

NATIONAL INSTITUTES OF HEALTH ETHICS PROGRAM

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

BACKGROUND

Covered NIH employees are required to report certain financial interests to comply with the HHS Supplemental Standards of Ethical Conduct (5 CFR 5501.110) and the HHS Supplemental Financial Disclosure Requirements (5 CFR 5502.107). Specifically, employees are required to report financial interests in Substantially Affected Organizations (SAO), as defined at 5 CFR 5501109(b)(10):

(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.

Who: Covered employees subject to the requirement to report their SAO interests include:

- those who file the Public Financial Disclosure Report (OGE-278);
- those who file the Confidential Financial Disclosure Report (OGE-450); and
- those who are designated as a Clinical Investigator, as defined in the regulation, on an NIH protocol (operationally, that means named on the cover page of the form NIH-1195).

What: Form HHS-717-1, Confidential Report of Financial Interests in Substantially Affected Organizations for Employees of the National Institutes of Health

When:

Original Submission: Your original HHS-717-1 is due no later than 30 days after you become either a public or confidential financial disclosure report filer OR you become a clinical investigator.

Extension of Due Date: An extension is permitted for form HHS-717-1 only if it is submitted with a New Entrant Public Financial Disclosure Report (OGE-278) or a New Entrant Confidential Financial Disclosure Report (OGE-450) and an extension was granted for the OGE-278 or OGE-450. However, the extension may not apply only to the HHS-717-1, i.e., filers may not request and receive an extension for the OGE-278 or OGE-450 and then submit that report but not the HHS-717-1, thus using the extension for only the HHS-717-1.

Reporting an Acquisition: Employees who previously filed an original HHS-717-1 (or HHS-716) must file a new form when they acquire a financial interest in a Substantially Affected Organization (SAO) via any means, including by gift, marriage, purchase, or reinvesting dividends. The new report is due no later than 30 days after acquiring the new interest. Report all interests in SAOs, not just the acquired interests.

Extension of Due Date: No extension is permitted for reporting an acquisition.

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).

Availability of the Report Form: Currently, the electronically available form HHS-717-1 (08/11) is used. When NIH implements electronic submission and review of form HHS-717-1, employees will submit reports via the designated system. The blank form is available in fillable pdf format on the NIH Ethics Program forms page, under the Financial Disclosure heading: <http://ethics.od.nih.gov/forms.htm#fd>

Submit Report to:

- Most employees, except as noted below: Submit to your IC's Ethics Office. Names and addresses of the IC ethics officials are available on the NIH Ethics Program web site at: <http://ethics.od.nih.gov/coord.pdf>
- NIH Senior (Top 5), Institute/Center (IC) Deputy Ethics Counselors (DEC), and supervisors of DECs: Submit to the NIH Ethics Office (NEO) (Bldg 2, Room BE-04, MSC 0201).
- NIH DEC and NEO staff: Submit to the HHS Office of the General Counsel Ethics Division (Bldg 31, Room 2B-47).

Help: For help in completing the HHS-717-1, contact your IC's Ethics Office staff. See above link.

Content of Report: Report all currently held financial interests in SAOs as defined in Part III of the form, for yourself, your spouse, and your minor children.

Preparation:

1. Gather information regarding your financial interests in substantially affected organization (SAO). See Form HHS-717-1, Part III, Box 1, for a definition of an SAO. See the web site page about SAOs: <http://ethics.od.nih.gov/topics/sao/sao-intro.htm>
2. Retrieve your copy of your most recent certified OGE-450 or OGE-278 if you are a filer.
3. Carefully read and complete the first five pages of the form, save the file, and then print, sign and forward the original signed report to your IC's Ethics Office. You may also print and manually complete the form. When NIH implements electronic submission and review of form HHS-717-1, employees will submit reports via the designated system.

COMPLETING AND SUBMITTING YOUR REPORT

The organization of the remainder of this instruction matches the sections on the form. When using the fillable pdf format form, open it and immediately "Save As" in a location where you can find the file. Once it is saved and named, enter the requested information and tab to the next field. Save frequently to avoid losing your data.

Check Employee Filing Status:

Indicate the reason for submitting the HHS-717-1 by marking the appropriate option, as explained below.

