



**Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
Chicago, IL. 60612**

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SOP: INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH

PURPOSE

The purpose of this policy is to outline relationships that may produce a real or perceived institutional conflict of interest (COI) for research conducted at Jesse Brown VA Medical Center.

POLICY

The policy of Jesse Brown VA Medical Center is to ensure 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 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.

Any Institutional COI is reported or identified by the R&D will be managed and reported to Medical Center Director at Jesse Brown VA Medical Center for review and resolution.

SCOPE

This policy applies to all human subjects' research and sponsor research conducted at Jesse Brown VA Medical Center. This policy applies to investigators, IRB members and staff, R&D Committee members and staff, and institutional officials.

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. Examples of institutional conflict of interest include but are not limited to:
 - a. The VA has an equity interest in a company or the VA holds a patent, license, or some type of intellectual property interest related to the product that is the subject of the research
 - b. A VA institutional official acting within his or her authority on behalf of the institution has equity interest, serves on an advisory or other Board, or serves in a fiduciary role in an entity that has an interest in the outcome of human subjects research
 - c. Gifts to the VA or VA institutional official from a company or other entity that has an interest in the outcome of human subjects research.
- 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 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 \$10,000.

RESPONSIBILITIES

The R&D Committee will be responsible for evaluating potential **institutional** conflict 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.

OR

If there is an **Institutional Conflict of Interest Committee**, the committee members should be individuals who have sufficient seniority, expertise, and independence to evaluate the competing interests at stake and make credible and effective recommendations. All members of the COI committee should be independent of the direct line of authority for HRPP oversight within the institution. One or more external (public) members are strongly urged as the inclusion of public members will increase the transparency of the committee's deliberations and enhance the credibility of its determinations.

PROCEDURES

A. Assessment of Potential Institutional Conflict of Interest (COI)

(i) 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.

(ii) **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 CTAs are developed by the TTP staff, Office of General Counsel (OGC) and the Academic Affiliate.

(iii) **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.

(iv) **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.*

(v) **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 above agreements will be reviewed by the ACOS/R&D and shared with the R&D Committee if there is a potential conflict. The R&D Committee 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

(i) 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/ Human Subject Research Subcommittee 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 Committee has approved an effective conflict management plan.

(ii) 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.

(iii) Evaluation of risk

Each case should be evaluated based upon the following:

- a. the nature of the science;
- b. the nature of the interest;
- c. how closely the interest is related to the research;
- d. the degree of risk that the research poses to human participants; and
- e. 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.

(iv) Potential actions

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

- a. Disclosure of the financial interest to potential subjects;
- b. Not conducting proposed research each 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 between the decision-making regarding the financial and the research activities;
- e. Requiring an independent data and safety monitoring committee or similar monitoring body;
- f. 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
- 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.

REFERENCES

1. VHA Handbook 1200.05 paragraph 7.A (9)
2. VHA Handbook 1200.18
3. OHRP Final Guidance Document. Financial relationships and interests in research involving human subjects: Guidance for human subject protection. May 5, 2004.
4. 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.

