NATIONAL INSTITUTES OF HEALTH

CONFIDENTIAL FINANCIAL DISCLOSURE FILER DEFINED

The confidential financial reporting system set forth in 5 CFR Part 2634, Subpart I is designed to complement the public financial disclosure reporting system. Public financial disclosure report filers are delineated in the law, and additional positions may be identified by the Office of Government Ethics (OGE) as equivalent. Employees in other positions where the duties involve the exercise of significant discretion in certain sensitive areas may be required to file the confidential financial disclosure report. This includes executive branch special Government employees who are not required to file a public financial disclosure report. The purpose of this document is to assist the ICs in identifying positions where the incumbents must file the OGE-450 and to enhance consistency across the NIH.

A. Positions Subject to Filing

A position requires confidential disclosure when its duties and responsibilities require the employee to participate *personally and substantially* through decision or the exercise of significant judgment, and without regular personal involvement of the supervisor, in taking certain Government actions.

Personal and substantial participation occurs when an employee participates in a particular matter through: direct involvement; direct and active supervision of subordinates' involvement; decision; approval; disapproval; recommendation; investigation; or giving advice. Consider whether the employee's decision is independent or accepted with little or no review by the supervisor. Participation is substantial even if does not determine the outcome; it is substantial if it is significant to the outcome of the matter. Personal and substantial participation does not include general knowledge, perfunctory involvement, or involvement in an administrative or peripheral issue relating to the particular matter.

Therefore, disclosure is required when official duties entail personal and substantial participation, without substantial supervision and review, in making official decisions or using significant judgment in the following positions/activities:

1. Contracting or Procurement:

a. Contracting officers and specialists, procurement analysts and agents, and all employees with authority to obligate Federal funds. Included are:

- all individuals with a warrant, regardless of level (i.e., all individuals with purchasing authority above the micro-purchase level);
- all contracting officers and specialists and procurement analysts at or above grade 13 or equivalent[1];
- other individuals in the above positions who meet any other filing criteria regardless of level; and

b. Project Officers and other employees who are responsible for the technical monitoring of a contract, or who are personally and substantially involved in the initiation and development of a contract, e.g., providing personal and substantial input into the statement of work, the negotiation of a contract, or the selection of the vendor.

[1] "Or equivalent" means those in other pay/grade systems, such as Commissioned Officers and Title 42 appointees, who have equivalent levels of responsibility. An AO in the Commissioned Officer pay plan may have the same level of authority as a GS-12 AO. "Or equivalent" intends to capture such individuals.

2. Administering or Monitoring Grants, Licenses or Other Benefits:

a. Grants Management Officers and Specialists with Grants Management Officer (GMO) authority (official authority to commit Federal funds).

b. Technology Transfer Specialists and Technology Transfer Licensing Specialists.

c. Extramural Health Scientist Administrators, Scientific Review Administrators, and other employees who oversee a scientific program and the progress of grants in his/her portfolio or area of scientific expertise. Examples of other covered positions include Scientific Review Group Leader, Program Manager, or Program Official.

Example 1: As a Health Scientist Administrator, Pat's duties involve assisting in the review of applications, determining relevance to IC programs, and making funding recommendations. Pat also manages a portfolio of already funded grant applications. In particular, Pat is involved directly in making funding recommendations for specific research applications. Pat's supervisor typically accepts these recommendations without further clarification. Such independent stewardship and the ability to affect the financial interest of outside organizations would be the basis for designating Pat as an OGE-450 filer.

Example 2: Nehad is a junior grants management specialist who assists with the administration of grants. Nehad's participation in such matters is reserved to providing a technical review of grants and he does not complete assignments independently nor without significant guidance. Therefore, Nehad does not need to file a Confidential Financial Disclosure Report. Once Nehad is given significant authority to provide a technical review of grants and make recommendations and decisions that are generally accepted without further review (GMO authority), Nehad's participation would then be of a substantive nature that could affect the economic status of outside organizations seeking grants. Nehad would then file the OGE-450.

