

FINANCIAL CONFLICTS OF INTEREST IN RESEARCH HANDBOOK

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook establishes policy and procedures to enable all Department of Veterans Affairs (VA) medical centers to develop comprehensive programs to prevent or manage financial conflict(s) of interest in research and enable investigators to comply with applicable VA and other Federal and state regulations regarding conflicts of interest in research. **NOTE:** *The provisions of this Handbook apply to all VHA research regardless of funding source.*
- 2. SUMMARY OF MAJOR CHANGES:** This VHA Handbook establishes new policy which must be implemented no later than June 1, 2005. **NOTE:** *Anytime VA Form 10-1313-14, Financial Conflict of Interest Statement and Certification, is required, a similar form may be used if it contains exactly the same information required by VA Form 10-1313-14.*
- 3. RELATED DIRECTIVE:** VHA Directive 1200.
- 4. RESPONSIBLE OFFICE:** The Office of Research and Development (12) is responsible for the contents of this VHA Handbook. Questions may be referred to (202) 254-0183.
- 5. RESCISSION:** None.
- 6. RECERTIFICATION:** This VHA Handbook is scheduled for recertification on or before the last working date of December 2009.

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1. PURPOSE

This Veterans Health Administration (VHA) Handbook establishes policy and procedures to enable all Department of Veterans Affairs (VA) medical centers to develop comprehensive programs regarding financial conflicts of interest in research, and to enable investigators to comply with applicable VA and other Federal and state regulations regarding conflicts of interest in research. *NOTE: The provisions of this Handbook apply to all VHA research regardless of funding source.*

2. BACKGROUND

As a public agency, VHA has an obligation to preserve public trust in the integrity and quality of research carried out by its investigators, among its patients, and in its facilities, and to exercise prudent stewardship of public resources, including public funds that support research programs. Appropriate mechanisms must be in place to ensure that actual or perceived financial conflicts of interest do not undermine that trust.

a. 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 impact of the conflicts may occur in any phase of the research from the development of the study design, obtaining consent from research subjects, and to the management of the study. The conflicts may also bias review of proposals, analysis of data and dissemination of research results through publications and presentations. The perception that a financial conflict of interest exists may not affect the actual development, management and evaluation of the study but rather may negatively impact on the perceived validity of the study and the credibility of both the investigator and the institution.

b. In addition to the obligations set forth in this Handbook, 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. Compliance with the provisions in this Handbook does not necessarily satisfy the requirements of these criminal and regulatory conflict of interest provisions. 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. *NOTE: 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 III (023).*

c. VA employees may be subject to other conflict of interest regulations or policies, e.g., a grant from the National Institutes of Health, Department of Health and Human Services (HHS), other Federal agencies, or other granting entities requiring compliance with their conflict of interest policies. VA employees should seek guidance from VA Regional Counsels, the Office of the General Counsel, or other appropriate authorities concerning these issues.

3. SCOPE

a. VA investigators (compensated or uncompensated, part-time or full time) must comply with all laws, regulations and policies of appropriate Federal agencies including VA in addition to the requirements of this Handbook.

b. All research proposals submitted to VA for review must contain a VA Form 10-1313-14, Financial Conflict of Interest Statement and Certification, identifying conflicts of interest for each principal investigator (PI), co-principal investigator, investigator, and each collaborator contributing 5 percent or more effort (see App. A). This requirement applies to all research activities conducted completely or partially in VA facilities, conducted in approved off-site locations or facilities, or conducted by VA investigators while on official VA duty time, whether funded by VA or by other sources, or unfunded. Further, it applies to all proposals submitted to a VA medical center for local initial or continuing review, and to proposals submitted to VHA Central Office for scientific merit review and funding consideration.

(1) VA Form 10-1313-14 must be submitted with, but not physically attached to the research proposal. If the research proposal is submitted electronically, VA Form 10-1313-14 must be submitted in a separate file.

(2) Distribution of VA Form 10-1313-14 must be limited to only those persons who are required to review it as part of their responsibilities as VA employees (compensated or uncompensated). All persons reviewing VA Form 10-1313-14 must maintain the investigators privacy and confidentiality.

