corporation as a specific party or parties.

§ 5501.106 Outside employment and other outside activities.

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

(b) *Definitions.* For purposes of this section:
- (1) *Compensation* has the meaning set forth in 5 CFR 2635.807(a)(2)(iii).
- (2) *Consultative services* means the provision of personal services by an employee, including the rendering of advice or consultation, which requires advanced knowledge in a field of science or learning customarily acquired by a course of specialize instruction and study in an institution of higher education, hospital, or other similar facility.
- (3) *Professional services* means the provision of personal services by an employee, including the rendering of advice or consultation, which involves the skills of a profession as defined in 5 CFR 2636.305(b)(1).

(c) *Prohibited outside employment and activities*–
- (1) *Prohibited assistance in the preparation of grant applications or contract proposals*. An employee shall not provide consultative or professional services, for compensation, to or on behalf of any other person to prepare, or assist in the preparation of, any grant application, contract proposal, program report, or other document intended for submission to HHS.
- (2) *Prohibited employment in HHS-funded activities.* An employee shall not, for compensation, engage in employment, as defined in 5 CFR 2635.603(a), with respect to a particular activity funded by an HHS grant, contract, cooperative agreement, cooperative research and development agreement, or other funding mechanism authorized by statute.
- (3) *Prohibited outside activities applicable to employees of the Food and Drug Administration*. An employee of the Food and Drug Administration who is required to file a public or confidential financial disclosure report pursuant to 5 CFR part 2634 shall not:
  - (i) Engage in any self-employed business activity for which the sale or promotion of FDA-regulated products is expected to constitute ten percent or more of annual gross sales or revenues; or
  - (ii) Engage in employment, as defined in 5 CFR 2635.603(a), whether or not for compensation, with a significantly regulated organization, as defined in § 5501.101(c)(2), unless the employment meets either of the following exceptions:
    - (A) The employment consists of the practice of medicine, dentistry, veterinary medicine, pharmacy, nursing, or similar practices, provided that the employment does not involve substantial unrelated non-professional duties, such as personnel management, contracting and purchasing responsibilities (other than normal "out-of-stock" requisitioning), and does not involve employment by a medical product manufacturer in the conduct of biomedical research; or
    - (B) The employment primarily involves manual or unskilled labor or utilizes talents, skills, or interests in areas unrelated to the substantive programmatic activities of the FDA, such as clerical work, retail sales, service industry jobs, building trades, maintenance, or similar services.
- (4) *Prohibited outside practice of law applicable to attorneys in the Office of the General Counsel.*
  - (i) An employee who serves as an attorney in or under the supervision of the Office of the General Counsel or the Office of Counsel to the Inspector General shall not engage in any outside practice of law that might require the attorney to:

(A) Assert a legal position that is or appears to be in conflict with the interests of the Department of Health and Human Services, the client to which the attorney owes a professional responsibility; or

(B) Interpret any statute, regulation or rule administered or issued by the Department.

(ii) *Exceptions.* Nothing in this section prevents an employee from:

(A) Acting, with or without compensation, as an agent or attorney for, or otherwise representing, the employee's parents, spouse, child, or any person for whom, or for any estate for which, the employee is serving as guardian, executor, administrator, trustee, or other personal fiduciary to the extent permitted by 18 U.S.C. 203 and 205, or from providing advice or counsel to such persons or estate; or

(B) Acting, without compensation, as an agent or attorney for, or otherwise representing, any person who is the subject of disciplinary, loyalty, or other personnel administration proceedings in connection with those proceedings to the extent permitted by 18 U.S.C. 205, or from providing uncompensated advice or counsel to such person; or

(C) Giving testimony under oath or from making statements required to be made under penalty for perjury or contempt.

(iii) *Specific approval procedures.*

(A) The exceptions to 18 U.S.C. 203 and 205 described in paragraph (c)(4)(ii)(A) of this section do not apply unless the employee obtained the approval of the Government official responsible for the appointment of the employee to a Federal position.

(B) The exception to 18 U.S.C. 205 described in paragraph (c)(4)(ii)(B) of this section does not apply unless the employee has obtained the approval of a supervisory official who has authority to determine whether the employee's proposed representation of another person in a personnel administration matter is consistent with the faithful performance of the employee's duties.

