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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 nonprofessional 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).

[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: