

Version Number: 2	Research & Development Policy 151-05	Supersedes Document Dated: 1/31/2010
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1 POLICY

It is Syracuse VA Medical Center's policy to comply with all applicable federal, state, and local regulations, and ICH guidelines in the conduct of human subject research studies. Conflicts of interest have increased as the relationships of investigators with private corporations, pharmaceutical companies, and outside institutions have become more complex. Written procedures are required for the management of conflict of interest in research.

All VA employees, VA investigators and R&D Committee and subcommittee members, and consultants must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal criminal code. The obligation to follow applicable ethics laws and regulations also applies to WOC employees and IPAs conducting VA research or participating as a committee or subcommittee member or a consultant. R&D Committee and subcommittee members, consultants and VA investigators must comply with VA policies on financial conflicts of interest in research.

R&D Committee and subcommittee members and consultants with outside consulting, employment, or royalty payment opportunities must ensure that these activities do not present any actual or perceived financial conflict of interest, and must recuse themselves from the review of proposals for which any conflict of interest may exist.

2 PURPOSE

This policy describes the processes for identifying, managing, and minimizing actual or potential conflicts of interest related to investigators and research staff conducting research, members of the Research and Development Committee (R&D), its subcommittees and consultants within the Syracuse Veterans Affairs Medical Center (SVAMC) and its entities. This policy also applies to actual or potential conflicts of interest of the SVAMC and its entities as an Institution.

- 3 SCOPE:** This policy applies to all research personnel conducting human subject research approved by the Syracuse VAMC R&D and IRB committees, members of the Research and Development Committee (R&D) and its Subcommittees, including the Institutional Review Board (IRB), consultants to the R&D Committee or its subcommittees, the Syracuse VAMC Research administrative staff, the Institutional Official and the Institution itself.

4 DEFINITIONS –Refer to R&D SOP 151-01 Appendix B

5 FORMS

Conflict of Interest Disclosure Form

Potential Conflict of Interest Assessment Form for R&D Committee
Members, IRB Members & Consultants

6 PROCEDURE

All initial human subject research proposals submitted to the Syracuse VA must contain a Syracuse VA Medical Center “Conflict of Interest Disclosure Form” for each member of the research team.

If the form(s) is missing or information is incomplete, the IRB staff will contact the Principal Investigator to submit the form(s) or the missing information. Final approval for the research will not be issued until the document is completely reviewed and approved by all appropriate signatory officials.

The ACOS/R conducts a preliminary review of the disclosure statement(s). If satisfied, the ACOS/R approves the disclosure statement(s).

The ACOS/R contacts the research team member if there are questions concerning the information in the disclosure.

The Compliance & Business Integrity Officer (CBI), appointed by the Medical Center Director, reviews the Conflict of Interest Disclosure Form from each member of the research team *if a conflict is identified*, and with consultation from the Network Compliance Officer will:

determine whether there is an actual or potential conflict of interest that could impact an investigator’s proposed or current research. The conflict may affect the design, conduct, or reporting of the research. The determination should evaluate:

risks to subjects

anticipated benefits, if any, to subjects

the scientific or scholarly integrity of the research

the selection of subjects

the possibility of coercion or undue influence during the consent process

the information provided to the participant

provisions for monitoring the data collected to provide for the safety of subjects

provisions to protect the privacy interests of subjects and to maintain the confidentiality of identifiable data

the credibility of the human research protection program

determine, in consultation with the Office of VA Regional Counsel, what conditions or restrictions, if any, should be imposed to manage, reduce, or eliminate the conflict.

report findings and identify steps to manage the conflict of interest to the appropriate institutional official, the IRB, the R&D Committee, and the research team member.

establish, in consultation with the Office of VA regional counsel a process to allow the research team member to appeal a decision restricting the conduct of research and requiring specific steps to manage, reduce, or eliminate the conflict of interest.

establish criteria for evaluating a research team member's appeal.

Criteria may include the nature of the research, the unique experience or qualifications required to conduct the research, the number of other investigators that may possess these qualifications, the nature and magnitude of the conflict of interest, as well as any substantial effect of the research on the conflict of interest such as increasing financial gains for the investigator.

The Compliance & Business Integrity Officer will maintain records of all disclosures and all actions taken by the medical center with respect to each conflicting interest for the period that the protocol records are maintained.

The IRB is responsible for identifying, reviewing, and requiring appropriate changes in protocols affected by COI for research involving human subjects.

The IRB may determine that, based on the actions and recommendations of the CBI Officer and the research team member's COI Disclosure statement, that the research protocol should not be conducted at the institution.

The IRB should be aware of the funding arrangements and determine if the protocol addresses any COI and the management of the COI.

The IRB may determine that the Principal Investigator must disclose to the research subject financial arrangements with the research sponsor.

The disclosure to the subjects may be in discussion in the consent regarding the source of funding, the payment arrangements for the Principal investigator, the nature of the COI, how the COI is being managed, and the additional protections that have been put in place.

The additional protections may include special measures to modify the consent process, having a non-biased third party obtain the consent, and recruit subjects, or having the investigator recuse him or herself from decision making that may influence the outcome or reporting of the research results.

At the time of initial or continuing review of research, the IRB will consider the impact of the COI on the subject, the risk to the subject, the subject's willingness to participate in the research after disclosure of the conflict, and the impact on the research and the research results.

