

NATIONAL INSTITUTES OF HEALTH

Summary of HHS Supplemental Standards of Ethical Conduct for Outside Activities (5 CFR 5501) (The “3-3-9 Framework”)

In addition to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR 2635), the HHS Supplemental Standards of Ethical Conduct (5 CFR 5501) regulate outside activities for NIH employees. Analysis of each request can be accomplished using this “3-3-9” framework. If an activity listed in Part A is proposed with an entity listed in Part B, the activity cannot be approved unless one of the exceptions in Part C negates the prohibition (i.e., yes, yes, yes). If either A or B is no, the activity is not prohibited. This is a summary only. Full definitions as stated in the regulation govern. **Activities that are approvable under this section must still be evaluated under 5 CFR 5501.106, 5 CFR 2635 and the COI statutes before being approved.** Note that this summary also identifies activities which are not subject to the prior approval requirement.

A. 3 Types of Activities [5 CFR 5501.109(c)(1)]

1. Employment with any one of the 3 types of entities, regardless of compensation [(i)]
2. Compensated teaching, speaking, writing, or editing for any of the 3 types of entities [(ii)]
3. Employment or self-employed activities involving the sale or promotion of products or services of any one of the 3 types of entities [(iii)]

B. 3 Types of Entities

1. **Substantially Affected Organizations** [109(b)(10)]
 - biotech, device, and pharmaceutical companies, and others significantly involved (directly or indirectly through subsidiaries) in health/medical research, development or manufacture
 - any organization a majority of whose members are such entities
 - other entities determined to be substantially affected by the work of the NIH (by the DAEO or the NIH in consultation with the DAEO)
2. **Supported Research Institutions** [109(b)(11)]

Any educational institution or non-profit independent research institute that:

 - is, or within the last year was, an NIH grant, cooperative agreement, or R&D contract applicant, recipient, or partner
 - is, or within the last year, proposed or was an NIH CRADA partner
 - is any organization a majority of whose members are such entities
3. **Health Care Providers and Insurers** [109(b)(8)]
 - a hospital, clinic, skilled nursing facility, rehabilitation facility, durable medical equipment supplier, home health agency, hospice program, or other provider of health care items and services
 - health maintenance organization, managed care organization, or other entity licensed as a risk-bearing entity eligible to offer health insurance or benefits coverage

* *Activities otherwise meeting this exception may be approved only if any SAO support is unrestricted.*

C. Exceptions to the Prohibitions

1. Teaching a course requiring multiple presentations, when that course is part of the regular curriculum of an educational institution (elementary, secondary, higher education) or giving a single lecture within an established higher education course [109(c)(3)(i)]
2. Clinical, medical, or health-related professional practice involving the provision of care to individuals [109(c)(3)(ii)]
3. Teaching, speaking, writing or editing unrelated to official duties (under 2635.807) if the activity is part of a continuing professional education program conducted by an educational activity provider* [109(c)(3)(iv)]
4. Writing or editing unrelated to official duties (under 2635.807) if the resulting product is subject to scientific peer review or a substantially equivalent editorial process* [109(c)(3)(v)]
5. Service on a DSMB for a study conducted by a supported research institution or health care provider or insurer** [109(c)(3)(vi)]
6. Grand Round lectures for accredited educational institutions* [109(c)(3)(vii)]
7. Grant or scientific review committees** [109(c)(3)(viii)]
8. Employment involving manual or unskilled labor, hobbies, artistic endeavors, or interests unrelated to the health and scientific research of the NIH, including clerical work, retail sales, building trades [109(c)(3)(iii)] *Prior approval required only if the outside entity is a prohibited source.*
9. Employment and other activities with political, religious, social, fraternal, or recreational organizations. *Prior approval required only if the activity is compensated or involves the provision of professional services.*

** *Provided SAO does not select, or pay costs, and the protocol/program is not funded by NIH. If protocol/program is funded by HHS, compensation is not permitted.*