

## Appendix C

# VA Standards of Ethical Conduct and What May Constitute a Real or Potential Conflict of Interest

February 1, 2010

### 1. Basic Obligations of Public Service

Public service is a public trust. To ensure that every citizen and human subject can have complete confidence in the integrity of the Department of Veterans Affairs research protocol submission, approval, and monitoring processes, as well as in the conduct of the research, each VA investigator and their staff as well as each NF/SG VHS R&DC and sub-committee member must respect and adhere to the principle of ethical conduct as set forth in 5 CFR 2635, Standards of Ethical Conduct for Employees of the Executive Branch, and must disclose and manage any conflicts of interest.

The following principles apply to every NF/SG VHS Investigator and committee member:

- Public service is a public trust, requiring employees to place loyalty to the Constitution, the laws, and ethical principles above private gain.
- Employees shall not hold financial interests that conflict with the conscientious performance of duty.
- Employees shall not engage in financial transactions using nonpublic government information or allow the improper use of such information to further any private interest
- Employees shall not solicit or accept any gift or other item of monetary value from any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interests may be substantially affected by the performance or nonperformance of the employee's duties.
- Employees shall not use public office for private gain.
- Employees shall act impartially and not give preferential treatment to any private organization or individual.
- Employees shall protect and conserve public property and shall not use it for other than authorized activities.
- Employees shall not engage in outside employment activities, including seeking or negotiating for employment, that conflict with official government duties and responsibilities.

While all government employees must adhere to all the above principles, there are several of these principles which investigators and committee members involved in VA research can expect to receive greater scrutiny. These involve real or potential conflicts of interest, particularly financial, and the acceptance of gifts.

## 2. Financial Conflicts of Interest (FCOI)

In accordance with 5 CFR 2635, government employees are prohibited from participating personally and substantially in an official capacity in any particular matter in which, to his/her knowledge, he/she, or any person whose interests are imputed to him/her, has a financial interest, if the particular matter will have a direct and predicable effect on that interest. A particular matter will have a direct effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. An effect may be direct even though it does not occur immediately.

The financial interests of the following persons are considered to be **imputed** interests to the investigator and will serve to disqualify an investigator to the same extent as if they were the investigator's own interests:

- Employee's spouse
- Employee's minor child
- Employee's general partner in a business
- An organization in which the employee serves as officer, director, trustee, general partner, or employee
- Any person with whom the employee is negotiating or has an arrangement concerning prospective employment

The researcher should report any financial interest which may be related to the proposed research, entities supporting the research, or participants in the research. The following are considered significant financial conflicts of interest including but not limited to the following monetary interests, as qualified by the following paragraphs:

- Non-VA salary or other payments (e.g., consulting fees or honoraria)
- Equity interests (e.g., stocks, mutual funds, stock options, or other ownership interests)
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights) that would reasonably be expected or appear to affect the proposed research
- Consulting fees, honoraria, gifts, or other "in kind" compensation for any purpose not directly related to the reasonable costs of the research
- 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, including any bonuses or milestone payments to the investigators in excess of reasonable costs incurred
- Service as an officer, director, or in any other fiduciary role for a company with financial interests in the proposed research

**NOTE:** All real or potential COI should be reported to our local Conflict of Interest Administrator for his/her assessment and consultation with general counsel and others as needed. A FCOI can only be ruled out by consultation with the Regional Counsel, or within the Office of General Counsel at the VA Central Office.

Significant financial conflicts of interest do not include:

- Salary, royalties or other remuneration from the Department of Veterans Affairs or other federal salary

### **APPEARANCE OF CONFLICT OF INTEREST**

Review is recommended to rule out appearance of conflict of interest where the proposed research would potentially impact any of the following:

- (i) A person, other than a prospective employer described in § 2635.603(c), with whom the employee has or seeks a business, contractual or other financial relationship that involves other than a routine consumer transaction;  
NOTE: An employee who is seeking employment within the meaning of § 2635.603 shall comply with subpart F of this part rather than with this section.
- (ii) A person who is a member of the employee's household, or who is a relative with whom the employee has a close personal relationship;
- (iii) A person for whom the employee's spouse, parent or dependent child is, to the employee's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee;
- (iv) Any person for whom the employee has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; or
- (v) An organization, other than a political party described in 26 U.S.C. 527(e), in which the employee is an active participant. Participation is active if, for example, it involves service as an official of the organization or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, or participation in directing the activities of the organization. In other cases, significant time devoted to promoting specific programs of the organization, including coordination of fundraising efforts, is an indication of active participation. Payment of dues or the donation or solicitation of financial support does not, in itself, constitute active participation.

Where a committee member knows that a particular matter involving a protocol to be reviewed by the committee on which they serve is likely to have a direct and predictable effect on the financial interests of any of his/her imputed interests or where the committee member determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his/her impartiality in the matter, the committee member must immediately recuse himself/herself from the review of that particular protocol or matter. This includes leaving a fully convened meeting during the vote on the protocol or particular matter and only returning after the vote is complete. If a member is assigned a protocol for review, he/she must immediately return it to the committee Chair if a real or the appearance of conflict of interest exists. If it is necessary for the committee to obtain preliminary information pending resolution of the potential conflict of interest, the committee Chair may ask the member to remain to answer any questions. Once all questions have been answered, the member must leave the meeting.

