

INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH

1. **PURPOSE:** To define the policy regarding objectivity in VA research and procedures for identifying and addressing potential institutional conflicts of interest (COI) relating to research conducted at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC).
2. **POLICY:** To identify potential institutional COI within research and to manage, mitigate or eliminate any potential conflicts that are identified.
 - a. These procedures apply to all research conducted under the auspices of the LSCDVAMC. This policy applies to investigators, R&D Committee members, IRB Committee members and staff, IACUC members and staff, R&D Office Staff, and institutional officials.
 - b. The policy of the VA 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.
 - c. Although the 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.
3. **DEFINITIONS:**
 - a. **Institutional Conflict of Interest (COI):** 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.
 - b. **Institutional officials.** These are individuals in a position to make decisions with institution-wide implications. These include the medical center Director/Institutional Official (IO), COS, ACOS/R, and other senior officers and management officials.
 - c. **Outside Advisors:** Outside advisors are 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. Using outside advisors will increase the transparency of the deliberations and enhance the credibility of determinations.

- d. **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.
- e. **Inventor**. The inventor is the individual responsible for the conception or reduction to practice of a device or process.
- e. **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.
- f. **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.
- g. **Royalty**. A royalty is compensation for an invention.
- h. **Dually-Appointed Personnel**: An individual holding both a LSCDVAMC and an academic affiliate position.

4. RESPONSIBILITIES:

- a. **Research and Development (R&D) Committee**: The R&D Committee is 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 advice from the Office of Regional Counsel. The R&D Committee is responsible for communicating its conclusions, along with management plans to the IRB and the IO.
- b. **Institutional Review Board (IRB)**: For research involving human subjects, the IRB is responsible for reviewing and requiring appropriate changes in protocols and informed consent forms affected by institutional COI.

5. PROCEDURES

- a. Assessment of Potential Conflict of Interest (COI)
- (1) Invention/Intellectual Property Disclosure
- (a) In the case of an invention (including a new use or improvement of an invention) or believed invention, the inventor must complete an "Outline for Report of Inventions and Certification Made by Employees of the Department of Veterans Affairs" and a "Certification of Reporting of Inventions." These documents are available at the Technology Transfer Program website at http://www.research.va.gov/programs/tech_transfer/default.cfm.
- (b) The inventor's supervisor must review the "Outline" and "Certification" forms.

(c) The file is then submitted to the Director, Technology Transfer Program (TTP), via the R&D Office, for review and approval. The TTP recommends one of three outcomes:

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

(d) The Office of General Counsel issues the final agency decision.

(2) Cooperative Technology Administration Agreements (CTAA)

(a) Since many VA researchers hold appointments at both VA and an academic affiliate, VA recognizes that the affiliate 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) which outlines relevant definitions, terms, and conditions for handling jointly owned intellectual property (IP) between both organizations.

(b) Case Western Reserve University and VHA have a CTAA.

(c) The Cleveland Clinic Foundation and VHA have a CTAA

(3) Cooperative Research and Development Agreement (CRADA)

(a) A CRADA is an agreement between the VA facility and one or more non-federal parties (such as an academic affiliate or external research sponsor) 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 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

(a) Royalty income to the VA will be accepted, monitored, and distributed by the TTP. All royalties go to VACO. 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.

(b) Note: Royalties paid to employees from non-federal sources such as universities are not subject to this ceiling.

(5) Review

(a) The R&D Committee will review protocols to ensure that, when applicable, the above arrangements are in place in regards to ownership, administration, and management of potential inventions involving a dual-appointed VA researcher.

(b) The R&D Committee is responsible for reviewing the potential for institutional conflict of interest, including IP agreements, and to evaluate whether the potential conflict is managed adequately for the protection of human subjects.

b. Management of Conflict of Interest

(1) Assumption of Conflict of Interest

(a) If the LSCDVAMC retains a significant financial interest, or if the IO 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 subjects.

(b) When reviewing potential institutional conflict of interest, the R&D Committee will generally not approve conducting human subjects research at, or under the auspices of, LSCDVAMC unless the circumstances are compelling and an effective conflict management plan is in place.

(2) Decision Making

(a) 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.

(b) 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 and the R&D Committee most likely would disapprove the research application.

(3) Evaluation of Risk

(a) Each case should be evaluated based upon the following:

- 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 subjects; and
- The degree to which the interest may be affected by the research.

(b) 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.

(4) Potential actions

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

- Disclosing the financial interest to potential subjects;
- Not conducting proposed research at the LSCDVAMC;
- Halting research that has commenced;
- Reducing or otherwise modifying the financial (equity or royalty) stake involved;
- Increasing the segregation between the decision-making processes for financial and research activities;
- Requiring an independent data and safety monitoring committee or similar monitoring body;
- Modifying the role(s) of particular study staff, e.g., a change of the person who seeks consent, or a change in investigator, or changing location for certain research activities; and/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.

6. **REFERENCES:** VHA Handbooks 1200.1 Research and Development Committee, 1200.5 Requirements for the Protection of Human Subjects in Research, LSCDVAMC Human Research Protection Program Standard Operating Procedures.

7. **RESCISSION:** Review date for this policy is September 1, 2010.

8. **FOLLOW UP RESPONSIBILITY:** ACOS/R.

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