

Effective 09/2023
Next Review 11/2026

Sponsor Marcia Gonzales:
VP & Chief
Compliance
Officer

Area Compliance,
Ethics, and
Integrity -
Institutional

Applicability FHCC
Institutional
Policies

References Org Wide/
Institutional



Individual Conflict of Interest and Conflict of Commitment Policy

SCOPE:

This policy applies to all Covered Persons as defined below at Fred Hutchinson Cancer Center ("Fred Hutch").

PURPOSE:

Covered Persons have a primary obligation to provide services and conduct their work 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 Covered Persons 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 Conflict of Interest and Commitment policy provides guidelines, oversight and standards for identifying and mitigating potential and actual conflicts of interest and conflicts of commitment to help ensure Fred Hutch's commitment to integrity and objectivity.

DEFINITIONS:

- **Affiliate** -- An individual who has been granted access to Fred Hutch facilities and resources at the request of a Fred Hutch representative. See Non-Employee.
- **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 Management Plan** -- A written plan developed by the Compliance Office that addresses a situation that gives rise to an existing and/or potential conflict of interest or conflict of commitment and which sets forth the management mechanism that will be implemented to mitigate or eliminate the conflict.
- **Conflict of Commitment** -- A situation in which the Outside Activities of a Covered Person interfere, or appear to interfere, with the Covered Person's ability to perform their Institutional Responsibilities at Fred Hutch. Typically, this involves activities that exceed the permitted time allowance set forth in this policy.
- **Conflict of Interest** -- A Conflict of Interest may occur when a Covered Person or their Family Member:
 - Receives a financial or other significant benefit as a result of the Covered Person's position at Fred Hutch;
 - Has the opportunity to influence grant, business, administrative, or other material decisions in a manner that leads to personal gain or advantage; or
 - Has an existing or potential financial or other significant interest which impairs or might appear to impair the individual's independence in the conduct of their Institutional Responsibilities to Fred Hutch.
- **Covered Person(s)** -- Any workforce members who hold the following appointments, titles and/or roles at Fred Hutch:
 - A clinical or nonclinical Faculty appointment with Fred Hutch, including joint appointments with University of Washington.
 - Any clinical provider who can independently write orders or prescriptions (e.g., physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists).
 - Any workforce member with the authority to purchase of medical devices, supplies, and equipment to be used in the provision of healthcare services.
 - Scientific staff, a term denoting all individuals who are responsible for, participate in or are engaged in the design, conduct or reporting of research. This may include collaborators or consultants.

This is applicable to all workforce members whose conduct in the performance of work for (or at) Fred Hutch is under the direct control of Fred Hutch or subject to the policies of Fred Hutch, whether or not they are paid by Fred Hutch. This includes but is not limited to workforce members classified as Non-Employees, volunteers, trainees and affiliates.

- **Faculty** --
 - Primary (employed by Fred Hutch) at the assistant, associate, or full professor rank;

or

- External joint (employed by another institution) at the assistant, associate, or full professor rank
- **Family Member** – The spouse, domestic partner, or dependent child of a Covered Person.
- **Financial Interest** – Financial Interests include, but are not limited to:
 - 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 Covered Person'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 Covered Person 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 Covered Person'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.
 - Any of the following types of support provided directly or indirectly to or by a Covered Person (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, or (iii) any foreign institution of higher education and/or research institute or medical center affiliated with a foreign institution of higher education:
 - Grant, award, or other research funding not administered through Fred Hutch
 - Position in a foreign talent program
 - Laboratory supplies, equipment, or space
 - Biospecimens
 - Research support staff, including visiting scientists, post-docs, fellows, or graduate students
 - Faculty appointment, even if Honorary
 - Personal gifts (e.g., housing, cars, cash, etc.)
 - Travel support or reimbursement
 - Foreign patents
 - Foreign working groups