(d) *Prior approval for outside employment and other outside activities*–

(1) *General approval requirement*. Except as provided in paragraph (d)(3) of this section, an employee shall obtain written approval prior to engaging, with or without compensation, in outside employment, including self-employed business activities, or other outside activities in which the employee seeks to:

(i) Provide consultative or professional services, including service as an expert witness;

(ii) Engage in teaching, speaking, writing, or editing that:

(A) Relates to the employee's official duties within the meaning of 5 CFR 2635.807(a)(2)(i)(B) through (E); or

(B) Would be undertaken as a result of an invitation to engage in the activity that was extended to the employee by a person or organization that is a prohibited source within the meaning of 5 CFR 2635.203(d), as modified by the separate HHS component agency designations in § 5501.102; or

(iii) Provide services to a non-Federal entity as an officer, director, or board member, or as a member of a group, such as a planning commission, advisory council, editorial board, or scientific or technical advisory board or panel, which requires the provision of advice, counsel, or consultation.

(2) *Additional approval requirement for employees of the Food and Drug Administration and the National Institutes of Health*. In addition to the general approval requirements set forth in paragraph (d)(1) of this section, an employee of the Food and Drug Administration or the National Institutes of Health shall obtain written approval prior to engaging, with or without compensation, in any outside employment, as defined in 5 CFR 2635.603(a), with, or any self-employed business activity involving the sale or promotion of products or services of, any person or organization that is a prohibited source of the employee's component agency.

(3) *Exceptions to prior approval requirements*.

(i) Notwithstanding the requirements of paragraphs (d)(1) and (d)(2) of this section, prior approval is not required for participation in the activities of a political, religious, social, fraternal, or recreational organization unless:

(A) The activity or the position held in the organization requires the provision of professional services within the meaning of paragraph (b)(3) of this section; or

(B) The activity is performed for compensation other than the reimbursement of expenses.

(ii) Notwithstanding the requirements of paragraphs (d)(1) and (d)(2) of this section, prior approval is not required for participation in an employment or other outside activity that has been exempted under paragraph (d)(7) of this section.

(4) Submission of requests for approval.

(i) An employee seeking to engage in any of the activities for which advance approval is required shall make a written request for approval a reasonable time before beginning the activity. This request shall be directed to the employee's supervisor. The supervisor shall submit the request and a statement addressing the extent to which the employee's duties are related to the proposed outside activity to an agency designee, who shall make a final determination with respect to the request.

(ii) All requests for prior approval shall include the following information:

(A) The employee's name, contact information, organizational location, occupational title, grade, step, salary, appointment type, and financial disclosure filing status;

(B) The nature of the proposed outside employment or other outside activity, including a full description of the specific duties or services to be performed;

(C) A description of the employee's official duties that relate to the proposed activity;

(D) A description of how the employee's official duties will affect the interests of the person for whom or organization with which the proposed activity will be performed;

(E) The name and address of the person for whom or organization with which the work or activity will be done, including the location where the services will be performed;

(F) A statement as to whether travel is involved and, if so, whether the transportation, lodging, meals, or per diem will be at the employee's expense or provided by the person for whom or organization with which the work or activity will be done, and a description of the arrangements and an estimate of the costs of items to be furnished or reimbursed by the outside entity;

(G) The estimated total time that will be devoted to the activity. If the proposed outside activity is to be performed on a continuing basis, a statement of the estimated number of hours per year; for other employment, a statement of the anticipated beginning and ending date;

(H) A statement as to whether the work can be performed entirely outside of the employee's regular duty hours and, if not, the estimated number of hours and type of leave that will be required;

(I) The method or basis of any compensation to be received (e.g., fee, honorarium, retainer, salary, advance, royalty, stock, stock options, non-travel related expenses, or other form of remuneration tendered in cash or in-kind in connection with the proposed activity) from the person for whom or organization with which the work or activity will be done;

(J) The amount of any compensation to be received from the person for whom or organization with which the work or activity will be done;

(K) The amount and date of any compensation received, or due for services performed, within the current and previous six calendar years immediately preceding the submission of the request for approval from the person for whom or organization with which the work or activity will be done (including any amount received or due from an agent, affiliate, parent, subsidiary, or predecessor of the proposed payor);

(L) A statement as to whether the compensation is derived from an HHS grant, contract, cooperative agreement, or other source of HHS funding or attributed to services related to an activity funded by HHS, regardless of the specific source of the compensation;

(M) For activities involving the provision of consultative or professional services, a statement indicating whether the client, employer, or other person on whose behalf the services are performed is receiving, or intends to seek, an HHS grant, contract, cooperative agreement, or other funding relationship;

(N) For activities involving teaching, speaking, or writing, a syllabus, outline, summary, synopsis, draft or similar description of the content and subject matter involved in the course, speech, or written product (including, if available, a copy of the text of any speech) and the proposed text of any disclaimer required by 5 CFR 2635.807(b)(2) or by the instructions or manual issuances authorized under paragraph (d)(6) of this section; and

(O) Such other relevant information that the designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102(a) determines is necessary or appropriate in order to evaluate whether a proposed activity is likely to involve conduct prohibited by statute or Federal regulations, including 5 CFR part 2635 and this part.

