

Ethics Officials' 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 on the 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: The Deputy Ethics Counselors (DECs) or their designees have jurisdiction for making the final determination for all employees in their area of responsibility except NIH Senior employees, DECs, and supervisors of DECs, whose reports are reviewed by the NIH Ethics Office (NEO) with final determination made by 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 will submit the report in a timely manner to the appropriate ethics office.

Supervisors will follow the separate detailed instructions for supervisory review of the HHS-717-1, which includes review of the official responsibilities, identification of outside entities which could be affected, and comparison of the employee's financial interests to the potentially affected outside entities. The supervisor will then respond to all questions in Part IV. Supervisor Review, specifically

explaining whether the employee's financial interests can be affected by official duties, and resolution options for the potential conflict. Supervisors review only those HHS-717-1 which meet the supervisor review criteria and which are sent by the ethics official to the supervisor.

ETHICS OFFICIAL REVIEW OF THE HHS-717-1 REPORT

Initial Ethics Official (Reviewer) Review: The Ethics Official (Reviewer) with jurisdiction will conduct an initial review to confirm reported holdings are SAOs, ensure consistency with other ethics records, obtain supervisor review if required, and recommend appropriate determination to the Deputy Ethics Counselor (DEC) or designee.

1. **Examine the SAOs reported.** Review the HHS-717-1 and confirm that each financial interest listed meets the definition of an SAO.
 - a. Check the SAO documents on the NIH Ethics Program web site, including the full list of SAOs, the list of additional SAOs, and the list of entities which have been determined to not be SAOs. Also check the list of SAO sector funds. If all of the employee's reported holdings are determined to be SAOs and the status is confirmed based on the various documents reviewed, continue with step 2.
 - b. If any employee holding is not listed on the web site and it is not clear whether the entity is an SAO, research the company, e.g., via the internet or other means. Forward the information and your evaluation to the NIH Ethics Office (NEO) Ethics Specialist who supports your IC for concurrence. The NEO will confirm or deny the determination. Once you receive the NEO determination, continue with step 2.

Example: The McKesson Company provides infrastructure support for pharmacies, e.g., software for tracking prescriptions. It does not provide medical products. Therefore, McKesson is not considered an SAO. You would redact this from an employee's report. An entity on the SAO list which is determined to not be an SAO will be added to the "non-SAO" web page with the date the determination of non-SAO was made.
 - c. If the financial interest reported is determined not to be an SAO, the ethics official should redact the interest from the HHS 717-1. Beside the redacted entry, annotate the report with initials and date and state that the holding is not reportable, e.g., if a publicly available, diversified mutual fund.
2. **Compare the HHS-717-1 to the employee's financial disclosure report and other ethics records.** Based on the reason stated for submission of the HHS-717-1 and the review of relevant ethics records, ensure there is consistency between ethics records, i.e., holdings are appropriately reported as required.
 - a. If there are no financial interests listed, and this is confirmed by comparison to the employee's financial disclosure report (OGE-278 or OGE-450) and other ethics records, no further review is required. Proceed to Part V. DEC Determination.
 - b. For reports with SAOs listed, continue with step 3.

Note: If it is discovered during the review of a clinical protocol or an annual financial disclosure report that an incumbent HHS 717-1 filer has acquired an SAO interest since he or she last filed an HHS 717-1 (or HHS 716), a new HHS 717-1 must be filed. The new HHS-717-1 must report all currently held financial interests in SAOs, not just the SAO identified. If the filer previously held an

asset that was not an SAO and is now determined to be an SAO, a conflicts analysis must be completed and documented. Note that we cannot collect an HHS 717-1 unless there is an acquisition. The DEC will follow NIH policy regarding managing non-compliance with ethics requirements in accordance with Manual Chapter 2400-08 *Managing Employee Non-Compliance with Government Ethics Requirements* (8/15/08), available at:

<http://oma.od.nih.gov/manualchapters/ethics/2400-08/>

3. **Correct the report as necessary.** Based on the comparison of the HHS-717-1 to the employee's financial disclosure report and other records, and the above steps, clarify the needed corrections. Request permission from the employee to correct his or her report. Once permission is received, correct the report for the employee. Redact holdings which do not meet the definition of SAO. **Redact the information across the entire line and initial next to the identification letter in the first column on the report form to indicate who corrected the report.** In background notes or –information, document the phone call or maintain the email giving permission to revise an employee's report. DO NOT attach such information to the form, i.e., do not staple it to the form or attach with a paper clip. To do so makes it “part of the form.” Maintain background information separately in the file, e.g., a separate folder of background information and notes regarding financial disclosure reports and upload a copy into the employee's EMIS record.

If, after corrections, no financial interests in SAOs remain on the report, treat the HHS-717-1 as if it was submitted with the “None” box marked on page 4, indicating no interests in SAOs.

