

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONFIDENTIAL REPORT OF FINANCIAL INTERESTS IN SUBSTANTIALLY AFFECTED ORGANIZATIONS FOR EMPLOYEES OF THE NATIONAL INSTITUTES OF HEALTH

(HHS Supplemental Ethics Regulation 5 CFR 5501.110 HHS Supplemental Financial Disclosure Regulation 5 CFR 5502.107)

CHECK EMPLOYEE FILING STATUS:		
New Entrant Public or Confidential Filer or New Clinical Investigator	who Entered on Duty at NIH u	nder an Initial Appointment or by Reassignment
Incumbent Non-Filer Newly Designated as a Public or Confidential F	Filer or Clinical Investigator in a	n IRB-Approved Clinical Research Protocol
Incumbent Filer or Clinical Investigator who Acquired a Financial Int 716 or 717-1	erest in a Substantially Affected	d Organization (SAO) after Filing a Prior HHS Form
I. EMPLOYEE INFORMATION		
ENTER DATE OF FILING STATUS EVENT 1. EMPLOYEE'S NAME	(Last, First, MI)	
/		
AGENCY (Institute/Center/Office)	(Subcomponent)	
3. TITLE OF POSITION	4. GRADE/STEP	5. FEDERAL SALARY
6. APPOINTMENT TYPE		7. FINANCIAL DISCLOSURE FILING STATUS
PAS/PA Non-Career SES Career SES Schedule C	Commissioned Corps	Public (OGE 278)
General Schedule Title 42 Other		Confidential (OGE 450) None
8. OFFICE ADDRESS		
STREET		
CITY	STATE	ZIP
9. OFFICE CONTACT INFORMATION		
TELEPHONE	FAX	
CELL	EMAIL	
10. NAME OF IMMEDIATE SUPERVISOR	44 TITLE OF CUREDVIC	OR
10. NAME OF IMMEDIATE SUPERVISOR	11. TITLE OF SUPERVIS	OR
12. SUPERVISOR CONTACT INFORMATION	1	
TELEPHONE	FAX	
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AGENCY USE ONLY		
(Enter Date Received		

II. SUMMARY OF CONFLICT OF INTEREST LAW

1. Disqualification

Under the Federal criminal conflict of interest statute, 18 U.S.C. 208, you are prohibited from working on any government matter that directly and predictably affects your own or an imputed financial interest. If your spouse or minor child(ren), among others, have financial interests, such as stocks, stock options, bonds, or sector mutual funds, that are affected by government matters on which you work, you are disqualified to the same extent as if those investments were your own. You would violate the law if you participate personally, or by directing subordinates, and if you contribute substantially to the resolution of the matter. The test is whether the matter itself affects a financial interest of a company in which you are invested, and not whether your actions affect the company. Therefore, you need not be a decision-maker for a violation to occur. Rendering advice or arguing the merits of a study or policy, even if your views are not accepted, can be substantial participation in the matter.

Certain regulatory exemptions found at 5 CFR Part 2640, which are tied to the type and value of the conflicting holdings, may permit you to participate despite the potential for conflict. For example, if the combined value of publicly traded securities you own individually and with others does not exceed certain monetary caps, you are free to work on a matter affecting those holdings. Consult the regulations and your Deputy Ethics Counselor (DEC) for details. On the other hand, if your individual and imputed financial assets exceed those limits or otherwise do not qualify for a regulatory exemption (for example, stock options or nonpublicly traded securities are not covered), you must disqualify yourself from participation in the matter if the company that issued the securities potentially faces any gain or loss from the resolution of the matter. A violation can occur even though the stock price is unaffected. The question essentially is whether the company, from a financial point of view, would care how the government matter turns out.

The disqualification required by the statute is often called a "recusal." If your holdings create a conflict, you cannot pick and choose among the various aspects of a particular matter and stay away only from the important decisions. Such incomplete recusals will not protect you from a criminal conflict of interest violation. Unless a waiver, approved in advance, identifies specific permitted activities, you must refrain entirely and absolutely from participating personally and substantially in a government matter that affects your own or imputed financial interests.

You must recuse not only from those government matters that specifically involve or affect the company that issued the stock, but from those matters that affect generally the industry or economic sector in which the company operates. Your obligation to recuse is one for which you are personally responsible and is not contingent upon someone telling you to do so. Recusal is triggered immediately whenever a matter arises that would pose a conflict. If these recusal obligations impede your ability to do your work, the agency can address the conflict through a waiver or by ordering divestiture. An advance waiver to allow your participation in conflicting matters may be granted only if your appointing authority concludes that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government expects of you.

