

## § 5501.107

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

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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.

[61 FR 39763, July 30, 1996, as amended at 70 FR 5558, Feb. 3, 2005; 70 FR 51568, Aug. 31, 2005]

### **§ 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