

CONFLICT OF INTEREST POLICY

I. Statement of Policy.

In order to prevent Conflicts of Interest or the appearance of such Conflicts by Representatives, the Center adopts the following Policy. Capitalized terms and phrases used in this Policy are defined in Section II below.

A. Human Subjects Research.

1. Introduction. The Center recognizes that research with human subjects is a privilege that imposes unique obligations. Because the welfare of human subjects is always of foremost concern, financial interests relating to Human Subjects Research require heightened scrutiny. Therefore, in addition to the general Conflict of Interest provisions in Section I.B. below, Representatives involved in Human Subjects Research at the Center are also required to comply with the provisions in this Section I.A.

2. Prohibition on Participation in Human Subjects Research by Financially Interested Representatives. A Representative may not Participate in a Human Subjects Research protocol a) if such Human Subjects Research is sponsored by or is designed to test a product or service of a for-profit entity in which that Representative (or his/her spouse, domestic partner or dependent child) has or receives a Prohibited Financial Interest; or b) if the Conflict of Interest Committee determines that the Representative (or his/her spouse, domestic partner or dependent child) has or receives a Prohibited Financial Interest in a for-profit entity that could in any way directly and significantly affect or be affected by the outcome or conduct of such Human Subjects Research.

3. Disclosure in Publications and Presentations. A Representative who is the author on a paper or presentation concerning Human Subjects Research must disclose any Prohibited Financial Interest held or received by that Representative (or his/her spouse, domestic partner or dependent child) which could directly and significantly affect or be affected by the Human Subjects Research discussed in the paper or presentation. Issues concerning the necessity and scope of disclosures under this section will be referred to the Conflict of Interest Committee.

B. General Conflict of Interest Provisions.

1. Prohibition on Payment for Results. A Representative shall not receive payments from any source conditioned upon a particular research result or that are tied to successful research outcomes.

2. Limitations on Participation in Transactions Involving Financially Interested

Representatives. A Representative shall not participate in any Transaction involving the Center in which the Representative (or his/her spouse, domestic partner or dependent child) has or receives a Significant Financial Interest unless the Transaction is reviewed and approved in accordance with this Policy after full disclosure of all relevant facts to ensure that any Conflict of Interest is managed, reduced or eliminated to prevent bias, improper influence, or misuse of Center or government resources.

3. Limitations on Participation in Transactions Involving Certain Business Entities. A Representative shall not participate in any Transaction involving the Center and a Business Entity in which the Representative (or his/her spouse, domestic partner or dependent child) has or receives a Significant Financial Interest or a Business Entity of which the Representative (or his/her spouse, domestic partner or dependent child) is a trustee, director or officer unless the Transaction is reviewed and approved in accordance with this Policy after full disclosure of all relevant facts to ensure that any Conflict of Interest is managed, reduced or eliminated to prevent bias, improper influence, or misuse of Center or government resources.

4. Employment of Family Members. A Family Member may be employed by the Center; however, the Center will recruit, hire, train, and compensate individuals in all job classifications based solely on the applicant's qualifications, abilities or potential abilities.

5. Personnel Actions Involving Family Members. Representatives shall not participate in any Personnel Action involving a Family Member or a person with whom the Representative is sexually or romantically involved.

6. Supervision of Family Members. A Representative shall not supervise a Family Member or any person with whom the Representative is sexually or romantically involved unless the Director grants prior written approval.

C. Disclosure and Review Process.

1. Disclosure Process. Each trustee and the Director will disclose any Significant Financial Interests he or she may have which reasonably appear to create a Conflict of Interest and any positions held by that Representative (or his/her spouse, domestic partner or dependent child) as a trustee, director or officer of another Business Entity. Disclosures by trustees and the Director should include Significant Financial Interests held in entities with which the Center has a material licensing, vendor or other business relationship. Each member of the scientific staff (including postdoctoral fellows) and other Representatives responsible for the design, conduct or reporting of research activities will disclose a) any consulting or similar relationship between the Representative (or his/her spouse, domestic partner or dependent child) and any Business Entity; b) any Financial Interest he or she (or his/her spouse, domestic partner or dependent child) has or receives which could reasonably appear to be related to the Representative's Institutional Responsibilities; c) any

positions held by that Representative (or his/her spouse, domestic partner or dependent child) as a trustee, director or officer of another Business Entity; and d) other matters as may be required by the Center's Policy and Guidelines for Involvement with Outside Interests or by the Director. The Director may require similar disclosures from other employees. Disclosures must be updated at least annually and as otherwise requested by the Executive Committee (in the case of trustees and the Director) or by the Director (in the case of scientific staff and other employees).