The IRB will determine if actions in addition to those required by the CBI Officer, should be taken to manage, reduce, or eliminate the COI.

The Research & Development (R&D) Committee is responsible for reviewing the actions taken by the IRB, and may approve the IRB's actions and add other stipulations or changes to the proposal, but may not disallow any of the IRB's stipulations or required changes regarding the COI.

R&D Committee and subcommittee members and consultants must recuse themselves from review of protocols for which the conflict exists.

IRB members and consultants may not participate in the review of any research in which the member has a conflict of interest, except to provide information requested by the IRB. The research will not be voted upon should quorum be lost due to the absence of the member(s) with a conflict of interest.

IRB members and consultants with a conflict of interest in the research are expected to declare the reasons for the conflict to the IRB prior to the review of research.

The conflict of interest findings of the CBI Officer, IRB, and R&D are reported to the research team member and the Medical Center Director. The Medical Center Director may add to the stipulations or requirements but may not lessen them. In situations where the COI cannot be resolved, the Medical Center Director will make the final binding decision regarding the COI.

Any member of the research team may appeal the recommendations of the CBI Officer, IRB and/or R&D Committees in accordance with VA and medical center policies and procedures.

The research team member must comply with the final decision of the Medical Center Director in managing the COI.

The medical center may take the following actions to manage, reduce, or eliminate COI:

Public disclosure of significant financial interests;
Monitoring of research by independent reviewers;
Modification of the research plan and/or the informed consent documents;
Disqualification from participation in all or a portion of the research;
Divestiture of significant financial interests; or
Severance of relationships that create actual or potential conflicts.

If a COI is identified after a research protocol has been approved or initiated, the CBI Officer, along with the IRB and R&D, will identify the impact of the conflict on the protocol and the research subjects, if applicable, and corrective actions to be taken to decrease the impact. Corrective actions may include:

Modifying the protocol and consent;
Reconsenting subjects or removing the research team member from a role in subject selection;
Supervision of the protocol by independent reviewers; and/or
Requiring that the COI must be disclosed in all publications or presentation resulting from the research.

When a significant COI exists and cannot be eliminated (as indicated in 7.12), the consent form must contain a discussion of the financial arrangement, and how the conflict of interest is being managed and the additional protections that have been put in place. The inability to resolve a significant COI will be reported to the Medical Center Director through the appropriate committees.

If a research team member fails to comply with the COI policy or with corrective actions, the CBI Officer will report the failure to comply to the Medical Center Director and this failure may result in the following conditions or restrictions:

Termination of the research protocol;
Removal of the investigator from the research team; or
Revocation of the privilege to conduct research within the VA.

The research team member may also be sanctioned by the Public Health Service, Food and Drug Administration, or other applicable entities depending on the seriousness of the non-compliance and the determination of the research sponsor.

ASSESSMENT OF INSTITUTIONAL 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 by the ACOS/R&D. 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:

- Maintains right, title, and interest in, and to, any invention of a Government employee;
- Is entitled to a royalty free license with ownership remaining with the inventor; or
- 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 an Academic Affiliate. The CTAA's are developed by the TTP staff, Office of General Counsel (OGC) and an Academic Affiliate.

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 Regional Counsel, they are returned to the VA 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 (FRI) 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.

The IRB Committee and R&D Committee will review projects 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. Projects involving a potential institutional conflict of

interest will be referred to VA Regional Council for determination whether an institutional conflict of interest exists and strategies for management. The IRB Committee cannot approve a project with an institutional conflict of interest as determined by VA Regional Council until a final management plan has been agreed upon.

8 IDENTIFICATION OF INSTITUTIONAL COI

The ACOS/R&D is responsible for maintaining awareness of the financial interests of the VA facility and reviewing research to determine whether the organization has a financial interest in the research. This awareness will be facilitated by the Compliance & Business Integrity Officer's annual review of Potential Conflict of Interest Assessment Form for R&D Committee Members & IRB Members.

9 MANAGEMENT OF INSTITUTIONAL 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 IRB Committee and R&D Committee must assess the potential conflict of interest and weigh the magnitude of any risk to human participants. Specifically referring to invention disclosure and inventions that are patentable, the ACOS/R&D will refer to the IRB Committee and R&D Committee his/her review and approval of invention disclosure documents for IRB Committee and R&D Committee evaluation of potential institutional conflict of interest.

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. VA Regional Council will be consulted for management strategies of institutional conflict of interest.

Evaluation of risk: 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 participants; and
- the degree to which the interest may be affected by the research.

The IRB Committee and 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 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/or of the VA.

10 REFERENCE DOCUMENTS

Title 21 CFR 54 Revised as of April 1, 2005, Food and Drugs, Chapter I--Food and Drug Administration, Department Of Health And Human Services, Subchapter A—General, Part 54, Financial Disclosure by Clinical Investigators

VHA Handbook 1200.5, July 31, 2008 Requirements for the Protection of Human Subjects In Research

AAHRPP Evaluation Instrument for Site Visitors, For VA Facilities and Academic Affiliates, Updated January 19, 2006

Title 42 CFR 50, Title 42--Public Health, Chapter I--Public Health Service, Department Of Health And Human Services, Part 50--Policies Of General Applicability, Subpart F--Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought.



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