- Expert on foreign projects
- **Founder (and Co-Founder)** -- Any person who is:
 - Instrumental in the creation of a Spin-Off, including:
 - Business-related activities, such as writing or advising on a business plan, formation of a management team, securing of funding; or
 - Science-related activities, such as being a named inventor on licensed intellectual property or serving as a scientific advisor;
 - Granted equity or equity-like instruments (e.g. options, warrants) within the first year of initial funding of such Spin-Off.
- **Human Subjects Research** -- A human research protocol subject to review by an Institutional Review Board (IRB).
- **Institutional Responsibilities** -- All conduct and activities that are within the course and scope of a Covered Person's duties, responsibilities, and activities on behalf of or in relation to Fred Hutch, and includes without limitation the design, conduct, reporting, review and oversight of research, teaching, committee membership, management and administrative duties, clinical care, mentoring or supervision of trainees or students, and any other professional responsibility carried out in furtherance of Fred Hutch business, programs, and activities.
- **Non-Employee** -- Also referred to as an Affiliate, an individual who has been granted access to Fred Hutch facilities and resources. Non-employees include:
 - A contractor or consultant providing an ongoing service on behalf of Fred Hutch.
 - An employee of a Fred Hutch affiliate institution who is primarily located on the Fred Hutch campus or who needs frequent access to Fred Hutch facilities and/or resources. A visiting scientist or affiliate investigator who is invited by a sponsoring Covered Person to utilize Fred Hutch facilities and resources.
 - 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** -- Any activity related to the Institutional Responsibilities of a Covered Person but falling outside the normal scope and course of their 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 and Seattle Children's Hospital. 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. Outside Activities do not include (i) participation in federal agency committees (e.g., NIH peer review panels), (ii) activities associated with non-profit professional associations related to one's clinical or scientific expertise, or (iii) activities that a Covered Person has been requested by the Institution to undertake as part of one's Institutional Responsibilities.
- **Prior Approval** -- The process through which a Covered Person seeks review and written

consent by the relevant party, including but not limited to the relevant Director, Division Director, Senior Vice President, Executive Vice President, and/or the President with direct oversight of the Covered Person, to engage in Outside Activities or to receive a Financial Interest that is reasonably related to their Institutional Responsibilities. This is also required if the Covered Person's Family Member engages in such Outside Activities or holds such Financial Interest.

Prior 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 Conflicts of Interest Advisory Committee.

- **Prohibited Activity** -- An activity involving:
 - Use of financial information for personal gain.
 - Use of Fred Hutch workforce members and/or resources for reasons unrelated to the statement of work or Institutional Responsibilities of said person.
 - Activities in which the time and commitment demand will unduly impair their abilities to perform their Institutional Responsibilities at Fred Hutch.
 - Arrangements with outside organizations which have not been approved as required by this policy.
 - Involvement in the process for purchases or equipment, instruments, materials, or services for Fred Hutch from a Business Entity in which the Covered Person, or Family Member, has a Financial Interest.
 - Giving, offering, or promising anything of value as a representative of Fred Hutch to any government official to enhance relations with that official or the government.
 - Soliciting favors or contributions from supplies, vendors, or customers for any nonprofit or charitable organization in which they, or Family Member, have a Financial Interest or hold Outside Leadership.
 - Accepting cash or cash-equivalent gifts (e.g., gift cards, cashiers check), gratuities, entertainment, travel or hospitality from a supplier or vendor.
 - Engaging in a Conflict of Interest or Conflict of Commitment that cannot be effectively managed.
 - Any activities prohibited by law.
 - Serving as protocol Principal Investigators or perform essential duties (i.e., recruit, consent, evaluate responses of human subjects enrolled) in Human Subjects Research if the Covered Person (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.
 - Serving on the Board of Directors of for-profit entities of which one is a Founder or Co-Founder.
 - Speaking at or providing education in situations where the content is controlled by pharmaceutical, biotechnology, medical device, or other for-profit entities.

