

## POLICY AND GUIDELINES FOR INVOLVEMENT WITH OUTSIDE INTERESTS

This policy applies to all faculty and other employees who are responsible for the design, conduct or reporting of research (including visiting investigators, trainees and affiliates); all employees who are a principal investigator or who consent, recruit, or evaluate the response of human subjects; and such other employees as the President and Director of the Fred Hutchinson Cancer Research Center (“Director”) may from time to time designate (collectively referred to as “Scientific Staff.”)

### I - PRINCIPLES

- A. Mission. Fred Hutchinson Cancer Research Center (“Center”) was established, and is maintained, to foster the development of new knowledge essential to the understanding of the causes, prevention, diagnosis, treatment and after care of cancer. An essential component of this mission is transfer of knowledge and technology developed within the Center to products and practices that will reduce the burden of cancer-related illnesses.
- B. Primary Professional Obligation. The primary professional obligations of the membership of the Scientific Staff of the Center are to the Center and its goals and missions.
- C. Prohibition Against Improper Use of Confidential Information. Scientific Staff may not improperly disclose to third parties or use for their personal benefit confidential information (including confidential information of third parties) acquired by reason of their position at the Center. Special care must be taken to ensure that information from which the identity of patients can be determined is disclosed and used only in accordance with Center policies and applicable law.
- D. Openness in Research. The right and obligations of the Scientific Staff of the Center to publish and in other ways communicate results of their scientific findings is considered of paramount importance to the effective functioning of the Center, and to carrying out its missions and objectives. This includes the right to discuss internally the methods and results of their research with other Center scientists prior to their publication or public disclosure. Scientific Staff should not undertake research that is subject to unreasonable restrictions on its publication or disclosure or which otherwise unreasonably impairs their ability to communicate and discuss the results of their scientific findings.
- E. Participation in Professional, Scholarly and Public Activities. The Scientific Staff may hold office or serve on various committees or in other ways participate in professional associations and societies, and serve on editorial boards or other scholarly or advisory bodies related directly to their scientific work. In some instances, the Scientific Staff will be asked to volunteer their time in public activities or within philanthropic organizations. Consistent with maintaining their primary obligations to the Center, the Scientific Staff is encouraged to

participate in these and other scholarly activities which include presentations of their scientific work, lectures, seminars or short-course participation, and serving on scientific grant review panels and site visit teams.

F. Prohibition Against Payment for a Particular Result. Scientific Staff may not receive payments from any source conditioned upon a particular research result or tied to successful research outcomes.

G. Conflicts of Financial Interest - General. The Scientific Staff's involvement with outside interests must not violate the Center's Conflict of Interest Policy or applicable government regulations. The Center's Conflict of Interest Policy and applicable regulations of Public Health Services and the National Science Foundation require that certain transactions be reviewed and approved 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. The Food and Drug Administration also requires disclosure of relevant financial interests. Scientific staff with significant financial interests (as defined by the Center's Conflict of Interest Policy) may need to have potential conflicts of interest managed, reduced or eliminated in accordance with this Policy. The following situations create potential conflicts of interest that may need to be managed, reduced or eliminated:

1. Significant or prohibited financial interests of a member of the Scientific Staff (or his/her spouse, domestic partner or dependent child(ren)) that could directly and significantly affect or be affected by research in which that member of the Scientific Staff is involved.
2. Any other transaction involving the Center, in which a member of the Scientific Staff (or his/her spouse, domestic partner or dependent child(ren)) has or receives a significant financial interest; and
3. Any other transaction involving the Center and another entity in which a member of the Scientific Staff (or his/her spouse, domestic partner or dependent child(ren)) has or receives a significant financial interest or of which the member of the Scientific Staff (his/her spouse, domestic partner or dependent child) is a trustee, director or officer.

Significant financial interests are defined in the Center's Conflict of Interest Policy and include the following types of financial interests: (a) payments from a for-profit entity to Scientific Staff which exceed \$10,000 in a twelve (12) month period when aggregated with similar payments to the staff member's spouse, domestic partner or dependent child(ren). This includes any type of payment such as consulting fees, expense reimbursement, honoraria, gifts or in-kind compensation; and (b) stock or any other ownership interest held by Scientific Staff in an entity which either exceeds \$10,000 or

which exceeds 5% of the total ownership interest when aggregated with similar interests of the staff member's spouse, domestic partner or child(ren). The term does not include salary, royalties or other remuneration from the Center; income from seminars, lectures or teaching engagements sponsored by public entities or non-profit entities or income from service on advisory committees or review panels for public or non-profit entities.

