

Department of Veterans Affairs  
Harry S. Truman Memorial Veterans' Hospital  
800 Hospital Drive  
Columbia, Missouri

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Issued by: Research

INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH

1. **PURPOSE:** This policy describes the relationships that may produce a real or perceived institutional conflict of interest (COI) for the research being conducted at the Harry S. Truman Memorial Veterans' Hospital (HSTMVH).

2. **POLICY** The welfare of human participants 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.

3. **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. Institutional Conflict of Interest: An institutional conflict of interest may occur when the institution, any of its senior management, or an affiliate foundation or organization has an external relationship or a financial interest in a company that itself has a financial interest in a VA investigator's research project.

c. Institutional Officials: Individuals in a position to make decisions with institution-wide implications. These include the Hospital Director, Chief of Staff (COS), Associate Chief of Staff for Research and Development (ACOSR&D), and other senior officers.

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

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

f. 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.

g. 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.

h. Royalty: A royalty is 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.

4. **RESPONSIBILITY**: The R&D Committee will be responsible for evaluating potential institutional conflict of interest and will take actions as required to avoid, or 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 direct line 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 University of Missouri-Columbia Health Sciences Institutional Review Board (HS-IRB). The R&D Committee also will communicate conclusions and COI management strategies to the Institutional Official. All relevant conflicts will be disclosed to research participants in a form to be determined by the HS-IRB.

5. **PROCEDURE**:

a. Assessment of Potential Conflict of Interest

(1) Invention 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](http://www.vard.org). The inventor's supervisor must review the employee inventor's statement, and then submit the documents to the Research and Development (R&D) Office for review and approval. The disclosure documents are then sent to the R&D Technology Transfer Program in VA Central Office. The Technology Transfer Program pursues one of three outcomes for the Government as follows:

(a) Maintains right, title, and interest with regard to any invention of a Government employee,

(b) Claims a royalty-free license with ownership remaining with the inventor, or

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

(2) Cooperative Technology Administration Agreements (CTAA): A CTAA may be developed to address potential co-ownership of intellectual property or invention by the VA and the Academic Affiliate. CTAA's are developed by the TTP staff, Office of General Counsel (OGC), and the Academic Affiliate.

(3) Cooperative Research and Development Agreement (CRADA): A CRADA is an agreement between VA and one or more non-federal parties 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 research and development in the context of 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 OGC, CRADAs are returned to the medical center for execution.

(4) Royalties: Royalty income to VA is accepted, monitored, and distributed by the TTP. Centralized handling of royalty income allows compilation of data for evaluating and reporting on the program'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.

(5) Review: The Research and Development (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. Management of Conflict of Interest

(1) If the 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 appears to exist. However, the assumption may be overturned when the circumstances are compelling and the Committee has approved an effective conflict management plan.

(2) A key aspect of 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 conflict 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.

(3) Each case should be evaluated based upon the nature of the science, the nature of the interest, how closely the interest is related to the research, the degree of risk that the research poses to human participants, and the degree to which the interest may affect the research.

(4) Potential actions to be considered for improving the protection of participants may involve any or a combination of the following:

- (a) Disclosure of the financial interest to potential participants,
- (b) Denying the proposed research at that institution, or halting it if it has commenced,
- (c) Reducing or otherwise modifying the financial (equity or royalty) stake involved,

(d) Increasing the segregation of the decision-making between the financial and the research activities,

(e) Requiring an independent data and safety monitoring committee or similar monitoring body,

(f) Modification 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

(g) 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.

**6. 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 participants: 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 participants research*. October 2002.

**7. FOLLOW-UP RESPONSIBILITY:** The ACOS/R&D is responsible for the follow-up of this HPM.

**8. REVISIONS:** None.

**APPROVED:**

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Acting Director