



**FRED HUTCH**  
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## **Policy on Conflict of Interest and Conflict of Commitment for Scientific Staff**

**I. Purpose:** Fred Hutch Scientific Staff have a primary obligation to conduct their research according to the highest ethical standards and to focus their professional activities in ways that support the mission of Fred Hutch. As part of this obligation, Fred Hutch expects that Scientific Staff will apply their time and effort appropriately, use Fred Hutch resources responsibly, and avoid any interaction that creates, or appears to create, a Conflict of Interest or Conflict of Commitment.

The purpose of this policy is to establish standards for disclosing, reviewing, and managing certain Financial Interests and Outside Activities of Scientific Staff. Scientific Staff funded by the Public Health Service (PHS) and/or other federal agencies or entities that abide by PHS Conflict of Interest regulations are subject to additional requirements as specified in this policy.

**II. Scope:** This policy applies to all Scientific Staff, including:

- All Fred Hutch faculty, including Senior Vice Presidents/Division Directors and Deputy Directors with respect to their academic activities. (Senior Vice Presidents/Deputy Directors are subject to additional conflicts of interest policies applicable to their leadership responsibilities.)
- All other Fred Hutch Employees and Non-Employees (see definition in section XIV) involved in the design, conduct, or reporting of research, or who recruit, consent, or evaluate the responses of human research participants
- Such other individuals as the Fred Hutch President and Director may designate in writing

**III. What to Disclose:** All Scientific Staff members are required to disclose to Fred Hutch and, as appropriate, obtain Prior Approval for their Outside Activities and Financial Interests (and those of their Family Members) that are or reasonably appear to be related to their Institutional Responsibilities. Examples of such Outside Activities and Financial Interests include, but are not limited to:

- **Executive Roles.** Any compensated or uncompensated leadership position (such as director, trustee or officer) in any for-profit or non-profit entity.
- **Ownership Interests.** All ownership interests (e.g., stock, options, warrants, partnership interests), regardless of value, in any entity, publicly-traded or privately-held. *This excludes ownership or equity interests through personal retirement accounts, mutual*

*funds, or other diversified investment vehicles provided that the Scientific Staff member (or his/her Family Member) does not control investment decisions.*

- **Intellectual Property payments.** Payments or the right to receive payments relating to intellectual property that is the subject of an agreement (e.g., license, option, assignment, industry sponsored research) with an outside entity, including those associated with patents, licenses, or copyrights.
- **Income.** Any direct or indirect remuneration for services, such as consulting fees, advisory board compensation, honoraria, expert witness fees, speaking fees, and paid authorship from any entity. *This excludes salary or remuneration paid by/through Fred Hutch or the Fred Hutch/University of Washington Cancer Consortium partners (University of Washington, Seattle Children’s Hospital, Seattle Cancer Care Alliance); payment for seminars, lectures or teaching engagements sponsored by, or from service on advisory committees or review panels for US federal, state, or local governmental agencies; US institutions of higher education; US academic teaching hospitals; US medical centers; or US research institutes affiliated with US institutions of higher education.*
- **Reimbursements.** Any direct or indirect reimbursements or coverage of costs by outside entities, such as travel-related expenses (i.e., transportation, lodging, etc.), associated with Outside Activities.
- **Foreign Support.** Any of the following types of support that are not already covered by the categories above, provided **to or by** a Scientific Staff member (not through an agreement with Fred Hutch) **from or to** (i) any foreign (non-US) government, (ii) any organization owned, controlled or financed in whole or in part by a foreign government, (iii) foreign entity or person, or (iv) any foreign institution of higher education and/or research institute or medical center affiliated with a foreign institution of higher education:
  - Grants, awards, or other research funding;
  - Laboratory supplies, equipment, or space;
  - Research support, including staff, materials, data, data analysis, intellectual property, know-how, and the production of scholarly writings, papers, and manuscripts;
  - Faculty appointment (even if ‘honorary’);
  - Personal gifts or support (i.e., housing, cars, etc.); and
  - Travel support or reimbursement.