- H. Conflicts of Interest – Human Subjects Research. 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, Scientific Staff with certain prohibited financial interests (as defined by the Center's Conflict of Interest Policy) may be unable to participate in human subject research financed in whole or in part by funds administered by the Center.

Members of the Scientific Staff may not "participate" (as defined in the Center's Conflict of Interest Policy) in human subjects research financed in whole or in part by funds administered by the Center (1) if that research is sponsored by or is designed to test a product or service of a for-profit entity in which that staff member (or his/her or spouse, domestic partner or dependent child(ren)) has or receives a prohibited financial interest or (2) if the Center's Conflict of Interest Committee otherwise determines that such a prohibited financial interest directly and significantly affects or could be affected by the research in question. Prohibited financial interests are defined to mean (a) stock, stock options, partnership interests, or any other ownership interest in any amount in a for-profit entity except an interest in a publicly traded, diversified mutual fund; (b) royalties, fees or any other type of payment or the right to receive any such payment in the future under any agreement relating to any technology, software or creative work (whether or not patentable or copyrightable) which the Center's Conflict of Interest Committee determines is directly and significantly related to the research in question; (c) any type of payment from a for-profit company (including consulting fees, expense reimbursement or honoraria, gifts or in-kind compensation) that in the aggregate has in the prior calendar year or is expected to exceed \$10,000 in the next twelve (12) months. Payments under a multi-year agreement with a for-profit entity that 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 staff member at least every twelve (12) months and the payments under the agreement do not otherwise constitute a prohibited financial interest. The Center may disclose to prospective and current human subject research participants upon request the source and amount of payments received from for-profit entities by Center staff who participate in human subjects research.

- I. Technology Transfer. In carrying out the goals and missions of the Center, and importantly to provide incentives for the timely transfer of new technology and information such that it can be exploited for public good, incentives to the Scientific Staff are provided. These

incentives are described explicitly in the Center policies and procedures governing the distribution of royalty and other income from patented and non-patented technology, where appropriate arrangements have been made between an outside interest and the Center for sharing in the income derived from the results of research. Members of the Scientific Staff who participate in human subjects research as described in the Center's Conflict of Interest Policy that could directly and significantly affect or be affected by the interest in the licensed technology must either elect to forego receipt of their share of this income or discontinue such participation. All members of the Scientific Staff are required to acknowledge an understanding of and agree to be bound by the Center's Patent and Invention Policy.

- J. Appointments and Promotions. Policies and procedures governing appointments and promotions of the Scientific Staff include careful and periodic review of the accomplishments of the staff. It is definitely to the advantage of the Scientific Staff insofar as possible to pursue and receive outside sources of peer reviewed support for their research activities, although significant support may accrue through non-peer reviewed mechanisms which recognize the unique capabilities of the Scientific Staff and of the Center to perform certain kinds of research. It is the policy of the Center to maintain an appropriate balance between peer reviewed and non-peer reviewed research. Non-peer reviewed research directed specifically towards product development, and conducted on research of outside interests, is generally considered to represent a less important use of the space and resources of the Center than is peer-reviewed research.
- K. Use of Human Specimens. Any use of human specimens collected at the Center or otherwise under the Center's control in commercially sponsored research or any transfer of such specimens to a commercial entity requires prior review and approval under the Center's Policy on Management of Tissue and Serum Collections in research collaborations with commercial entities.

## II - GUIDELINES

The following guidelines have been developed to assist in the evaluation of arrangements between the Scientific Staff with outside interests and conflicts of interest that may arise from those arrangements.

Members of the Scientific Staff must fully disclose their arrangements with outside entities and financial interests from or in outside entities as well as the arrangements and financial interests of his/her spouse, domestic partner or dependent child(ren). Scientific staff must receive the necessary approvals before entering into any such arrangement with or acquiring such financial interests from or in outside entities. Each division may adopt additional guidelines appropriate to the activities of that division; provided that any additional guidelines must be approved by the Director and can be no less restrictive than applicable Center policies and government regulations.

