

May 19, 2008

MANAGING INSTITUTIONAL CONFLICT OF INTEREST

1. **PURPOSE:** To outline the Research and Development (R&D) Office procedure for dealing with a real or perceived institutional conflict of interest (COI) for the research being conducted at the South Texas Veterans Health Care System (STVHCS). For individual investigator financial conflict of interest refer to Research Service Memorandum 22, titled Managing Conflict of Interest.

2. **POLICY:**

a. 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.

b. A conflict of interest occurs when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Concerns are based on the potential effects the conflicts may have on the real or perceived quality of the research and the treatment of research participants. The perception that a conflict of interest exists may not affect the actual development, management and evaluation of the study, but may negatively impact on the perceived validity of the study and the credibility of both the investigator and the institution.

3. **ACTION:**

a. Assessment of Potential Institutional 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.research.va.gov/programs/tech_transfer/. The inventor's supervisor must review the employee inventor's statement, and then submit the documents to the 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

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developed to address potential co-ownership of intellectual property or invention by the VA and the Academic Affiliate. CTAs 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. CRADA templates are approved at the national level. Minor changes (e.g. wordsmithing) to the CRADA templates are negotiated by the Collaborator, investigator, and regional counsel attorneys and do not require TTP review. Significant changes to the CRADA template are forwarded to TTP for review and approval. TTP will coordinate with OGC for legal review of the significant changes. Following review and recommendations by OGC, TTP will return the proposed CRADA with significant changes, indicating approval, disapproval or recommended changes, and suggesting next steps. Once approved, 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) Tracking: The R&D Office will maintain a tracking log of invention disclosures, patents, and royalties received from TTP. Protocols which may be affected by income received from TTP will be flagged for discussion by the R&D Committee regarding potential institutional COI.

(6) 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. The R&D Committee will obtain input from the VA Regional Counsel if a significant institutional conflict of interest is identified.

b. Management of Institutional 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, with the assistance of Regional Counsel, 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.

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(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) Monitoring of research by independent reviewers

(c) Modification of role(s) of particular research staff (e.g., a change of the person who seeks consent, or a change in investigator)

(d) Disqualification from participation in all or portion(s) of the research

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

(f) Denying the proposed research at the institution, or halting it if it has commenced

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

(5) 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 Counsel. 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.

(6) After reviewing a significant institutional COI in research, the R&D Committee will:

(a) Communicate its conclusions, along with any management arrangements to be imposed, to the University of Texas Health Sciences at San Antonio Institutional Review Board (UTHSCSA IRB). If appropriate, all relevant conflicts will be disclosed to research participants in a form to be determined by the UTHSCSA IRB and the STVHCS R&D

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Committee and

(b) Communicate conclusions and institutional COI management strategies to the Institutional Official.

4. REFERENCES: VHA Handbook 1200.18; VHA Standard Operating Procedures for Phase I, II, III, and IV Clinical Trial Cooperative Research and Development Agreements

5. RESPONSIBILITY: Associate Chief of Staff for Research and Development (151)

6. RESCSSION: None

7. RECERTIFICATION: May 2011

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RICHARD J. BALTZ, FACHE
Director

DISTRIBUTION: A