Any of the foregoing types of support that are provided indirectly to a Scientific Staff member, such as through an entity controlled by the Scientific Staff member, also constitute Foreign Support.

**IV. When to Disclose:** Scientific Staff members are required to disclose to Fred Hutch their Outside Activities and Financial Interests (and those of his/her Family Member) that are or

reasonably appear to be related to their Institutional Responsibilities at the following times:

- Upon initial hire, appointment or grant of Affiliate or Non-Employee status;
- At least annually, even if attesting to no change from previous disclosures;
- Upon submission of an application for funding;
- Upon engagement in research regulated by the US Food and Drug Administration, if required by law; and
- Whenever there is an obligation under this policy to disclose an Outside Activity or Financial Interest.

Scientific Staff members with appointments at affiliated institutions, such as the University of Washington or Seattle Children's Hospital, may be required to file disclosure forms at each institution and may be subject to more than one conflict of interest policy.

Additionally, Scientific Staff members must request Prior Approval for Outside Activities, as defined in this policy. If Prior Approval is not sought, then as soon as the oversight is realized, approval must be requested in accordance with the procedures set forth in this Policy for Prior Approval. Fred Hutch may require the cessation of the Outside Activity pending review and disposition of the Outside Activity in accordance with this Policy. The repeated failure to seek Prior Approval of Outside Activities may result in disciplinary action.

**V. External Time Allowance.** Scientific Staff members employed on a full-time basis are expected to maintain a minimum 40-hour work week, exclusive of vacation periods. Those Scientific Staff members may seek prior approval from their Senior Vice President/Division Director to spend up to one half-day per week (four hours) engaged in allowable Outside Activities. Scientific Staff members who are not employed (or engaged in Non-Employee activities) on a full-time basis may also be permitted to engage in allowable Outside Activities, depending on the facts and circumstances of each case. The determination shall be made by the Senior Vice President/Division Director in consultation with the Deputy Director and the Vice President Research Administration and Faculty Affairs. *Participation in federal agency committees (such as NIH peer review panels) or activities associated with non-profit professional associations related to one's clinical or scientific expertise (such as the American Society of Clinical Oncology (ASCO)) are considered part of Scientific Staff members' Institutional Responsibilities and are not considered to be Outside Activities for the purposes of this policy.*

**VI. Foreign Activities.** Outside Activities involving foreign governments, agencies, entities, institutions, or persons, or Outside Activities occurring in foreign countries must, in all cases, be approved in advance by Fred Hutch.

**VII. Prohibited Activities:** Certain activities or Financial Interests are prohibited because, by their very nature, they conflict with fundamental values of scientific integrity and/or the mission of Fred Hutch. These include the following:

- **Human Subjects Research.** Fred Hutch recognizes that research involving human research participants is a privilege that imposes unique obligations. Because the welfare of human research participants is always of foremost concern, Scientific Staff

members will not be permitted to serve as protocol Principal Investigators or perform essential duties (i.e., recruit, consent, evaluate responses of human subjects enrolled) in Human Subjects Research if they (or their Family Member) has a Prohibited Financial Interest in a for-profit entity (or a Related Entity) that is sponsoring the Human Subjects Research or if the Human Subjects Research is designed to test a product or service of that for-profit entity (or Related Entity), or if that for-profit entity (or Related Entity) could in any way directly and significantly affect or be affected by the Human Subjects Research.