- A. Arrangements with Outside Entities. Any arrangement with an outside entity must have prospective benefits both to the member of the Scientific Staff and to the Center and must comply with the Center's Policy on Conflicts of Interest and applicable government regulations on conflicts of interest.
- B. Conflicts of Interest. In the case of human subjects research as defined in the Center's Conflict of Interest Policy, members of the Scientific Staff with prohibited financial interests (See Section I.H. above) will not be allowed to participate in such human subjects research activity. "Human subjects research" includes research in which 1) data about living individuals is obtained by the Scientific Staff member through intervention or interaction; and 2) the Scientific Staff member has access to individually identifiable private information about the subjects. The term "participate" is defined in the Center's Conflict of Interest Policy as follows: "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 3) evaluating the response of human subjects enrolled on such protocol. In the case of research not involving human subjects research protocols or human subjects research protocols in which the Scientific Staff member is involved but not as a participant, the Center's Conflict of Interest Policy requires that any significant financial interest (See Section I.G. above) creating a conflict of interest be reduced, managed or eliminated. Frequently, conditions or restrictions are imposed. Examples include the following:
1. Public disclosure of any significant financial interest including disclosure in any publication and/or presentation relating to the research;
  2. Monitoring of research by independent reviewers;
  3. Modification of the research plan;
  4. Disqualification from participation in all or a portion of the research by that member of the Scientific Staff;
  5. Divestiture of the significant financial interest in question; or
  6. Severance of the relationship that creates the conflict of interest.
- C. Publication of Scientific Findings. Scientific Staff may not undertake research that is subject to unreasonable restrictions on its publication or disclosure or which otherwise unreasonably impairs their ability to communicate and discuss the results of their scientific findings. The following restrictions are considered reasonable: (1) delay of a publication or disclosure (normally not to exceed sixty (60) days) for patenting purposes or to permit review and

comment by a research sponsor; (2) delay of a publication or disclosure (normally not to exceed sixty (60) days) when it is in the best interests of the research such as in the case of a multi-site study requiring review of data by a publication committee; (3) nondisclosure of confidential information provided by a third party; and (4) requirements that confidential information provided by a third party be disclosed or used only as permitted by the third party. Restrictions on publications or public disclosures other than those referenced above must be approved by the Director or his or her designee.

- D. Limitation on Time Spent in Outside Activities. Scientific Staff who are assistant, associate and full members, associates, staff investigators, and other professional personnel employed on a full-time basis are expected to maintain a minimum 40-hour work week, exclusive of vacation periods. If such member of the Scientific Staff intends to spend in excess of one half (1/2) day each seven-day week in activities with outside interests or intends to hold a management position with an outside interest, he or she must receive the prior written approval of the Center's Appointment and Promotions Committee.
- E. Practice of Medicine. Members of the Scientific Staff who are physicians will not engage in the practice of medicine other than under the rules and regulations of the Division of Clinical Research or as otherwise expressly permitted by the Director.
- F. Management Positions in Outside Entities. Holding of management positions or responsibility for management and other decisions within an outside interest are to be avoided. Under exceptional circumstances and with prior approval of the Center's Appointment and Promotions Committee, a member of the Scientific Staff may be granted a leave of absence for a reasonably short period of time (generally no more than one year) to assume such functions. The space and resources assigned to a member or members requesting such unique arrangements with an outside interest would need to be evaluated as to an appropriate disposition during such a leave of absence and as to any commitments for space and resources available after return from a leave of absence.
- G. Use of Center Space and Resources in Outside Entities. Activities with outside interests will generally not involve the use of Center space or resources. Center stationery will not be used in conjunction with activities for outside interests. However, stationery used by a Scientific Staff member may mention the nature and location of the individual's appointment at the Center.

### **III – PRIOR APPROVAL, DISCLOSURE AND REVIEW PROCEDURES**

The Center has established a process for prior approval, disclosure, and review of outside activities and financial interests to enforce the Center's Conflict of Interest Policy and comply with federal

law. Review of financial disclosures is conducted in a confidential manner. However, under certain circumstances, the existence of certain financial interests held by Scientific Staff will be disclosed in publications or presentations of research results and to prospective or current human subjects in clinical trials that could affect or be affected by such interests. Disclosure of financial interests held or received by Scientific Staff (and their spouses, domestic partners and dependent child(ren)) will be reviewed by the Division Director, the Office of the General Counsel and the Director. Disclosure of financial interests held or received by Scientific Staff members (and their spouses, domestic partners and dependent child(ren)) in cases in which the Scientific Staff member is a participant in human subjects research may also be reviewed by the Center's Conflict of Interest Committee. The prior approval, disclosure and review process is described more fully below.

