

FRED HUTCHINSON CANCER RESEARCH CENTER INSTITUTIONAL CONFLICT OF INTEREST POLICY

I. Guiding Principles

Fred Hutchinson Cancer Research Center (“Center”) affirms that certain core principles have guided the development of its Institutional Conflict of Interest Policy:

- The central mission of the Center is to foster the development and application of new knowledge essential to the understanding of the causes, prevention, diagnosis, treatment and after-care of cancer and other diseases.
- Research collaborations and the transfer of technology between the Center and industry are encouraged under federal policy and play a critical role in furthering the Center’s mission by generating new scientific discoveries and facilitating the translation of those discoveries into effective medical products, practices, therapies and public health approaches.
- As reflected in existing Center policies including i) the Conflict of Interest Policy and the Policy and Guidelines for Involvement with Outside Interests (which limit the ability of individual investigators to hold certain financial interests in for-profit companies engaged in collaborative research activities with the Center), ii) the Policy on Openness in Research (which mandates publication of the results of research activities conducted at the Center), iii) the Scientific Misconduct Policy (which prohibits certain conduct undermining the integrity of research conducted at the Center) and iv) the policies and procedures for review and oversight of human subjects research conducted at the Center, the welfare of human subjects and the integrity of the research enterprise are matters of paramount concern that must be protected from improper influence or bias caused by financial conflicts of interest.
- To further ensure that the Center’s mission is accomplished in an environment free of improper influence or bias, the Center must regularly review and manage the effect of its various relationships with industry on its structure, programs and activities.

II. Statement of Policy

In order to continue to ensure a human subjects research environment free of improper influence or bias, the Center adopts the following Institutional Conflict of Interest Policy (“Policy”).

A. Segregation of Administrative Oversight for Human Subjects Research Program.

The functions and responsibilities related to administrative and scientific oversight of Center research programs involving human subjects shall remain segregated from the functions and responsibilities related to the administration and management of i) the Center’s technology transfer program and ii) the Center’s investments and endowment. Notwithstanding the foregoing, it is understood that the Center President and Director, as chief executive officer and scientific head of the Center, shall have overall responsibility

for all administrative and scientific activities at the Center; provided, however, that the Center President and Director shall not actively participate in any investment decisions made by the Center.

B. Conflict of Interest Policy for Institutional Review Board Members. The Center shall establish a financial interest disclosure and conflict of interest policy for members of its institutional review boards (“IRB”) consistent with applicable law and other Center policies. The policy will require IRB members to disclose financial interests that reasonably relate to the matters presented to the IRB and will require the exclusion of IRB members with such financial interests from participation in IRB deliberations concerning any affected matters.

C. Disclosure, Review and Resolution. Institutional conflicts of interest will be disclosed, reviewed and resolved by an Institutional Conflict of Interest Committee in accordance with the terms of this Policy.

1. Institutional Conflict of Interest Defined. For purposes of this Policy, an “Institutional Conflict of Interest” that would trigger review and resolution is defined as any of the following types of external relationships or financial interests:

- a) Equity interests (stocks, stock options or other ownership interests) held by the Center or a Key Official (as defined below) in a for-profit entity (“Company”) that is sponsoring human subjects research at the Center or whose product or service is being tested in such research (but excluding i) equity interests which are held as part of Center investment portfolios under management by outside consultants and ii) equity interests in publicly-traded mutual funds);
- b) Receipt by the Center or a Key Official of 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 arising from the sale of a product or service that is being tested in human subjects research at the Center;
- c) Receipt or pledge of a gift or gifts to the Center exceeding \$500,000 in aggregate value from a Company that is sponsoring human subjects research at the Center or whose product or service is being tested in such research;
- d) Appointment of a Key Official to serve as an officer, director or board member of a Company sponsoring human subjects research at the Center or whose product or service is being tested in such research (not including an appointment as a member of a scientific advisory board of the Company);
- e) Receipt by a Key Official of or the right to receive consulting fees, honoraria, gifts or other compensation exceeding \$10,000 per year from a Company sponsoring human subjects research at the Center or whose product or

service is being tested in such research; provided that such payments are received or such rights accrue during the course of the research or within one year of the start or completion of the research; or

f) Such other external relationships and financial interests that could directly and significantly affect human subjects research at the Center.

