

Washington University Policy on Institutional Conflict of Interest

I. Introduction

An institutional conflict of interest (“ICOI”) may include situations in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care or other activities of the institution. ICOI’s are of particular concern when financial interests create the potential for inappropriate influence over the institution’s research activities, where the integrity of the institution’s research and the welfare of human research participants may actually be, or reasonably appear to be, compromised or injured by the conflicting financial interest. This Policy is intended to protect against harm to human research participants and to protect the integrity of research performed at or under the auspices of Washington University.

Washington University, including its officials, must balance many competing interests. University-industry relationships are important to advancing scientific frontiers and essential to enabling the commercial development of academic discoveries for the benefit of the public. In addition, the University engages in relationships with a variety of companies that may lead to financial benefit for the University in many forms, including royalty payments, other payments and equity from licensing intellectual property, sponsored educational and research agreements, and major gifts. Such relationships with commercial entities are generally part of legitimate educational, research, and business activities, and predictably will lead in some cases to conflicts of interest. The intent of this Policy is not to prohibit or discourage such relationships, but, as much as possible, to manage them so that they do not compromise, or reasonably appear to compromise, the integrity of the University’s primary missions, including the safety and integrity of its research mission. The protection of human research participants, and the protection of the integrity of the University and its research programs, must remain for the University its highest priority.

II. Definitions

- A. For purposes of this Policy, a covered “Institutional Official” includes the chancellor, executive vice chancellors, provost, vice chancellors, deans, department chairs, department heads and division chiefs at the School of Medicine, executive chair of the IRB, chairs of the conflict of interest disclosure review committees, chair of the institutional conflict of interest committee, and any other University official or volunteer so designated by the Chancellor.
- B. For purposes of this Policy, an ICOI exists whenever the financial interests of the University or the personal financial interests of an Institutional Official either affect, or reasonably appear to affect, the design, conduct, reporting, review, or oversight of research.

- C. For purposes of this Policy, “research” includes, but is not limited to, basic and applied research, clinical research, research fellowships and training programs, and research related activities in undergraduate and graduate education.
- D. For purposes of this Policy, a financial interest is “significant” when it exceeds the applicable threshold for each specific category of financial interest, as established and periodically disseminated by the ICOI Review Committee. Such thresholds shall be consistent with the provisions of all University policies and with applicable federal laws and regulations regarding institutional conflict of interest.

III. Identification of Potential Institutional Conflicts of Interest

As a general guide, an ICOI may exist and a formal review will be warranted where the University, or any of its Institutional Officials, has a significant financial or governance interest in a company that itself has a financial interest in research conducted at or under the auspices of the University.

The following significant financial and fiduciary interests of the University warrant formal review of potential ICOI with respect to research, as provided in this Policy. The University’s receipt or possession of such financial or fiduciary interests in a company does not, standing alone, warrant formal review of potential ICOI unless that company itself obtains or has a financial interest in University research.

- A. Royalties: The University has the potential to receive significant milestone payments and/or royalties from the commercialization of a product based at least in part on technology that is the subject of University research.
- B. Non-publicly traded equity: Through its technology licensing activities or investments related to such activities, the University has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a *non-publicly traded* company that is (i) the sponsor of research at the University, or (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed here.
- C. Publicly traded equity: Through technology licensing activities or investments related to such activities, the University has obtained a significant ownership interest or an entitlement to significant equity (including options and warrants), in a *publicly-traded* company that is (i) the sponsor of research at the university, or (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed here.

- D. Governance/Fiduciary roles: Through technology licensing activities or investments related to such activities, the University has obtained the right to appoint one or more directors to the governing board of any company that is (i) the sponsor of research at the University, or (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed here.
- E. Gifts from companies. The University is offered or has received significant gifts (including, but not limited to, gifts in kind, discounts, fellowships, and unrestricted educational grants) from a company or a foundation established by or closely affiliated with a company that is (i) sponsoring or offering to sponsor research at the University, (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed here; or (iii) a company known to be a business competitor of companies described in (i) or (ii) above.

The following circumstances, among others, should be evaluated in the gifting context:

1. Whether a gift is of sufficient magnitude that even when held in the general endowment, it might affect, or reasonably appear to affect, oversight of research at the University;
2. Whether a gift is held for the express or limited benefit of a school, department, institute or other unit where some or all of the research is conducted; or
3. Whether any Institutional Official who has the authority to affect or reasonably appear to affect the design, conduct, reporting, review, or oversight of the research has also been actively involved in solicitation of the gift, or in the management of the gift once received by the University.

