

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

5501.106 Outside employment and other outside activities.

5501.109 Prohibited outside activities applicable to employees of the National Institutes of Health.

§ 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.

§ 5501.109 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).