4. RESPONSIBILITIES OF VHA CENTRAL OFFICE, OFFICE OF RESEARCH AND DEVELOPMENT (ORD)

a. VHA Central Office, Office of Research and Development (ORD), consisting of the research services (Biomedical Laboratory Research and Development [BLR&D]), Rehabilitation Research and Development [RR&D], Health Services Research and Development (HSR&D), and Clinical Science Research and Development [CSR&D]), is responsible for administratively reviewing all research proposals submitted for funding consideration to ensure the inclusion of VA Form 10-1313-14. Proposals submitted without the required statements will be returned to the originating medical center without review. If the VA Form 10-1313-14 was submitted to the Financial Conflict of Interest (FCOI) Committee prior to the development of the current

proposal, the investigator must include a statement with the protocol or application that states there have been no changes to the information contained in VA Form 10-1313-14 submitted on a specific date.

b. Scientific peer review committees convened by ORD or its research services when applicable will review VA Forms 10-1313-14 during consideration of research proposals and address any concerns raised during the review process. At the discretion of ORD, the FCOI Committee's or other review committee's findings may be requested.

c. ORD may require actions to be taken to manage, reduce or eliminate any perceived or actual financial conflict of interest. ORD may also elect to not fund a proposal based on a perceived or actual financial conflict of interest.

d. ORD will develop procedures for handling and reviewing FCOI forms and information that will protect the privacy of the investigators.

5. RESPONSIBILITIES OF THE MEDICAL CENTER DIRECTOR OR CHIEF EXECUTIVE OFFICER (CEO)

a. The medical center Director or Chief Executive Officer (CEO) is the institutional official responsible for the Research and Development (R&D) Program within the medical center and as such, represents the facility in issues related to financial conflicts of interest in research and administers the medical center's program related to financial conflicts of interest in research.

b. The medical center Director will appoint a FCOI Committee; the chair of this committee may serve in the role of FCOI Administrator, but may not be a member of the R&D Committee. The FCOI Committee must have representation from the R&D Committee and/or the IRB.

NOTE: The majority of the FCOI Committee members may not serve on either the R&D Committee or the IRB. The medical center may use the FCOI Committee of another VA; if another facility's committee is used, there must be at least one voting member that is from the medical center Director's institution.

c. For research that is carried out by a contractor or non-VA collaborator, the medical center Director is responsible for ensuring that the investigators comply with the provisions of this VHA Handbook and any applicable laws, regulations, and Executive Orders; and for ensuring that VHA research contracts contain a provision that the contract is subject to the provisions of this Handbook and that the contract indicates that failure to comply with the requirements of this Handbook may result in termination of the contract. Failure to comply with VA policy or an equally stringent policy regarding financial conflicts of interest in research may result in termination of the contract or collaboration.

d. The medical center Director, or designee, must regularly assess compliance with all VA and facility policies related to financial conflicts of interest through audits or other mechanisms.

e. The medical center Director, or designee, must develop procedures to disseminate financial conflicts of interest policies and educational programs to ensure all investigators and research staff are familiar with this policy.

f. The medical center Director will regularly review findings of the FCOI Committee, the IRB, the Institutional Animal Care and Use Committee (IACUC) and/or R&D Committee regarding identified conflicts of interest. The medical center Director may add to the stipulations or requirements identified by the FCOI Committee and/or recommended by the IRB, IACUC, and/or R&D committees, but may not lessen them. In situations in which a financial conflict of interest cannot be resolved, it is the medical center Director who makes the final binding decision regarding the financial conflict of interest and its management.

6. RESPONSIBILITIES OF THE INVESTIGATOR

a. The investigator is the individual who is directly involved in some or all aspects of the research study, including the study design, conduct, analysis and interpretation of data, resulting manuscripts and dissemination of research findings. In the context of this VHA Handbook, the term “investigator” includes the Principal Investigator (PI), co-investigators and all other protocol investigators. An investigator may be employed by the VA full-time or part-time, have a without compensation (WOC) appointment, or be assigned through an Intergovernmental Personnel Act (IPA).

(1) A PI is an individual who actually conducts an investigation, i.e., under whose immediate direction research is conducted or, in the event of an investigation conducted by a team of individuals, the responsible leader of that team.

(2) The PI of a protocol must ensure that all investigators or other individuals associated with the protocol have submitted their disclosure forms to the FCOI Committee.

(3) In submitting a protocol to the applicable research review committee(s) (IRB, IACUC, or R&D committee) the PI must also submit a discussion of any actual or perceived conflict of interest, the findings of the FCOI Committee and a discussion of how the requirements of the FCOI Committee will be implemented. If VA Form 10-1313-14 was submitted to the FCOI Committee prior to the development of the current proposal, the investigator must include a statement with the protocol or application that states there has been no changes to the information contained in VA Form 10-1313-14 submitted on a specific date.

b. The investigator in designing research protocols whether involving human subjects, animals, or in other biomedical research not involving either humans or animals, must consider the potential effect that any FCOI would have on the conduct or outcome of the research. A discussion of these issues must be included in the proposal itself or attachments when the effect on the research is actual or perceived. The discussion must include: the conflict; the type of effect it would have on the investigator or the research; and steps taken to manage, reduce, or eliminate the conflict. If the research involves human subjects, the protocol must contain specific information on how the conflict would effect the interactions with human subjects including, but not limited to the consenting process and the written informed consent.