Although the listed circumstances are potential areas of concern, the goal of this Policy is not to preclude or discourage the University from accepting philanthropy from companies that support research, or that own or control products whose underlying technologies are developed, studied or tested in research at the University, provided that such gifts do not limit or reasonably appear to limit the professional independence of faculty and staff engaged in the research or research related activities. This Policy is intended to help the University develop means of identifying and examining such circumstances, and of managing, through disclosure, separation of responsibilities, and as otherwise appropriate, any actual or reasonably apparent conflicts of interest

that may result. The solicitation and receipt of gifts should be reported to and coordinated with the Dean of the appropriate school and the Office of Alumni and Development.

The following significant financial and fiduciary interests of Institutional Officials warrant formal review of potential ICOI with respect to research.

- F. Institutional Officials: An Institutional Official with responsibility for the design, conduct, reporting, review, or oversight of research at the University also holds a significant financial or fiduciary (*e.g.*, governance or management) interest in (i) the sponsor of research at the University, (ii) the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed there; or (iii) a company known to be a business competitor of companies described in (i) or (ii) above. “Significant financial interest” is defined for the purpose of this paragraph as being consistent with the University’s implementation of its policies on individual Conflict of Interest and Conflict of Interest in Clinical Research.

IV. Administration of Institutional Conflicts of Interest Policy

Administration of institutional conflict of interest matters will be handled by the ICOI Office. To identify situations and transactions that give rise to potential ICOI, the ICOI Office will gather information annually on interests described in Section III of this Policy from Central Fiscal Unit departments or other business offices within the schools or departments, and, to the extent relevant and complete information is not available from those sources, from such other offices and individuals as may be designated by the Chancellor or the Chair of the ICOI Committee. Some of the Central Fiscal Unit departments likely to have existing databases of the greatest value to the ICOI Office include the Office of Technology Transfer, the Research Office, the Office of Alumni and Development, Sponsored Projects Accounting, etc.

At least annually, the Research Ethics and Compliance Office will provide the individual financial disclosure reports of covered Institutional Officials to the ICOI Office for review, and in the event a potential ICOI is identified, referral to the ICOI Committee.

V. Composition of the ICOI Committee

The ICOI Committee will ordinarily consist of six to nine members appointed by the Chancellor, or his designee, for staggered four-year terms. The ICOI Committee will be comprised of individuals with sufficient independence, expertise, and seniority. Ordinarily, the committee should include at least one member with no affiliation with Washington University; two senior faculty (representing both the Danforth and Medical School campuses); and the sitting chair of at least one of the Disclosure Review

Committees. Emeriti faculty shall be eligible to serve. The Chancellor shall designate a chair of the committee. A quorum will consist of one more than half of the voting committee members, at least one of whom should be either a trustee or a member with no affiliation with the University. A representative of the Office of the Executive Vice Chancellor and General Counsel shall attend meetings and serve as legal advisor to the ICOI Committee.

In relation to a specific matter before it, the ICOI Review Committee may invite a member of the University community with special expertise not otherwise available to the Committee to serve as a non-voting ad hoc member. At its discretion, the ICOI Review Committee may appoint non-voting, ex-officio members for renewable one-year terms.

VI. Review and Management of Institutional Conflict of Interest

The ICOI Review Committee shall evaluate potential ICOIs and provide its written conclusions and recommendations, if any, for ICOI management to the Dean or Officer with the relevant decision-making authority, with a copy to the Chancellor and Chairman of the Audit Committee of the Board of Trustees. Final authority for the management of ICOI rests in the Chancellor and Board of Trustees.

In discharging its responsibilities to assess and manage potential ICOIs, the ICOI Review Committee shall take as its point of departure the overarching imperatives of preserving both the reality and appearance of professional integrity in the research enterprise at Washington University, and the minimization of risk to all individuals participating as subjects in human research at Washington University.

- A. In assessing and managing potential ICOIs respecting research that **do not** involve human subjects, the ICOI Review Committee should conduct its case-by-case analysis with due regard for the following factors, among others:
 1. the nature of the science,
 2. the nature of the financial interest,
 3. the nature of the overlapping interests,
 4. how closely the financial interest is related to the research,
 5. the degree to which the financial interest may be affected by the research,
 6. the degree of risk that any overlapping and conflicting interests pose to the integrity (and reasonable appearance of integrity) of the research, and
 7. the degree to which the ICOI can be effectively managed.