- New Entrant Public or Confidential Filer or New Clinical Investigator who Entered on Duty at NIH under an Initial Appointment or by Reassignment:
This means employees new to NIH.
- Incumbent Non-Filer Newly Designated as a Public or Confidential Filer or Clinical Investigator in a IRB-Approved Clinical Research Protocol
This means current NIH employees who were recently designated as a financial disclosure filer (OGE-278 or OGE-450) or clinical investigator and this is their first HHS-717-1.
- Incumbent Filer or Clinical Investigator who Acquired a Financial Interest in a Substantially Affected Organization (SAO) after Filing a Prior HHS Form 716 or 717-1.
This means current NIH financial disclosure filer (OGE-278 or OGE-450) or clinical investigator who previously reported their SAO interests on either form listed and now are reporting acquisition of a financial interest in an SAO.

Part I. Employee Information

Enter Date of Filing Status Event Enter the date (mm/dd/yy) of the event explained above which triggered your requirement to file an HHS-717-1, e.g., designated as a filer or acquisition of an interest in an SAO.

1. Name: Self explanatory
2. Agency: Institute/Center/Office: Enter your **IC**'s acronym, e.g., OD, NIA, NCI, etc.
Subcomponent: Enter your Division, Branch, or Office acronym
3. Enter your official job title. Self explanatory
4. Enter your pay Grade and Step (i.e., GS, GM or WG). If you are in a non-graded pay system (e.g., Title 42, SES), enter N/A (for not applicable).
5. Enter the total amount of your annual federal salary, including locality and other adjustments.
6. Check the relevant box to indicate your appointment type:
 - PAS/PA: Presidential Appointee Senate Confirmed / Presidential Appointee
 - Non-Career SES
 - Schedule C
 - Career SES: applies to SES appointees at the NIH
 - General Schedule: GS, GM, and WG employees
 - Title 42: includes SBRS, AD pay plans

- Commissioned Corps
 - Other: indicate the appointment type if none of the above fit
7. Financial Disclosure Filing Status: indicate which financial disclosure report you are required to file, or None if you are not required to file either financial disclosure report.
 8. Office Address: Self-explanatory. Give complete information for your office address, as requested.
 9. Office Contact Information: Self-explanatory. Give complete information to contact you. Use your NIH contact information; personal cell phone is not required.
 10. Name of Immediate Supervisor: Self-explanatory.
 11. Title of Supervisor: Self-explanatory.
 12. Supervisor Contact Information: Self-explanatory. Give complete information.

Part II. Summary of Conflict of Interest Law

Read this section thoroughly. It contains information about conflict of interest law in understandable terms, and information about your responsibility to avoid conflicts of interests. It provides details about disqualification (recusal), divestiture, your obligation to monitor your holdings, and your obligation to report your interests in SAOs. You may wish to keep a copy of this information available to periodically refresh your knowledge.

Part III. Financial Interests in Substantially Affected Organizations

Read the information and instructions on the form carefully. Instructions specify whose financial interests must be reported. "Substantially affected organization" (SAO) is defined. Information about SAOs is available on the NIH Ethics Program web site, including a list of entities already identified as SAOs, and entities which are not SAOs. These lists are routinely updated as information becomes available.

See: <http://ethics.od.nih.gov/topics/sao/sao-intro.htm>

If you do NOT have financial interests in SAOs to report, check the NONE box, and proceed to block #4, Certification. Read the certification, sign and date the form, make a copy for yourself, and submit the HHS-717-1 as instructed above.

If you DO have financial interests in SAOs to report, follow the steps below.

1. **Report:** After reading the instructions and reviewing the examples, enter your financial interests which meet the criteria.
 - *Description:* Insert the name of the company, organization, partnership or other entity.
 - *Type of investment:* self-explanatory, see example on the form.
 - *EB: Employee Benefit.* Add a checkmark to indicate whether the financial interest is an employee benefit from your prior employment, or from your spouse's current employment or prior employment, such as an interest held in a pension plan (see the example on the form).
 - *Value:* Insert the whole dollar value of the holding as of the date of the event which required you to file. See descriptions of "filing events" above.
 - *Ownership:* As described in the second paragraph of the instructions on the form, indicate ownership by using the following initials:
 - I = Individual; your own holding, not jointly owned with your spouse, minor child, or others
 - S = Spouse's financial interest; not jointly owned with you, a minor child, or others
 - MC = Minor child's interest; not jointly owned with you or your spouse.