c. The investigator is responsible for disclosing any financial conflicts of interest to the FCOI Committee. VA Form 10-1313-14 may be used for this disclosure (see App. A). This disclosure may be initiated at any time including when first appointed as a VA investigator but

must occur prior to the submission of a protocol to any research review committee such as the IRB, IACUC, or the R&D committee. The time from submission of the required disclosure forms to the submission of the protocol must be sufficient to allow the FCOI Committee to review the disclosure and make any required determinations.

d. The investigator must update the disclosure when there are any changes. *NOTE: The research review committees may request the disclosure forms if necessary, to adequately review the protocol and the impact of the FCOI on the research.*

e. When submitting a protocol for continuing review in which there has been no change in VA Form 10-1313-14, the investigator submits a statement certifying that the financial conflicts disclosed during initial review have not changed. If an updated VA Form 10-1313-14 has been submitted to the FCOI Committee, the findings of the committee must be submitted with the continuing review material.

f. An investigator may appeal the recommendations of the FCOI Committee, the IRB, the IACUC, and/or the R&D Committee in accordance with VA and medical center policies and procedures.

g. The investigator must comply with the final decision of the medical center Director in managing the financial conflicts of interest. *NOTE: For protocols that will be submitted to VA Central Office for funding see subparagraph 4a.*

h. VA Form 10-1313-14, must be updated as new conflicts of interest are identified or current ones cease to exist.

7. RESPONSIBILITIES OF THE FINANCIAL CONFLICT OF INTEREST (FCOI) COMMITTEE

a. The FCOI Committee is responsible for reviewing the VA Forms 10-1313-14 from each investigator who is planning to participate in the facility's research program. These VA Forms 10-1313-14 must be reviewed prior to review of the relevant protocol by the R&D Committee, the IACUC, or IRB.

b. The FCOI Committee is responsible for:

(1) Determining whether there are actual or perceived FCOI that could affect an investigator's proposed, current, or future research in accordance with criteria set out in subparagraphs 11a and 11b. The FCOI may affect any aspect of the research including the design, conduct, or reporting of the research findings.

(2) Determining what conditions or restrictions, if any, need to be imposed to manage, reduce, or eliminate the conflicts (see par. 12).

(3) Reviewing any updates to the financial disclosure forms submitted by investigators and making a determination regarding the need to modify requirements for management of the FCOI.

(4) Reviewing individual protocols or summaries of protocols and the investigator's plan to manage the financial conflict of interest when appropriate.

(5) Reporting findings and identifying steps to manage the FCOI to the appropriate institutional official, the IRB, the IACUC, and/or the R&D Committee, and to the investigator.

NOTE: Significant conflicts of interest must be managed with the assistance of VA Regional Counsel.

(6) Establishing a process to allow the investigator to appeal a decision restricting the conduct of research and requiring specific steps to manage, reduce or eliminate the FCOI.

(7) Establishing criteria for evaluating an investigator's appeal. Criteria may include the nature of the research, the unique experience or qualifications required to conduct the research, the number of other investigators that may possess these qualifications, the nature and magnitude of the financial conflicts of interest, as well as any substantial effect of the research on the financial conflicts of interest, such as increasing financial gains for the investigator. In addition, the magnitude of the risk to the human research subject posed by the financial conflicts of interest must be considered.

(8) Maintaining written records of its reviews and determinations. The minutes of meetings must be sent to the medical center Director for final approval.

(9) Developing policies and procedures for its recurring processes.

c. In the event that an investigator holds significant financial interest that cannot be adequately managed, reduced, or eliminated, determine whether compelling circumstances exist that would permit the investigator to conduct the research. Criteria may include the nature of the research, the unique experience or qualification required to conduct the research, the number of other investigators that may possess these qualifications, the nature and magnitude of the FCOI, as well as any substantial effect of the research on the FCOI, such as increasing financial gains for the investigator. In addition, the magnitude of the risk to the human research subject posed by the financial conflicts of interest must be considered.

d. The FCOI Committee, or FCOI Administrator, is responsible for maintenance of records of all financial disclosures and all actions taken by the medical center with respect to each conflicting interest for the time period that the protocol records are maintained; this is a minimum of 5 years after the protocol is completed or 5 years after the investigator leaves the facility, which ever is longer *NOTE: The investigator must update VA Forms 10-1313-14 as changes occur even after a specific protocol is closed.*

8. RESPONSIBILITIES OF THE INSTITUTIONAL REVIEW BOARD (IRB)

a. The IRB is responsible for identifying, reviewing, and requiring appropriate changes in protocols affected by actual or perceived financial conflicts of interest for research involving human subjects to ensure that the rights and welfare of the subjects are adequately protected. The IRB may also determine that the research protocol should not be conducted at the institution. In making their determination, the IRB must consider the actions and recommendations of the FCOI Committee.

