

# **Dana-Farber Cancer Institute**

## **Policy on Institutional Conflicts of Interest in Human Subjects Research**

### **Introduction:**

The Dana-Farber Cancer Institute (DFCI) is committed to advancing the understanding, treatment, cure, and prevention, of cancer and related diseases. Institutional relationships with industry are fundamental to the furtherance of this commitment, as they facilitate the exchange of knowledge that generates scientific advancement and improves medical care. For instance, the licensing of Institute intellectual property to the industrial sector is an integral step in translating research into treatments that will benefit patients. Thus, achieving one of the paramount goals of DFCI requires that the relationships between the Institute and industry remain preserved and viable. However, DFCI is also dedicated to ensuring the highest ethical standards in the conduct of all Institutional activities. Therefore, it is essential that DFCI's research programs not be compromised, or appear to be compromised, by actual or apparent bias due to such relationships.

The purpose of this Policy is to preclude the possibility that the financial interests of the Institute, or of its leaders, will compromise, or appear to compromise, the safety and protection of human research subjects and/or the integrity of the human subject research conducted at, or under the auspices of, DFCI. Interests that pose such risks will be subject to review, oversight, and, when appropriate, management. The existence of actual bias will not be permitted, and any conflict that creates actual bias will be eliminated.

### **Definitions:**

*Human subject* is "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." 45 CFR 46.102.

*Institutional Conflict of Interest (ICOI)* refers to any Material Institutional Interest that could affect, or reasonably appear to affect, the design, conduct, reporting, review, or oversight of the human subject research.

*Institutional Conflict of Interest Committee (ICOIC)* refers to the committee vested with the responsibility to address matters of institutional policy regarding ICOI, and the responsibility to review and manage any actual or potential ICOI.

*Institutional Interest* refers to:

1. the Financial Interests of DFCI. This includes, but is not limited to:
  - a. Interests derived from licensing of Institutional technology and intellectual property, such as revenue, royalties, milestones, and equity interests;
  - b. Institutional investments;
  - c. Gifts and donations made to DFCI where the donor has an interest in research activities conducted at or under the auspices of DFCI (e.g. where the corporate donor or its competitors sponsor research at DFCI).
2. the Financial Interests of an Institutional Official and/or his or her spouse and dependent children (collectively his or her “Family”). This includes, but is not limited to:
  - a. compensation or honoraria for services related to his or her institutional role;
  - b. payments for technology transfer (e.g. royalties, license fees, inventor revenue);
  - c. equity or options;
  - d. fiduciary or director positions;
  - e. gifts.

*Institutional Official* refers to anyone who, by virtue of his or her position at DFCI, has particular oversight and/or decision-making authority over Institutional activities. This includes:

1. Departmental Leadership: Individuals who are endowed with the authority to supervise research, delegate responsibilities, and/or control resources within the department, or who are responsible for determining salaries, allocating space, equipment, and other resources to individuals conducting research at the Institute. This includes Department and Division Chairs, and Program Leaders.
2. Human Subject Research Review and Oversight Leadership: Individuals are considered Institutional Officials when they are tasked with the review and/or oversight of human subject research. This includes but is not limited to members of the Scientific Review Committee, the Institutional Review Boards, and the Data Safety Monitoring Boards and Committees.
3. Executive Leadership: Individuals who are responsible for the overall conduct and oversight of research at the Institute. This includes but is not limited to the President/ Chief Executive Officer, Executive Vice President, Senior Vice Presidents, Vice Presidents, the Chief Scientific Officer, the Chief Operations Officer, the Chief Clinical Research Officer.

*Material Interest* is any Institutional Interest in a Relevant Business.

*Relevant Business* is any business that:

1. Sponsors or provides support for research on human subjects conducted at, or under the auspices of, DFCI; or
2. Owns or has licensed the technology that is being investigated in human subject research at, or under the auspices of, DFCI; or
3. Owns or has licensed technology that is in direct competition with technology that is being investigated in human subject research at, or under the auspices of, DFCI.

