

RESEARCH FINANCIAL CONFLICT OF INTEREST STATEMENT
Department of Veterans Affairs

Why Must I File?

The duties and responsibilities of your position as a principal investigator, co-principal investigator, investigator (including a collaborator who has a VA appointment), study chair or site principal investigator (hereinafter "Investigators") require you to file a Research Financial Conflict of Interest Statement (Statement) to avoid involvement in a real or perceived conflict of interest. Federal employees are prohibited from participating personally and substantially in official VA matters affecting their own financial interest or those imputed to them. In addition, in research a real or perceived conflict of interest occurs when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. This Statement is to assist employees to avoid a conflict between their official duties and private financial interests or affiliations. See VHA Handbook 1200.13.

When Must I File?

You must submit a completed, signed, and dated Statement:

A. Prior to:

- ◆ Initial review of a study protocol in which you are listed as Investigator,
- ◆ Continuing review of a study protocol in which you are listed as Investigator,
- ◆ Your being added as an Investigator to a study protocol,

OR

B. When you have a change in relevant information that requires you to change an answer on Section I of the Statement to "yes" or that changes the reason for a "yes" answer.

***Note:** The term "Investigator" includes: Principal Investigator (PI), Study Chair, Site PI, co-PI, or an Investigator, including a co-investigator or sub-investigator.*

Who Will Review My Statement?

The Financial Conflict of Interest Committee or Financial Conflict of Interest Administrator, with assistance from the Office of General Counsel (OGC) when necessary, is responsible for reviewing the Statement to determine whether there are any actual or perceived conflicts of interest. The Statement may be reviewed by other VA personnel only on an "as needed" basis when required by the responsibilities of their positions. The information you provide will be used only for legitimate purposes, and will not be otherwise disclosed unless authorized.

What if I Have Questions?

Contact the facility research Financial Conflict of Interest Administrator or Committee designated by the facility's Director as responsible for the facility's research conflict of interest program or an OGC Deputy Ethics Official.

RESEARCH FINANCIAL CONFLICT OF INTEREST STATEMENT
Department of Veterans Affairs

INSTRUCTIONS: Complete this Statement to the best of your knowledge. Answering any question in the affirmative does not itself prevent you from conducting VA research or receiving VA funding. You will, however need to provide additional information so that a determination can be made of how to best manage any conflict of interest that may be identified. **Complete all fields in Section I and III of the form. Fields in Section II may be required** depending on the responses in Section I.

IMPORTANT DEFINITIONS:

AFFECT THE FINANCIAL INTEREST - Means the possibility to impact, either positively or negatively, the value or amount of financial interest to any degree whatsoever.

CLOSE RELATIVE - An individual who is related as father, mother, son, daughter, brother, sister, uncle, aunt, first cousin, nephew, niece, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepfather, stepmother, stepson, stepdaughter, stepbrother, stepsister, half-brother, or half-sister.

DEPENDENT CHILD - A son, daughter, stepson, or stepdaughter and who either is (i) unmarried, under age 2 and living in your house, or (ii) considered dependent under the U.S. tax code.

ENTITY - Any person, for-profit or non-profit organization, institution (including a university), corporation, partnership, or governmental agency (other than a Federal agency).

OUTSIDE EMPLOYER - An entity with which you serve as officer, director, trustee, general partner, or employee.

NAME (Last, First, Middle)	Doe, Jane K
DUTY STATION	VAMC 123 Light Dr. City, GA 12345
TELEPHONE NUMBER	404-123-4567
VA EMAIL	jane.doe@va.gov
NAME OF STUDY	Therapeutic outcomes of the treatment of Hepatitis C using Drug XYZ
FACILITY PI	Doe, Jane K
SPONSOR OF STUDY	Big Pharma Co.
FUNDING SOURCE	Big Pharma Co.