(1) In reviewing protocols, the IRB needs to be aware of the source of funding and funding arrangements for each protocol; and is responsible for reviewing the findings of the FCOI Committee. If necessary for review, the IRB may request to see the VA Forms 10-1313-14 submitted to the FOIC Committee. The IRB must determine if the protocol addresses any FCOI and the management of the FCOI, or if additional information is required to review the research. In addition, the IRB must review the investigator's discussion regarding FOIC and the plan to manage any actual or perceived FCOI.

(2) The IRB may consider the possible IRB actions found in the DHHS guidance document (see subpar. 14k). These include determining:

(a) Whether methods used for management of financial interest of parties involved in the research adequately protect the rights and welfare of human subjects.

(b) Whether other actions are necessary to minimize risks to subjects.

(c) The kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

(3) In initial or continuing review of protocols, the IRB must consider the impact of the financial conflicts of interest on the subject, the risk to the subject, and the subject's willingness to participate in the research after disclosure of the conflicts. The IRB also considers the impact on the research and the research results.

(4) The IRB determines if actions in addition to those required by the FOIC Committee need to be taken to manage, reduce or eliminate the financial conflicts of interest. This decision is to be recorded in the IRB records (minutes or other records).

(5) The IRB may determine that significant FCOI exist that compromise the rights and welfare of human research subjects or the outcome of the research; and it may determine that the conflicts can not be sufficiently managed, reduced, or eliminated. If this determination is made, the IRB may disapprove the research or it may require that those investigators with the conflicts be eliminated as part of the research team (see par. 12).

(6) During the continuing review for previously identified FCOI, the IRB evaluates the effectiveness of the strategies for management of the conflicts as implemented at the initiation of

the research, and, if necessary, alters the previous requirements (by adding new strategies or by modifying current strategies). **NOTE:** *If the modification involves requirements set for the by the FCOI Committee, the FCOI Committee must concur with the modification.*

NOTE: *All determinations are to be recorded in the IRB minutes or other records.*

b. Members of the IRB who have a financial conflict(s) of interest must recuse themselves from review of proposals for which the conflict exists as provided in VHA Handbook 1200.5. **NOTE:** *VHA Handbook 1200.5 requires reviewers having other types of conflict of interest to recuse themselves during review of a protocol for which they are conflicted accept to provide information to the IRB.*

c. The IRB's findings regarding the financial or other conflicts of interest are reported to the R&D Committee and both committees' findings are reported in writing to the FCOI Committee and the medical center Director. This may be done by such mechanisms as memorandums or copies of committee meeting minutes. The medical center Director may add to the stipulations or requirements identified by the FCOI Committee and the other committees but may not lessen them. In situations where financial conflicts of interest cannot be resolved, it is the medical center Director who makes the final binding decision regarding the FCOI.

9. RESPONSIBILITIES OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

a. Both the United States Department of Agriculture (USDA) Animal Welfare Act Regulations (see 9 CFR Part 2, Subpart C, Section 2.31 (d)(2)) and Public Health Service (PHS) Policy (see PHS Policy on Humane Care And Use of Laboratory Animals, IV.C.2) stipulate that no IACUC member may participate in the IACUC review or approval of a research project in which the member is personally involved in the project, except to provide information requested by the IACUC. Policy 15 of the USDA, Animal and Plant Health Inspection Service (APHIS), Animal Care Policy Manual also makes it clear that no IACUC member can review the member's own proposal. The IACUC is responsible for ensuring that the protocol review process is not compromised by conflicts of interest arising from members participating in animal research reviewed by the IACUC.

b. Current Federal animal welfare regulations do not directly address conflicts of interest arising from financial or economic positions held by IACUC members. However, such conflicts can arise if an IACUC member has a significant financial interest in an entity that could benefit from the approval and conduct of a particular animal study funded by that entity, or performed on behalf of that entity. IACUC members are not to participate in the IACUC review or approval of a research project in which the member is financially conflicted, except to provide information requested by the IACUC.

c. In reviewing protocols the IACUC must review the findings of the FOIC Committee. If necessary, the IACUC may request to see the disclosure forms submitted to the FCOI Committee. Should significant FCOI occur for investigators that have not been previously reported, the IACUC needs to report the nature of the conflicts to the R&D Committee, and the FCOI Administrator and/or FCOI Committee. The IACUC may not give final approval to the

protocol prior to reviewing the findings of the FCOI Committee. In situations in which a financial conflict of interest cannot be resolved, it is the medical center Director who makes the final binding decision regarding the financial conflicts of interest.