(5) Standard for approval. Approval shall be granted only upon a determination that the outside employment or other outside activity is not expected to involve conduct prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part.

NOTE**:** The granting of approval for an outside activity does not relieve the employee of the obligation to abide by all applicable laws governing employee conduct nor does approval constitute a sanction of any violation. Approval involves an assessment that the general activity as described on the submission does not appear likely to violate any criminal statutes or other ethics rules. Employees are reminded that during the course of an otherwise approvable activity, situations may arise, or actions may be contemplated, that, nevertheless, pose ethical concerns.

Example 1: A clerical employee with a degree in library science volunteers to work on the acquisitions committee at a local public library. Serving on a panel that renders advice to a non-Federal entity is subject to prior approval. Because recommending books for the library collection normally would not pose a conflict with the typing duties assigned the employee, the request would be approved.

Example 2: While serving on the library acquisitions committee, the clerical employee in the preceding example is asked to help the library business office locate a missing book order. Shipment of the order is delayed because the publisher has declared bankruptcy and its assets, including inventory in the warehouse, have been frozen to satisfy the claims of the Internal Revenue Service and other creditors. The employee may not contact the Federal bankruptcy trustee to seek, on behalf of the public library, the release of the books. Even though the employee's service on the acquisitions committee had been approved, a criminal statute, *18 U.S.C. 205,* would preclude any representation by a Federal employee of an outside entity before a Federal court or agency with respect to a matter in which the United States is a party or has a direct and substantial interest.

(6) *Duration of approval*. Approval shall be effective for a period not to exceed one year from the date of approval. Upon a significant change in the nature of the outside activity or in the employee's official position or duties, the employee shall submit a revised request for approval using the procedure in paragraph (d)(4) of this section. If the outside activity is anticipated to exceed one year from the date of the most recent approval, the employee shall renew the request for approval no later than thirty days prior to the expiration of the period authorized.

(7) *Responsibilities of the designated agency ethics official and component agencies.*

(i) The designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102 may issue an instruction or manual issuance exempting categories of employment or other outside activities from a requirement of prior written approval based on a determination that the employment or activities within those categories would generally be approved and are not likely to involve conduct prohibited by statute or Federal regulations, including 5 CFR part 2635 and this part.

(ii) HHS components may specify internal procedures governing the submission of prior approval requests and designate appropriate officials to act on such requests. The instructions or manual issuances may include examples of outside employment and other outside activities that are permissible or impermissible consistent with 5 CFR part 2635 and this part. With respect to teaching, speaking, writing, or editing activities, the instructions or manual issuances may specify preclearance procedures and/or require disclaimers indicating that the views expressed do not necessarily represent the views of the agency or the United States.

(iii The officials within the respective HHS components who are responsible for the administrative aspects of these regulations and the maintenance of records shall make provisions for the filing and retention of requests for approval of outside employment and other outside activities and copies of the notification of approval or disapproval.

(e) *Waivers.* The designated agency ethics official may grant a written waiver, for an individual or class of similarly situated individuals, from any prohibited outside activity provision in this section or in § 5501.109 based on a determination that the waiver is not inconsistent with part 2635 of this title or otherwise prohibited by law and that, under the particular circumstances, application of the prohibition is not necessary to avoid the appearance of misuse of position or loss of impartiality or otherwise to ensure confidence in the impartiality and objectivity with which agency programs are administered. An individual or class waiver under this paragraph may impose appropriate conditions, such as requiring execution of a written disqualification.

§ 5501.107 Teaching, speaking and writing by special Government employees in the Public Health Service.

(a) *Applicability.* This section applies to special Government employees in the Public Health Service who otherwise are prohibited from accepting compensation for teaching, speaking or writing that is related to their official duties, within the meaning of 5 CFR 2635.807(a)(2)(i)(C), because the invitation or the offer of compensation for the activity was extended at a time when the special Government employee was assigned to perform official duties that may substantially affect the interests of the inviter or offeror.