2. Divestiture

If your ability to do your job would be materially impaired because you have to recuse from working on central or critical matters, or agency efficiency would be adversely affected because your work cannot be readily assigned to another employee, then the agency can require you to divest the conflicting financial interest. In addition, the HHS Supplemental Ethics Regulation at 5 CFR 5501.110, among other limitations, bars senior NIH employees, their spouses, and minor children from acquiring or holding financial interests in substantially affected organizations (SAOs), such as biotechnology, pharmaceutical, or medical device companies, that exceed \$15,000 in value in any one holding or in sector mutual funds that state in their prospectus the objective of investing in SAOs that, when combined, exceed \$50,000 in value.

II. SUMMARY OF CONFLICT OF INTEREST LAW (continued)

3. Monitoring Obligations

If you are a senior NIH employee subject to the prohibited holdings rule at 5 CFR 5501.110, the value of any residual holdings that you are allowed to keep cannot exceed the applicable caps (\$15,000 single issuance/\$50,000 combined SAO sector funds). If you are not a senior NIH employee, you must limit any retained SAO holdings that pose a conflict to an amount at or beneath the applicable regulatory exemption amounts in 5 CFR 2640.202, or you will have to recuse immediately from government matters affecting the conflicting financial interests. You must monitor capital appreciation and dividend reinvestments to ensure that the caps are not exceeded. Issuing a standing sell order to your broker to limit your positions in conflicting stock may be necessary.

In order to avoid conflicts, you will need to monitor the business activities of the companies in which you invest and be familiar with their commercial products, including those publicly disclosed to be under research and development. This task can be exacerbated by mergers, acquisitions, joint ventures, partnerships, and even name changes, within SAO industries that, on any given day, may make it difficult for you to know whether a situation requiring your disqualification has arisen.

You must assess on an ongoing basis whether any company in which you are invested would be affected financially by the resolution of government matters on which you presently or in the future are assigned to work. Therefore, you must be attentive to any change in your duties or assignments and consider how the new matters on which you work will affect companies that you previously thought posed no conflict.

In addition, although the reporting obligation for this form centers on SAOs, remember that your holdings in non-SAO securities may require recusal or divestiture as well. You must be constantly alert to other situations that pose conflicts, for example, procuring information resources from outside contractors when you have considerable holdings in data management, computer, or information processing firms.

4. Reporting Obligations

This form has been developed to assist you in complying with the SAO reporting obligations specified in 5 CFR 5502.107(c)(1) through (c)(3). If you are a new NIH employee or have been reassigned to the agency and you concurrently are designated a public or confidential financial disclosure report filer or a clinical investigator, you must file an HHS Form 717-1 to report whether you, your spouse, or minor child(ren) have any financial interests in SAOs. This report is due within 30 days after you enter on duty with, or are reassigned to, the NIH. If you are an incumbent employee who is not currently a public or confidential filer but who is later designated as a filer, you must submit your report within 30 days of your designation as a filer. If you are an incumbent employee, irrespective of financial disclosure filing status, who is later designated a clinical investigator, you must file a report within 30 days of the approval of the clinical research protocol by the relevant institutional review board (IRB). In addition, if, at any time after your initial appointment, reassignment, or designation as a public or confidential filer or a clinical investigator, you, your spouse, or minor child(ren) acquire(s), while holding such status as a filer or investigator, a financial interest in an SAO, for example, through marriage, gift, or inheritance, you are required by 5 CFR 5502.107(c)(3) to file another HHS Form 717-1, within 30 days of acquiring the financial interest.

For new entrant and reassigned employees respectively, the identifying information and value of the holdings on the report must be current as of the date the employee entered on duty or the effective date of the reassignment. For incumbent employees designated as filers or clinical investigators respectively, the report must be accurate as of the date of the filer designation or the IRB approval. For incumbent employees who subsequently acquire interests in SAOs, the report must provide the required information and values as of the date of acquisition of the SAO interests.

If the SAO interest poses a conflict and a regulatory exemption does not apply, you must disqualify yourself immediately from government matters affecting the holding. Your obligation to recuse is one for which you are personally responsible; the disqualification applies without regard to the circumstances under which you obtained the asset; and it is not contingent upon prior notification to recuse nor dependent upon the filing of a disclosure report.