- **Boards of Directors.** Scientific Staff are prohibited from serving on the Board of Directors of for-profit entities of which they are a Founder or Co-Founder.
- **Industry-sponsored Speaker's Bureaus.** Participation by Scientific Staff in Speakers' Bureaus or other speaking or educational activities where content is controlled by pharmaceutical, biotechnology, medical device or other for-profit entities is prohibited. Outside entities may not require specific content or materials or have any approval rights over content or materials. When participating in Speaker's Bureaus, Scientific Staff must present a balanced assessment of the current state of relevant research and/or practice in the field and must make clear that the views expressed are their own and not those of Fred Hutch.
- **Ghostwriting.** Scientific staff may not be an author or co-author on papers or presentations Ghostwritten by an outside entity. A transparent writing collaboration with attribution between academic and industry investigators, medical writers, and/or technical experts is allowable.
- **Payment for a Particular Result.** Scientific Staff may not engage in any Outside Activity that conditions payment upon a particular research result or tied to specific research outcomes favorable to the sponsor.
- **Endorsement of products or commercial ventures.** Scientific Staff may not endorse commercial products or commercial ventures without the written permission of Fred Hutch's Vice President of Communications and Marketing. Scientific Staff members approached to represent Fred Hutch on any activity that could be construed as an endorsement must seek the approval of the Vice President of Communications and Marketing prior to engaging in any such activity. See also the Use of Center Name or Logo and Endorsement of Products/Services Policy ([link](#)).

**VIII. Discouraged Activities, subject to additional review:** Certain Outside Activities result in Conflicts of Interest or Conflicts of Commitment which are difficult to mitigate or manage. Therefore, Fred Hutch strongly discourages Scientific Staff members from engaging in the following Outside Activities. Any such proposed Outside Activities must be submitted for additional review for exceptional circumstances and, where approved, will be actively managed.

- **Executive Officer Roles.** Scientific Staff are strongly discouraged from serving in executive officer roles (e.g., Chief Executive Officer (CEO), Chief Operating Officer (COO), Chief Scientific Officer (CSO)) in for-profit entities whose activities reasonably could affect or be affected by the Scientific Staff member's Institutional Responsibilities. Under exceptional circumstances, Scientific Staff may be approved to hold executive officer roles during an approved, time-limited Leave of Absence from Fred Hutch. Requests to serve in an executive officer role must be made in writing and submitted to the Vice President Research Administration and Faculty Affairs, according to the implementing procedures for this policy.
- **Board of Directors Positions.** Scientific Staff are strongly discouraged from engaging in Outside Activities that involve service on the board of directors of for-profit entities whose activities reasonably appear to be related to his/her Institutional Responsibilities. Under exceptional circumstances, Scientific Staff may be approved to hold a board position, if the board service advances the interests of Fred Hutch and the focus of the for-profit entity is consistent with Fred Hutch's mission. Requests to engage in an Outside Activity involving service on the board of directors of a for-profit entity must be made in writing and submitted to the Vice President Research Administration and Faculty Affairs, according to the implementing procedures for this policy.

**IX. Review of Disclosures:** Disclosures of Financial Interests and Outside Activities will be reviewed according to the implementing procedures for this policy and as developed by the Vice President for Research Administration and Faculty Affairs, the Senior Vice Presidents/Division Directors, and the Deputy Director or designee. In reviewing disclosures, Fred Hutch considers the nature and extent of Scientific Staff member's Financial Interests and Outside Activities in relation to their Institutional Responsibilities and considers any sources of bias that could unduly influence decision-making or undermine research integrity.

**X. Management of Conflicts of Interest:** In the case of Human Subjects Research, Scientific Staff with Prohibited Financial Interests, as defined in this policy, will not be allowed to act as protocol Principal Investigator; recruit human subjects to participate in the study; consent human subjects to participate in the study; or evaluate the responses of human subjects in the study.

In other cases, Scientific Staff with Significant Financial Interests resulting in a Conflict of Interest will be subject to a conflict management plan to reduce, mitigate, or eliminate the Conflict of Interest, as described in the implementing procedures of this policy.

The conflict management plan is approved by the Vice President Research Administration and Faculty Affairs. Appeals may be made to the President and Director or designee, in writing, for final decision.