d. The IACUC may determine that significant FCOI exists that can not be sufficiently managed, reduced, or eliminated. If this determination is made, the IACUC may disapprove the research or it may require that those investigators with the conflicts be eliminated as part of the research team (see par. 12).

e. In its continuing review of protocols, the IACUC considers any changes in the conflicts of interest (new, resolved or changed conflicts), and the impact of these changes on the research and the research results.

f. During the continuing review, for previously identified FCOI, the IACUC evaluates the effectiveness of the strategies for management of the conflicts as implemented at the initiation of the research and if necessary, alter the previous requirements (adding new strategies or modifying current strategies). *NOTE: If the modification involves requirements set forth by the FCOI Committee, the FCOI Committee must concur with the modifications.*

g. The IACUC may consider the actions and recommendations of the FCOI Committee that have taken place since the initial review in making its determination. If the FCOI Committee is not aware of the changes in the FCOI, the IACUC must request that the investigator submit the information to the FCOI Committee. The IACUC Committee may not complete the annual review of the research until it reviews the findings of the FCOI Committee.

h. Decisions regarding financial conflict of interests should be recorded in the IACUC's records (minutes or other records).

10. RESPONSIBILITIES OF THE R&D COMMITTEE

a. The R&D Committee is responsible for reviewing and initially approving all research conducted at the medical center prior to its initiation. As part of its review, the R&D Committee is responsible for identifying or reviewing previously identified FCOI, and evaluating these conflicts. The R&D Committee determines what actions, in addition to those required by the FCOI Committee, or the R&D Committee's subcommittees (e.g., the IRB and IACUC), the institution or the investigator must take to manage, reduce, or eliminate the FCOI.

(1) The R&D Committee may consider the actions and recommendations of the FCOI Committee in making its determination. If necessary for the review, the R&D Committee may request to see the VA Form 10-1313-14 submitted to the FCOI Committee. The R&D Committee may not disallow any of the FCOI Committee's stipulations or required changes, but may add to them.

(2) For research involving human subjects, the R&D Committee is responsible for reviewing actions taken by the IRB. The R&D Committee may approve the IRB's actions, may add other stipulations or changes to the proposal, but may not disallow any of the IRB's stipulations or required changes to their findings regarding the FCOI.

(3) For research involving the use of animals, the R&D Committee is responsible for reviewing actions taken by the IACUC. The R&D Committee may approve the IACUC's actions, and may add other stipulations or changes to the proposal, but may not disallow any of the IACUC's stipulations or required changes to their findings regarding the financial conflicts of interest.

(4) The R&D Committee may determine that significant FCOI exists that can not be sufficiently managed, reduced, or eliminated. If this determination is made, the R&D Committee may disapprove the research or it may require that those investigators with the conflicts be eliminated as part of the research team (see par. 12).

(5) In its annual review of protocols, the R&D Committee considers any changes in the conflicts of interest (new, resolved, or changed conflict), and the impact of these changes on the research and the research results.

(6) During the annual review, for previously identified FCOI, the R&D Committee evaluates the effectiveness of the strategies for management of the conflicts as implemented at the initiation of the research and, if necessary, alters the previous requirements (adding new strategies or modifying current strategies). *NOTE: If the modification involves requirements set forth by the FCOI Committee, the IRB, or the IACUC, these committees must concur with the modifications.*

(7) The R&D Committee may consider the actions and recommendations of the FCOI Committee that have taken place since the initial review in making its determination. If the FCOI Committee is not aware of the changes in the FCOI, the R&D Committee must request that the investigator submit the information to the FCOI committee. The R&D Committee may not complete the annual review of the research until it reviews the findings of the FCOI Committee.

(8) The R&D Committee may consider the continuing review findings of the IRB and IACUC in making its decision to approve the annual review of the research or to approve the annual review with new or altered strategies to manage the FCOI.

b. Members of the R&D Committee who have a financial conflict(s) or other conflict(s) of interest must recuse themselves from review of proposals for which the conflict(s) exist except to provide information requested by the committee.

c. The R&D Committee findings are reported to the FCOI Committee and the medical center Director. The medical center Director may add to the stipulations or requirements identified by the FCOI Committee and the applicable R&D Committee's subcommittees (R&D, IRB, or IACUC), but may not lessen them. In situations in which financial conflicts of interest cannot be resolved or there is disagreement between any of the involved committees, it is the medical center Director who makes the final binding decision regarding the financial conflicts of interest and its management.

d. Decisions regarding financial conflict of interests are to be recorded in the R&D Committee's records (minutes or other records).