III. FINANCIAL INTERESTS IN SUBSTANTIALLY AFFECTED ORGANIZATIONS

1. Report

For you, your spouse, and minor child(ren), report all financial interests, such as stocks, bonds, stock options, and other investments or ownership interests, in **substantially affected organizations** held as of the date specified in Part II, Box 4. Include any sector mutual fund that states in its prospectus the objective of concentrating its investments in the securities of substantially affected organizations. A "substantially affected organization" means: (1) 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; (2) any organization a majority of whose members are these types of entities; and (3) any other organization determined by the agency to be substantially affected by the programs, policies, or operations of the NIH. **Consult the NIH**Deputy Ethics Counselor or the DEC for your institute or center for assistance in identifying companies in the biotechnology, biostatistics, pharmaceutical, medical device, and related industries and any other organizations that are substantially affected.

Describe the financial interest, indicate the type of investment, and if the interest was acquired as a form of compensation or other benefit derived from prior or current employment with a substantially affected organization, check the employee benefit (EB) column. Provide the value of the financial interest (actual dollar amount as of the date specified in Part II, Box 4), and specify whether the financial interest is owned individually (I), by your spouse (S), or minor child(ren) (MC). If held jointly with a spouse, minor child(ren), or others (O), indicate the co-owner(s), for example, J/S, J/MC,or J/O. Indicate the relationship of any co-owners other than a spouse or minor child in the Comments section in Part III, Box 3.

Senior NIH employees only must answer the questions in Part III, Box 2. All employees must sign and date the certification in Part III, Box 4. File this report with your DEC by the date specified in Part II, Box 4.

If none, check this box. NONE

Letter Block	Description	Type of Investment	ЕВ	Value \$	I/S/J MC/O
Example	Zyzex Pharmaceuticals	Bonds		7,205	S
Example	Medical Products Technology Co.	Common stock in 401(k) pension from prior employment	√	56,382	I
Example	Orion Advisors Biotech Fund	SAO Sector Fund		18,855	J/S
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III. FINANCIAL INTERESTS IN SUBSTANTIALLY AFFECTED ORGANIZATIONS (continued)	
2. QUESTIONS FOR SENIOR NIH EMPLOYEES ONLY	
(NIH Director, NIH Deputy Directors, OD Senior Staff who are Direct Reports to the NIH Director; IC Directors, IC Deputy Directors, and IC Clinical Directors; Extramural Program Officials who are Direct Reports to an IC Director; and Designated Equi	
a. Does any equity interest in a substantially affected organization listed above in Part III, Box 1, constitute 1% or more of the to of the organization?	otal outstanding equity
Yes (If this box is checked, identify the financial interest and explain in Part III, Box 3.)	
b. Does the actual value of the holdings listed above in Part III, Box 1, in substantially affected organizations and sector mutual their prospectus the objective of investing in substantially affected organizations, when totaled, account for 50% or more of the combined investment portfolio of you, your spouse, and minor child(ren)?	
Yes	
□ No	
3. COMMENTS (If additional space is required, use the space provided at the end of this form.)	
4. CERTIFICATION Locatify that I have read and understand the Summers of Conflict of Interest Law in Bort II, that to the extent any concert of the	no doporimtion ···
I certify that I have read and understand the Summary of Conflict of Interest Law in Part II, that to the extent any aspect of the unclear to me, I have asked and received clarification from the DEC, and that the statements I have made on this form are trecorrect to the best of my knowledge.	
EMPLOYEE SIGNATURE	DATE

IV. SUPERVISOR REVIEW

Supervisors must review the information provided by the employee and answer the questions below.

1. Description of Potential Conflicts

For each interest in a substantially affected organization reported in Part III, Box 1, indicate whether the employee would be expected to participate in proposing, planning, advising, deciding, or implementing an official action, either individually or by actively directing subordinates, that would be of significance to the resolution of government matters that affect the identified companies specifically or generally as part of an industry class. Indicate whether a potential conflict would arise and explain your answer.

2. Resolution of Potential Conflicts

The employee must be disqualified from participating personally and substantially in government matters that directly and predictably affect a conflicting financial interest, unless the conflict has been waived by the employee's appointing authority or a regulatory exemption applies. The recusal obligation extends not only to particular matters that specifically involve or affect the issuer of the identified securities, such as a contract, CRADA, or clinical trial involving the company's products or those of certain competitors, but to those matters that affect generally the industry or economic sector in which the company operates, such as policy decisions on research priorities.

a. Reassignment of Work to Another Individual

For each interest in a substantially affected organization reported in Part III, Box 1, indicate whether the employee's work assignments that potentially affect the company specifically or that could affect the company generally as a part of an industry class can be readily assigned to another individual. Explain your answer.

