



**Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
Chicago, IL. 60612**

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SOP: FINANCIAL CONFLICT OF INTEREST IN RESEARCH

PURPOSE

The purpose of this policy is to outline processes for identifying, managing, and minimizing individual financial conflicts of interest of investigators conducting research at Jesse Brown VA Medical Center.

The purpose of this Standard Operating Procedure is to establish procedures for dealing with the following areas of potential financial conflicts of interest.

POLICY

It is the policy of the VAMC to disclose potential conflicts of interest, to evaluate the potential impact on the research and research subjects, and to manage the conflicts so they do not negatively impact subjects or the credibility of the Human Subjects Protection Program (HSPP). Research personnel, IRB members, IRB Chairpersons, managers in the VA Medical Center (VAMC) Research and Development Office, the Institutional Official, and **research sponsors** may all have certain conflicts of interest. Such conflicts of interest may arise because of the intellectual property involved in many research discoveries or **industry-academic partnerships**. For example, financial incentives offered to researchers by pharmaceutical or biotech companies to conduct trials or enroll subjects can become a conflict of interest.

Chairs and members of the Research & Development Committee and subcommittees who have a conflict of interest are prohibited from participating in the initial or continuing review of research protocols. The Chair or member(s) with a conflict of interest will verbally disclose the conflict of interest to the Research & Development Committee or subcommittee and will recuse himself/herself from any discussion and voting on such research except when asked to answer questions directed by the Research & Development Committee or Subcommittee. The recusal will be noted in the minutes of the Research & Development Committee or Subcommittees.

For all sponsored research, the Principal Investigator must disclose any financial or other interests that she /he and/or any Co-Principal Investigator, Co-Investigator, or key subject on the study may have with the sponsor.

Any Financial COI is reported or identified by R&D Committee will be forwarded to UIC-IRB # 4 for review and resolution. The procedures followed by the Collaborative IRB for identifying, handling and managing financial conflict of interest are described in the **Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB** (section III.J.). If UIC-IRB # 4 fails to resolve financial COI, it will notify R&D Committee. If R&D Committee fails, it will be forwarded to Medical Center Director for final resolution.

BACKGROUND

RESEARCH FINANCIAL CONFLICT OF INTEREST STATEMENT

What is Conflict of Interest?

A financial conflict 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. Concerns related to conflicts of interest have increased as the relationships of investigators with private corporations, pharmaceutical companies, and outside institutions have become more complex. These concerns are based on the potential effects the conflicts may have on the actual or perceived quality of the research and the treatment of research participants.

The main conflict of interest statute in the federal criminal code, 18 U.S.C. § 208, prohibits all VA employees (full-time, part-time, WOC, and IPA) from participating personally and substantially, as part of their official duties, in any particular matter, including research, that directly and predictably affects their own financial interests or any financial interests imputed to them. Financial interests that are imputed to a VA employee include the financial interests of a spouse; minor child; general partner; an organization in which the VA employee serves as an officer, director, trustee, general partner, or employee; or an organization with which the VA employee is negotiating or has an arrangement for prospective employment. Imputed financial interests are treated as if they were the VA employee's own financial interests for purposes of this prohibition.

In addition to the disclosures required in the attached form, all VA employees are subject to the criminal conflict of interest statutes at Title 18, United States Code (U. S.C.) Chapter 11, and the Executive Branch Standards of Conduct at Title 5 Code of Federal Regulations (CFR), 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.

Getting Ethics Advice

VA Regional Counsels and the Assistant General Counsel for Professional Staff

Group III (023), the designated agency ethics official, maintain ethics expertise and provide ethics counseling services to employees. Employees with questions regarding these requirements are encouraged to contact their respective Regional Counsels. Those in VA Central Office should contact the Assistant General Counsel for Professional Staff Group I (023).

NOTE: For Publicly Traded Companies

- a) Investigator must aggregate the interests of himself, spouse and dependent children when determining if you have reached the threshold amount.
- b) If your (investigator) research involves human subjects, THE THRESHOLD AMOUNT IS \$10,000 (not \$15,000).

Members of the Research & Development Committee and any of its Subcommittees may find themselves in any of the following personal conflicts of interest when reviewing research:

- a. When the Chair or member of the R&D Committee or Subcommittees is listed as an investigator on the research.
- b. When any Investigator must report to or is under the supervision of the Chair or member of the R&D Committee or Subcommittees.
- c. When the Chair or member of the R&D Committee or Subcommittees competes for research grants or contracts in the same or similar field as an investigator whose research is scheduled for review.