**XI. External Reporting Requirements:** Reviews of financial disclosures and Prior Approval requests are conducted in a confidential manner, but information may be shared internally, as necessary, for institutional purposes, including with the Institutional Review Board (IRB), Internal Audit, the Office of General Counsel, and Human Resources. Moreover, under certain

circumstances, information about the Outside Activities and certain Financial Interests of Scientific Staff may be disclosed externally to comply with laws, regulations, or Fred Hutch policies. Some external sponsors, such as PHS, require Fred Hutch to provide initial and ongoing reports relative to Scientific Staff Conflict of Interest determinations as they relate to specific research activities. For Conflicts of Interest related to PHS-funded research, Fred Hutch must perform the required conflict of interest reporting prior to the expenditure of funds for new projects, within 60 days of a newly-determined Conflict of Interest, and on an annual basis thereafter, prior to progress report submission, during the life of the project. Additionally, PHS requires Fred Hutch to make public, upon request, specific information regarding Conflicts of Interest determined for senior and key personnel on PHS-funded projects. Fred Hutch will make a good faith effort to notify any individuals for whom such a request has been received prior to releasing the information. Under certain circumstances, certain financial interests and/or conflicts of interest of Scientific Staff will be disclosed to prospective or current human subjects in clinical trials at Fred Hutch.

**XII. Mandatory training:** All Scientific Staff must complete Conflict of Interest training at least once every four years, as required by PHS. Additionally, training must occur when:

- Fred Hutch revises its Conflict of Interest policies in any way that affects the requirements for Scientific Staff
- A new Scientific Staff member joins Fred Hutch
- A member of the Scientific Staff has not complied with this policy
- A member of the Scientific Staff has not complied with a conflict management plan

**XIII. Compliance and Enforcement:** The COI administrator, as well as Fred Hutch Internal Audit, will routinely monitor and audit compliance with the conditions of this policy and other related policies using risk-based and random approaches to:

- Verify the accuracy of disclosures made in compliance with this policy
- Assess compliance with management plans, including a review of the relevant documentation (including publications, presentations, notice to study teams, etc.)

External and/or publicly available information may also be used to compare with disclosures made to Fred Hutch.

Failure to comply with any aspect of this policy may result in disciplinary action, up to and including termination of employment.

#### **XIV. Definitions:**

**Affiliate:** An individual who has been granted access to Fred Hutch facilities and resources at the request of a Fred Hutch representative. See the definition of Non-Employee for further information.

**Business Entity:** A sole proprietorship, corporation, limited liability company, trust, joint venture, or any other form of enterprise, whether conducted for profit or not.

**Conflict of Commitment:** A situation in which the Outside Activities of a Scientific Staff member interfere, or appear to interfere, with the ability to perform his/her Institutional Responsibilities at Fred Hutch. Typically, this involves activities that exceed permitted time limits of four (4) hours per week in total or activities that, by their nature, run counter to the mission of Fred Hutch.

**Conflict of Interest:** A situation in which the Outside Activities and/or certain Financial Interests (i.e., Prohibited or Significant Financial Interests) of a Scientific Staff member (or his/her Family Member) as defined in this policy, conflict, or reasonably appear to conflict, with the Institutional Responsibilities of the Scientific Staff member.

**Family Member:** For the purposes of this policy, a Family Member is the spouse, domestic partner, or dependent child of a Scientific Staff member.

