Appendix E

Department of Veterans Affairs
VA Nebraska-Western Iowa Health Care System
Omaha, NE 68105

Memorandum No. 151-13
October 2009

Institutional Conflict of Interest (COI) in Research

1. PURPOSE: This policy describes the relationships that may produce an actual or perceived institutional conflict of interest (COI) for the research being conducted in the Nebraska-Western Iowa Health Care System (NWIHCS).

2. SCOPE: This policy applies to all human subject, animal subject and basic science research conducted in the NWIHCS. This policy applies to investigators, IRB members IACUC members and staff, R&D members, R&D staff, and institutional officials.

3. POLICY: The policy of the VA is to ensure that the welfare of human subjects, animal subjects, and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations. Although the Department of Veterans Affairs (VA) has separated technology transfer functions from research administration, circumstances may exist in which separation of function is not sufficient to avoid the appearance of institutional conflict of interest. In addition, because NWIHCS is a federal agency and its officials are federal employees, the policy of VA is to comply with all government-wide ethics rules governing outside activities and financial interests of its employees.

4. DEFINITIONS:

a. Disclosure. Disclosure is the formal written process of documenting all aspects relating to the development of potential intellectual property for the purpose of determining and assigning ownership.

b. Equity. The money value of a property or of an interest in a property in excess of claims or liens against it.

c. 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 project.

d. Institutional Officials. Individuals in a position to make decisions with institution-wide implications. These include the Medical Center Director, Chief of Staff, Associate Chief of Staff/R&D, and other senior officers.

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. Re-disclosure. Re-disclosure is the formal written process of documenting all aspects relating to any improvement of a previously disclosed invention for the purpose of issuing a new determination on the improved invention.

i. Royalty. A royalty is compensation for an invention.

j. 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

The ACOS/R&D, R&D Committee, IRB, IACUC, and VA Regional Counsel have responsibilities to review and evaluate potential institutional conflict of interest and take actions as required to avoid, or to appropriately manage, institutional COI. These actions may involve referral to appropriate advisors outside the facility, although the official ethics advise relating to conflicts of interest of NWIHCS employees must come from the VA designated ethics official. 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) and the Animal Care and Use Program within the institution.

6. PROCEDURES

6.1 Assessment of Potential Conflict of Interest (COI)

a. Invention/Intellectual Property Disclosure: In the case of an invention (to include improvement of an invention) or believed invention, the inventor must complete a VA certification page and prepare a statement for submission to the inventor's supervisor. These documents are available at the Technology Transfer Program (TTP) website http://www.research.va.gov/programs/tech_transfer. The inventor's supervisor must review the employee inventor's statement. The file is then submitted via the Research and Development (R&D) Administrative Office for review and approval by the ACOS/R&D. It is then sent to the Director, R&D Technology Transfer Section in VA Central Office. The Technology Transfer Section provides one of several outcomes three of which are mentioned below:

(1) Maintains right, title, and interest in, and to, any invention of a Government employee;

(2) Is entitled to a royalty free license with ownership remaining with the inventor; or

(3) Claims no interest or license; i.e., all rights remain with the inventor.

b. Cooperative Technology Administration Agreements (CTAA): The CTAA is developed when the intellectual property or invention is co-owned by the VA and the Academic Affiliate. The CTAAs are developed by the TTP staff, Office of General Counsel (OGC) and the Academic Affiliate.

c. 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.

d. Royalties: Royalty income to a VA facility is accepted, monitored, and distributed by the TTP. Centralized handling of royalty income allows compilation of data for evaluating and reporting on the TTP's effectiveness, and ensures compliance with applicable laws; e.g., the current Federal Royalty Income (FRI) cap of $150,000 per year per employee. *Note: Royalties paid to employees from non-Federal sources such as universities are not subject to this ceiling.*

e. Review: The ACOS/R&D, R&D Committee, IRB, IACUC and Regional Counsel have 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 and other types of research.

6.2 Management of Conflict of Interest

a. 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 or other R&D program holds a significant financial interest in the invention, then the R&D Committee must assess the potential conflict of interest and weigh the magnitude of any risk to human participants when applicable. Specifically referring to invention disclosure and inventions that are patentable, the ACOS/R&D will refer to the R&D Committee, IRB or IACUC his/her review and approval of invention disclosure documents for R&D Committee evaluation of potential institutional conflict of interest. VA legal counsel will be consulted to determine whether an institutional conflict of interest exists.

b. 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, in these latter instances, the conflict should be avoided by disapproving the research application.

c. 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.

The R&D, IRB or IACUC will consider whether a research proposal determined to have an institutional financial conflict of interest is approvable. The R&D Committee cannot approve a protocol if the IRB/IACUC determines that an institutional conflict of interest exists which does not allow the research to be approvable. VA legal counsel will be involved in all cases when there is potential institutional conflict of interest to evaluate whether an institutional conflict of interest exists and if or what actions are required to address an institutional conflict of interest.

d. Potential actions: Potential actions to be considered to better protect subjects are any (or a combination) of the following:

(1) Disclosure of the financial interest to potential human subjects;

(2) Not conducting proposed research at that institution, or halting it if it has commenced;

(3) Reducing or otherwise modifying the financial (equity or royalty) stake involved;

(4) Increasing the segregation between the decision-making regarding the financial and research activities;

(5) Requiring an independent data and safety monitoring committee or similar monitoring body;

(6) Modifying of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent, or a change in investigator; or

(7) Establishing a research monitoring process conducted by the Research Compliance Officer, so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the work and/or of the VA.

(8) Other actions are determined by VA Legal Counsel, the IRB, IACUC and the R&D Committee or other entities.

7. REFERENCES:

a. VHA Handbook 1200.5

b. VHA Handbook 1200.18

c. VHA Handbook 1200.7

d. VHA Handbook 1200.01

e. OHRP Final Guidance Document. *Financial relationships and interests in research involving human subjects: Guidance for human subject protection.* May 5, 2004.

8. RESCISSION: None

9. RECERTIFICATION: Three years from the date of this Memorandum.

10. FOLLOW-UP RESPONSIBILITY: Research and Development Committee

DEBRA J. ROMBERGER, M.D.
ACOS/R&D

Distribution: R&D Committee
IACUC
IRB
All Principal Investigators