- B. In assessing and managing potential ICOIs respecting research that **do** involve human research participants, the ICOI Review Committee shall begin from the default position that either the University's or the relevant Institutional Official(s)' significant financial interest(s) should be eliminated, **or** that the research should not be conducted at or under the auspices of the University.

However, the ICOI Review Committee may approve conducting the research at or under the auspices of the University if it determines that compelling circumstances warrant proceeding with the research at the University, and that an effective ICOI management plan can be implemented under the circumstances to fully protect the welfare of human research participants and the integrity of the University's research. Whether the circumstances are "compelling" and sufficiently warrant proceeding with the research under an effective ICOI management plan will depend in each case upon an analysis of all the factors identified in the preceding paragraph, among others, as well as an assessment of:

1. the degree of risk that any overlapping or conflicting interests pose to the welfare of human research participants;
2. whether the University is uniquely qualified, by virtue of distinctive resources (e.g. special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and appropriately safeguard the welfare of the human research participants involved.

If the ICOI Review Committee determines that there are compelling circumstances for allowing the research to proceed in the presence of the ICOI *without* elimination or significant reduction of the financial interest, those circumstances should be documented in the ICOI Review Committee report on the matter. Management plans for ICOI arrangements should be designed effectively to address the: (i) nature of the conflict; (ii) specific risks to human research participants; (iii) actual or perceived risk to the integrity of the research as a result of the conflict; and (iv) actual or perceived risk to the reputation of the University.

The ICOI Review Committee is authorized to develop guidelines and procedures for specific categories of ICOI that present minimal risk to the integrity of the research and no risk for human research participants, and that can be handled administratively with pre-defined management plans and documentation. Such cases will be reviewed by the ICOI Review Committee.

- C. In crafting case-specific ICOI management plans, the ICOI Review Committee may in its discretion include one or more of the following management strategies among any others it may devise:
 1. Disclosure of the ICOI in informed consent processes;
 2. Where the ICOI involves an Institutional Official, formal recusal of the conflicted official from the chain of authority over the project and possibly also from authority over salary, promotion, and space allocation decisions

affecting the investigator, as well as communication of the recusal arrangements to the official's superior and colleagues;

3. Where the ICOI involves an Institutional Official, designation of a "safe haven" (e.g. a non-conflicted senior individual) with whom the investigator can address ICOI-related concerns;
4. Use of an external IRB;
5. External monitoring of the study, particularly endpoint assessments;
6. Use of an external Data Safety Monitoring Board ("DSMB") or similar review board to evaluate the design, analytical protocols, and primary and secondary end-point assessments, and to provide ongoing evaluation of the study for safety, performance issues and the reporting of results;
7. Disclosure of the ICOI in public presentations and publications, and to all individuals, including (but not limited to) graduate students and other trainees, engaged in the design, conduct or reporting of the research;
8. Disclosure of the ICOI to other centers in a multi-center trial.
9. Disclosure to the sponsors of the research as required by the sponsor and all applicable regulations and laws.

If in the course of its responsibilities under this Policy, the ICOI Review Committee happens to identify a potentially material ICOI that is not research related and, therefore, does not fall within the scope of this Policy, the ICOI Review Committee shall refer the matter to the appropriate institutional office for review and management. Potential ICOIs that may reasonably call into question the integrity of clinical care shall be referred to the Dean of the School of Medicine or Provost, as appropriate. Potential ICOIs that may reasonably call into question the integrity of procurement decisions shall be referred to the Office of Internal Audit. Potential ICOIs that may reasonably call into question the integrity of the University's educational mission shall be referred to the Dean of the School of Medicine or to the Provost, as appropriate. Potential non-research ICOIs concerning the Deans, the Provost or the Compliance Officer shall be directed to the Chancellor.

VII. Implementation and Monitoring

Each ICOI management plan should state specifically who will be responsible for the plan's implementation and monitoring.

Additional monitoring of, and assistance with, compliance with ICOI management plans will be performed by the Office of Research Administration and the University's Compliance Office.

Violations of the requirements of this Policy by any employee shall, if not resolved, subject the employee to review and, where appropriate, corrective action and/or sanctions permitted by University policy, including (for those covered by its terms) the University Policy on Academic Freedom, Responsibility and Tenure.