THIS IS A COOPERATIVE STUDIES PROGRAM Yes No

I DO NOT HAVE AN APPOINTMENT WITH THE UNIVERSITY AFFILIATE

I HAVE A SALARIED APPOINTMENT WITH THE UNIVERSITY AFFILIATE

I HAVE A NON-SALARIED APPOINTMENT WITH THE UNIVERSITY AFFILIATE

SECTION I

1. INCOME AND COMPENSATION Do you, your spouse, dependent child or general partner receive income or other compensation (including non-Federal salary, consulting fees, honoraria, gifts, and in-kind compensation) from an entity (including the university affiliate) whose financial interests could be affected by this study?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
2. BUSINESS RELATIONSHIPS. A. Current Relationships: Are you, your spouse, dependent child, general partner or parent serving, or seeking to serve, as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee (paid or unpaid) with any entity (other than the Federal Government, but including the university affiliate) whose financial interest could be affected?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
B. Covered Relationships: Could this study affect the financial interest of you, your spouse, close relative, household member or general partner?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
C. Relationships in the Past Year: Have you, within the last year, served as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee for any entity whose financial interest could be affected by this study?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
D. Business Arrangement or Agreements: Are you seeking, negotiating for, or do you have, any business arrangement or agreement, such as a future employment agreement, re-employment rights, consultant agreement, pending severance arrangement or retirement plan, with any entity whose financial interest could be affected by this study?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
3. INTELLECTUAL PROPERTY . With respect to intellectual property that could be affected by this study, are you, your spouse, dependent child, general partner, or outside employer: <ul style="list-style-type: none"> (i) listed as the inventor on an invention disclosure or a patent application; (ii) the owner of any intellectual property; (iii) the holder of a license of a patent, copyright, software or other intellectual property; (iv) entitled to earn royalties now or in the future; (v) the author of written materials that are, or are going to be, commercialized; (vi) otherwise earning compensation from, or have a financial interest in, intellectual property (not covered elsewhere in this form); OR (vii) holding any other financial relationship not covered elsewhere in this form? 	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
4. NON - PUBLICLY TRADED COMPANIES. Do you, your spouse, dependent child, or general partner have any stock, stock options, or other equity interest in a non-publicly traded company whose financial interest could be affected by this study?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

5 . SPECIFIC TYPES OF FINANCIAL INTERESTS.			
A. Publicly-Traded Companies: Do you, your spouse, or dependent child (in the aggregate) own or have an equity interest (stock ownership, stock options, etc.) valued at more than \$15,000 in a publicly-traded company or companies (aggregate value of all stocks in all such companies) whose financial interest could be affected by this study? <i>Note: This does not include stock controlled through a diversified mutual fund or a blind trust</i>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
B. Sector Mutual Funds: Do you, your spouse or dependent child (in the aggregate) have equity holdings valued at more than \$50,000 in any sector mutual fund (or funds that concentrate in the same sector) whose holdings could be affected by this study? <i>Note: A sector mutual fund concentrates its investments in an industry, business, single country other than the United States, or bonds of a single State within the United States</i>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	



- If you answered “yes” to any of the statements in Section I, you must respond to the associated question in Section II. Only items for which you answered “yes” in Section I will be available in Section II.
- If you answered “no” to all statements in Section I, skip Section II, and proceed to Section III.

Name Doe, Jane K

SECTION II

1. INCOME AND COMPENSATION. If you answered yes in paragraph 1 of Section I, explain the source, value, and reason for the income or other compensation.

My spouse is CEO at Big Pharma Co.

2. BUSINESS RELATIONSHIPS A. Current or Future Relationships. If you answered yes in paragraph 2.A. of Section I, provide: (i) relationship to you of person serving or seeking to serve, (ii) the name of the entity in which the person serves/seeks to serve, (iii) the type of business, and (iv) how the entity's financial interest could be affected by this study

My spouse is seeking to become chairman of the board at Big Pharma, which is a corporation specializing in extensive infectious disease diagnosis and treatment. Presuming the study is successful, the company would see a significant rise in stock price as well as sales of their treatment for Hepatitis C.

B. Covered Relationships. If you answered yes in paragraph 2.B. of Section I, identify: (i) the relationship between you and the person whose financial interest could be affected by this study, (ii) how this person's financial interest could be affected by this study.

My spouse would see a significant increase in salary both as CEO due to the success and profitability of the treatment, and our collective stock shares would see an increase in value.

C. Relationships in Past Year. If you answered yes in paragraph 2.C. of Section I, provide: (i) name of the outside business, (ii) the type of business; (iii) your position with the outside business, and (iv) the date your relationship with the business ended.