4. **Identify whether supervisor review is required.** Based on the full and correct holdings report, determine which, if any, regulatory exemption is applicable with respect to the scenarios below. If a 717-1 report requires supervisor review, then the values of holdings must be redacted.– The values below are only for establishing the thresholds for sending the report to the supervisor. When the supervisor's comments are returned, the Ethics Official (Reviewer) will determine which *de minimis* values apply, (particular matter with specific parties, non-parties, matter of general applicability), and which DEC determination is appropriate. 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. 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 exceeds the *de minimis* and falls outside the exemption.

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.

- b. The aggregate market value of all SAO publicly traded securities is greater than \$25,000 (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.

- c. 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.

- d. 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.

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

Therefore, ***if either of the following two scenarios exist, no supervisor review is required and no conflicts analysis is needed.*** Skip to the DEC DETERMINATION section, on page 6 of the HHS-717-1 report. Start with #2 in that section.

- » Reports which indicate ***no holdings in SAOs*** (including reports which were corrected and all reported entities were removed).
- » 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, and no conflicts analysis is needed because by regulation, the values are defined as no conflict.

Note: Acting Top 5 Employees may hold SAOs over the *de minimis* value while acting, provided there is no conflict of interest pursuant to 18 U.S.C. § 208.

All other reports which indicate SAO holdings, other than the two scenarios 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. Continue with Step 5, Initial Conflict Review.

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.**

5. **Initial Conflicts Review, Ethics Official (Reviewer):** If the report **does not require supervisor** review, on page 13 (Additional Space), document the review and make a recommendation to the DEC. Continue with Part V. DEC Determination.

Example: 4/25/16 Report is consistent with ethics file. No prior conflict identified. Employee's holdings are valued below the *de minimis*. No supervisor review is required. Recommend no further action. PJones

For reports which **require supervisor review**, ascertain from prior financial disclosure reports or other ethics records whether potential conflict has been identified in the past. On page 13 of the form (Additional Space), insert the date and a note documenting the outcome of the review, and sign. Continue with the next step (# 6).

Example: 4/25/16 Report is consistent with ethics file. No prior conflict identified. Employee's holdings are valued above the *de minimis*. Supervisor review is required. PJones

6. **Prepare the report for supervisor review.** Steps 6 through 11 assume that there are SAOs listed which meet the requirement for supervisor review.

- a. Copy pages 4 and 5 of the form, and the Additional Space page (page 13) to include the ethics official review note.
- b. On the copy, redact the value (actual dollar amount). For each SAO, use "White Out", "Redaction Tape", or a comparable redaction method to cover the amount and owner.
- c. Copy the redacted pages and produce a copy for the supervisor, to include:
 - Page 1, the employee information page
 - Pages 2 and 3, Summary of Conflict of Interest Law
 - Pages 4 and 5, the Employee Financial Interests pages
 - Pages 6 and 7, the Supervisor Review pages
 - Blank Additional Space page for supervisor to add comments, if needed.

7. **Attach the pages of the redacted copy together and send the report to the Supervisor.** If you will send the report to the supervisor via email, do so via encrypted (secure) NIH email, and include a due date back to you. Remind the supervisor to address any specific issues, such as in the example above.

8. **Keep track of reports and remind supervisors** as needed to ensure timely review and return of reports.

9. **When the report is received back from the supervisor**, review the supervisor comments and recommendations, if any. Replace the supervisor pages (6, 7) and add the supervisor's Additional Space page (if used), into the original report so that the revised report contains original signatures of the employee, the supervisor, and the reviewer. Save the redacted pages separate from the final form to document what was sent to the Supervisor.
10. **Add a note to page 13** (Additional Space), including a recommendation to the Deputy Ethics Counselor for each SAO. Date and sign the note.
Example: 4/25/16 Supervisor indicated no conflict exists. Recommend no recusal or divestiture. Employee must monitor any change in duties and responsibilities to avoid future potential conflict. PJones
11. **The Deputy Ethics Counselor will return** the report to the Ethics Official (Reviewer) following marking the final determination for each SAO held.

Deputy Ethics Counselor Determination: Upon receipt of the report from the ethics reviewer, the DEC or designee reviews the initial reviewer comments, and the supervisor's evaluations if applicable, and completes Part V.

1. **Add personal information:**
 - Name of DEC or Designee: Self explanatory
 - Contact Information: Self explanatory.
 - Title of DEC or Designee: Official position title. DEC is sometimes a function of an employee with another official title, such as Executive Officer.
 - Organization: Enter the full organizational name and address for the DEC or Designee.
2. **Read the statements carefully and mark the appropriate box(es):** Having reviewed the ethics official's review comments and the supervisor comments, if applicable, the DEC or designee will make the final determination. For each SAO held, insert the letter identifying the SAO (from page 4) in a box below the appropriate determination paragraph for that SAO. Each SAO must have a final determination identified.
 - **Total Divestiture of Specified Interests:** (first box on page 8) Check this box to instruct the employee to divest the full amount of certain types of holdings as identified in the boxes below this section. Use the identification letters associated with each interest listed on page 4.
 - **Partial Divestiture by non-Senior Employees:** (second box on page 8) Check this box to instruct the employee to divest down to a certain level (i.e., the *de minimis*). Indicate the letter identification for each holding that must be partially divested.
 - **Partial Divestiture by Senior NIH Employees:** (third box on page 8) Check this box and indicate the letter identification of each prohibited financial interest which the NIH Senior Employee must divest down to the *de minimis* level.
 - **Recusal with respect to Particular Matters:** (fourth box on page 8) Check this box and indicate the letter identification of each SAO which the employee may retain, but which requires the employee to be recused from all official particular matters involving that specific SAO.
 - **Divestiture or Recusal Not Required:** (first box on page 9) Check this box if the identified holdings pose no conflict and the employee does not have to divest the holding nor recuse him/herself from official particular matters involving the entities listed.