Where an investigator or member of his research team knows that the protocol on which they are working, would cause a reasonable person with knowledge of the relevant facts to question

his/her impartiality in the matter, they must disclose this to the COI Administrator and the Research Office.

### 3. Acceptance of Gifts

With a few exceptions, an investigator or a NF/SG VHS R&DC or sub-committee member, shall not, directly or indirectly, solicit or accept a gift from a **prohibited source** or which is given because of the employee's official position or function.

A **prohibited source** is any person who meets one or more of the following criteria:

- Is seeking official action by the employee's agency
- Does business or seeks to do business with the employee's agency
- Conducts activities regulated by the employee's agency
- Has interests that may be substantially affected by performance or nonperformance of the employee's official duties
- Is an organization, the majority of whose members are engaged in or have interests in the activities described in the above bullets

In general, a government employee may not:

- Accept a gift in return for being influenced in the performance of an official act or for reviewing a particular protocol
- Solicit or coerce the offering of a gift
- Accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee had a conflict of interest
- Receive any salary or any contribution to or supplementation of salary from any source other than the United States as compensation for services as a government employee
- Accept vendor promotional training contrary to applicable regulations, policies, or guidance relating to the procurement of supplies and services for the government.

A gift is any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. It includes services as well as gifts of training, transportation, local travel, lodgings and meals, whether provided in-kind, by purchase of a ticket, payment in advance, or reimbursement after the expense has been incurred. It **does not** include the following:

- Modest items of food and refreshments, such as soft drinks, coffee, and donuts, offered other than as part of a meal
- Greeting cards and items with little intrinsic value, such as plaques, certificates, and trophies, which are intended solely for presentation
- Loans from banks and other financial institutions on terms generally available to the

public

- Opportunities and benefits, including favorable rates and commercial discounts, available to the public or to a class consisting of all federal government employees, whether or not restricted on the basis of geographic considerations
- Rewards and prizes given to competitors in contests or events, including random drawings, open to the public unless the employee's entry into the contest or event is required as part of their official duties
- Pension and other benefits resulting from continued participation in an employee welfare and benefits plan maintained by a former employer
- Anything which is paid for by the government or secured by the government under government contract
- Anything for which market value is paid for by the employee

There are many exceptions to the prohibition on accepting gifts. Only a few of the more common ones are detailed below. **When in doubt about the acceptance of a gift, you should contact your Regional Counsel.**

- A government employee may accept unsolicited gifts having an aggregate market value of **\$20.00 or less per source per occasion** provided that the aggregate market value of the individual gifts received from any one person shall not exceed **\$50 in a calendar year**. This exception does not apply to gifts of cash or of investment interests such as stock, bonds, or certificates of deposit, which are strictly prohibited.
- A government employee may accept a gift given under circumstances which make it clear that the gift is motivated by a family or personal friendship rather than the position of the employee. Relevant factors in making such a determination include the history of the relationship and whether the family member or friend personally pays for the gift.
- A government employee may accept discounts and other similar opportunities and benefits if they are offered to all government employees or to members of a group, class, or organization to which the investigator belongs that is not related to their government employment or does not otherwise discriminate among government employees on the basis of their official position or rank.

#### **4. Other Potential Conflicts of Interest**

Two other areas that may result in a conflict of interest or the appearance of a conflict of interest that require a short mention are the **use of nonpublic information and compensation for teaching, speaking and writing.**

A government employee shall not engage in a financial transaction using nonpublic information, nor allow the improper use of nonpublic information to further his/her own private interest or that of another, whether through advice or recommendation, or by knowing unauthorized disclosure. Nonpublic information is information that the employee gains by reason of federal

employment and that he/she knows or reasonably should know has not been made available to the general public.

Finally, a government employee should not receive compensation from any source for teaching, speaking, and writing other than the government, that relates to his/her official duties. This generally means an employee may not be compensated for teaching, speaking, or writing on any matter to which the employee is presently assigned or to which the employee had been assigned during the previous one-year period or on any ongoing or announced policy, program, or operation of the employee's agency. There are many nuances to this particular prohibition, such as teaching certain courses in a regularly established curriculum of an institution of higher education. Again, if in doubt, please consult your Regional Counsel.

## **5. Disclosure of Conflicts of Interest**

Where a NF/SGVHS R&DC or sub-committee member or a researcher knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interests of any of his/her imputed interests or where the individual determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his/her impartiality in the matter, they must **disclose** to the NF/SGVHS COI Administrator that a conflict of interest exists. Committee members must not participate in the review of the particular matter.

*After reading this information, each NF/SGVHS R&DC and/or sub-committee member as well as each study team member listed on Addendum A of a specific project must complete a NF/SG VHS Conflict of Interest Attestation Form and submit it to the Research Office Compliance Core via inter-office mail, Commerce Building room E101 or place in the document submission safe in room E584-1.*

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