D. Business Arrangement or Agreements. If you answered yes in paragraph 2.D. of Section I, provide: (i) name of entity with whom you are seeking, negotiating, or have an arrangement, (ii) type of business conducted by entity, (iii) brief description of the arrangement or agreement you are seeking, negotiating, or have with the entity, and (iv) description of the entity's relation to this study.

3. INTELLECTUAL PROPERTY . If you answered yes in paragraph 3 in Section I, identify (i) what you, your spouse, dependent child, general partner, or outside employer has, and (ii) how it could be affected by this study.

Name Doe, Jane K

4. NON-PUBLICLY TRADED COMPANIES. If you answered yes in paragraph 4 of Section I, provide additional information below.

Name of Company

Type of Equity Interest

Describe the nature of the company and how its financial interest could be affected by this study.

5. SPECIFIC TYPES OF FINANCIAL INTERESTS

A. Publicly Traded Companies. If you answered yes in paragraph 5.A. of Section I, provide additional information below for each affected company.

Name of Company

Type of Equity Interest

Value of Equity Interest

Describe the company's business and how it is related to your area of research.

B. Sector Mutual Funds. If you answered yes in paragraph B of Section I, identify the names of the relevant fund(s)

Name Doe, Jane K

SECTION III

All Investigators must read, initial, and sign the acknowledgement below. Submit completed Statement to the facility research Financial Conflict of Interest Administrator or Committee designated by the facility's Director as responsible for the facility's research conflict of interest program: a) in sealed envelope, b) as attachment to encrypted message, or c) by uploading to FCOI Committee/Administrator secure website, if applicable.

Acknowledgement

By signing below, I certify that, to the best of my knowledge and belief, all of the information on this Statement is true, correct, and complete as of the date of my signature below, and I authorize the reviewer of this Statement to share the information contained herein with the appropriate Research and Development Committee and sub-committees on a need-to-know basis.

JD
(Initial) I understand that false or fraudulent information on this Statement may be grounds for not approving the research proposal and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001).

JD
(Initial) I agree to update relevant information, contact my supervisor, and notify the R&D Committee or appropriate sub-committee with respect to any new financial interest(s) that requires me to change an answer in Section I of this Statement to "yes" or that changes the reason for a "yes" answer.

JD
(Initial) I understand that in addition to the disclosures required in this Statement, I am subject to the criminal conflict of interest statutes at Title 18 of the United States Code, Chapter 11, and the Executive Branch Standards of Conduct at Title 5 of the Code of Federal Regulations, Part 2635. Violation of these provisions may be sanctioned by civil and criminal penalties, as well as employment-related discipline such as removal or suspension.

(Signature)

For Use by Reviewing Official Only

On the basis of information contained in this report, I conclude that the filer is in compliance with applicable laws and regulations, except as noted in the "comments" box below.

Signature

Email

Telephone

I am the Facility Financial Conflict of Interest Administrator or Committee member authorized to certify Statements

I am an OGC Deputy Ethics Official

Comments:

PRIVACY ACT STATEMENT

Title I of the Ethics in Government Act of 1978 (5 U.S.C. App.), Executive Order 12674, and 5 CFR 2634, Subpart I, of the Office of Government Ethics regulations require the reporting of this information. The primary use of the information on this form is for review by the VHA R&D Committee or appropriate sub-committee, and when necessary the VA Office of General Counsel, to determine compliance with applicable Federal conflict of interest laws and regulations and the impact of any real or perceived financial conflicts of interest on VA research. Additional disclosures of information in this report may be made:

- (1) to other VA research review committees and VA officials responsible for the approval or funding of research protocols;
- (2) if there is an indication of a violation or potential violation of law, whether civil, criminal or regulatory in nature and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, to the appropriate Federal, State or local agency charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto;
- (3) to qualified reviewers for their opinion and evaluation of a proposal as part of the application review management inspections; and
- (4) to the Department of Justice (DOJ) upon official request in order for VA to respond to pleadings, interrogatories, orders or inquiries from DOJ and to supply to DOJ the information to enable DOJ to represent the U.S. Government in any phase of litigation or in any case or controversy involving VA.

Failure to file or report information or the falsification of required information may subject you to disciplinary action by the VA or other appropriate authority. This may include limitation on or revocation of the privilege to conduct VA-approved research. It may also be subject to criminal prosecution.