(b) *Permissible compensation.* A special Government employee may accept compensation for teaching, speaking or writing in circumstances described in paragraph (a) of this section only where the special Government employee recuses from the official assignment that may substantially affect the interests of the person who extended the invitation to engage in the activity or the offer of compensation.

§ 5501.108 Exception to the prohibition against assisting in the prosecution of claims against, or acting as an agent or attorney before, the Government, applicable only to employees assigned to federally recognized Indian tribes or Alaska Native villages or regional or village corporations pursuant to the Intergovernmental Personnel Act.

(a) *18 U.S.C. 205.* Section 205 of title 18 of the United States Code prohibits an employee, whether or not for compensation, from acting as an agent or attorney for anyone in a claim against the United

States, or from acting in such capacity on behalf of another before any department, agency, or other specified entity, in any particular matter in which the United States is a party or has a direct and substantial interest.

(b) *Exception applicable only to employees assigned to federally recognized Indian tribes or Alaska Native villages or regional or village corporations pursuant to the Intergovernmental Personnel Act.* Notwithstanding the provisions of 18 U.S.C. 205, the Indian Self-Determination Act (25 U.S.C. 450i(f)) authorizes Federal employees detailed or assigned to Indian tribes or Alaska Native villages or regional or village corporations, pursuant to the Intergovernmental Personnel Act (5 U.S.C. 3372), to act as agents or attorneys for, or appear on behalf of, such tribes or Alaska Native villages or corporations in connection with any matter pending before any department, agency, court, or commission, in which the United States is a party or has a direct and substantial interest. Such employees must advise, in writing, the head of the agency, with which they are dealing on behalf of an Indian tribe or Alaska Native village or corporation, of any personal and substantial involvement they may have had as an officer or employee of the United States in connection with the matter concerned.

§ 5501.109 Prohibited outside activities applicable 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:

(1) *Compensation* has the meaning set forth in 5 CFR 2635.807(a)(2)(iii).

(2) *Continuing professional education* means a course, a program, a series of courses or programs, or other educational activity provided to members of a profession, as defined in 5 CFR 2636.305(b)(1), or academic discipline and designed principally to maintain or advance the skills and competence of practitioners in a field of specialized knowledge and to expand an appreciation and understanding of the professional responsibilities, fiduciary obligations, or ethical aspirations incumbent upon members of the group. For those members of a profession or academic discipline that does not subject its members to licensure or continuing education requirements, the term continuing professional education includes those educational activities that exemplify a purpose and content similar to those offered to or required of members of a licensed profession.

(3) *Data and safety monitoring board* (DSMB) means a board, committee, or panel constituted in connection with an ongoing clinical study and comprised of individuals, other than the study sponsors, organizers, and investigators, who possess expertise in relevant specialties and disciplines, such as trial design, biostatistics, and bioethics, and who review accumulating safety and outcome data in order to ensure the continuing safety of the participating human subjects and of those yet to be recruited, and to assess the continuing validity and scientific merit of the investigation.

(4) *Educational activity provider* means a supported research institution or a health care provider or insurer that presents Grand Rounds or offers accredited continuing professional education (or, in the case of a profession or academic discipline whose members are not subject to licensure and which does not have program accreditation requirements, an education program determined by the designated agency ethics official or his designee or, in consultation with the designated agency ethics official or his designee, the NIH Director or the NIH Director's designee to be substantially equivalent to an accredited continuing professional education program), but does not include a substantially affected organization.

(5) *Employment* has the meaning specified in 5 CFR 2635.603(a).

(6) *Grand Rounds* means a regularly scheduled, interactive presentation or series of educational seminars that focus on clinical cases, recent biomedical or behavioral research results, or a

review of scientific research methods and findings in a specific field, with supporting basic and clinical science information, that are conducted in an accredited medical school or an affiliated teaching hospital setting that provides practicing physicians, faculty, fellows, resident physician trainees, medical students, graduate students, and post-doctoral fellows, as well as allied and associated health professionals, and other staff, an opportunity to evaluate outcomes of patient treatment decisions, a forum to discuss clinical decision making, and a means to impart updates in diagnosis, treatment, therapy, and research as indicated by the context of the cases presented.

(7) *Grant or scientific review committee* means a board, committee, or panel of qualified experts assembled by an external grant-making entity or other funding institution for the purpose of making a funding decision, the members of which review, evaluate, rate, rank, or otherwise assess a proposed or ongoing project or program for which grant support is sought on the basis of various factors, such as scientific merit, feasibility, significance, approach, and originality (and scientific progress in any previous period of funding), and gauge the ability of the applicant(s), principal and associate investigators, and scientific team members to complete successfully the project or program, and then recommend to the grantor whether to fund or continue to fund a particular proposal or ongoing program.