3. Positions with Other Duties Involving Decision or Action that will have a Direct and Substantial Economic Effect on non-Federal Entities:

a. All employee members of an NIH Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).

b. All employees who serve as a Principal Investigator or co-Principal Investigator on matters such as a clinical protocol, Cooperative Research and Development Agreement (CRADA), or M-CRADA.

c. Senior level officials who have personal and substantial input into or influence on the programs and directions of the IC, such as employees whose responsibilities involve identifying new areas of research, analyzing grant or contract portfolios, or providing advice or proposing policy to top IC management. Examples of such positions include senior policy advisor, senior science policy advisor, special assistant, and similar positions.

Example 1: Merced is a newly appointed intramural scientist whose specialized expertise warrants serving as a principal investigator on a new clinical protocol. Merced is required to file the OGE-450.

Example 2: Joni is a newly appointed intramural scientist who just finished post-doctoral training and is beginning a new career. Joni will serve as an associate investigator on multiple projects but not as a principle investigator. Joni is not required to file the OGE-450.

Example 3: As a special assistant to the IC Director, Kim's duties include, among other things, analyzing research grant and contract portfolios for adherence to policy. In this senior level position, Kim has personal and substantial input into IC policies regarding awarding research grants and contracts. Kim is required to file the OGE-450.

4. Other Positions Determined by the NIH Deputy Ethics Counselor, in consultation with affected persons, to Require Filing to Prevent a Conflict of Interest, the Appearance of Favoritism, or Loss of Impartiality (i.e., a real or apparent conflict of interest):

a. Supervisors, when any subordinate is required to file a confidential financial disclosure report.

b. Intergovernmental Personnel Authority (IPA) appointees and detailees whose positions do not require filing the OGE-278 but who meet the definition of a covered individual as defined in SOP 21 Conflict of Interest Requirements for Researchers and Research Staff (see "definition" section below), or who otherwise meet any of the filing criteria.

c. Deputy Ethics Counselors (DECs) and Ethics Specialists/Coordinators (ECs) who do not otherwise meet any of the above criteria, and other staff who participate personally and substantially in ethics actions, e.g., making a final determination regarding an ethics request or a financial disclosure report.

d. All NIH employee members of federal advisory committees having Special Government Employee (SGE) members that are managed by the NIH.

B. Exclusion: Any employee or group of employees may be excluded from the reporting requirement if the IC DEC and supervisor recommend that a report is unnecessary because the possibility of impairment of the integrity of the Federal Government is remote, and the HHS DAEO agrees. Submit the recommendation in writing to the NIH Ethics Office for routing to the HHS DAEO.

C. Appeals: If an employee believes that s/he is improperly designated as a filer, s/he may appeal to the IC DEC for reconsideration of the designation, who will evaluate the duties of the position and make a recommendation to the NIH DEC. All final determinations are under the jurisdiction of the NIH DEC, whose decisions are final. Submit the request for re-evaluation in writing to the NIH Ethics Office, with the memo routed through the IC DEC to the NIH DEC.

D. Definitions:

a. Covered Individual (per SOP 21): Personnel who have independent decisional roles in conducting a specific covered research protocol (defined below). These individuals are influential in the design, direction, or conduct of a covered research protocol, or are engaged in the analysis or interpretation of data. Covered individuals include the principal investigator, personnel whose resume or CV is provided to a sponsor, personnel listed on a FDA 1572 Form, and personnel who obtain informed consent or who make decisions about research eligibility and others who have decisional responsibilities that meet the definition of a covered individual, e.g. as co-investigator, research nurse, and associate investigator. Individuals who participate only through isolated tasks that are incidental to the research (for example, scheduling patient tests), and those individuals who support research of many protocols through the performance of routine patient care tasks <u>are not</u> covered individuals.

b. Covered Research Protocol (per SOP 21): Those that may lead to the financial benefit or loss of any individual or entity. This includes studies of investigational drugs or devices, studies whose research question involves a commercially available drug or device, studies involving a CRADA or Clinical Trials Agreement, studies involving collaboration with a substantially affected organization, or studies involving intellectual property, and NIH research protocols.

NEO: TM/FP/HBJ, with input from NIH DEC, OGC/ED, DDIR, DDER, DDM, HCA
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