J/S = Jointly owned by you and your spouse.

J/MC = Jointly owned by you and your minor child.

J/O = Owned jointly by you and one or more others (other than your spouse or minor child), or by your spouse and/or minor child and one or more others (other than you).

Enter each financial interest on its own line, A through L. If you need additional space, use the Additional Space on pages 13 and 14. Label your additional information "Part III, #1" and enter the information in the same columnar format, designating each additional interest with a letter, beginning with the letter M. Use blank paper if more pages are needed after using pages 13 and 14. If you hold more than 26 interests (A through Z), use numbers, beginning with #1.

2. **Questions for Senior NIH Employees:** These two questions apply ONLY to senior NIH employees, as defined on the form. If you are not an NIH senior employee based on that definition, skip this section. Senior employees will answer "yes" or "no" for Questions a and b, and indicate the holdings applicable to each response. If additional space is needed, use the "Additional Space" on pages 13 and 14. Label the additional information "Part III, #2." Use blank paper if more space is needed.
3. **Comments:** This option is for all filers. Insert any required and other relevant comments in this block, such as comments about a particular financial interest reported in Box 1, e.g., explaining any exceptional circumstances affecting your acquisition of the interest or issues affecting your ability to divest that financial interest. You may continue the comments in the Additional Space on pages 12 and 13. Label the continuation information "Part III, #3." Please write legibly, or type in your additional information. You may also attach copies of emails or other communications clarifying questions or issues. If you attach other information, add "See attached" and indicate what is attached and its date. If the attachment is multiple pages, also indicate the number of pages. For example: "See attached statement dated 3/23/16. 3 pages"
4. **Certification:** Review your entries and comments, and confirm that they are clear and accurate. Read the certification statement. Sign and date where indicated to certify that your report is "true, complete, and correct" to the best of your knowledge.

Make a copy of the report for your records and forward the original report to the appropriate ethics official (see page 2, "Submit Report To"), so that it is received no later than close of business on your due date as defined above. Names and addresses of ethics officials are located on the NIH Ethics Program web site at: <http://ethics.od.nih.gov/coord.pdf>

Note: Once your ethics official reviews your report, you may be contacted for additional information. In addition, depending on the contents of your report, it may be forwarded to your supervisor (without values) for your supervisor to provide input regarding whether your financial interests can be affected by your official responsibilities. Specific criteria for supervisor review are outlined in the supervisor review instructions, available on the NIH Ethics Program web site, on the Procedures page:

<http://ethics.od.nih.gov/procedures.htm#fd>

Part IV. Supervisor Review

If the ethics officials responsible for reviewing your report determines that your interests meet the criteria for supervisor review, he or she will cover the values and make a copy for your supervisor, who will then review it for potential conflicts between your financial interests and your official responsibilities.

The supervisor will return the report to the ethics official with comments. See supervisor questions in Part IV of the form. Supervisor instructions are in the supervisor review procedure, available at the link above.

Part V. Deputy Ethics Counselor (DEC) Determination

Regardless of whether your supervisor reviews your form, it may be reviewed by one or multiple ethics officials. In most cases, an ethics coordinator or specialist first reviews your report. Final determination regarding whether a conflict exists is made by your Deputy Ethics Counselor (DEC) or designee. Specific instructions for ethics official review of your report are available on the NIH Ethics Program web site, on the procedures page: <http://ethics.od.nih.gov/procedures.htm#fd>

Continued processing of your report is guided by whether you reported any financial interests in SAOs and whether there is any potential for conflict between your holdings and your official duties. Once the DEC determines whether you must take some action and identifies what action is necessary, your report will be signed and returned to you.

When you receive your HHS-717-1 report back from your ethics official, read all comments by the supervisor, if applicable, and by the reviewer and DEC or designee, if applicable. Examine Part V. Deputy Ethics Counselor Determination. The possible DEC determinations are explained below.