(8) *Health care provider or insurer* means a hospital, clinic, skilled nursing facility, rehabilitation facility, durable medical equipment supplier, home health agency, hospice program, health maintenance organization, managed care organization, or other provider of health care items and services as defined in sections 1877(h)(6) or 1903(w)(7) of the Social Security Act (42 U.S.C. 1395nn(h)(6) or 1396b(w)(7)) and any entity organized and licensed as a risk-bearing entity eligible to offer health insurance or health benefits coverage.

(9) *Scientific peer review* is the evaluation of scientific research findings for competence, significance, and originality by qualified experts who research and submit work for publication in the same field and which provides systematized accountability for adherence to ethical guidelines commonly accepted within the relevant research community for disseminating scientific information.

(10) *Substantially affected organization* means:

(i) A biotechnology or pharmaceutical company; a medical device manufacturer; or a corporation, partnership, or other enterprise or entity significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products;

(ii) Any organization a majority of whose members are described in paragraph (b)(10)(i) of this section; and

(iii) Any other organization determined by the designated agency ethics official or, in consultation with the designated agency ethics official, by the NIH Director or the NIH Director's designee that is substantially affected by the programs, policies, or operations of the NIH.

(11) *Supported research institution* means any educational institution or non-profit independent research institute that:

(i) Is, or within the last year has been, an applicant for or recipient of an NIH grant, cooperative agreement, or research and development contract;

(ii) Is, or within the last year has been, a proposer of or party to a cooperative research and development agreement (CRADA) with the NIH; or

(iii) Any organization a majority of whose members are described in paragraphs (b)(11)(i) or (ii) of this section.

(12) *Unrestricted educational grant* means funds received by or available to an educational activity provider from another source that are granted without stipulated conditions for their use other than the limitation that the funds shall be used to advance an educational program of the grant

recipient. For purposes of this section, an educational grant shall not be considered unrestricted if the funding source for a continuing professional education program directly or indirectly:

(i) Selects or recommends the moderators, speakers, or presenters at the sponsored event;

(ii) Independently provides additional funding to the moderators, speakers, or presenters in connection with the educational activity;

(iii) Determines or recommends the audience composition;

(iv) Specifies or recommends the topics to be addressed, or

(v) Controls or recommends the planning, content, or implementation of the program in a manner inconsistent with guidelines established by a relevant professional association or accrediting organization that are designed to ensure that such activities are accurate, balanced, educational, free from commercial bias, nonpromotional, and independent of the influence of the funding source.

(13) *Unrestricted financial contribution* means funds received by or available to a publisher, academic press, editorial board, or other entity affiliated with or operated by a supported research institution or a health care provider or insurer from another source that are provided without stipulated conditions for their use other than the limitation that the funds shall be used to advance peer-reviewed writing or editing by the funds recipient. For purposes of this section, a financial contribution shall not be considered unrestricted if the funding source for peer-reviewed writing or editing directly or indirectly:

(i) Selects or recommends the author, reviewer, referee, or editor;

(ii) Independently provides additional funding to the author, reviewer, referee, or editor in connection with the writing or editing activity;

(iii) Determines or recommends the targeted audience of the writing or editing activity;

(iv) Specifies or recommends the topics to be addressed, or

(v) Controls or recommends the planning, content, or distribution of the written or edited product in a manner inconsistent with ethical guidelines commonly accepted within the relevant research community for disseminating scientific information which are designed to ensure that such writing or editing is accurate, unbiased, nonpromotional, transparent with respect to disclosure of potential conflicts, and independent of the influence of the funding source.

(c) *Prohibitions*–

(1) *Prohibited outside activities with substantially affected organizations, supported research institutions, and health care providers or insurers*. Except as permitted by paragraph (c)(3) of this section, an employee of the NIH shall not:

(i) Engage in employment with a substantially affected organization, a supported research institution, or a health care provider or insurer;

(ii) Teach, speak, write, or edit for compensation for any substantially affected organization, supported research institution, or health care provider or insurer; or

(iii) Engage in any employment or self-employed business activity that involves the sale or promotion of products or services of a substantially affected organization or a health care provider or insurer, except for the purpose of commercializing invention rights obtained by the employee pursuant to Executive Order 10096, 15 U.S.C. 3710d, or implementing regulations.

(2) *General exception*. Nothing in paragraph (c)(1) of this section prevents an employee from engaging in employment with, or teaching, speaking, writing, or editing for, a political, religious, social, fraternal, or recreational organization.

