Department of Veterans Affairs
VA Healthcare Network
Upstate New York at Albany

Memorandum No. SL- 151-07
July 12, 2006

Institutional Conflict of Interest (COI) in Research

1. PURPOSE: To define the policy regarding objectivity in VA research and to define procedures for identifying potential financial and personal conflict of interest and addressing such instances.

2. SCOPE: This policy applies to all human subjects research conducted in a VA facility regardless of administering entity. This policy applies to all investigators and staff, study monitors, the members and the staff of the Research & Development committee, the members and staff of all research sub committees, and institutional officials.

3. POLICY: The policy of the VA is to ensure that the welfare of human subjects and the scientific objectivity and integrity in the conduct of research under VA auspices be maintained. All individuals who fall within the scope of this policy will complete a general conflict of interest statement on an annual basis. The VA has separated technology transfer functions from research administration, however, circumstances may exist in which separation of function is not sufficient to avoid the appearance of institutional conflict of interest. Procedures to identify potential conflicts of interest are defined in this policy. If conflicts are identified, there are procedures for managing, mitigating or eliminating them.

4. DEFINITIONS:

A. Institutional Conflict of Interest – An institutional conflict of interest may occur when the institution, or any of its senior management or an affiliate foundation or organization, has an external relationship or financial interest in a company or organization that itself has a financial interest in a VA investigator's research study. Examples of other institutional conflicts of interests are:

1. Pressure to protect the institution at the expense of protecting subjects
2. Pressure or desire to protect investigators or employees at the expense of protecting subjects
3. Non-disclosure of serious non-compliance to avoid potential liability
4. Institutional or community values which undermine subject protections
5. Pressure for speedy reviews
6. Financial pressures
7. Pressures from research sponsors

B. Institutional Official – Individuals in a position to make decisions with institution-wide implications. These include the Medical Center Director, Chief of Staff, Associate Chief of Staff for Research and Development, and other senior officials. No institutional official will serve as a voting member of the Institutional Review Board (IRB).

C. Financial Interest – Anything of monetary value including, but not limited to, salary; payments for services, e.g., consulting fees or honoraria; equity interests, e.g., stocks, stock options or other ownership interests; intellectual property rights, e.g., patents, copyrights and royalties from such rights; and service as an officer, director or other fiduciary role for a financially interested company.

D. Financial Disclosure – This is a complete listing of all financial and employment relationships between a Principal Investigator, his/her spouse or domestic partner, and his/her dependent children or involved institutional employee, his/her spouse or domestic partner, and his/her dependent children and (1) the sponsor of a study OR (2) a profit or not for profit entity with a potential financial interest in the outcome or conduct of the research.

E. Intellectual Property (Invention) – Intellectual property is any art, machine, manufacture, design, or composition of matter, or any variety of plant, which is or may be patentable under the patent laws of the United States.

F. Inventor – The inventor is the individual responsible for the conception or reduction to practice of a device or process.

G. Patent – A patent is an official written document securing to an inventor for a term of years the exclusive right to make, use, or sell an invention.

H. Royalty – A royalty is a compensation for an invention.

I. Significant Financial Interest – Any equity interest, royalties, compensation valued (when valued in reference to current public prices, or where applicable, using accepted valuation methods) at equal or greater than $10,000.

5. RESPONSIBILITIES:

A. Research and Development Committee – Is responsible, in addition to other duties, for reviewing, recommending resolutions and monitoring oversight of potential institutional conflicts of interest and will take actions as required to avoid, or to appropriately manage, apparent institutional COI. These actions may involve referral to appropriate advisors outside the facility or obtaining advisement from the Office of Regional Council. If used, outside advisors will be individuals who have sufficient seniority, expertise, and independence to evaluate the competing interests at stake and to make credible and effective recommendations. All outside advisors will be independent of the management of oversight for the Human Research Protection Program (HRPP) within the institution. The utilization of outside advisors will increase the transparency of the deliberations and enhance the credibility of determinations. After reviewing a significant financial interest in research, the R&D Committee will communicate its conclusions, along with any management arrangements to be imposed, to the IRB. All relevant conflicts will be disclosed to research participants in a form to be determined by the IRB. The R&D Committee also will communicate conclusions and COI management strategies to the Institutional Official and the Principal Investigator.

B. Research Compliance Officer – Is the Conflict of Interest Administrator and is responsible for managing the review process, including initial review of all Ad Hoc Disclosure Forms for determination of referral to the Research and Development Committee; serving as staff for the review process; maintaining all records and official files for the conflict of interest process.

6. PROCEDURES:

A. Assessment of Potential Conflict of Interest (COI)

1. Invention/Intellectual Property Disclosure: In the case of an invention (to include a new use or improvement of an invention) or believed invention, the inventor must

complete a VA outline for reporting and certification forms. These documents are available at the Technology Transfer Program (TTP) website at www.vard.org. The inventor's supervisor must review the outline for reporting of inventions and certification forms. The file is then submitted to the Director, Technology Transfer Program, via the Research and Development (R&D) Office, for review and approval. The Technology Transfer Program recommends one of three outcomes. The Office of General Counsel issues the final agency decision. The possible outcomes are as follows:

(a) The government maintains right, title, and interest in, and to, any invention of a government employee;
(b) The government is entitled to a royalty free license with ownership remaining with the inventor; or
(c) The government claims no interest or license; i.e., all rights remain with the inventor.