- **Divestiture or Recusal Not Required:** (second box on page 9) Check this box if the employee reports no financial interests in SAOs in Part III.
- **Other Disposition:** (third box on page 9) Check this box if some other resolution is being used, and describe that resolution in block 7 (Comments) or on the blank page 13. Clearly identify the comments as “Part V, Other Disposition.” For example, the NIH DEC may recommend an authorization to manage an identified appearance of a conflict.

3. **Sign and date the report. Return it to Ethics Official (Reviewer)** to obtain employee compliance where needed, and to finalize the report and file it.

Ethics Official (Reviewer) Finish Processing the Report: The Ethics Official (Reviewer) will ensure that the report is properly processed, depending on the DEC determinations and the desire of the employee. These instructions also apply to the NEO ethics officials (for NIH senior, “top 5” staff, DEC’s, and supervisors of DEC’s) and to the Office of the General Counsel, Ethics Division (for NEO officials).

1. **Review the DEC Determinations:**

- a. If there are no required employee actions, continue with step #6 below, in this section.
- b. If the employee must divest or take other remedial action, e.g., provide an explanation for one or more questions in Part VII. Compliance, retain the original and forward a copy to the employee with instructions to review the DEC Determination in Part V, and to follow the employee instructions for Parts VI and VII. Also refer the employee to the Employee Instructions for Completing the HHS-717-1 on the website. Give a deadline of 2 weeks to request a CD. Inform the employee that if divestiture is required, the 90 days includes the time to request it, and to receive the approval (or denial) for the Certificate of Divestiture from the Office of Government Ethics, so it is important to decide quickly, and submit required information immediately.

2. **Periodically follow up with employee** to check on progress, e.g., weekly. If the employee wishes to request a Certificate of Divestiture (CD), the employee must notify the DEC within 2 weeks of the DEC signature date in Part V by returning the original form with the CD request, as outlined in Part VI, box 2 of the form.

3. **Receive Signed Part VI. Certificate of Divestiture from the Employee:** Confirm that the employee checked the appropriate box, signed the report, and provided the additional information as needed. Insert the signed page into the original report and discard the blank page.

- If the employee requests a CD, continue with the next step.
- If the employee does NOT request a CD, continue with step #5 below, in this section.

Note that an employee may request a CD for some financial interests but not for others. Keep track of which financial interests will have which resolution.

4. **Employee Requests a CD:**

- a. Immediately initiate the CD request package with input from the employee and the Office of the General Counsel, Ethics Division (OGC/ED). Submit the request package to OGC/ED quickly.

- b. When the CD approval/disapproval document is received, forward it to the employee with a copy of page 11, Part VII. Compliance.
- c. Follow up with employee to remind him/her of the divestiture deadline, normally 90 days after the DEC signature date, as noted on page 9, block 6, Divestiture Date.
- d. If other actions (e.g., recusal) are also required, remind the employee of the need to quickly comply with those requirements also. Assist the employee with required documentation, e.g., recusal memo template.
- e. Continue with step 6.

5. *Employee Does Not Request a CD:*

- a. If the employee has NOT submitted a signed Part VII. Compliance page, add the signed Part VI. Certificate of Divestiture to the original report and discard the blank page. Remind the employee of the need to divest within 90 days of the DEC signature date, as indicated on page 9, block 6 "Divestiture Date.
- b. Remind the employee of the need to comply with the other remedial requirements, e.g., recusal, as needed. If no other actions are required, continue with Step 6, in this section.
- c. If the employee does not need to divest, or divests and submits a signed Part VII. Compliance, continue to step #6 below, in this section.

6. *Receive Signed Part VII. Compliance, From the Employee:* Upon receipt of the signed page, insert the original signed Part VII (page 11) into the original report form and discard the blank page. Confirm that all original signature pages are included, thus creating the original final report. Scan to a pdf file, named as follows:
EmployeeName-FormNumber-Date.pdf

Example: Dr. Pat A. Smith's HHS-717-1 submitted on March 12, 2016 would be named:
SmithPA-717-March-2016.pdf

- 7. *Enter data in EMIS.*** Applicable to all offices which handle the reports. Upload the final pdf file to the EMIS record.
- 8. *Confirm with the employee that he or she has a full copy of the report. If not, scan and send a copy electronically, or make a paper copy and send.***
- 9. *If the report is in hard copy, file the original report in the employee's hard copy file,*** in the financial disclosure section.

Document History

File Name: HHS-717-1-Ethics-Official-Review-Instructions-2015.doc