Investigators may have the potential for conflict of interest when approached to conduct research sponsored by organizations with which they have a financial interest.

Financial conflicts of interests are addressed and, when necessary, management plans developed for review and approval by the IRB, by the Conflict of Interest Office at NU for NU affiliated investigators and by the Conflict of Interest Office at UIC for UIC and VA-only affiliated investigators. .

SCOPE

This policy applies to all research personnel conducting human subject research at the JBVAMC. Investigators must comply with all laws, regulations, and policies of applicable Federal Agencies, including VA, and any applicable state regulations pertaining to financial conflict of interest in research. All research proposals submitted to the JBVAMC for review must contain a Conflict of Interest Statement & Certification identifying conflicts of interest. This requirement applies to all research activities conducted at JBVAMC whether funded by VA or by other sources, or unfunded.

DEFINITIONS

- a. **Business:** Any corporation, partnership, sole proprietorship, limited liability company, limited liability partnership, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes, but excluding the VA, any affiliated hospital, any private medical practice, or any other entity controlled by, controlling, or under common control with the VA.
- b. **Business:** Any patient care, research, teaching, or similar biomedical/health sciences activities; purchasing of goods and/or services for the provision of biomedical/health sciences activities; contracting or attempting to contract for the provision of goods and/or services to be used in biomedical/health sciences activities.
- c. **Conflict of Interest (COI)** is defined as any situation in which financial or personal obligations may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing, or reporting research.
- d. **Executive Position:** Any position that includes responsibilities for a material segment of the operation or management of a business. This would include a position on a Board of Directors.
- e. **Family:** A spouse and/or dependent child/children.
- f. **Financially Interested Business** means any business with financial interests that would reasonably appear to be affected by the conduct or outcome of any of this research project (including the sponsor of the research and/or the manufacturer or licensee of an investigational product or technology used in the research). This term includes businesses that compete with the sponsor or the manufacturer/licensee of an investigational product, if the covered individual actually knows that the financial interests of such a business would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a financially interested business (e.g., a contract research organization).
- g. **Human Subjects Protection Program (HSPP).** An HSPP is a comprehensive system to ensure the protection of human subjects participating in research. The HSPP consists of a variety of individuals and committees such as: the Medical Center Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the Administrative Officer (AO) for R&D, compliance officers, the R&D Committee, the IRB, other committees or subcommittees addressing human subjects protection (e.g., Bio-safety, Radiation Safety, Radioactive Drug Research, Conflict of Interest), investigators, IRB staff, research staff, health and safety staff (e.g., Bio-safety Officer, Radiation Safety Officer) and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.
- h. **Intellectual Property:** Intellectual property includes any invention or improvement in technology, whether patentable or not, conceived or developed using the expertise for which an employee is employed by the VA, VA facilities, personnel, information, or other resources; educational professional or tangible

materials, whether or not registered for copyright or trademark, that result from the instructional, research, or public service activities of the VA and data developed using VA facilities, personnel, or other resources or resulting from the instructional, research, or public service activities of VA.

- i. **Investigator** means the principal investigator and any other person who is responsible for the design, conduct, or reporting of the research. For purposes of determining financial interests, the Investigator's interests include those of his/her spouse and dependent children.
- j. **Non-Financial Conflict of Interest:** This may exist when an individual serves dual roles, such as investigator and health care provider. Other interests, such as publication, promotion or tenure, can also become conflicts of interest that may affect an individual's judgment.
- k. **Participate:** To be part of the described activity in any capacity or position that may influence an outcome.
- l. **Project Period:** The project period should match the performance dates on the grant or contract or similar document. This may be an anticipated start and completion date.
- m. **Significant financial interest** means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). Financial interests which are subject to reporting for any given research proposal include those which would reasonably appear to be affected by the specific research proposed; and/or are interests in entities whose financial interests would reasonably appear to be affected by the research, including:
 - (1) Payments in excess of \$10,000 (US) in aggregate (including benefits of a spouse and dependent children) including salary, consulting fees, royalty or licensing payments from intellectual property, honoraria and/or gifts in the previous 12 months or anticipated in the next 12 months.
 - (2) Any proprietary interest in the product tested in the study, including but not limited to, intellectual property, patent rights, trademarks, copyrights, royalties, or licensing agreements whose value may be affected by the outcome of the research.
 - (3) Any significant equity interest in the sponsor of the study, such as position as director, officer, partner, trustee, employee or other position of management, ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices (e.g. start-up companies) that exceeds \$10,000 (US) (excluding mutual funds) or represents more than a 5% ownership interest in aggregate (including benefits of a spouse and/or dependent children).