**Financial Interest:** For the purposes of this policy, a Financial Interest is defined as:

- Any compensation received for service in a leadership position (such as director, trustee, officer) for any for-profit or non-profit entity.
- All ownership or equity interests (e.g., stock, options, warrants, partnership interests), regardless of value, in any entity, publicly-traded or privately-held, whose activities could reasonably affect or be affected by the Scientific Staff member's Institutional Responsibilities. *This excludes ownership or equity interests through personal retirement accounts, mutual funds, or other diversified investment vehicles to the extent that the employee does not control investment decisions.*
- Payments or the right to receive payments relating to intellectual property that is the subject of an agreement (e.g., license, option, assignment, industry sponsored research) with an outside entity, including those associated with patents, licenses, or copyrights.
- Any direct or indirect remuneration for services, such as consulting fees, advisory board compensation, honoraria, expert witness fees, speaking fees, and paid authorship from any entity whose activities could reasonably affect or be affected by the Scientific Staff member's Institutional Responsibilities.
- Any direct or indirect reimbursements or coverage of costs by outside entities such as travel-related expenses (i.e., transportation, lodging, etc.) associated with Outside Activities. The Fred Hutch President and Director or designee may apply a per trip rate for calculation of expense reimbursement or coverage.
- Any of the following types of support provided **directly or indirectly to or by** a Scientific Staff member (not through an agreement with Fred Hutch) **from or to** (i) any foreign (non-US) government, (ii) any organization owned, controlled or financed in whole or in part by a foreign government, (iii) any foreign entity or person, or (iv) any foreign

institution of higher education and/or research institute or medical center affiliated with a foreign institution of higher education:

- Grants, awards, or other research funding;
- Laboratory supplies, equipment, or space;
- Research support including staff, materials, data, data analysis, intellectual property, know-how, and the production of scholarly writings, papers, and manuscripts staff;
- Faculty appointment (even if 'honorary');
- Personal gifts or support (i.e., housing, cars, etc.);
- Travel sponsorship or reimbursement

**Founder (and Co-Founder):** Any person who is (1) instrumental in the creation of a Spin-off, including (a) business-related activities, such as writing or advising on a business plan, formation of a management team, securing of funding; or (b) science-related activities, such as being a named inventor on licensed intellectual property or serving as a scientific advisor, and (2) granted equity or equity-like instruments (e.g. options, warrants) within the first year of initial funding of such Spin-off.

**Ghostwriting:** "Ghostwriting" is defined as the provision of written or oral material that is officially credited to someone other than the writer(s) of the material.

**Human Subjects Research:** For the purposes of this policy, Human Subjects Research means an interventional human research protocol subject to review by a duly constituted institutional review board (IRB) convening as a full committee. This typically involves, but is not limited to, studies that are considered greater than minimal risk.

**Institutional Responsibilities:** For the purposes of this policy, Institutional Responsibilities broadly encompass all of the conduct and activities that are within the course and scope of a Scientific Staff member's duties, responsibilities, and activities on behalf of or in relation to Fred Hutch and includes without limitation the design, conduct, reporting, review or oversight of research, teaching, committee membership, management and administrative duties, mentoring or supervision of trainees or students, and any other professional responsibility carried out in furtherance of Fred Hutch business, programs, and activities.

**Investigator:** The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS (e.g., NIH), or proposed for such funding, which may include, for example, collaborators or consultants.

**Non-Employee:** A Non-Employee (also referred to as an Affiliate) is an individual who has been granted access to Fred Hutch facilities and resources at the request of a Fred Hutch representative. Non-employees include:

- A contractor or consultant providing an ongoing service on behalf of Fred Hutch (only those requiring unsupervised or after-hours access)

- An employee of a Fred Hutch affiliate institution who is primarily and not temporarily located on the Fred Hutch campus or who needs frequent access to Fred Hutch facilities and/or resources
- A visiting scientist who is invited by a sponsoring Scientific Staff member to utilize Fred Hutch facilities and resources in support of a collaborative research project or program
- A student or trainee receiving education or mentorship at Fred Hutch, including students, interns, pre- or post-doctoral students or fellows and/or research associates
- A volunteer
- A temporary employee contracted through an outside agency

**Outside Activity:** For the purposes of this policy, an Outside Activity is defined as any activity related to the Institutional Responsibilities of a Scientific Staff member but falling outside the normal scope and course of his/her Fred Hutch employment. This includes consulting for outside entities, participating on the boards of other organizations, and teaching engagements, other than teaching engagements on behalf of the University of Washington, Seattle Children's Hospital, or Seattle Cancer Care Alliance. Outside Activity includes service in a leadership position (such as a director, trustee or officer) for any non-profit or for-profit entity, whether such service is compensated or not.