11. IDENTIFYING SIGNIFICANT FINANCIAL CONFLICTS OF INTEREST

a. A financial conflict or perceived conflict of interest exists when the financial interest has the perceived potential to significantly affect the design, review, conduct or reporting of the research results. **NOTE:** *A FCOI can only be ruled out by consultation with a Deputy Ethics Officer within the VA Office of General Counsel, or within the Office of General Counsel at VA Central Office.* Consistent with the PHS Regulations (42 CFR Part 50 Subpart F), and Food and Drug Administration (FDA) guidance (21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860), a significant financial conflict of interest includes, but is not limited to the following monetary interests, as qualified by the following paragraphs:

(1) Non-VA Salary or other payments for services from private or for-profit entities (e.g., consulting fees or honoraria);

(2) Compensation to the investigator if the amount of the compensation could be affected by study outcome;

(3) Equity interests (e.g., stocks, stock options, or other ownership interests); and

(4) Intellectual property rights (e.g., patents, copyrights, and royalties from such rights) that would reasonably be expected or appear to affect the proposed research. **NOTE:** *VHA Handbook 1200.1 defines and gives further guidance on issues related to intellectual property.*

(5) Consulting fees, honoraria, gifts, or other "in kind" compensation from a financially interested company for any purpose not directly related to the reasonable costs of the research that in the aggregate have in the prior calendar year exceeded \$10,000, or are expected to exceed that amount in the next 12 months.

(6) Any non-royalty payments or entitlements to payments in connection with the proposed research that are not directly related to the reasonable costs of the research. This includes any bonuses or milestone payments to the investigators in excess of reasonable costs incurred.

(7) Service as an officer, director, or in any other fiduciary role for a company with financial interests in the proposed research.

b. Significant financial conflict of interest does not include:

(1) Salary, royalties, or other remuneration from the applicant's home institution;

(2) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; and

(3) Income from service on advisory committees or review panels for public or non-profit entities.

c. Financial conflicts of interest may be more readily identified if the following points are considered:

(1) Financial relationships that could create conflicts of interest may be created by:

(a) The persons or entity supporting or financing the research,

(b) Where and who designed the study, and

(c) Where and who will analyze the resulting data.

(2) Understanding what interests are created by the financial relationships involved in the situation such as:

(a) The institution or individuals receive compensation that may be affected by the study outcome;

(b) The institution or individuals have proprietary interests in the product including patents, trademarks, copyrights, and licensing agreements;

(c) The institution or individuals have equity interest in the research sponsor whether a publicly or a non-publicly traded company; and

(d) The institution or individuals receive payment per participant or incentive payments that are not within the norm.

NOTE: See Department of Health and Human Services Draft guidance “Financial Relationships and Interests in Research Involving Human Subjects: guidance for Human Subject Protection” (68 Federal Register pages 5456-15460, dated March 31, 2002).

12. MANAGING FINANCIAL CONFLICTS OF INTEREST

a. When FCOI exist, research should not be permitted to be conducted, unless the medical center takes action to manage, reduce, or eliminate those conflicts. **NOTE:** Significant FCOI can only be managed by consultation with a Deputy Ethics Officer within the VA Office of general Counsel, or within the Office of General Counsel at VA Central Office. Such actions may include, but are not limited to the following:

(1) Public disclosure of significant financial interests;

(2) Monitoring of research by independent reviewers;

(3) Modification of the research plan and/or the informed consent documents;

(4) Disqualification from participation in all or a portion of the research;

- (5) Divestiture of significant financial interests; or
- (6) Severance of relationships that create actual or potential conflicts.

NOTE: Other actions may be identified by the institution.

b. If conflicts of interest are identified after a research protocol has been approved or initiated, the FCOI Committee in consultation with the IRB, or IACUC when appropriate, and the R&D Committee must identify the impact of the conflicts on the protocol and the research subjects, and identify the corrective actions which need to be taken to decrease the impact. Corrective actions may include but are not limited to:

- (1) Modifying the protocol and the consent process and/or form;
- (2) Re-obtaining consent from subjects or removing the investigator from a direct role in subject selection or obtaining consent;
- (3) Supervision of the protocol or consent process by independent reviewers;
- (4) Requiring that the conflicts of interest must be disclosed in all publications or presentation resulting from the research; and/or
- (5) Investigator recusal, or removal (with appropriate substitution), and
- (6) Project termination.

c. When significant FCOI exist and is not eliminated by the process described in preceding paragraphs and the research involves human subjects, the IRB may determine that the consent form must contain a discussion of the financial arrangement and how the FCOI is being managed and the additional protections that have been put in place. The inability to resolve significant conflicts of interest must be reported to the medical center Director through the appropriate committees.