The term “significant financial interest” does not include the following:

- (1) Interests of any amount in publicly traded, diversified mutual funds.
- (2) Stock or stock options in a publicly-traded company that (when valued in reference to current public prices or using accepted valuation methods)

doesn't exceed \$10,000 in value and does not represent more than 5% ownership interest in any single entity.

- (3) Payments to the institution, or via the institution to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the institution.
- (4) Salary or other remuneration from the VA, including earnings and the distribution of those earnings that may be established by departmental or other similar agreements provided that those agreements and departmental/divisional group plans are approved by the Medical Center Director.
- (5) Income from occasional seminars, lectures, or teaching engagements sponsored by public or nonprofit entities. Income from service on advisory committees or review panels for public or nonprofit entities (including scientific and technical groups) commissions, committees of professional associations related to the employee's work and consultations with persons in other governmental agencies or not for profit organizations on matters of mutual interest to the entity and the VA

n. **DISCLOSURE** : Disclosure means a complete listing of all financial and employment relationships between a Principal Investigator or his/her immediate family and (1) the sponsor of a project or (2) a profit or not for profit entity with a potential financial interest in the outcome or conduct of the research.

o. **FINANCIAL AND EMPLOYMENT RELATIONSHIPS**: Financial and employment relationships include but are not limited to salary or other payments for services (e.g. consulting fees or honoraria), equity interests (e.g. stocks, stock options or other ownership interests), appointed position in the sponsoring agency including positions on a Board of Directors, consultant ship, or advisory group, and intellectual property rights (e.g. patents, copyrights, and royalties from such rights).

RESPONSIBILITIES

Research Personnel

For researchers, financial or other incentives may negatively impact the collection, analysis and interpretation of data, scientific objectivity and integrity, and ultimately the public trust in the research enterprise. In addition, if also the treating physician, a researcher may unwillingly exert coercion or undue influence on patients to participate in research. It is the responsibility of research personnel to disclose potential financial COI and comply with management decisions as directed by the IRB.

Institutional Review Board (IRB)

The IRB is responsible for ensuring that risks are minimized and the rights and welfare of research subjects are protected through appropriate disclosure and

effective management of Financial COI. IRB is responsible to report either resolve or unresolved Financial COI to the R&D Committee.

Research and Development Committee

R&D Committee will review unresolved Financial COI and try to resolve Financial COI with investigator. If R&D Committee fail to resolve financial COI with investigator than it will be reported to hospital Director. The Hospital Director will make the final binding decision regarding the Financial COI and how it should be managed.

Medical Center Director

Medical Center Director is the institutional official responsible for the R&D program, including resolution of issues related to Financial COI in research or if an investigator fails to comply with the COI policy. Hospital Director has authority to invite outsider to resolve this Financial COI with investigator.

Investigator

The investigator is responsible for disclosing any Financial COI. This disclosure must be documented through the use of Financial COI statement and Certification is available on UIC-IRB website and included in the R&D Committee meeting packet. It is the responsibility of the investigator to report the R&D Committee any time whenever financial COI is identified by sending an amendment to UIC-IRB # 4.

PROCEDURES

Step 1

Investigators are required to disclose real and potential personal financial conflicts of interest for themselves and key research personnel on the JBVAMC / UIC-IRB # 4 financial conflict of interest forms found in the R&D Committee meeting packet and in the IRB initial review application. After initial approval, investigators must monitor on an ongoing basis for any new conflicts of interest. Additionally, investigators are required to disclose potential conflicts of interest via an amendment that submits a revised JBVAMC financial conflict of interest form if a new conflict occurs after initial approval. At the time of continuing review, the investigator is also prompted to summarize any new conflicts of interest that occurred since the initial or most recent IRB review including those reported via an amendment that submits a revised JBVAMC financial conflict of interest form during the approval period.

