

Supervisor Instructions for Review of the HHS-717-1, Confidential Report of Financial Interests in Substantially Affected Organizations for Employees of the National Institutes of Health

BACKGROUND

The purpose of this document is to provide detailed guidance to review and process the form HHS-717-1, Confidential Report of Financial Interests in Substantially Affected Organizations for Employees of the NIH, as required by the HHS Supplemental Financial Disclosure Requirements (5 CFR 5502.107). The report is required for public and confidential financial disclosure filers (OGE-278 and OGE-450) and clinical investigators, as defined in 5 CFR 5502.107(b). Substantially affected organizations (SAOs) are defined in the HHS Supplemental Standards of Ethical Conduct (5 CFR 5501.109(b)(10) and the definition is on the HHS-717-1 report form in Part III:

(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.

Authority for Review and Determination: IC Deputy Ethics Counselors (DECs) or their designee have jurisdiction for making the final determination for all employees in their area of responsibility except NIH senior "top 5" employees, DECs, and supervisors of DECs, who are handled by the NIH Ethics Office (NEO) and the NIH DEC. The authority to review and make determinations may be re-delegated to officials who are knowledgeable and at a high enough level within the organization to be consistent with good management of this authority and to main program integrity, e.g., an experienced Ethics Coordinator or Ethics Specialist. (See NIH Manual Chapter 2400-09 HHS Supplemental Financial Disclosure Reporting Requirements (HHS-717-1) (pending).)

Employees will follow the separate detailed instructions to complete the following parts of the HHS-717-1.

- Part I. Employee Information.
- Part II. Summary of Conflict of Interest Law. The employee will read this part.
- Part III. Financial Interests in Substantially Affected Organizations (SAOs): The employee will report all financial interests in substantially affected organizations, regardless of value and submit the report in a timely manner to the appropriate ethics office.

Ethics Officials will review the report, determine whether supervisor review is required, obtain the supervisor review when needed, and provide a final decision regarding any employee action, e.g., divestiture or recusal. The ethics officials will complete Part V, Deputy Ethics Counselor Determination, and will ensure that the employees appropriately complete Part VI. Certificate of Divestiture and Part VII. Compliance.

SUPERVISOR REVIEW OF THE HHS-717-1

Supervisor Review Criteria: Any HHS-717-1 with holdings which meet one or more of the following criteria will be forwarded to the supervisor for review, with values redacted. These values are only for establishing the thresholds for sending the report to the supervisor. When the supervisor's comments are returned, the ethics officials' evaluation will determine which *de minimis* will apply (i.e., particular matter with specific parties, non-parties, matter of general applicability), and which DEC determination is appropriate.

1. The market value of any one SAO publicly traded security is greater than \$15,000 (5 CFR 2640.202(a), particular matter with specific party).

Example: Holding in one SAO security is \$16,000, which is over the *de minimis*.

For senior, "Top 5", employees, the employee's ethics office would most likely address this conflict without involving a supervisor.

For non-senior, "non-Top 5" employees, the employee's ethics office evaluates and sends the report to the supervisor for review of conflicts.

2. The aggregate market value of all SAO publicly traded securities is greater than \$15,000 (5 CFR 2640.202(a) & (b), particular matter, combining SAOs covered by party and non-party exemptions).

Example: Holdings are: SAO-G is \$5000; SAO-P is \$6700, SAO-S is \$8000, and SAO-T is \$10,000. Aggregate is \$29,700, which exceeds the *de minimis* and falls outside the exemption.

This scenario would likely create a conflict for most clinical investigators that would require either divestiture, recusal, or reassignment. It may not be a conflict for all employees, however, i.e. administrative staff.

The employee's ethics office evaluates and sends the report to the supervisor for review of conflicts.

3. The market value of any one SAO sector fund is greater than \$50,000 (5 CFR 2640.201(b), particular matter with specific party).

Example: Health sector fund (HSF) value is \$59,000, which exceeds the *de minimis* and falls outside the exemption.

This scenario would likely create a conflict for all senior, "Top 5" employees, as well as clinical investigators and would require either divestiture, recusal, or reassignment. It may not be a conflict for all employees, however, i.e. administrative staff.

For senior, "Top 5" employees, the employee's ethics office would most likely address the conflict without involving a supervisor.

For non-senior, "non-Top 5" employees, the employee's ethics office evaluates and sends the report to the supervisor for review of conflicts.

4. The aggregate market value of all SAO sector funds is greater than \$50,000 (5 CFR 2640.201(b), particular matter with specific party).

Example: Holdings are HSF-H is \$20,000; HSF-J is \$15,000; and HSF-K is \$25,000. Aggregate is \$60,000, which exceeds the *de minimis* and falls outside the exemption.

This scenario would likely create a conflict for all senior “Top 5” Employees, as well as clinical investigators that would require either divestiture, recusal, or reassignment. It may not be a conflict for all employees, however, i.e. administrative staff.

For senior, “Top 5” employees, the employee’s ethics office would most likely address the conflict without involving a supervisor.

For non-senior, “non-Top 5” employees, the employee’s ethics office evaluates and sends the report to the supervisor for review of conflicts.

5. Financial interests in SAOs which are not publicly traded, regardless of value.

Therefore, ***if either of the following two situations apply, no supervisor review is required.*** See [5 CFR 2640 Subpart B](#) for *de minimis* values. See also the summary on the web site:

<http://ethics.od.nih.gov/topics/deminimis.htm>

- a. Reports which indicate **no holdings in SAOs**.
- b. Reports which indicate **publicly traded SAO holdings**, where **all SAOs** included on the report are valued **at or below** the *de minimis* for that type of holding, **AND** the **aggregate value** for the type of holding regarding parties/non-parties is **at or below** the applicable *de minimis*.