13. FAILURE TO COMPLY WITH FINANCIAL CONFLICTS OF INTEREST POLICY

a. If an investigator fails to comply with the financial conflicts of interest policy or with corrective actions determined by the FCOI Committee, the IRB, and/or the R&D Committee, the FOIC Committee reports the failure to comply to the medical center Director. Any failure to comply with FCOI policy and/or corrective actions pertaining to a specific FCOI may result in other conditions or restrictions that would be consistent with applicable policies, regulations, and laws. These conditions or restrictions may include:

- (1) Termination of the research protocol;
- (2) Removal of the investigator from the research protocol team; or

(3) Revocation of the privilege to conduct research. This sanction may include a prohibition on submitting proposals to the IRB and the R&D Committee, and suspension of the investigator's privilege to conduct research within VA.

b. The investigator may also be sanctioned by the PHS, the FDA, or other applicable entities depending on the seriousness of the non-compliance and the determination of the research sponsor.

c. Violation of the Standards of Ethical Conduct for Employees of the Executive Branch may result in corrective or disciplinary actions. Violation of criminal conflict of interest statutes may result in referral to the U.S. Department of Justice. Punishment may include civil and criminal penalties.

14. REFERENCES

- a. Title 18 U.S.C. Chapter 11.
- b. Title 5 CFR Part 2635, Executive Branch Standards of Conduct.
- c. Title 38 CFR Part 16.
- d. Title 21 CFR Parts 50, 54, 56, 312, 314, 320, 330, 601,807, 812, 814, and 860.
- e. Title 9 CFR Part 2, Subpart C, Section 2.31(d)(2).
- f. Title 42 CFR Part 50 Subpart F.
- g. PHS Policy on Human Care and Use of Laboratory Animals, 1996.
- h. USDA Animal Care Policy Manual, Policy 15, April 14, 1997.
- i. VHA Handbook 1200.5.
- j. VHA Handbook 1200.18.
- k. DHHS Guidance "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" (69 Federal Register, pages 26393-26397, dated May 12, 2004).



THIS COMPLETED FORM MAY ONLY BE REVIEWED BY PERSONNEL ON AN "AS NEEDED" BASIS WHEN REQUIRED BY THE RESPONSIBILITIES OF THEIR POSITION.

ALL INFORMATION CONTAINED IN THIS FORM MUST REMAIN CONFIDENTIAL AND MUST HAVE ONLY LIMITED DISTRIBUTION.

This form or a similar document that requests exactly the same information, must be completed, signed and submitted by each principal investigator, co-principal investigator, investigator and collaborator who plans to devote 5 percent or more effort to the proposed project. 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 and be reviewed. See VHA Handbook 1200.13 for further information.

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).

NAME Last, First, Middle

[Empty text box for name]

TITLE OF RESEARCH PROPOSAL

[Empty text box for title of research proposal]

ROLE (check one)

Principal Investigator

Co-Principal Investigator

Investigator

Collaborator

PERCENT EFFORT ON RESEARCH PROTOCOL

[Empty text box for percent effort]

NOTE: If more space is needed to provide information for the questions below, use space provided on page 4.

SECTION I - SALARY OR COMPENSATION

Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner receive salary or other compensation (to include consulting fees, honoraria, gifts, and/or in kind compensation, other than regular VA salary/compensation) that in aggregate has in the prior year exceeded \$10,000 and/or is expected to exceed \$10,000 in the next 12 months?

Yes

No

If Yes, explain source, value, and reason for compensation:

[Large empty text box for explanation of compensation]

FINANCIAL CONFLICT OF INTEREST STATEMENT

(continued)

SECTION II - PATENTS

Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner own any patents that are related to the research project proposal? **Yes** **No**

If Yes, please provide additional information below.

PATENT NUMBER	<input type="text"/>	DATE OF PATENT	<input type="text"/>
---------------	----------------------	----------------	----------------------

TITLE OF PATENT	<input type="text"/>
-----------------	----------------------

Have any active or pending license agreements been issued? **Yes** **No**
(If Yes, attach a copy of each license).

If Yes, describe the period covered by each license and the projected royalty by year.

<input type="text"/>

SECTION III - COPYRIGHTS

Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner hold any copyrights that are related to the research project proposal? **Yes** **No**

If Yes, please provide additional information below.

<input type="text"/>

SECTION IV - ROYALTIES

Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner receive any royalties that are related to the research project proposal? **Yes** **No**

If Yes, please provide additional information below.

<input type="text"/>

FINANCIAL CONFLICT OF INTEREST STATEMENT

(continued)

SECTION V - PROVISIONAL PATENTS

Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner receive any royalties that are related to the research project proposal? **Yes** **No**

If Yes, please provide additional information below.

PATENT APPLICATION NUMBER	<input type="text"/>	DATE FILED	<input type="text"/>
---------------------------	----------------------	------------	----------------------

TITLE OF PROVISIONAL PATENT	<input type="text"/>
-----------------------------	----------------------

Have any active or pending license agreements been issued? **Yes** **No**

If Yes, attach a copy of each license.