- Credit as an author or co-author on papers or presentations where ghostwritten by an outside entity. Ghostwriting is the provision of written or oral material that is officially credited to someone other than the writer(s) of the material. Transparent writing collaboration(s) with attribution between academic and industry investigators, medical writers, and/or technical experts is allowable.
 - Outside Activities where payment is conditional upon a particular research result or tied to specific research outcomes favorable to the sponsor.
 - Endorsing commercial products or commercial ventures without written permission of Fred Hutch's Vice President of Marketing & Communications.
- **Prohibited Financial Interest** -- A Financial Interest consisting of one or more of the following interests of a Covered Person or their 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 at Fred Hutch or whose product or device is being tested in Human Subjects Research at Fred Hutch; 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 at Fred Hutch or whose product or device is being tested in Human Subjects Research at Fred Hutch.
- **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, either directly or indirectly.
- **Significant Financial Interest (SFI)** -- A Financial Interest consisting of one or more of the following interests of a Covered Person member or their Family Member:
 - More than \$5,000, 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; or
 - 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, or a U.S. institution of higher education, academic teaching hospital, medical center, or research institute;

- Income from service on advisory committees or review panels for a Federal, state, or local government agency or a U.S. institution of higher education, academic teaching hospital, medical center, or research institute; or
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Person member (or their 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 Directors 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.

POLICY:

Training

All Covered Persons must complete Conflict of Interest and Conflict of Commitment training at least once every four (4) years. Additionally, training must occur when:

- A Covered Person becomes a workforce member Fred Hutch
- Fred Hutch revises this policy in any way that affects the Covered Person
- A Covered Person is required to undertake remediation training for non-compliance with this policy
- A Covered Person is required to undertake remediation training for non-compliance with a Conflict Management Plan as determined by the Compliance Office

Disclosure Requirement

Covered Persons must make disclosures so that a reasonable determination can be made regarding whether a potential or actual conflict exists, and whether it can be managed. All pertinent Financial Interests of a Covered Person must be disclosed in order to be evaluated for a Significant Financial Interest. All Covered Persons have a continuing duty to update their information after any changes in facts that are required by this policy.

By submitting a disclosure upon hire or designation and continuing to do so through employment or affiliation, Covered Persons attest to (1) reading and understanding this policy; (2) disclosing all potential Conflicts of Interest and Conflicts of Commitment as required by this policy; and (3) compliance with this policy and the law.

All Covered Persons are required to disclose to Fred Hutch and, as appropriate, obtain Prior Approval for their Outside Activities and Financial Interests (and those of Family Members) that are or reasonably appear to be related to their Institutional Responsibilities, paid or not. If Prior Approval was not sought before engaging in Outside Activities, then as soon as the oversight is realized, approval must be requested in accordance with the procedures set forth in this policy. Fred Hutch may require the cessation of the Outside Activity pending review and/or the disgorgement of any compensation. The repeated failure to seek Prior Approval of Outside Activities may result in disciplinary action. See attached Guidance for examples of Outside Activities and Financial Interests that should be disclosed.

Covered Persons 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.

Disclosure Intervals

All Covered Persons are required to complete an electronic conflict of interest disclosure form:

- Upon hire, appointment or designation
- At a minimum, once in a 365-day period, even if attesting to no change from previous disclosures
- Within 30 days of a change to the currently reported status of your Financial Interest or Outside Activity
- Upon submission of an application for funding
- Upon engagement in research regulated by the U.S. Food and Drug Administration, if required by law
- Prior to engaging in all Outside Activities both domestic and those involving foreign governments, agencies, entities, institutions, or person or occurring in foreign countries whether paid or not.

Outside Time Allowances

Outside Activities that do not adversely affect a Covered Person's responsibilities at Fred Hutch are permitted provided that their full-time obligations are also being met. Prior approval from a Covered Person's Director, Division Director, Senior Vice President, Executive Vice President, and/or the President must be obtained prior to engaging in the Outside Activity at Fred Hutch. Factors to be taken into consideration for each Outside Activity include:

- Is the Outside Activity or role consistent with the Fred Hutch mission, values, and objectives?
- Are there institutional benefits to Fred Hutch?
- Is there a clear delineation of the roles?
- Will this Outside Activity exceed the permissible time limits in this policy?
- Can any potential conflicts of interest be effectively managed?

A Covered Person employed on a full-time basis is permitted to spend up to one day per week (eight

hours) engaged in allowable Outside Activities. The maximum number of days permissible is 13 days per quarter. A limited amount of “averaging” of time among full-time quarters is permissible if, on occasion, the Covered Person plans to work for more than 13 days in one quarter but no more than 52 days for a full fiscal year.

A Covered Person who is 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 Director, Division Director, Senior Vice President, Executive Vice President, and/or the President with direct oversight of the Covered Person in consultation with the Office of General Counsel and the Compliance Office.