1. **You Reported Holding No SAOs:** If you reported holding no financial interests in SAOs, **and** the final determination indicated on your form HHS-717-1 is the second option on page 9, "Divestiture or Recusal NOT CURRENTLY REQUIRED for Financial Interests in Substantially Affected Organizations Because the Employee Reported NONE in Part III," you will need to sign the Compliance page, Part VII, and return your report to your ethics office.

Remember -- if you acquire a financial interest in an SAO in the future, you must report that acquisition within 30 days of the acquisition date by submitting a new HHS-717-1.

2. **You Reported Holding at Least One SAO:** Your DEC or designee will indicate a determination for each SAO you hold by inserting the ID letter for each SAO (the "Letter Block" on your list of interests) into one of the boxes below the determination, or decision, for that holding. Review the DEC determination in Part V, #5, identifying the DEC's decision for each SAO you hold. If you do not understand each one, seek immediate guidance from your ethics official. You may have several different requirements, depending on the outcome of the conflicts analysis. Your additional action depends on which determination is marked for each SAO you hold. The following paragraphs explain the determination options in Part V, #5, on pages 8 and 9. ***This is a summary only. Read the details on the form itself.***

A. Total Divestiture before the date indicated in #6 on the next page (Divestiture Date). Your DEC determined that you must divest (sell) **all** of your financial interests in each SAO listed in the boxes below this paragraph. You have the option to request a Certificate of Divestiture (CD), which may defer capital gains tax. See "Part VI. Certificate of Divestiture," below. In addition, you must provide full responses as described in Part VII. Compliance, questions #1 Divestiture and #3 Monitoring Obligation. See details in section Part VII. Compliance, below.

B. Partial Divestiture for non-Senior employees. Your DEC determined that you must divest (sell) **some** of your financial interests in SAOs before the date indicated in #6 on the next page (Divestiture Date). Review the boxes below the paragraph and identify which SAOs are affected (the letters refer to the identification letter in your list of SAO holdings in Part III). You have the option to request a Certificate of Divestiture (CD), which may defer capital gains tax. See Part VI. Certificate of Divestiture, below. In addition, you must provide full explanations as described in Part VII. Compliance, #1 Divestiture and #3 Monitoring Obligation. See details in Part VII. Compliance, below.

- C. Partial Divestiture for Senior employees. Your DEC determined that since you are an NIH Senior employee, you are subject to the regulatory prohibitions on holding financial interests in SAOs, and therefore you must divest each SAO indicated in the boxes below this paragraph down to the level permitted in the regulation (5 CFR 5501.110). You have the option to request a Certificate of Divestiture (CD), which may defer capital gains tax. See “Part VI. Certificate of Divestiture,” below. In addition, you must provide full responses as described in Part VII. Compliance, questions #1 Divestiture and #3 Monitoring Obligation. See details in section Part VII. Compliance, below.
- D. Recusal: Your DEC determined that you must be recused from official particular matters affecting the financial interests of the SAOs indicated in the boxes below this paragraph. See details in the paragraph. In addition, you must provide full explanations as described in Part VII. Compliance, question #2 Recusal. See details in section Part VII. Compliance, below.
- E. Divestiture or Recusal Not Required: Your DEC determined that you may retain all of your currently held financial interests in SAOs, and that a recusal is not necessary, for the SAOs listed in the boxes below this paragraph, i.e, neither divestiture nor recusal is required. In addition, you must provide full responses as described in Part VII. Compliance, questions #2 Recusal and #3 Monitoring Obligation. See details in section Part VII. Compliance, below.

Part VI. Certificate of Divestiture

If your DEC instructs you (in Part V) to divest (options A, B, and C described above) and you will realize a capital gain as a result of divestiture, you will use this section to indicate whether you wish to request a Certificate of Divestiture (CD). Carefully read the information about CDs and determine whether you wish to request a CD.

IF YOU REQUEST A CD, DO NOT DIVEST UNTIL YOU RECEIVE THE APPROVED CD. IF YOU DIVEST OF YOUR FINANCIAL INTERESTS BEFORE YOUR CD IS ISSUED, YOU WILL NOT BE ELIGIBLE TO USE THE CD.