(3) *Specific exceptions*. Notwithstanding the prohibitions in paragraph (c)(1) of this section:

(i) *Teaching*. An employee may engage in and accept compensation for:

(A) Teaching a course requiring multiple presentations as permitted under 5 CFR 2635.807(a)(3); or

(B) Delivering a class lecture that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the activity is performed as part of a regularly scheduled course offered under the established curriculum of an institution of higher education as defined at 20 U.S.C. 1001.

(ii) *Clinical, medical, or health-related professional practice*. An employee may engage in and accept compensation for the outside practice of medicine, dentistry, pharmacy, nursing, or similar health-related professional practice that involves the personal provision of care, treatment, or other health-related professional services to or in connection with individual patients, provided that:

(A) The provision of health-related professional services to such individuals is not part of any ongoing research project conducted or funded by the NIH;

(B) The employee does not establish a private practice relationship with a current or recently discharged NIH patient or subject of an NIH-conducted or NIH-funded clinical trial or protocol;

(C) The employee does not personally refer private practice patients to the NIH; and

(D) The professional practice does not involve substantial unrelated non-professional duties, such as personnel management, contracting and purchasing responsibilities (other than "out-of- stock" requisitioning), and does not involve employment by a medical product manufacturer in the conduct of biomedical research.

(iii) *Clerical, retail, service industry, building trades, maintenance, or similar services*. An employee may engage in and accept compensation for any outside employment or self-employed business activity that primarily involves manual or unskilled labor or utilizes talents, skills, or interests in areas unrelated to the health and scientific research activities of the NIH, such as clerical work, retail sales, service industry jobs, building trades, maintenance, or similar services.

(iv) *Continuing professional education*. An employee may engage in and accept compensation for a teaching, speaking, writing, or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the activity is performed as part of a continuing professional education program conducted by an educational activity provider. If a substantially affected organization provides financial support for a continuing professional education program conducted by an educational activity provider, this exception is inapplicable unless the substantially affected organization is involved only as the funding source for an unrestricted educational grant.

(v) *Authorship of writings subjected to scientific peer review or a substantially equivalent editorial review process*. An employee may engage in and accept compensation for a writing or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the resulting article, chapter, essay, report, text, or other writing is submitted to a publisher, academic press, editorial board, or other entity affiliated with or operated by a supported research institution or a health care provider or insurer for publication in a scientific journal, textbook, or similar publication that subjects manuscripts to scientific peer review or a substantially equivalent editorial review process. If a substantially affected organization funds the publishing activities of a supported research institution or a health care provider or insurer, this exception is inapplicable unless the substantially affected organization is involved only as an unrestricted financial contributor and exercises no editorial control.

(vi) *Data and safety monitoring boards*. An employee may serve as a member of a data and safety monitoring board for a clinical study conducted by a supported research institution or health care provider or insurer, provided that:

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

(B) The clinical study is not funded under a grant, cooperative agreement, or research and development contract from, or 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 clinical study is not an HHS-funded activity described in § 5501.106(c)(2).

(vii) *Grand Rounds*. An employee may engage in and accept compensation for a teaching, speaking, writing, or editing activity that is unrelated to the employee's official duties within the meaning of 5 CFR 2635.807 if the activity is performed as part of a Grand 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).

§ 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.

§ 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;

(ii) The longevity of the awards program;

(iii) he source of award funds;

(iv) The size of the monetary component of the award recognition;

(v) The identity and credentials of past award recipients;

(vi) The degree of publicity attendant to receipt of the award; and

(vii) The impact of the substantive contribution being recognized;

(2) Absent the prohibition in paragraph (c)(1) of this section, the gift would be permitted under part 2635 of this title; and

(3) The designated agency ethics official shall have determined that the application of the prohibition in paragraph (c)(1) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which NIH programs are administered or to avoid a violation of part 2635 of this title.

(e) *Disposition of improperly accepted awards*–

(1) *Failure to obtain prior approval*. If an employee accepts an award for which approval is required under paragraph (c)(2) of this section without obtaining such approval, the employee may be required, in addition to any penalty provided by law and applicable regulations, to forfeit the award by returning it to the donor.

(2) *Receipt of prohibited award*. If an employee accepts an award prohibited by paragraph (c)(1) of this section, the employee shall be required, in addition to any penalty provided by law and applicable regulations, to:

(i) Reject the award and instruct the donor to strike the honoree's name from any list of award recipients;

(ii) Remove the recognition from the employee's résumé or curriculum vitae;

(iii) Return any tangible indicia of the recognition to the donor; and

(iv) Forfeit the award by returning it to the donor.