Example: An employee holds stock in 5 publicly traded pharmaceutical companies, each valued at \$2500. Each SAO holding is below the \$15,000 *de minimis* for securities (stock), AND the aggregate value is less than the \$15,000 *de minimis* for matters involving parties. No supervisor review required.

Because values are below the *de minimis*, no additional conflicts review is needed. In this case, the DEC determination will indicate “Divestiture or Recusal Not Currently Required” because the reported values do not exceed the *de minimis*. The employee will be required to provide a response to Part VII. Compliance, question #3 Monitoring Obligation, and explain how he or she will monitor the values to ensure that they remain under the *de minimis*.

All other reports which indicate SAO holdings, except as noted above, require a two-level review, first by the IC Ethics Office staff and then by the supervisor. The IC DEC will make the final determination.

Example: An employee holds stock in 3 publicly traded pharmaceutical companies, each valued at \$7,000. Each SAO holding is below the \$15,000 *de minimis* for securities (stock), but the aggregate value is greater than the \$15,000 *de minimis* for matters involving parties. **The supervisor must review.**

Review Procedure for Supervisors: Reports from non-senior NIH employees which list SAO holdings will be forwarded to the supervisor indicated in Part I, Box 10, for a conflict of financial interest review only if the report meets the supervisor review criteria, above. The supervisor will complete the following steps.

1. **Read the information that the employee is required to read on pages 2 and 3.**
2. **Examine the employee’s current official duties** and identify whether the employee has official responsibilities of significance to the resolution of Government matters that affect any SAO. Keep in mind that the employee’s official responsibilities might directly or indirectly affect an outside organization.

- » **Directly affected** outside entities may include those organizations with which the employee has some official interaction, such as a partner in an official collaborative endeavor. These entities may be a 'party' to a particular matter, such as a CRADA partner.
 - » **Indirectly affected** outside entities includes those organizations which could be affected by the results of a matter, even though the entity may not be involved in the matter. These entities would be considered 'non-parties' since they are not part of the particular matter, but could be affected by the outcome. For example, the outcome of a drug trial can affect not only the maker of the drug being tested, but also the maker of a competing drug.
3. **Compare those affected outside organizations** with the financial interests reported on the employee's HHS-717-1, in Part III (pages 4 and 5). If the employee holds any SAO interest which can be affected by official duties, be sure to fully explain in Part IV. Supervisor Review.
 4. **Read the ethics official's comments on page 13, if any.**
 5. **Using information gained in the above steps, complete Part IV of the HHS-717-1:** (pages 6-7)
 - a. **Box 1. Description of Potential Conflicts.** Read the instructions and provide the requested evaluation. Describe the potential conflicts. Use the Additional Space on page 13 as needed. Clearly identify your comments as Part IV, #1.

Examples:

Employee has a financial interest in Merck, which produces a competing drug to one being used in a protocol on which he works. Employee is in charge of data collection on the protocol, which is personal and substantial participation.

Employee is the PI on a CRADA, has a financial interest in Merck, and the CRADA uses materials from Pfizer, which makes similar materials. As PI, employee makes or oversees all decisions regarding the CRADA.

- b. **Box 2. Resolution of Potential Conflicts:** Read the instructions and provide the requested information. Indicate any concerns and share the evaluation with the DEC regarding resolution of any identified potential conflicts. Respond to all three issues as directed. Use the Additional Space on page 13 as needed. Identify your comments as Part IV, #2a, #2b, or #2c, as appropriate.

- » **Question a. Reassignment of Work to Another Individual:** Read the instructions and indicate whether the work can be reassigned and why.

Examples:

Employee is a clinical nurse whose function on several protocols is to collect data. The employee's financial interest in Merck can be affected by one protocol, entitled xxx. Since several clinical nurses function as data collectors across several protocols, this employee can be reassigned to another protocol without harming the integrity of the protocol nor negatively affecting the employee's workload or that of other data collection staff.

Employee is PI on a CRADA entitled XX with Pfizer, because of his expertise in that specific area. The outcome of the CRADA can reasonably be expected to affect his own financial interests in Merck. The PI responsibility cannot be reassigned without harming the expected contribution of the protocol.

- » **Question b. Nature of Work Assignments.** Read the instructions and indicate whether the affected work is a critical portion of the employee's work.

Examples:

Handling data collection is a major portion of the employee's work, but it is not critical that the employee do so on this particular protocol.

The employee's work as PI is critical to the CRADA, and central to the employee's research work.

- » **Question c. Material Impairment of Ability to Perform Duties of Position:** Read the instructions and indicate whether the employee's ability to perform official work would be significantly affected if the employee were removed from performing the official work which affects the outside organization.

Examples:

There would be no significant impairment for the protocol or the employee if the employee is recused from data collection on the particular protocol. Workloads can be realigned to permit employee to work on other protocols.

There would be substantial impairment of the employee's ability to perform his official duties if he were recused from the CRADA.

6. **Box 3. Comments:** See the instructions. You may also direct the DEC to your comments on Page 13, Additional Space.
7. **Sign and date the report.**
8. **Return it to the Ethics Office** which sent it to you. Do NOT keep a copy of the report.

Document History

File Name: HHS-717-1-Supervisor-Review-Instructions-2015Sept.doc and .pdf