## **Identifying and Reviewing Institutional Financial Conflicts of Interest:**

### **A. Identifying Material Interests Held by Institutional Officials**

Each Institutional Official must disclose all financial interests related to his or her institutional role, held either individually or by a Family Member, using the DFCI electronic Outside Activity Reporting (OAR) system. The Office of Research Integrity will review these disclosures to identify Material Institutional Interests, which shall be reviewed by the ICOIC. The following are considered Material Interests requiring review by the ICOIC:

1. Compensation (for example, consulting fees, advisory board participation, remuneration, honoraria) and other “in-kind” payments from a Relevant Business;
2. Equity interest or entitlement to equity in any amount in a Relevant Business;
3. Service in any fiduciary or executive capacity for a Relevant Business, whether or not compensation is received in exchange for such service;
4. The receipt of, or right to receive in the future, royalties, fees, or any other periodic and/or success-based payments or revenue resulting from the sale, license, or assignment of copyright or patent rights to an investigational technology to a Relevant Business.

### **B. Identifying Material Interests Held by the Institution**

The ORI shall maintain and keep current a database of Institutional Interests, which shall be reviewed and updated at least quarterly. Each office, program, or department at DFCI that receives revenue from a Relevant Business, either on behalf of DFCI or of a particular

investigator, laboratory, or program, shall provide regular reports of these interests to ORI, including:

1. Office of Research and Technology Ventures
2. Development Office
3. Office of General Counsel
4. Academic Departments
5. Disease Programs
6. Clinical Trials Office

The following are considered Institutional Interests which shall require review by the ICOIC:

1. Equity interests, or the entitlement to equity (including options), in a Relevant Business, with particular attention given to interests in a Relevant Business that is not publicly traded.
2. The receipt of, or right to receive in the future, royalties, fees, or any other periodic and/or success-based payments or revenue resulting from the sale, license, or assignment of copyright or patent rights of an investigational technology to a Relevant Business.
3. The receipt or pledge of substantial gifts (including gifts in-kind) from a for-profit Relevant Business.

### **Assessing Material Institutional Interests for ICOI:**

The ICOIC shall determine on a case-by-case basis whether the Material individual interests of DFCI or an Institutional Official, and/or his or her Family have the potential to affect, or reasonably appear to affect, the design, conduct, reporting, review, or oversight of human subject research, and by so doing constitute a FCOI. In making such a determination, the ICOIC may take into account any factors it deems relevant to the analysis, but shall give particular consideration to the potential risk to human research subjects. Additionally, the ICOIC shall consider:

1. in the case of the Material Interests of an Institutional Official:
  - a. the degree of authority, if any, that she or he has over the relevant research and research personnel;
  - b. the degree to which the value of the interest could be affected by the human subject research;
  - c. the degree to which the interests of the Relevant Business could be affected by the human subject research;
  
2. in the case of the Material Interests of DFCI:
  - a. the degree to which the value of the Material Institutional Interest could be affected by the human subject research;
  - b. the degree to which the interests of the Relevant Business could be affected by the human subject research.

If the ICOIC concludes that a Material Interest constitutes an ICOI, it shall determine whether and under what circumstances the research may be conducted at, or under the auspices of, DFCI. It may, in its sole discretion, establish a plan which shall identify the necessary steps required to manage the conflict, which may include the following:

1. Modification of the research plan;
  
2. Modification of the financial interest, for example through the divestment of equity interest, or the termination of a consulting relationship;
  
3. Formal recusal of the conflicted official from the chain of authority. If the Institutional Official would be unable to fulfill his or her responsibilities due to recusal, the ICOIC may require the individual to either divest or vacate the position;
  
4. The assignment of substitute decision-making or negotiating authority in the case of purchasing or supply contracts or other financial transactions;
  
5. Disclosure of the ICOI to all faculty, staff, and students under the Institutional Official's supervision, including the designation of a 'safe-haven,' or a non-conflicted senior official, to whom they may address ICOI-related concerns;
  
6. Disclosure of the ICOI to research subjects in the informed consent form;
  
7. Disclosure of the ICOI to other investigators participating in the research, and to all other sites if the research is being conducted at multiple sites;

8. Use of external non-DFCI oversight/monitoring units, including IRBs, DSMBs, or statisticians;
9. Increasing or establishing firewalls to separate the Institutional Official's role from the research;
10. Disclosure of the ICOI in public presentation, publications, and to all other participating research sites (in the case of a multi-center trial).

[Effective 10/15/15]