2. Review of Trustee Disclosures. The Executive Committee or a person or persons designated by the Executive Committee will review all disclosures by trustees and will determine what conditions or restrictions should be imposed to ensure that any Conflict of Interest or apparent Conflict of Interest is appropriately managed, reduced or eliminated to prevent bias or other improper influence or misuse of Center or government resources.

3. Review of Scientific Staff and Employee Disclosures. The Director or the Director's designee will review all disclosures by scientific staff and other employees of the Center; provided, that disclosures involving Prohibited Financial Interests or potential Prohibited Financial Interests which could reasonably affect or be affected by Human Subjects Research will be referred to the Conflict of Interest Committee. The designated official or the Conflict of Interest Committee, as the case may be, will recommend to the Director what conditions or restrictions should be imposed to ensure that any Conflict of Interest or apparent Conflict of Interest is appropriately managed, reduced or eliminated in accordance with Center policy and applicable law to prevent bias or other improper influence or misuse of Center or government resources. All recommendations shall be subject to the approval of the Director; provided, that if a Conflict of Interest involves the Director or his/her spouse, domestic partner or dependent child, the recommendations will be reviewed and approved by the Chair of the Board of Trustees or his or her designee. Conflicts of Interest involving scientific staff or other persons responsible for the design, conduct or reporting of research activities will be subject to the further requirements and guidelines stated in the Policy and Guidelines for Involvement with Outside Interests or specified by the Director. In no event may the terms of any other policy, guidelines or specifications be less restrictive than the terms of this Policy.

4. Records Retention. All records relating to the disclosure of Conflicts of Interest and any action taken with respect thereto will be maintained for at least three years or as required by applicable government regulations, whichever is longer.

D. Violations. Violations of this Policy by trustees or the Director will be reported to the Executive Committee for appropriate action. Violations of this Policy by scientific staff or other employees responsible for the design, conduct or reporting of research activities will be reported to the Director or the Director's designee and will be addressed pursuant to the Policy and Guidelines for Involvement with Outside Interests or as otherwise provided by the Director. Violations of this Policy involving other employees of the Center will be reported to the Director or the Director's designee for appropriate action. The Director may seek the guidance of the Executive Committee concerning the handling of any Conflict of Interest or violation of this Policy. Intentional violations of this Policy by Center scientific staff or employees may result in immediate suspension or

dismissal in accordance with the Center's established personnel policies.

E. Mandatory Training. All Representatives involved in the design, conduct, or reporting of research will complete training regarding this Policy at least once every four years.

II. Definition of Terms.

The following definitions are adopted:

“Business Entity” means a sole proprietorship, partnership, joint venture, or any other form of enterprise, whether conducted for profit or not.

“Center” means Fred Hutchinson Cancer Research Center and other entities under its control.

“Conflict of Interest” means any situation in which a Representative has the opportunity or appears to have the opportunity to influence the Center's decisions or use resources or confidential or proprietary information of the Center in ways that could lead to professional, personal or financial gain, or otherwise give improper advantage to the Representative (or his/her spouse, domestic partner or dependent child) or organizations in which he or she (or his/her spouse, domestic partner or dependent child) hold official positions or Prohibited or Significant Financial Interests.

“Conflict of Interest Committee” means the committee responsible for reviewing Conflict of Interest issues relating to Human Subjects Research and advising the Director on such issues. The Conflict of Interest Committee is composed of one trustee appointed by the Center's Board Chair, one member from each of the Center's scientific divisions appointed by the director of that division and such other members as may be appointed by the Director in his or her discretion. All appointees to the Conflict of Interest Committee other than the trustee appointee shall be approved by the Director.