Step 2

NU and UIC manage financial and institutional conflicts of interest for research involving their respective faculty in accordance with their own policies. The UIC COI Office also develops management plans for financial conflicts of interest for personnel with JBVAMC only appointments. A research protocol with an identified potential conflict of interest is reviewed by the appropriate NU and UIC conflict of interest office to determine whether it requires a conflict management plan. Institutional conflicts of

interest for JBVAMC are reported to the ACOS for R&D by UIC and NU and evaluated by the Associate Chief of Staff for R&D or designee at the time of the IRB pre-review by the JBVAMC R&D office. If an institutional conflict of interest is found, the Medical Center Director consults with the ACOS for R&D and regional counsel to develop a management plan.

Step 3

The UIC-IRB # 4 has the final, authority to decide whether the conflict of interest and management plan are acceptable and allow the research to be approved. Final IRB approval is not granted until a conflict management plan has been submitted, reviewed and approved by the IRB. The protocol is not forwarded to the JBVAMC R&D Committee until after IRB approval of the research, including any conflict of interest management plan.

Step 4

The identification and management of conflicts of interest of the UIC- IRB # 4 members, *ad hoc* consultants, and UIC Office of Protection Research Subjects in the review of research protocols is contained in the UIC human subject protection program policy *IRB member, Ad Hoc Consultant, and Office of Protection Research Subjects Staff Conflict of Interest*.

Step 5

R&D office will screen Financial COI form when IRB checklist is reviewed and P.I. declare Financial COI Interest under new /continuing / amendment submission, the R&D office will mark on checklist that this protocol submission has Financial COI to inform UIC-IRB # 4 as well as e-mail notice to UIC/NU liaison in the R&D Committee to report IRB so they will pay attention to this issue.

Step 6

Financial COI will be resolved by UIC-IRB # 4. The UIC-IRB has authority to call the investigator for clarification and discuss to resolve the conflict. If IRB fails to resolve the conflict, UIC-IRB # 4 will report to the ACOS R&D for resolution. ACOS R&D will forward this request to the R&D Committee for resolution. The R&D Committee has the right to call the investigator for resolution process. If the R&D Committee fails to resolve this conflict then the R&D Committee will report back to ACOS R&D in writing. The ACOS R&D will forward this conflict to Medical Center Director for resolution.

Step 7

The Medical Center Director has authority to form a committee or request outside personnel to help resolve this Financial COI.

Step 8

Final outcome of this issue will be communicated with UIC-IRB # 4 and the R&D Committee. If Financial COI is resolved that UIC-IRB # 4 will give final approval to this protocol and communicate with R&D Committee. The R&D Committee will review and give final approval. After R&D Committee approval P.I. can start his / her research at JBVAMC.

Financial Conflict of Interest will be handled according to the current Operating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC-IRB # 4).

REFERENCES

1. Operating Procedures for the Administration of the Collaborative JBVAMC /NU/UIC IRB (UIC-IRB # 4).
2. VHA Handbook 1200.13 Financial COI in Research Handbook (rescinded since February 2005)
3. VHA Handbook 1200.05
"Objectivity in Research," 42 CFR Part 50 and 45 CFR Part 94, with NSF regulations, Investigator Financial Disclosure Policy.

"Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider When Dealing with Issues of Financial Interests and Human Subject Protection."

<http://ohro.osophs.dhhs.gov/humansubjects/finreltn/finguid.htm>

FDA HHS, Part 54 "Financial Disclosure by Clinical Investigators"

www.fda.gov/oc/guidance/financialdis.html

Form 3454 Certification: Financial Interests and Arrangements of Clinical Investigators
<http://forms.psc.gov/formsIFDA/fda3454.pdf>

Form 3455 Disclosure: Financial Interests and Arrangements of Clinical Investigators
<http://forms.psc.gov/formsIFDA/fda3455.pdf>

Appendix

1. Research Financial COI Statement VA Form
2. Statement of Disclosure by P.I.
3. statement of Disclosure by R&D Committee Member
- 4.

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
3.4; April 5, 2011	3.4; April 30, 2009	



RESEARCH FINANCIAL CONFLICT OF INTEREST STATEMENT

This completed form may only be reviewed by personnel on an "as needed" basis when required by the responsibilities of their position.