§ 5501.112 One-year disqualification of employees of the National Institutes of Health from certain matters involving an award donor.

An employee, other than a special Government employee, of the National Institutes of Health who has, within the last year, accepted an award permitted under 5 CFR 2635.204(d) or § 5501.111 shall not participate in any particular matter involving specific parties in which the donor is or represents a party unless authorized to do so under 5 CFR 2635.502(d).

PART 5502 – SUPPLEMENTAL FINANCIAL DISCLOSURE REQUIREMENTS FOR EMPLOYEES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sec.

5502.101 General.
5502.102 Annual supplemental report of outside employment or activities.
5502.103 Content of annual supplemental reports.
5502.104 Confidentiality of reports.
5502.105 Agency procedures.
5502.106 Supplemental disclosure of prohibited financial interests applicable to employees of the Food and Drug Administration.
5502.107 Supplemental disclosure of financial interests in substantially affected organizations applicable to employees of the National Institutes of Health.

AUTHORITY: 5 U.S.C. 301, 7301, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2634.103.

SOURCE: 70 FR 5543, February 3, 2005; 70 FR 37009, June 28, 2005; 70 FR 51559, August 31, 2005, and 70 FR 61713, October 26, 2005, unless otherwise noted.

§ 5502.101 General.

The regulations in this part apply to employees of the Department of Health and Human Services and supplement the Executive Branch Financial Disclosure Regulations in 5 CFR part 2634. Any regulation in this part made applicable only to the employees of an HHS component designated as a separate agency under § 5501.102(a) of this chapter shall apply to the employees of that component as defined in § 5501.102(b)(1) of this chapter.

§ 5502.102 Annual supplemental report of outside employment or activities.

Any employee, other than a special Government employee, for whom an outside employment or activity has been approved, or who has participated in any outside employment or activity for which prior approval is required, under part 5501 of this chapter shall file on or before February 28 of each year a report concerning all such activities that were approved or undertaken in the previous calendar year. The annual report shall be filed with the employee's supervisor who shall review the form, in consultation with an agency ethics official, and determine whether the employee has complied with applicable laws and regulations and whether approval of any ongoing outside activity should be cancelled because the activity does not meet the standard in § 5501.106(d)(5) of this chapter.

§ 5502.103 Content of annual supplemental reports.

The annual supplemental report of outside employment or activities required by § 5502.102 shall include the following information:

(a) The employee's name, contact information, organizational location, occupational title, grade, step, salary, appointment type, and financial disclosure filing status;

(b) A list of all outside activities for which prior approval is required under part 5501 of this chapter that were approved pursuant to 5 CFR 5501.106(d) or undertaken within the reporting period. The report

must identify the person or organization for whom or with which the employee was to perform the activity and the approval date;

(c) A statement as to whether the anticipated work described in a previously approved outside activity was actually performed for the person or organization named in the request for approval;

(d) For each outside activity actually performed, the beginning date of the relationship with the outside entity, the date(s) personal services were provided, the total number of hours spent and leave used on the activity within the reporting period, and the ending date;

(e) For each outside activity that remains ongoing at the time of filing the report, a statement as to how long the activity is anticipated to continue, the date on which prior approval expires, and whether a request for renewal of approval is anticipated;

(f) For each outside activity actually performed, the type and amount of any income and/or reimbursements actually received during the reporting period and the date paid;

(g) For each outside activity actually performed, the type and amount of any income and/or reimbursements earned during or attributable to the reporting period that were not in fact received during the reporting period and remain due;

(h) A statement as to whether any change has occurred or is anticipated with respect to information supplied in the original outside activity approval request;

(i) A description of any change in the nature, scope, or subject matter of any approved activity; and

(j) A description of any change in jobs or in the duties and responsibilities of the employee's position that occurred after the outside activity was approved.

§ 5502.104 Confidentiality of reports.

Each report filed under this part is confidential and shall not be disclosed to the public, except as provided under § 2634.604(b) of this title.

§ 5502.105 Agency procedures.

(a) The designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in § 5501.102(a) of this chapter may prescribe forms for the collection of information under this part and establish procedures for the submission and review of each report filed. These procedures may provide for filing extensions, for good cause shown, totaling not more than 90 days.

(b) For good cause, the designated agency ethics official may extend the reporting deadlines for reports required under this part during the initial implementation phase for any reporting requirement, without regard to the 90 day maximum specified in paragraph (a) of this section.