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 Covered Person’s Institutional Responsibilities and are not considered to be Outside Activities for the purposes of this policy.

Review of Disclosures and Management of Conflicts

All Disclosures will be reviewed by the Compliance Office or designated representatives to determine if a potential or actual conflict may exist. Determinations regarding a conflict will be made in consultation with the Covered Person, the Covered Person’s supervisor(s) as applicable, the Office of General Counsel, the Office of Sponsored Research, the Institutional Review Office or other areas at the discretion of the Compliance Office. The Compliance Office may also refer to or consult with members of the Conflicts of Interest Advisory Committee.

Covered Persons found to have a Conflict of Interest or Conflict of Commitment will be subject to a Conflict Management Plan to reduce, mitigate, or eliminate the conflict if it is possible to reasonably reduce, mitigate or eliminate the conflict. If it is not possible to reasonably reduce, mitigate or eliminate the conflict, the Outside Activity will not be approved and the Covered Person will not be allowed to engage in the Outside Activity.

Conflict Management Plans may be shared internally as necessary for institutional purposes. Covered Persons may be asked to disclose Conflict Management Plans to Fred Hutch employees and affiliates, patients, research subjects, and others as per individual Conflict Management Plans. Under certain circumstances, information about the Outside Activities and certain Financial Interests of Covered Persons may be disclosed externally to comply with laws, regulations, or Fred Hutch policies. Fred Hutch will make a good faith effort to notify Covered Persons in advance of external disclosures.

Conflicts of Interest Advisory Committee (COIAC)

The Conflicts of Interest Advisory Committee shall be appointed by the President of Fred Hutch or their designee to provide assistance and guidance to the designated representatives of the Conflict of Interest Program regarding the review of disclosures under this policy. The COIAC will review potential and actual conflicts and make recommendations regarding acceptance of, the acceptance with conditions of, or the management of the potential or actual conflict in question. Such review and recommendation must be completed before the acceptance of any funds or agreement is made. The COIAC shall meet

semiannually or on an as needed basis as determined by the needs of the Conflict of Interest Program.

Recommendations may also be made by ad hoc members as determined by an appointed member of the COIAC. All approval conditions or restrictions will be included in a written Conflict Management Plan reviewed at least annually by the COIAC.

See charter for additional information.

Monitoring

The Compliance Office, 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 and assess compliance with management plans, including a review of the relevant documentation such as publications, presentations, notice to study teams and other material.

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

External Reporting Requirements

For conflicts related to PHS-funded research, Fred Hutch must perform the required reporting prior to the expenditure of funds for new projects, within 60 days of a newly determined conflict and on an annual basis thereafter, prior to progress report submission, during the life of the project. Additionally, federal regulation requires Fred Hutch to make public specific information regarding Conflicts of Interest determined for senior and key personnel on PHS-funded projects within 5 days of written request. 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 Covered Person will be disclosed to prospective or current human subjects in clinical trials at Fred Hutch.

In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflict that was not managed or reported by the Fred Hutch, as required by the regulation, necessitates that the Investigator (1) disclose the conflict in each public presentation of the results of the research, and (2) request an addendum to previously published presentations

Failure to Comply with Policy

Covered Persons who fail to comply with this policy, including failure to disclose or resolve a Conflict of Interest or Conflict of Commitment or failure to seek prior approval of an Outside Activity when required, will be subject to discipline, up to and including termination of employment or affiliation with Fred Hutch.

REQUIREMENTS:

REFERENCES:

- This policy replaces legacy policy "ADM205 Conflicts of Interest and Commitment" under FHCC Outpatient, and legacy policy "Conflicts of Interest and Conflicts of Commitment for Scientific Staff" under FHCC Research Center Policies.
- Reviewed and passed by Fred Hutch Board of Directors on September 22, 2023. See attached, signed resolution.

Attachments

[BoD Resolution approving COI Policy final.pdf](#)

Approval Signatures

Step Description	Approver	Date
	Natalie Simpson: Policy & Practices Mgr	11/2023
	Marcia Gonzales: VP & Chief Compliance Officer	10/2023
	Marcia Gonzales: VP & Chief Compliance Officer	10/2023