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

**File?**

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** The Financial Conflict of Interest Committee or Financial Conflict of Interest

**My Statement?** 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** Contact the facility research Financial Conflict of Interest Administrator or Committee

**Questions?** 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.

**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 21, 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)* \_

DUTY STATION

\_

TELEPHONE AND VA EMAIL \_

NAME OF STUDY

NAME OF PI AT YOUR FACILITY

SPONSOR OF STUDY

FUNDING SOURCE

THIS IS A COOPERATIVE STUDIES PROGRAM STUDY **□**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

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**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 □ | No □ |
| **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 by this study? | Yes □ | No □ |
| B. Covered Relationships: Could this study affect the financial interest of  you, your spouse, close relative, household member or general partner? | Yes □ | No □ |
| 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 □ | No □ |
| 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 □ | No □ |
| **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:  (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 □ | No □ |

|  |  |  |
| --- | --- | --- |
| **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 □ | No □ |
| **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? *Note: This does not include stock controlled through a diversified mutual fund or a blind trust*. | Yes □ | No □ |
| 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? *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.* | Yes □ | No □ |



**● If you answered “yes” to any of the statements in Section I, you must fill out Section II.**

**● If you answered “no” to all statements in Section I, skip Section II, and proceed to**

**Section III.**

**SECTION II: SUPPLEMENTAL INFORMATION**

Please attach additional pages, if you need more space to fully respond.

**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.

**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.

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.

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.

**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.

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 5.B. of Section I, identify the names of the relevant fund(s).

Name

SECTION Ill

All Investigators must read,initial,and sign the acknowledgement below. Submit completed Statement to the facility research FinancialConflict 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 FCOCI ommittee/Administrator secure website, if applicable.

Acknowledgement

By signing below,Icertify 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.

Iunderstand that false or fraudulent information on this Statement may be

*(Initial)* grounds for not approving the research proposaland may be punishable by fine or

imprisonment (U.S.Code,Title 18,section 1001).

I agree to update relevant information,contact my supervisor,and notify the

*(initial)* R&D Committee or appropriate sub-committee with respect to any new financialinterest(s) that requires me to change an answer in Section ;of this Statement to "yes" or that changes the reason for a "yes" answer.

Iunderstand that in addition to the disclosures required in this Statement,Iam

*(initial)* subject to the criminalconflict 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 removalor suspension.

(Signature ) (Date Signed)

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 and Title of Reviewing Official Date (mm/dd/yy) ... .

Email

Telephone

D I am the Facility Financial Conflict of Interest Administrator or Committee member authorized to certii)r

Statements

0 I am an OGC Deputy Ethics Official

Comments:

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Name \_

**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 statue or particular program statue, 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.

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