§ 5502.106 Supplemental disclosure of prohibited financial interests applicable to employees of the Food and Drug Administration.

(a) *Applicability*. This section does not apply to special Government employees.
(b) *Definitions*. For purposes of this section:

(1) *Confidential filer* means an employee who meets the criteria in 5 CFR 2634.904 and who has not been excluded from the requirement of filing a confidential financial disclosure report under the procedures in 5 CFR 2634.905.
(2) *Prohibited financial interest* means a financial interest prohibited by § 5501.104(a), including those financial interests that are excepted under §§ 5501.104(b) of this chapter.
(3) *Public filer* means an employee who meets the criteria in 5 CFR 2634.202 and who has not been excluded from the requirement of filing a public financial disclosure report under the procedures in 5 CFR 2634.203.
(4) *Remainder of HHS* has the meaning set forth in § 5501.102(b)(2) of this chapter.
(5) *Separate agency component* has the meaning set forth in § 5501.102(a) of this chapter.

(c) *Report of prohibited financial interests*.–
(1) *New entrant employees*. A new entrant employee shall report in writing within 30 days after entering on duty with the FDA any prohibited financial interest and the value thereof held upon commencement of employment with the agency.
(2) *Reassigned employees*. An employee of a separate agency component other than the FDA or of the remainder of HHS who is reassigned to a position at the FDA shall report in writing within 30 days of entering on duty with the FDA any prohibited financial interest and the value thereof held on the effective date of the reassignment to the agency.
(3) *Incumbent employees*. An incumbent employee of the FDA who acquires any prohibited financial interest shall report such interest and the value thereof in writing within 30 days after acquiring the financial interest.

§ 5502.107 Supplemental disclosure of prohibited financial interests applicable 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:
(1) *Clinical investigator* means an employee identified as a principal investigator, accountable investigator, lead associate investigator, medical advisory investigator, associate investigator, or other subinvestigator in an NIH clinical study involving human subjects under a clinical research protocol approved by an institutional review board.
(2) *Clinical research* has the meaning set forth in 42 U.S.C. 284d(b).
(3) *Institutional review board* (IRB) means any board, committee, or other group formally designated by an institution to review a clinical research protocol and approve the initiation of biomedical research involving human subjects and to assess periodically the progress of the investigation to protect the rights and welfare of the trial participants.
(4) *Confidential filer* means an employee who meets the criteria in 5 CFR 2634.904 and who has not been excluded from the requirement of filing a confidential financial disclosure report under the procedures in 5 CFR 2634.905.
(5) *Public filer* means an employee who meets the criteria in 5 CFR 2634.202 and who has not been excluded from the requirement of filing a public financial disclosure report under the procedures in 5 CFR 2634.203.
(6) *Remainder of HHS* has the meaning set forth in § 5501.102(b)(2) of this chapter.
(7) *Separate agency component* has the meaning set forth in § 5501.102(a) of this chapter.
(8) *Substantially affected organization* has the meaning set forth in § 5501.109(b)(10) of this chapter.

(c) *Report of financial interests in substantially affected organizations*.–
(1) *New entrant employees*. A new entrant employee who is a public filer or confidential filer or who is designated to serve as a clinical investigator shall report in writing within 30 days after

entering on duty with the NIH any financial interest in a substantially affected organization and the value thereof held upon commencement of employment with the agency.

(2) *Reassigned employees*. An employee of a separate agency component, other than the NIH, or of the remainder of HHS who is either a public filer, a confidential filer, or a clinical investigator who is reassigned to a position at the NIH shall report in writing within 30 days of entering on duty with the NIH any financial interest in a substantially affected organization and the value thereof held on the effective date of the reassignment to the agency.

(3) *Incumbent employees*. An incumbent employee of the NIH who is either a public filer, a confidential filer, or a clinical investigator who acquires any financial interest in a substantially affected organization shall report such interest and the value thereof in writing within 30 days after acquiring the financial interest. Any incumbent employee, irrespective of financial disclosure filing status, who is designated a clinical investigator shall report in writing within 30 days of the approval of the clinical research protocol by the relevant institutional review board any financial interest in a substantially affected organization and the value thereof held on the date of the IRB approval.

(4) *Initial report by on duty employees*. An employee on duty at the NIH on August 31, 2005, who is either a public filer, a confidential filer, or a clinical investigator shall report in writing on or before October 31, 2005, any financial interest in a substantially affected organization and the value thereof held on the date the report is filed.

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