

Chapter 16

Financial Conflict of Interest/Objectivity in Research

The purpose of this policy to promote objectivity in research by establishing standards that ensure a reasonable expectation that the design, conduct, or reporting of research is not biased by any conflicting financial interest of an investigator.

A conflict of interest (actual or perceived) occurs when any financial or other 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. Conflicts may be related to financial gain, reputation, promotion, or to the role of research investigator vs. health care provider, among others.

An investigator is required to disclose a conflict of interest when he or she, any of his or her family, or any associated entity possesses a significant financial interest in a research activity which involves his or her responsibilities as a member of SIBCR, VA Puget Sound Health Care System (VAPSHCS), and/or University of Washington (UW).

This policy covers not only SIBCR research sponsored by government grants (e.g., NIH), nonprofit foundations (e.g. American Diabetes Association), or private industry, but also subcontracts, subawards, or subgrants issued by SIBCR in support of an investigator's research project. Furthermore, SIBCR is subject to the requirements of 42 CFR Part 50, Subpart F and 45 CFR Part 94, which govern applicants and recipients of Public Health Service (PHS) funding.

DEFINITIONS

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority.

Investigator means the principal investigator (PI), co-investigators, and other individuals who are responsible for the design, conduct, or reporting of research. For purposes of this policy, it also extends to members of those individuals' immediate families (spouses and dependent children), and to any trust, organization, or enterprise over which an investigator, alone or together with his or her family, exercises a controlling interest. It is not intended to apply to individuals who provide primarily technical support or who are purely advisory and without direct access to the data (e.g., control over its collection or analysis), unless they are in a position to influence the study's results or have privileged information as to the outcome.

Significant financial interest means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria), compensation and reimbursements, royalties, equity interests (e.g., stocks, stock options or other ownership interests), and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

In the case of clinical trials, **any** financial interest is considered significant, regardless of amount or source.

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Where projects other than clinical trials are concerned, the “significant financial interest” does *not* include:

- Salary and other forms of non-royalty and non-equity remuneration from SIBCR, VAPSHCS, or UW;
- Reasonable compensation paid by a public or nonprofit entity in exchange for seminars, lectures, or service on advisory committees or peer review panels;
- An equity interest that when aggregated for the investigator and the investigator's spouse and dependent children does not represent more than a 5% ownership interest in any single entity;
- For research involving human subjects that is not a clinical trial, salary, royalties or other non-equity payments that, when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$5,000;
- For research not involving human subjects, salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

IDENTIFICATION OF CONFLICT OF INTEREST

SIBCR reviews potential conflict of interest through the Conflict of Interest Subcommittee, in which VA and University of Washington are also represented. This subcommittee of the Research and Development Committee reviews proposed research and makes recommendations regarding management of conflicts of interest. The Conflict of Interest Subcommittee consists of five voting members:

- A representative of the management of SIBCR;
- The Associate Chief of Staff for R&D, in his/her capacity as a non-Chairing, R&D Committee member;
- An attorney of the VA Regional Counsel's Office;
- A representative of the UW's Office of the Associate Vice Provost for Research; and
- An experienced clinical or biomedical research scientist not currently serving on the R&D Committee.

The subcommittee meets on an ad hoc basis. Its membership is reviewed and authorized on a federal fiscal year basis. The subcommittee reports to the R&D Committee in the form of minutes of the meeting. These minutes include recommendations regarding management of the real or potential conflict of interest disclosed by the PI. Persons appointed to the subcommittee are required to disclose their own potential conflicts of interest to the subcommittee and recuse themselves from reviewing and voting on any matter in which they may have an interest.

The subcommittee retains information submitted by investigators, its minutes, and all related records for a period of at least three years from the date of submission or the project's final expenditure report or close-out date, whichever is later.

SIBCR investigators are also subject to the conflict of interest policies of affiliated institutions such as VAPSHCS and UW, and are responsible for disclosing financial interest in research partners to both institutions. VA employees are furthermore subject to the criminal conflict of

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interest statutes at 18 USC Chapter 11, and the Executive Branch Standards of Conduct at 5 CFR Part 2635.

The instruments used to disclose financial conflict of interest for SIBCR include:

Request for R&D Committee Review form, submitted by the PI to the VAPSHCS R&D Committee for review of any proposed research project performed at VAPSHCS or using VA resources (including VA salary, facilities, personnel, datasets or data warehouses, and/or patients). An indication on this form that the PI or any member of the research team has a financial relationship with the study sponsor requires disclosure to and review by the Conflict of Interest Subcommittee as a condition of approval.

SIBCR Significant Financial Interest Disclosure form must be completed and signed for each study being submitted to a sponsor for which there is a conflict of interest. Information disclosed on this form and related communications will be treated as confidential.

When there is no financial interest to be disclosed, the question on the SIBCR Grant Review form should be marked accordingly and the application can be forwarded to the sponsor.

MANAGEMENT OF CONFLICT OF INTEREST

The subcommittee will consider all information obtained from SIBCR, VA and UW in deciding how best to address conflicts of interest. Options for managing conflict of interest include, but are not limited to:

- Disclosure of significant financial interests to the public, human subjects, researchers and other participants, publishers and/or conference organizers;
- Requiring additional disclosures or actions with respect to IRB or IACUC applications or materials;
- Monitoring of research by disinterested co-researchers or independent reviewers or committees;
- Disqualification from participation in activity affecting or affected by a technology transfer transaction;
- Requiring that investigator participation in the recruitment or consent of subjects be prohibited or restricted;
- Requiring that the significant financial interest be divested, restructured or placed in a blind trust;
- Modification or severance of relationships that create potential conflicts of interest;
- Changing terms of the grant agreement or CRADA relating to the research;
- Requiring non-participation in any business transactions between the parties to agreements involving the research in question.

Investigators are responsible for disclosing new or changed financial relationships with study sponsors or collaborators as they occur. The subcommittee will review these disclosures in the same manner as original disclosures.

Conditions imposed by the Conflict of Interest Subcommittee or the R&D Committee must be met by the researcher in order to receive approval to conduct the proposed research project. SIBCR will not expend funds in support of a research project until that project has been

reviewed by the Conflict of Interest Subcommittee and any conflict of interest satisfactorily managed.

In the case of research supported by a grant from a PHS awarding component, such as NIH, the Department of Health and Human Services may inspect the subcommittee's records regarding that project. For any such research project, the subcommittee will also report to PHS its findings and management of conflict of interest, and any violations of the conflict of interest policy if they are later discovered. Failure to disclose a financial interest or to meet conditions of approval, or other violation of this policy, may result in (a) disapproval of the proposed research; (b) suspension of an ongoing research project; (c) restriction of the researcher's authority to conduct other research activity; and/or (d) disciplinary action against the researcher. In the case of research supported by PHS funding, any violation of this policy will be reported to the awarding PHS agency. Violations of 18 USC Chapter 11 and 5 CFR Part 2635 may be sanctioned by civil and criminal penalties as well.