A. Prior Approval of Outside Activities and Interests. Prior to the initiation of any arrangement with or acquisition of an interest in a for-profit entity of the type described in Section III.B.1 below, the Scientific Staff member must complete a "Request for Prior Approval of Outside Activities and Financial Interests" form. This form will solicit basic information about the proposed outside activity (e.g., consulting agreement) and/or the financial interest (e.g. stock ownership or patent license). If the request relates to approval of an outside activity involving consulting or service on an advisory board, for example, some of the information that will be requested includes the following:

1. The nature of the relationship proposed.
2. The short-term and long-term commitments of time and effort.
3. All financial aspects, including all compensation, expense reimbursements, equity and any indirect and/or potential economic value from the proposed relationship. The Director or designee will apply a per trip rate for the calculation of expense reimbursements.
4. The expected benefit to the Scientific Staff member and to his/her spouse, domestic partner or dependent child(ren) (if applicable).
5. The expected benefit to the Center.
6. Whether the proposed arrangement or relationship could reasonably affect or be affected by the research being conducted at the Center by the Scientific Staff member or those under his/her direction or control.

If the request relates to approval of an ownership interest (stock ownership) or intellectual property interest (patent license), information will be requested regarding any relationship of the interest in question to Center research activities, especially those involving human

subjects.

B. Disclosure of Individual Financial Interests.

1. Annual Disclosures. Upon commencement of employment and annually thereafter, Scientific Staff will be required to disclose the following information:
  - a. Any leadership position (e.g. director, trustee, officer) held by the Scientific Staff (or his/her spouse, domestic partner or dependent child(ren)) of any for-profit or non-profit entity whose activities could reasonably affect or be affected by the Scientific Staff's research or other activities at the Center;
  - b. All ownership interests (e.g. stocks, options, partnership interests) held by the Scientific Staff (or his/her spouse, domestic partner or dependent child(ren)) in any for-profit entity whose activities could reasonably affect or be affected by the Scientific Staff's research activities at the Center;
  - c. The receipt of income, or the right to receive income, by the Scientific Staff (or his/her spouse, domestic partner or dependent child(ren)) relating to intellectual property that is the subject of an agreement with an outside entity;
  - d. Payments received by the Scientific Staff (or his/her spouse, domestic partner or dependent child(ren)) from any for-profit entity which could reasonably affect or be affected by the Scientific Staff's research activities at the Center; and
  - e. Any other interest which could reasonably create a conflict of interest under the Center's Conflict of Interest Policy.

These interests and arrangements must be summarized on the "Annual Summary of Outside Activities" form. Disclosures must be submitted to the Division Director for the division in which the person holds primary appointment. If primary appointments are held in two divisions, copies of the form should be filed with both Division Directors.

2. External Funding Proposal Disclosures. On each application or proposal for external research funding, the principal investigator will be required to list all key personnel, defined as individuals who will be responsible for the design, conduct or reporting of

the research that is the subject of the funding proposal. The principal investigator and other key personnel will then be required to complete a project-specific disclosure form and, if necessary, an Annual Summary of Outside Activities form. Before any funds can be expended, the Center Director or designee will certify that either 1) no conflict of interest exists that could directly or significantly affect or be affected by the design, conduct or reporting of the research; or 2) that any conflict of interest has been managed, reduced or eliminated in accordance with the Center's Conflict of Interest Policy and applicable federal law.

3. Food and Drug Administration ("FDA") Disclosures. Members of the Scientific Staff engaged in research regulated by the Food and Drug Administration ("FDA") are required to disclose financial interests in and arrangements with the study sponsors and to certify what steps, if any, were taken to minimize potential bias. Copies of these FDA forms must be filed with the Division Director or his or her designee.
4. Affiliate Conflict Disclosures. Members of the Scientific Staff at the Center who hold appointments at affiliate institutions (e.g. University of Washington) may be required to file disclosure forms at each institution and be subject to more than one conflict of interest policy.