2. Key Officials Defined. “Key Officials”, as used in this Policy, mean the Center President & Director, the Division Directors of each of the four scientific divisions, the General Counsel, the Director of Technology Transfer and the Director of the Institutional Review Office and such other Center employees as the President and Director may designate in his discretion.

3. Institutional Conflict of Interest Committee.

a) Composition of Committee. The Institutional Conflict of Interest Committee (“ICOIC”) shall be composed of one member of the Center Board of Trustees appointed by the Board Chair; one member of the senior faculty from each of the scientific divisions appointed by the President and Director; and one community member nominated by the President and Director and approved by the Board Chair. The Board Chair, in consultation with the President and Director, shall appoint one member of the ICOIC as Chair. ICOIC members will not hold positions that require them to exercise responsibility over the administration of the Center’s human subjects protection program.

b) Role of Committee. The ICOIC will make findings as to whether an Institutional Conflict of Interest exists and how it might be resolved. The ICOIC will forward to the Executive Committee of the Board of Trustees a summary of the ICOIC findings and recommendations as to how any Institutional Conflicts of Interest should be resolved. The Executive Committee shall make the final determination.

c) Coordination with Conflict of Interest Committee. The ICOIC and the Conflict of Interest Committee established pursuant to the Center’s individual Conflict of Interest Policy will each share with the other information obtained or developed that may be relevant to coordinate the work of both committees.

4. Disclosure Process.

a) Disclosures by Key Officials. Disclosures of external relationships and financial interests held by Key Officials shall be made on an annual basis in accordance with the Center’s Conflict of Interest Policy. Copies of these annual disclosures shall be transmitted to the ICOIC Chair.

b) Disclosures of Intellectual Property and Equity Interests. Center management will report to the ICOIC Chair (or designee) when the Center takes

(or is committed to take) an equity interest (stocks, stock options or other ownership interest) or receives (or accrues the right to receive) royalties, fees or any other one time or periodic payment under a patent or a copyright license, assignment or other agreement from a Company.

c) Disclosures of Gifts. Center management will report to the ICOIC Chair (or designee) gifts or pledges to the Center from any Company sponsoring research at the Center or whose products or services are being tested at the Center, when such gifts or pledges exceed \$500,000 in a fiscal year. This report shall be made at least annually and more frequently if one-time gifts from any company exceed \$500,000.

5. Review Process. The ICOIC Chair (or designee) will review all disclosures referred to them and make a preliminary determination as to whether any of the external relationships and financial interests reported constitute Institutional Conflicts of Interest that require review by the ICOIC. The ICOIC will convene at the request of the Chair (and not less than annually) to review any disclosures of external relationships and financial interests referred to it by the ICOIC Chair. The ICOIC will determine whether an Institutional Conflict of Interest exists and how to resolve each Institutional Conflict of Interest on a case-by-case basis taking into consideration factors such as a) the nature of the affected research; b) the nature of the external relationship or financial interest; c) how closely the external relationship or financial interest is related to the research; c) the degree of risk that the research poses to human subjects; d) the degree to which the interest may affect or be affected by the research; e) whether the Center is well qualified to conduct the research; f) the degree of risk that the research will not be pursued if not conducted at the Center; g) the effectiveness of managing, reducing or eliminating the Institutional Conflict of Interest through recusal, divestiture or independent oversight of the affected research.

6. Resolution Process. Each determination by the ICOIC that an Institutional Conflict of Interest exists shall be transmitted to the Executive Committee of the Board of Trustees together with a recommendation on how the institutional conflict of interest should be managed, reduced or eliminated. The Executive Committee shall be responsible for resolving the Institutional Conflict of Interest. Institutional Conflicts of Interest will be resolved so as to ensure that the welfare of human subjects and the integrity of the research enterprise are not compromised. The following conditions or restrictions may be imposed on Institutional Conflicts of Interest identified under this Policy:

1. Public disclosure of the Institutional Conflict of Interest and how it will be resolved;
2. Monitoring of any affected research by independent reviewers;
3. Modification of the research plan;

4. Disqualification of the Center from participation in all or a portion of the research;
5. Divestiture of the financial interest in question; or
6. Severance of the relationship that creates the Institutional Conflict of Interest.

Effective January 1, 2004