If Yes, describe the period covered by each license and the projected royalty by year.

<input type="text"/>

SECTION VI - STOCK IN NON-PUBLICLY-TRADED COMPANY

Do you or your spouse, minor child, general partner, or an 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 may or may not own a patent that is related to the research project proposal?

Yes **No**

If Yes, what is the value of the stock/stock options?

Does this value represent more than a 5% ownership of the company? **Yes** **No**

SECTION VII - STOCK IN PUBLICLY-TRADED COMPANY

Do you or your spouse, minor child, general partner, or an 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 publicly-traded company that may or may not own a patent that is related to the research project proposal and is valued at more than \$10,000 (or value is projected to exceed \$10,000 in the next 12 months)?

Yes **No**

If Yes, what is the value of the stock/stock options?

Does this value represent more than a 5% ownership of the company? **Yes** **No**

FINANCIAL CONFLICT OF INTEREST STATEMENT

(continued)

SECTION VIII - VA DUTIES RELATED TO RESEARCH

Describe any of your VA duties that involve management of research projects or contracts other than those on which you are a principal investigator, co-principal investigator or investigator. This includes oversight, approval, advising, recommending, or initiating actions on research related projects.

[Empty box for describing VA duties related to research]

Use this space to add additional information from previous sections. Identify Section.

[Empty box for additional information]

FINANCIAL CONFLICT OF INTEREST STATEMENT

(continued)

CERTIFICATION

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).

(Signature of Investigator)

(Date Signed)

This Certification or a similar one should be submitted with research protocols when they are submitted to a protocol review committee (e.g., IRB, IACUC and R&D Committee). If the protocol is undergoing continuing review, and there has been a change in the information submitted on the Financial Conflict of Interest Statement, an updated Statement must be submitted to the FCOI Committee and a new Certification submitted to the applicable review committees at the time of continuing or annual review.

Certification of Review

by Financial Conflict of Interest Administrator or Committee

Name of Investigator
or Collaborator:

Name of Protocol:

This Financial Conflict of Interest Statement and applicable protocol have been reviewed for compliance with applicable policies and regulations, and for a determination of the existence of a financial conflict of interest.

A financial conflict of interest: [] has [] has not been identified for this investigator on this research protocol. If a financial conflict of interest has been identified, the following actions are recommended:

(Signature of Conflict of Interest Administrator or Committee Chair) (Date)

FINANCIAL CONFLICT OF INTEREST STATEMENT

(continued)

SECTION V - PROVISIONAL PATENTS

Do you or your spouse, minor child, general partner, or an organization in which you are an officer, director, trustee or general partner receive any royalties that are related to the research project proposal? **Yes** **No**

If Yes, please provide additional information below.

PATENT APPLICATION
NUMBER

DATE FILED

TITLE OF PROVISIONAL PATENT

Have any active or pending license agreements been issued? **Yes** **No**

If Yes, attach a copy of each license.

If Yes, describe the period covered by each license and the projected royalty by year.

SECTION VI - STOCK IN NON-PUBLICLY-TRADED COMPANY

Do you or your spouse, minor child, general partner, or an 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 may or may not own a patent that is related to the research project proposal? **Yes** **No**

If Yes, what is the value of the stock/stock options?

Does this value represent more than a 5% ownership of the company? **Yes** **No**

SECTION VII - STOCK IN PUBLICLY-TRADED COMPANY

Do you or your spouse, minor child, general partner, or an 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 publicly-traded company that may or may not own a patent that is related to the research project proposal and is valued at more than \$10,000 (or value is projected to exceed \$10,000 in the next 12 months)? **Yes** **No**

If Yes, what is the value of the stock/stock options?

Does this value represent more than a 5% ownership of the company? **Yes** **No**

FINANCIAL CONFLICT OF INTEREST STATEMENT

(continued)

SECTION VIII - VA DUTIES RELATED TO RESEARCH

Describe any of your VA duties that involve management of research projects or contracts other than those on which you are a principal investigator, co-principal investigator or investigator. This includes oversight, approval, advising, recommending, or initiating actions on research related projects.

[Empty box for describing VA duties related to research]

Use this space to add additional information from previous sections. Identify Section.

[Empty box for additional information]

FINANCIAL CONFLICT OF INTEREST STATEMENT

(continued)

CERTIFICATION

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).

(Signature of Investigator)

(Date Signed)

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Name of Investigator
or Collaborator:

Name of Protocol:

This Financial Conflict of Interest Statement and applicable protocol have been reviewed for compliance with applicable policies and regulations, and for a determination of the existence of a financial conflict of interest.

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(Signature of Conflict of Interest Administrator or Committee Chair) (Date)