2. Cooperative Technology Administration Agreements (CTAA): Since many VA's researchers hold appointments with both VA and a university, VA recognizes that a university may also have an interest in an invention made at a VA facility, resulting in joint ownership. In response to this situation, TTP developed a Cooperative Technology Administration Agreement (CTAA). This legal agreement outlines relevant definitions, terms, and conditions for handling jointly owned intellectual property (IP) between both organizations.

3. Cooperative Research and Development Agreement (CRADA): A CRADA is an agreement between the VA facility and one or more non-Federal parties (such as an academic affiliate) under which VA medical center Directors may accept, retain, and use funds, personnel, services, facilities, equipment, or other resources from collaborating parties in order to conduct R&D in a particular project. This may include the further development of a VA-owned invention and may be entered into in cooperation with a license agreement. CRADAs are negotiated by the VA medical center and Regional Counsel attorneys. Following review and approval by the Office of General Counsel (OGC), they are returned to the medical center for execution.

4. Royalties: Royalty income to the VA will be accepted, monitored, and distributed by the Technology Transfer Program (TTP). All royalties go to VA Central Office. Centralized compilation of royalty income data is required for evaluating and reporting on the program's effectiveness and to ensure compliance with applicable laws; e.g., current Federal royalty income cap of $150,000 per year. Note: Royalties paid to employees from non-Federal sources such as universities are not subject to this ceiling.

5. Review : The R&D Committee will review protocols to assure that, when applicable, the above arrangements are in place in situations where a VA researcher has an intellectual property interest. The R&D Committee also has a responsibility to review the potential for institutional conflict of interest, including intellectual property agreements, and to evaluate whether the potential conflict is managed adequately for the protection of human participants.

B. Assumption of Conflict of Interest: If the VA facility retains a significant financial interest, or if an institutional official with direct responsibility for the HRPP holds a significant financial interest, then the R&D Committee must assess the potential conflict of interest and weigh the magnitude of any risk to human participants. When reviewing potential institutional conflict of interest, the R&D Committee will assume an inclination against the conduct of human participants research at, or under the auspices, of the institution where a COI appears to exist. However, the assumption may be overturned by the Committee when the circumstances are compelling and the Committee has approved an effective conflict management plan.

C. Decision Making: A key aspect in decision-making is to analyze when it would be appropriate and in the public interest to accept and manage a COI, rather than require that the COI be eliminated. In some cases, the benefits of conducting a proposed research activity at the institution will be potentially high, and the risks will be low. In other cases, the scientific advantages of conducting the research may be speculative and the risks may be great. To these latter instances, the conflict should be avoided by disapproving the research application.

D. Evaluation of Risk: Each case should be evaluated based upon the following:
   1. the nature of the science;
   2. the nature of the interest;
   3. how closely the interest is related to the research;
   4. the degree of risk that the research poses to human participants; and
   5. the degree to which the interest may be affected by the research.

E. Managing the institutional conflict of interest:
   1. Institutional financial conflicts of interest must be disclosed to the IRB, to research subjects (in the consent form) and in all publications.
   2. Regulations call for the IRB to be independent from institutional influence. If the IRB decides to disapprove a study, the institution may not reverse the decision.
   3. Whenever a member of the IRB feels she/he has been subject to undue influence, the episode should be reported to the Associate Chief of Staff for Research and Development (ACOS R&D). See IRB SOP for more details.
   4. Whenever there is the appearance of institutional conflict of interest, the IRB may determine that the study should be conducted elsewhere.
   5. Training programs for all research personnel, IRB, R&D members, and institutional officials.

F. Compliance with this policy will be monitored in the following ways:
   1. Internal audits and other appropriate self-evaluation strategies
   2. HRPP reporting and complaint procedures
   3. Reports from research subjects
   4. Reports from oversight agencies and accreditation surveys

7. <u>REFERENCES</u>:

Federal Register Vol. 69, No. 92, May 12, 2004 Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection
5 CFR S2640.201-2640.206
21 CFR Part 54 Revised as of April 1, 2005, Food and Drugs, Chapter I---Food and Drug

Administration, Department of Health and Human Services, Subchapter A – General, Part 4, Financial Disclosure by Clinical Investigators

VA Handbook 1200.13 December 28, 2004 Financial Conflicts of Interest in Research Handbook, rescinded on February 1, 2005.

AAHRPP Evaluation Instrument for Site Visitors, For VA Facilities and Academic Affiliates, Updated January 19, 2006

8. RESCISSIONS: None

9. FOLLOW-UP RESPONSIBILITY: ACOS R&D, X65622

10. AUTOMATIC RESCISSION DATE: July 12, 2011

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MARY-ELLEN PICHÉ, FACHE