This form must be completed and submitted by each principal investigator, co-principal investigator, investigator and collaborator. The information will be used to determine if there is a perceived or real financial conflict of interest or if there is the potential for such financial conflicts of interest. The form will only be reviewed by persons on a need-to-know basis. The completed and signed document must be submitted to the financial conflict of interest (FCOI) committee.

Note: if any questions below are answered in the affirmative, the conflicts must be managed with the assistance of the VA Regional Counsel or, in Central Office, the Office of the General Counsel. Further, even if no question is answered in the affirmative, your financial holdings or arrangements may still pose a conflict of interest within the meaning of Chapter 11 of Title 18, United States Code, and the Executive Branch Standards of Conduct at 5 C.F.R. Part 2635. Compliance with the provisions in this handbook will not necessarily satisfy the requirements of these criminal and regulatory conflict of interest provisions. If you have questions regarding these requirements, you can contact your local Regional Counsel for assistance. If you are located in Central Office, you can contact the Assistant General Counsel for Professional Staff Group III (023).

[Empty text box for name entry]

LAST NAME- FIRST NAME- MIDDLE INITIAL

INSTRUCTIONS: If any of the following questions are answered in the affirmative you will be expected to provide such information as required to determine whether the financial holdings or business interests in question are sufficiently small that the potential conflict of interest should not preclude funding of or conducting VA research.

1. INCOME AND COMPENSATION. Do you or your spouse or dependent child receive income or other compensation for services (to include consulting fees, honoraria, gifts, and/or in kind compensation) from a single entity (or a group of affiliated entities) that when aggregated for you, your spouse and dependent child has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months? <i>NOTE:</i> An entity is any for profit organization, institution, corporation, partnership, or other entity (other than a Federal agency or university affiliate) that does or seeks to do business in an area related to your present research or research you are currently planning.	<input type="radio"/> YES
	<input type="radio"/> NO
2. PATENTS. Do you or your spouse, or dependent child, or an organization (other than a Federal agency) in which you are an officer, director, trustee, general partner or employee own any patents or provisional patents that are related to your present research or research you are currently planning or to any of your other research duties?	<input type="radio"/> YES
	<input type="radio"/> NO
3. COPYRIGHTS. Do you or your spouse, or dependent child, or an organization (other than a Federal agency) in which you are an officer, director, trustee, general partner or employee hold any copyrights that are related to your current research or research you are currently planning?	<input type="radio"/> YES
	<input type="radio"/> NO
4. ROYALTIES. Do you or your spouse, or dependent child, or any organization in which you are an officer, director, trustee, general partner or employee receive any royalty payments or non-monetary considerations from a business or organization that does business in an area related to your current research or research you are currently planning?	<input type="radio"/> YES
	<input type="radio"/> NO

5. BUSINESS CONCERNS. Do you or your spouse, or dependent child, or an organization in which you are an officer, director, trustee, general partner or employee have any business or financial relationship with any person or organization for which the results of your current research or research you are currently planning may be reasonably expected to affect the development or marketing of that person's or organization's product or service?	<input type="radio"/> YES
	<input type="radio"/> NO
6. NON-PUBLICLY TRADED COMPANIES. Do you or your spouse, dependent child, or any organization in which you are an officer, director, trustee or general partner own or have any equity interests by way of stock ownership or stock options in a non-publicly traded company that does business in an area that is related to your present research or research you are currently planning?	<input type="radio"/> YES
	<input type="radio"/> NO
7. PUBLICLY TRADED COMPANIES. Do you or your spouse, dependent child, or any organization in which you are an officer, director, trustee or general partner own or have an equity interest valued at more than \$15,000 (stock ownership or stock options, etc.) in a publicly traded company that does business in an area that is related to your present research or research you are currently planning? <i>NOTE: This does not include stock that is controlled through a widely diversified mutual fund or a blind trust.</i>	<input type="radio"/> YES
	<input type="radio"/> NO

IF YOU HAVE CHECKED NO TO ALL QUESTIONS CHECK THIS BOX

I certify that, to the best of my knowledge and belief, all of the information on this disclosure is true, correct, complete, and made in good faith. I understand that false or fraudulent information on this disclosure may be grounds for not accepting the research proposal and may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001).

<input type="text"/>	<input type="text"/>
Signature of Investigator	Date

1. INCOME & COMPENSATION. If you answered yes in Section I, explain source, and reason for compensation: (NOTE: the FCOI committee may request information on the values or amounts.)