“Director” means the President and Director of Fred Hutchinson Cancer Research Center.

“Family Member” means a spouse, domestic partner, child, parent, sibling, or in-law.

“Financial Interest” means anything of monetary value, whether or not the value is readily ascertainable.

“Human Subjects Research” means a systematic investigation which is designed to develop or contribute to generalizable knowledge in which a Representative (or those under the control of such Representative) a) obtains data about living individuals (“subjects”) through intervention or interaction; or b) has access to individually identifiable private information about such subjects. Intervention includes both physical procedures by which data are gathered and manipulations of the subjects' environment that are performed for research purposes. Interaction includes

communication or interpersonal contact between the Representative and subject.¹ For purposes of this definition, “Human Subjects Research” includes only research that is financed in whole or in part by funds administered by the Center.

“Institutional Responsibilities” means research, service on Center committees, management duties, mentoring, and any other professional responsibility of a Representative carried out in furtherance of Center programs and activities.

“Participate in Human Subjects Research” means, with respect to a specific IRB approved research protocol, 1) acting as principal investigator for such protocol; 2) consenting human subjects to such protocol; 3) recruiting human subjects to such protocol; or 4) evaluating the response of human subjects enrolled on such protocol.

“Personnel Action” means recruiting, hiring, sponsoring, appointing, terminating, promoting, demoting, setting compensation or other benefits, and allocating Center resources such as space and funding.

“Prohibited Financial Interest” means 1) an ownership interest of any amount or any nature in a for-profit Business Entity (including stock, stock options and partnership interests) but excluding an ownership interest in investment vehicles, such as mutual funds and retirement accounts, as long as the Representative (or his/her spouse, domestic partner or dependent child) does not directly control the investment decisions made in these vehicles; 2) royalties, fees or any other one time or periodic payment or the right to receive any such payment in the future under a patent or a copyright license, assignment or other agreement where the Conflict of Interest Committee determines that the technology or copyrighted work which is the subject of the license or other agreement is directly and significantly related to Human Subjects Research; and 3) payments of any kind (for example, consulting fees, expense reimbursement, honoraria, gifts or in-kind compensation) from a for-profit entity that in the aggregate have, in the prior calendar year, exceeded \$10,000 or are expected to exceed \$10,000 in the next twelve months. Payments under a multi-year agreement with a for-profit entity which are expected to exceed \$10,000 over the term of the agreement will constitute a Prohibited Financial Interest unless the agreement can be terminated at the election of the Representative not less frequently than every twelve (12) months, and the payments under the agreement do not otherwise constitute a Prohibited Financial Interest under Section 3 of this definition.

“Representative” means any member of the scientific staff, visiting investigator, employee, trainee, affiliate, director or trustee of the Center.

“Significant Financial Interest” means a Financial Interest consisting of one or more of the following interests of a Representative (or his/her spouse, domestic partner or dependent child):

1. With regard to any publicly traded entity, a Significant Financial Interest exists if

¹ Derived from U.S. Department of Health and Human Services human subjects research definitions. See 45 CFR Part 46.

the value of any remuneration received from the Business Entity in the twelve months preceding the disclosure and the value of any equity interest in the Business Entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (for example, consulting fees and honoraria); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

2. With regard to any non-publicly traded Business Entity, a Significant Financial Interest exists if the value of any remuneration received from the Business Entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Representative (or his/her spouse, domestic partner, or dependent children) holds any equity interest (for example, stock, stock option, partnership interest, or other ownership interest); or

3. Intellectual property rights and interests.

The term Significant Financial Interest does not include:

1. Salary, royalties or other remuneration from the Center;
2. Income from seminars, lectures or teaching engagements sponsored by a Federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
3. Income from service on advisory committees or review panels for a Federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
4. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Representative (or his/her spouse, domestic partner or dependent child) does not directly control the investment decisions made in these vehicles.

“Transaction” is used in its broadest sense and includes, but is not limited to, loans, buying or selling goods or services, research, investigation, testing or patient care. The term does not include the purchase by a Representative or Family Member of goods or services offered by the Center in the normal course of business.