b. Nature of Work Assignments	
For each interest in a substantially affected organization reported in Part III, Box 1, indicate whether the employee's work ass affect the company specifically or that could affect the company generally as a part of an industry class would be considered	ignments that potentia central or critical to the
performance of the employee's official duties. Explain your answer.	
c. Material Impairment of Ability to Perform Duties of Position	
Indicate whether the employee's ability to perform the duties of his or her position would be materially impaired if the employed participating in government matters affecting the identified financial interests. Explain your answer.	ee were disqualified fro
3. Comments	
Use this space to state any concerns or questions to be resolved by the DEC.	
SUPERVISOR SIGNATURE	DATE
SUI ENVISOR SIGNATURE	DAIL

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V. D	EPUTY ET	HICS CO	JNSELOF	R DETERM	INATION	(continue	d)						
	Divestiture or Recusal with respect to the Financial Interests Specified in the Box(es) Below NOT CURRENTLY REQUIRED (If this box is checked, the DEC has determined that the employee may retain the financial interest(s) reported in Part III, Box 1, identified by the corresponding Letter Block listed below, because the reported values do not exceed the de minimis holding amounts permitted by regulatory exemptions in 5 CFR Part 2640, or such interests do not currently pose a conflict in light of the employee's anticipated duties and responsibilities. The employee must monitor the value to ensure that capital appreciation and dividend reinvestments do not cause the holdings to exceed applicable caps. The employee must recuse, and may be required to divest, if the caps are exceeded or if a change in duties and responsibilities creates a conflict that previously did not exist.)												
	Divestitui Reported			CURRENT	LY REQU	JIRED for	Financial	Interests	in Substa	ntially Aff	ected Orç	ganizations	Because the Employee
	Other Dis	position (Specify in	the space	provided	in Part V, i	Box 7.)						
6. DIV	ESTITURE	DATE (D	ivestiture	must be co	ompleted o	on or befor	e the follo	wing date.))				
7. CO	MMENTS ((If addition	al space is	s required,	use the s _i	pace provi	ded at the	end of this	s form.)				
DEC S	SIGNATUR	E											DATE

(If "yes," you and/or other eligible persons anticipate realizing a capital gain on the sale of the conflicting financial intere Part V and request that a Certificate of Divestiture be issued. You and/or other eligible persons agree to divest the hold the date specified in Part V, Box 6, and to reinvest the proceeds in permitted property within 60 days after divesting the abide by applicable recusal obligations pending the disposition of the conflicting financial interests. In order to process	lings, as directed, on or before identified holdings. You must
supply the information specified in Part VI, Box 3, and resubmit this form promptly to your DEC. You must eithe DEC of the issuance of a CD or have the document in your possession prior to selling the conflicting financial interests deferral. Complete Part VII of this form when you have fully divested all prohibited holdings, and then resubmit this form document compliance.)	in order to receive the tax
No (If "no," the conflicting financial interests identified by the DEC in Part V must be sold or otherwise divested and all nece on or before the date specified in Part V, Box 6. Sign and date below to confirm your decision. Complete Part VII when holdings in substantially affected organizations in accordance with the DEC determination, and then resubmit this form document compliance.)	you have fully divested all
3. Description of Financial Interests In the space provided below, at the end of this form, or in an attached list, describe how you and/or the eligible person(s) a	cauired the identified holdings
and provide a full and specific description of the property that will be divested. Identify the record owner(s) and type of own property is corporate stock, the exact number of shares must be included: "Acme Co. common stock 125.750 shares John JTWROS (joint tenants with right of survivorship)."	nership. For example, if the
4. CERTIFICATION	
I confirm the election indicated above and certify that the statements I have made on this form and any attachments a	are true, complete, and
correct to the best of my knowledge.	DATE