2. PATENTS. If you answered yes in Section 1 provide additional information below. For additional patents provide same information on a separate sheet and attach.

2A. PATENT NUMBER:	<input type="text"/>		
2B. IS THIS A PROVISIONAL PATENT?	YES <input type="radio"/>	NO <input type="radio"/>	
2C. DATE OF PATENT:	<input type="text"/>	2D. PERIOD COVERED:	<input type="text"/>
2E. TITLE OF PATENT:	<input type="text"/>		
2F. PROJECTED ROYALTIES BY YEAR:	<input type="text"/>		
2G. HAVE ANY ACTIVE OR PENDING LICENSE AGREEMENTS BEEN ISSUED? (If yes, attach a copy of each license.)	YES <input type="radio"/>	NO <input type="radio"/>	

3. COPYRIGHTS. If you answered yes in Section 1, provide additional information below.	
4. ROYALTIES. If you answered yes in Section 1, provide additional information below.	
4A. SOURCE:	
4B. AMOUNT:	
5. BUSINESS CONCERNS. If you answered yes in Section I, provide additional information below including specific information on the business and on the development or marketing of the product or service.	
6. NON-PUBLICLY TRADED COMPANIES. If you answered yes in Section I, provide additional information below.	<input type="radio"/> YES
VALUE OF STOCK/STOCK OPTIONS: Does this value represent more than a 5% ownership of the company?	<input type="radio"/> NO
7. PUBLICLY TRADED COMPANIES. If you answered yes in Section I, provide additional information below.	<input type="radio"/> YES
VALUE OF STOCK/STOCK OPTIONS: Does This Value Represent More Than A 5% Ownership Of The Company?	<input type="radio"/> NO

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 Conflict of Interest Committee 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 the 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 process when a proposal is submitted for funding;
- (4) to the National Archives and Records Administration of the General Services Administration in records management inspections; and
- (5) to the Department of Justice (DOJ) upon official request in order for VA to respond to pleadings, interrogatories, orders or inquires 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.

**STATEMENT OF DISCLOSURE
Investigator COI**

PRINCIPAL INVESTIGATOR: _____

STUDY TITLE: _____

Except as noted below, I am not an employee (part or full-time, paid or unpaid) of any organization(s) either involved in this study or whose products or services would be clearly and directly affected in a major way by the outcome of the study, nor am I an officer, member, owner, trustee, director, expert, advisor or consultant of such an organization. It is important to recognize that conflict of interest applies if these interests or relationships exist or give the appearance of existing.

Except as noted below, I do not have any financial interest as set forth by the above criteria, nor does my spouse, minor child, nor any organization with which I am connected.

None []

Identify any exceptions [] -----

I will notify the R&D Chair if a change occurs in any of the above during the tenure of my responsibilities or if I discover that an organization with which I have a relationship meets the criteria.

I am aware of my responsibilities for the maintenance of confidentiality of any non-public information that I receive or become aware of through this activity and for the avoidance of using any such information for my personal benefit or for the benefit of my associates or of an organization which I am connected with or with which I have a financial involvement.

Signature of Principal Investigator

Date

□

**SOP: COI
MANAGEMENT PLAN**

FLOW CHART

COI AT JBVAMC IS MANAGED BY COLLABORATIVE UIC-IRB
COI FORMS ARE INCLUDED IN R&D COMMITTEE MEETING
PACKET & COLLABORATIVE UIC-IRB INITIAL REVIEW APPLICATION PACKET
OR A REVISED COI DISCLOSURE FORM IS SUBMITTED
VIA CONTINUING REVIEW OR AMENDMENT

Is P.I. from JBVAMC only, NU, or UIC?

PI is JBVAMC from NU

P.I. is JBVAMC
Only

P I is JBVAMC from UIC

COI statement is
sent to NU COI Office

COI statement is sent to
UIC COI Office

NU COI Office works with P.I. &
Recommends a management
plan to Collaborative UIC-IRB

UIC COI Office works with P.I. &
Recommends a management
plan to Collaborative UIC-IRB

The Management Plan is submitted to Collaborative UIC-IRB

Collaborative UIC-IRB makes a determination as to Management Plan

Determination Letter is sent to R&D Committee for Approval