**Prior Approval:** For purposes of this policy, Prior Approval is the process through which a Scientific Staff member seeks review and approval by the relevant Senior Vice President/Division Director of requests to engage in Outside Activities or to receive a Financial Interest that is reasonably related to their Institutional Responsibilities. Review and approval are also required if the Scientific Staff member's Family Member engages in such Outside Activities or holds such Financial Interest. This review and approval must occur *prior* to the onset of the Outside Activity or the receipt of such Financial Interest to the fullest extent possible. Prior Approval of certain Outside Activities will also require review and approval by the Fred Hutch Appointments and Promotions Committee.

**Prohibited Financial Interest:** A Financial Interest consisting of one or more of the following interests of a Scientific Staff member or his/her Family Member:

- Any ownership interest (including stock, stock options and partnership interests) in a for-profit entity (or a Related Entity) that is sponsoring Human Subjects Research or whose product or device is being tested in Human Subjects Research); or
- Royalties, fees or other one time or periodic payments or the right to receive any such payments in the future under a patent or copyright license, assignment or other agreement from an entity (or a Related Entity) whose technology or copyrighted work is directly and significantly related to Human Subjects Research; or Payments exceeding \$10,000 in the preceding 12 months or expected to exceed \$10,000 in the next 12 months, from a for-profit entity (or a Related Entity) that is sponsoring Human Subjects Research or whose product or device is being tested in Human Subjects Research.

**Related Entity:** Any parent entity, subsidiary, or affiliate to a Business Entity, and any business, corporation, partnership, limited liability company or other entity in which the Business Entity,

or the parent entity, subsidiary, or affiliate of the Business Entity holds a substantial ownership interest, directly or indirectly.

**Significant Financial Interest:** A Financial Interest consisting of one or more of the following interests of a Scientific Staff member or his/her Family Member:

- More than \$5000, in the aggregate, of income from a publicly-traded entity AND the value of equity interests in, a publicly-traded entity received in the preceding 12 months. Income includes salary and or other forms of payments for services, and equity interests include stock, stock options, or other ownership interests; or
- More than \$5,000 of income received in the preceding 12 months from a privately-held entity, or any ownership interest in a privately-held entity. Income includes salary and other forms of payment for services, and equity interests include stock, stock options, or other ownership interests; or
- Sponsored or reimbursed travel expenses exceeding the per trip rate allowance (link)
- Intellectual property rights and interests.

The term Significant Financial Interest does **not** include:

- Salary, royalties or other payments from Fred Hutch;
- Income from seminars, lectures or teaching engagements sponsored by a Federal, state, or local government agency, a U.S. institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education;
- Income from service on advisory committees or review panels for a Federal, state, or local government agency, a U.S. institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education; or
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Scientific Staff member (or his/her Family Member) does not directly control the investment decisions made in these vehicles.

**Spin-Off Company:** A for-profit Business entity that is directly or indirectly controlled by Fred Hutch, and/or whose business plan is based substantially on intellectual property that is licensed or otherwise obtained from Fred Hutch. The Executive Committee of the Board of Trustees may at any time and in its sole discretion determine that a Business Entity is no longer a Spin-Off Company for the purposes of this Policy.

#### **XV. Related Policies:**

[Academic Policies for Faculty and Scientific Staff](#)

[Ethical Conduct Policy](#)

Conflict of Interest for Trustees and Executives and Conflicts of Commitment for Executives (Coming Soon)

[Institutional Conflict of Interest Policy](#)

[Use of Center Name or Logo and Endorsement of Products/Services Policy](#)