5	VII. COMPLIANCE	
	Divestiture Describe the steps that you have taken to comply with your divestiture obligation and indicate the date by which you completed a transactions.	ll required
_	Date Divestiture Completed:	
2.	Describe the actions you have taken to fulfill your recusal obligation, indicate the screening mechanism(s) that you use to avoid p particular matters from which you are disqualified, and identify the individual(s) to whom responsibility for such matters has been delegated.	
_	Manufacture Obligation	
3.	Monitoring Obligation Describe the monitoring actions you will undertake to ascertain on a continuing basis the value of your individual and imputed hol applicable caps are not exceeded. Identify the means by which you will be informed of the business activities conducted by the care invested. Describe the steps you will take to assess whether any company in which you are invested would be affected finance government matters on which you presently or in the future are assigned to work.	ompanies in which you
4.	Certification I certify that I have read and understand the Summary of Conflict of Interest Law in Part II; that, to the extent any aspect was unclear to me, I have asked and received clarification from the DEC; that, where applicable, I have sold or otherwise financial interests in substantially affected organizations identified by the DEC in Part V, Box 5; that I will recuse, as req participation in specific party matters affecting any identified financial interest resulting from ownership of securities the permitted to retain; and that I will recuse, as required by law, from participation in general matters that affect the industrin which the issuer of such securities operates. I acknowledge my personal obligation under criminal conflict of interest value of my individual and imputed holdings, to be informed of the business activities conducted by the companies in we to assess whether any company in which I am invested would be affected financially by the resolution of government me presently or in the future am assigned to work, and to recuse whenever the type or value of any conflicting financial interest.	e divested the uired by law, from at I have been y or economic sector law to monitor the which I am invested, atters on which I
	not covered by a waiver or regulatory exemption. I certify that the statements I have made on this form are true, complet best of my knowledge.	e, and correct to the
ΕĪ	MPLOYEE SIGNATURE	DATE

PRIVACY ACT STATEMENT

The Ethics in Government Act. 5 U.S.C. App. § 101, et seq., Executive Order 12674, as amended by Executive Order 12731, Sections 301 and 7301 of Title 5 of the U.S. Code, and Sections 2634.103, 5501.110, and 5502.107 of Title 5 of the Code of Federal Regulations authorize the collection of this information. Disclosure of this information is mandatory for employees of the National Institutes of Health (NIH), except Special Government Employees, who are required to file a public or confidential financial disclosure report or designated as a clinical investigator as defined in 5 C.F.R. § 5502.107(b)(1). Falsification of information or failure to file or report information required to be reported may subject the employee to disciplinary action. Knowing and willful falsification of information required to be reported may subject the employee to criminal prosecution. The primary use of this information is to assist NIH supervisors, other management officials, and agency ethics officials in ensuring compliance with the prohibited holdings provisions of the HHS Supplemental Ethics Regulation applicable to senior NIH employees and the conflict of interest provisions of the Standards of Ethical Conduct applicable to all NIH employees. The information may also be used to counsel employees concerning their ethics responsibilities and to prevent violations of the statutes, regulations, and executive orders governing employee conduct. The information is also requested, pursuant to 5 C.F.R. §§ 2638.203(b)(9), (10), and (11), for the purpose of evaluating ethics program administration, as well as the Department's supplemental ethics regulations, to determine their continued adequacy and effectiveness in relation to current agency responsibilities and to ensure that prompt and effective action is taken to remedy violations or potential violations, or appearances thereof, of conflict of interest and related ethics provisions. Additionally, this information may be disclosed to: (1) the Office of Personnel Management, Office of Government Ethics, Merit Systems Protection Board, Office of the Special Counsel, Equal Employment Opportunity Commission, Federal Labor Relations Authority, Federal Service Impasses Panel, Federal Mediation and Conciliation Service, and an arbitrator, in carrying out their functions; (2) a Federal, State, or local agency charged with investigating or prosecuting violations of, or implementing, the law, in the event there is an indication of a violation or potential violation of civil, criminal or regulatory law; (3) a Federal, State, or local agency maintaining enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit; (4) the National Archives and Records Administration or the General Services Administration in records management inspections; (5) the Office of Management and Budget during legislative coordination on privacy relief legislation; (6) Federal agencies with power to subpoena other Federal agencies' records; (7) a court or party in a court or Federal administrative proceeding if the Government is a party or in order to comply with a judge-issued subpoena; (8) private firms with which the Department may contract for the purpose of collating, analyzing, aggregating or otherwise refining records; (9) a Member of Congress or a Congressional office, pursuant to an inquiry made at the request of the individual who is a subject of the record; (10) the Department of Justice in defense of litigation; and (11) contractors and other non-Government employees working for the Federal Government to accomplish a function related to an Office of Government Ethics Government-wide system of records. This confidential report will not be disclosed to any requesting person unless authorized by law. See the OGE/GOVT-2 Government-wide executive branch system of records.

ADDITIONAL SPACE	
Identify the part and box number to which the additional information refers.	
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ADDITIONAL SPACE

Identify the part and box number to which the additional information refers.



Department of Health and Human Services Office of the Secretary Office of the General Counsel Ethics Division Washington, DC 20201 (202) 690-7258