#### C. Review Procedures

##### 1. Review by Division Director.

The Division Director(s) of the division in which the person holds primary appointment or is employed will review all disclosure forms and requests to enter into arrangements with outside interests to determine whether any of the disclosures create a conflict of interest under the Center's Conflict of Interest Policy. If the Division Director determines that a conflict of interest involves human subjects research, he or she may refer the matter to the Conflict of Interest Committee (described in Section III.C.2) for its review and recommendation to the Director. The Division Director may seek assistance from the Office of the General Counsel in evaluating the disclosure forms. The Office of the General Counsel will review and approve all requests for prior approval for outside activities and financial interests and will review all consulting, commercial research and related agreements. If a Division Director identifies a conflict of interest or possible conflict of interest, the Division Director will discuss any proposed action with the individual involved and will make a recommendation as to how the conflict of interest should be managed, reduced or eliminated. If the individual involved does not agree with the recommendation of the Division Director, the Division Director will, upon the written request of the individual involved, refer the matter to the Conflict of Interest Committee. The recommendation of the Division Director or the Conflict of Interest Committee, as the case may be, and supporting

material together with such reasonable information as the individual involved wishes to provide, will be forwarded to the Director for a final decision.

2. Conflict of Interest Committee

The Conflict of Interest Committee (“COI Committee”) will be consulted with respect to possible conflicts of interest referred by the Division Director or Director relating to Scientific Staff especially those participating in human subjects research as defined in the Center’s Conflict of Interest Policy. The COI Committee is composed of one trustee appointed by the chair of the Center’s Board of Trustees, one member from each of the Center’s scientific divisions and such other members as the Director may select. The chair of the COI Committee will be selected by the Director, and the COI Committee will meet at least annually or more frequently as necessary. The primary role of the COI Committee shall be to determine whether the conflict of interest will trigger a prohibition of the Scientific Staff’s participation in human subjects research and shall have such other duties as the Director may assign. The COI Committee will also consider challenges by Scientific Staff to determinations made by a Division Director with respect to a conflict of interest finding and the plan for the management, reduction or elimination of a conflict. The COI Committee shall establish such internal rules and procedures as it deems appropriate, subject to the Director’s approval.

3. Review by Director.

The Director or designee will review the recommendation made by the Division Director or the COI Committee. If the Director believes that a conflict, not previously referred to the COI Committee, involves human subjects research, he may refer it to the COI Committee for its recommendation. Where necessary or appropriate, the Director will seek the advice of the Office of the General Counsel. The decision of the Director is final. Copies of all approved disclosure forms and prior approval requests will be maintained in the Office of the General Counsel.

4. Notice to Federal Funding Agencies.

In the case of an award involving federal funding, the awarding agency will be notified of any action taken to manage, reduce or eliminate the conflict as required by federal law.

5. Institutional Review Board (“IRB”) Review.

Research involving human subjects reviewed by a Center IRB requires confirmation that

any conflicts of interest involving the principal investigator and other individuals covered by the Center's Conflict of Interest Policy and federal law have been managed, reduced or eliminated. Under certain circumstances, the IRB or IRB chairs will be informed about the manner in which a conflict of interest has been managed, reduced or eliminated.

6. Enforcement.

a. Reporting Violations.

If, at any time, a member of the Scientific Staff becomes aware of any arrangement with outside interests or of any conflict of interest which that member was required to disclose pursuant to Center policy and which was not disclosed, that member must immediately (and in no event, later than 15 days after becoming aware of the nondisclosure) disclose the matter to the Director's Office.

b. Sanctions.

Violations of this policy by members of the Scientific Staff will be reported to the Director for appropriate action. If a violation of this policy has biased the design, conduct or reporting of any government funded research, the Director will determine what corrective action should be taken and will notify the awarding agency. The Director may, at his or her discretion, appoint an ad hoc committee to review the situation and determine what corrective action, if any, should be taken. Intentional violations of this policy or the Center's Conflict of Interest Policy may result in immediate suspension or dismissal in accordance with the Center's established personnel policies.

c. Disclosure

In any case in which it is determined that a clinical research project to evaluate the safety or effectiveness of a drug, medical device or treatment which is funded by the PHS or NSF has been designed, conducted or reported by a member of the Scientific Staff with a significant financial interest which was not disclosed or managed as required by applicable government regulations, the Center will require disclosure of the financial interest in each public presentation of the results of the research.