- 1. Capital Gains Tax Deferral:** Read the information very carefully about CDs. Review the material on the NIH Ethics Program web site, <http://ethics.od.nih.gov/topics/divest.htm>.
- 2. Certificate of Divestiture Election:** Determine whether you wish to request a CD. Continue to the next section based on your decision (#3 if you do not request a CD; #4 if you request a CD). If you wish to divest some interests but not others, you will follow the instructions in both sections.
 - YES, You request a CD:** If this is your choice, mark the “Yes” box and continue to the next question on the form (Part VI, #3).
 - NO, You Do Not Request a CD:** If this is your choice, mark the “No” box and continue to the next question on the form (Part VI, #3).
- 3. Description of Financial Interest:** Read the instructions carefully and provide the required information on page 10. Regardless of whether you request a CD, you must answer this question thoroughly. For each SAO explanation, indicate whether it will be included on the CD or sold without the CD. If you need more space, use the Additional Space pages (pages 13 and 14). If more space is needed after using the Additional Space pages, use blank paper. Add your name, HHS-717-1 Addendum, and the event date (from page 1) to the top of blank paper. For the Additional Space pages and blank paper, label your responses as “Part VI, #3.”

4. **Certification:** Read the certification statement, sign and date.
5. **Make a copy** of your completed and signed page 10 for your records and return the page with your original signature to your ethics official to inform him or her that you will divest by the date indicated in the prior section (top of page 9).

Note: The CD request must be received in the NIH Ethics Office within 2 weeks of the signature date of the DEC or designee at the bottom of Part V (Page 9). Therefore, you need to make your decision, indicate it on the form, and return the form to your IC's Ethics Office as quickly as possible.

- **If you do not request a CD**, divest before the date indicated in Part V, #6, on page 9. See Part VII. Compliance, below.
- **If you request a CD, wait to receive the approved CD. Do not divest until you receive the CD or you may not use it to defer capital gains tax.** Then divest before the date indicated in Part V, #6, on page 9. See Part VII. Compliance, below.

Part VII. Compliance

This section of the form is for you to explain how you have or will comply with the DEC's determinations regarding your financial interests in SAOs. Review the Summary of Conflict of Interest Law in Part II again and obtain guidance from your ethics official if you have any questions. Provide an explanation for each question relevant to your situation.

1. **Identify which questions you must answer**, based on which actions your DEC required you to complete. Note that you may need to respond to all three questions depending on your DEC's determinations. Answer each question about the applicable financial interests only.

If you were told to TOTALLY DIVEST, provide a response for question #1.

- Read the instructions for question #1, Divestiture. Identify each SAO covered by this requirement and provide a full response regarding how and when you divested. Your response is applicable only to the financial interests which you must totally divest. Proceed to step #2.

If you were told to PARTIALLY DIVEST, provide responses for questions #1 and #3:

- Read the instructions for question #1, Divestiture. Identify each SAO covered by this requirement and provide a full response regarding how and when you divested.
- Read the instructions for question #3, Monitoring Obligation. Provide a full response, explaining how you will ensure that the value of each SAO will remain at an acceptable level. Proceed to step #2.

If you were told to RECUSE, provide a response for question #2.

- Read the instructions and provide full responses to question #2. Be specific so that it is clear that no official matters affecting your financial interests will be assigned to you, nor will you see or discuss any matters involving those financial interests. Proceed to step #2

2. **Carefully review your responses** in Part VII. Compliance. Revise as needed.
3. **Read the Certification statement** in Part VII, #4.
4. **Sign and date** where indicated.

5. **Make a copy of this page** (# 11) for your records. You should now have a copy of every page of the form, and all pages should be complete. If any pages are missing or incomplete, request a copy when you submit this final signed page.
6. **Return** page 11 with your original signature to your ethics official.

You are now finished with this HHS-717-1, Confidential Report of Financial Interests in Substantially Affected Organizations for Employees of the National Institutes of Health. If you acquire an interest in an SAO in the future, submit your new HHS-717-1 within 30 days of the acquisition. If you have questions or concerns, contact your IC ethics officials. Names and contact information is on the NIH Ethics Program web site: <http://ethics.od.nih.gov/coord.pdf>

Document History

File Name: HHS-717-1-Employee-Instructions-2015September.doc and pdf