

VA Nebraska Western Iowa Health Care System
Omaha, NE 68105

Memorandum No. 151- 11
July 2008

CONFLICT INTERESTS OF INVESTIGATORS IN RESEARCH

1. PURPOSE: To establish policy and procedures regarding Conflict of Interest (COI) in research which will enable investigators (i.e., principal investigators, co-principal investigators, investigators, and collaborators with five percent [5%] or more effort) and immediate family members of investigators to comply with applicable VA and other federal and state regulations regarding conflicts of interest in research.

2. DEFINITIONS:

a. A conflict of interest is defined as any financial arrangement, situation, or action that exerts, or is perceived to exert, inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Investigators (i.e., principal investigators, co-principal investigators, investigators, and collaborators with five percent [5%] or more effort) and/or their immediate family members are **automatically** considered to have a *conflicting interest* when they or their spouse or dependent children have:

- (1) Involvement in the design, conduct or reporting of the research.
- (2) Ownership interest, stock options, or other financial interest related to the research unless it meets four tests:
 - (a) Less than \$10,000 when aggregated for you and your immediate family.
 - (b) Publicly traded on a stock exchange.
 - (c) Value will not be affected by the outcome of the research.
 - (d) Less than 5% interest in any one single entity when aggregated for you, your spouse and dependent children.
- (3) Compensation related to the research unless it meets two tests:
 - (a) Less than \$10,000 in the past year when aggregated for you, your spouse and dependent children.
 - (b) Amount will not be affected by the outcome of the research.
- (4) Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
- (5) Board or executive relationship related to the research, regardless of compensation.
- (6) Any other reason for which the member or consultant believes that he or she cannot provide an independent review.

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;

(3) Income from service on advisory committees or review panels for public or nonprofit entities;

(4) An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets all three of the following tests:

(a) any amount less than \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value,

(b) does not represent more than 5% of ownership interest in any single entity; and

(c) will not be affected by the outcome of the research; or

(5) Salary, royalties, or other payments that when aggregated for the investigator, spouse, and dependents over twelve (12) months, meets both of the following tests:

(a) is less than \$10,000; and

(b) will not be affected by the outcome of the research;

3. **SCOPE:** Investigators must comply with all laws, regulations, and policies of applicable Federal Agencies, including VA, and any applicable state regulations pertaining to conflict of interest in research. All research proposals submitted to the VA Nebraska Western Iowa Health Care System (NWIHCS) for review must contain a Conflict of Interest Statement (Appendix S) identifying conflicts of interest. This requirement applies to all research activities conducted completely or partially in VA facilities, conducted in approved off-site locations and/or facilities, and/or conducted by VA investigators while on official VA duty time, whether funded by VA or by other sources, or unfunded.

4. **RESPONSIBILITIES:**

a. **Medical Center Director:**

(1) The Medical Center Director is the Institutional Official responsible for the Research and Development (R&D) program, including resolution of issues related to COI in research.

(2) The Medical Center Director has designated the Associate Chief of Staff for Research & Development (ACOS/R&D) to serve as the COI Administrator and oversee the day-to-day activities related to the COI in the research program.

b. **Conflict of Interest Administrator:**

(1) The Associate Chief of Staff for Research & Development (ACOS/R&D) is the designated Conflict of Interest Administrator. The COI Administrator is responsible for reviewing financial disclosure statements from each investigator who is planning to participate in the NWIHCS research program. The COI reviews the financial disclosure statements submitted by the PI with the initial protocol submission and/or continuing review submission when need exists and shares his/her findings with the appropriate subcommittee which is then made

available to the R&D Committee. When the financial disclosure involves the COI Administrator, the Deputy ACOS/Designee will act as the COI Administrator.

(2) For research that is carried out through collaboration, the ACOS/R&D will ensure that all investigators comply with the provisions of VHA Handbook 1200.13 and all other policies, procedures, and regulations related to COI.

c. The appropriate subcommittee must evaluate the COI Administrator's recommendations and the submitted COI statement (disclosure of information) to determine whether any conflict of interest might adversely affect subject welfare and the integrity of the research. If so, the subcommittee must take steps to ensure that steps are taken to manage, reduce or eliminate potential or real conflicts of interest have been taken.

d. R&D Committee: The R&D Committee will review the actions taken by the appropriate subcommittee. They may approve the appropriate subcommittees' actions, and may add stipulations or changes to the proposal, but the R&D Committee may not disallow any of the subcommittee's stipulations or required changes regarding the COI.. The Committee will determine what actions should be taken by the institution or the investigator to manage, reduce, or eliminate COI.

e. Investigator: The investigator is responsible for disclosing any COI. This disclosure must be documented through the use of the COI Statement. If a COI develops after approval of the protocol, the conflict must be immediately reported. Conflicts of interest involving the investigator's spouse or dependent children that would reasonably appear to affect the research also must be reported. Investigators should consider the potential effect that a financial relationship of any kind might have on a clinical trial, including interactions with research subjects.

5. PROCEDURES: Conflicts of Interest will be evaluated and managed as follows:

a. Compliance with NWHCS policies related to COI will be assessed through periodic audits conducted by the institution.

b. The COI policy requires disclosure of any potential COI to appropriate officials or committees.

c. Investigators must submit the Conflict of Interest Statement as a component of the research application.

d. The COI Administrator will review the financial disclosure statement and determine if there will be a negative impact on the research.

e. Following review of the Conflict of Interest Statement, the COI Administrator will transmit to the appropriate subcommittee whether or not a COI appears to exist. If a declared financial interest is identified, the COI Administrator will (1) notify the appropriate subcommittee that the application must be tabled until an appropriate management plan has been incorporated into the protocol, and (2) notify the R&D Committee.)

Committee. Regional Counsel is alerted of significant conflicts and is involved in the development of a management plan.

f. When reviewing the protocol, the IRB must consider any matter that raises the possibility of coercion or undue influence in the consent process. If a COI is identified, the subcommittee will assess the necessary actions to minimize risks to subjects.

g. The appropriate subcommittee and R&D Committee may initiate remedies to manage or eliminate conflict of interest including, but not limited to: (a) modify the protocol, (b) change the consent to reflect the COI, (c) disclose significant financial interests; and/or (d) monitor the research by independent reviewers.

h. When a significant COI exists and is not remedied by the process described above, a non-biased third party may be authorized to obtain informed consent if a potential or actual COI could influence the tone, presentation, or type of information discussed during the consent process. Independent monitoring may be necessary in this instance.

6. REFERENCES:

- a. VHA Handbook 1200.1
- b. Draft VHA Handbook 1200.13 - Memorandum
- c. VHA Handbook 1200.5
- d. VHA Handbook 1200.7
- e. Executive Order 12674 Í
- f. 5 CFR Part 2635 Í

7. FOLLOW-UP RESPONSIBILITY: ACOS for Research and Development

8. RESCISSION: Memorandum No. 151-11 dated April 2004

9. REVIEW DATE: Every three years



AL WASHKO

Director

Attachment: Conflict of Interest Statement