

**Department of Veterans Affairs
Tuscaloosa VA Medical Center**

Human Research Protection Program SOP #9B

May 7, 2007

INSTITUTIONAL CONFLICT OF INTEREST

1. PURPOSE

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to ensuring that the welfare of human 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 (see VHA Handbook 1200.18) from research administration, circumstances may exist in which separation of function is not sufficient to avoid the appearance of institutional conflict of interest.

This policy describes the relationships that may produce a real or perceived institutional conflict of interest (COI) for the research being conducted at the TVAMC.

This policy establishes written procedures that ensure the identification, management, and minimization of institutional COI in human subject research.

2. RESPONSIBILITIES

TVAMC Medical Center Director is the institutional official responsible for the Research & Development Program, and as such, oversees the facility in issues related to institutional conflict of interest in research and administers the facility's program related to financial conflict of interest.

Coordinator for Research & Development (C/R&D) is responsible for:

- Developing and implementing policies and procedures for identifying, reviewing, eliminating and/or managing institutional COI in research.
- Ensuring all potentially significant financial or non-financial institutional COI have been either eliminated or minimized to uphold federal and institutional compliance and ethical standards of human research at the TVAMC.
- Making final decisions in collaboration with the Director and Chief of Staff (COS) regarding appeals of R&D Committee decisions for identifying and managing institutional COI.

The R&D Committee will be responsible for evaluating potential institutional COI 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 HRPP within the institution. The utilization of outside advisors will

increase the transparency of the deliberations and enhance the credibility of determinations.

3. DEFINITIONS

- a. **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** is the monetary value of a property or of an interest in a property in excess of claims or liens against it.
- c. **Institutional Conflict of Interest (COI)** 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** are individuals in a position to make decisions with institution-wide implications. These include the Medical Center Director, Chief of Staff, Coordinator for Research & Development, 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 \$50,000.

4. PROCEDURES

a. Assessment of Potential Conflict of Interest (COI)

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 www.vard.org.

The inventor's supervisor must review the employee inventor's statement. The file is then submitted via the Research and Development (R&D) Office for review and approval. It is then sent to the Director, R&D Technology Transfer Section in VA Central Office. The Technology Transfer Section provides one of three outcomes. They are that the Government:

- (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.

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 CTAA's are developed by the TTP staff, Office of General Counsel (OGC) and the Academic Affiliate. The TVAMC does not have a CTAA.

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 Director 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.

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 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.*

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. After reviewing a significant financial interest in research, the R&D Committee is responsible for communicating 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. Management of Conflict of Interest

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 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 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 appear to exist. However, the assumption may be overturned by the Committee when the circumstances are compelling and the R&D Committee has approved an effective conflict management plan.

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.

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 affect by the research.

The R&D committee will consider whether the institution is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved.

Potential actions

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

- Disclosure of the financial interest to potential subjects;
- Not conducting proposed research each at that institution, or halting it if it has commenced;
- Reducing or otherwise modifying the financial (equity or royalty) stake involved;
- Increasing the segregation between the decision-making regarding the financial and the research activities;
- Requiring an independent data and safety monitoring committee or similar monitoring body;
- 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

- Establishing a research monitoring process, so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the work and of the VA.

5. REFERENCES

- VHA Handbook 1200.5 paragraph 7.A(9)
- VHA Handbook 1200.18
- OHRP Final Guidance Document. *Financial relationships and interests in research involving human subjects: Guidance for human subject protection*. May 5, 2004.
- Association of American Medical Colleges. *Protecting subjects, preserving trust, promoting progress II: Principles and recommendations for oversight of an institution's financial interests in human subjects research*. October 2002.

6. ATTACHMENTS

- Financial Disclosure and Conflict of Interest Form

7. RESCISSIONS

IRB Standard Operating Procedures dated July 1, 2004.

8. REVIEW DATE

January 1, 2012

Signature on File in R&D Office

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