POLICY ON INSTITUTIONAL CONFLICTS OF INTEREST IN RESEARCH

**Purpose:** This policy is established to reduce the possibility that the financial interests of Dana-Farber Cancer Institute (DFCI), or of its senior leadership, will compromise or have the capacity to compromise, (i) the integrity of the results of Human Subjects Research and Industry-Sponsored Non-Human Subjects Research conducted at, or under the auspices of, DFCI; (ii) the safety and trust of participants in human subjects research studies (iii) the trust of patients, (iv) the trust of the research community and (v) the trust of the public in the endeavors of DFCI. Activities that pose risks to these paramount interests will be subject to review, oversight and, where appropriate, management.

**Scope:** This policy applies to (i) all Workforce members and (ii) all other individuals responsible for the design, conduct, reporting, or oversight of research at, or under the auspices of, DFCI, including Senior Institutional Officials.

**Policy:**

DFCI is dedicated to ensuring that the highest ethical standards are maintained in the conduct of its institutional activities. This includes being attentive to and, where appropriate, preventing or managing conflicts of interest that arise research conducted at, or under the auspices of, DFCI as a result of the institution’s (and its leadership’s) financial relationships with industry. Institutional relationships between DFCI and industry are critical for the exchange of knowledge, translation of discovery, and scientific innovations that improve standard medical care and broaden treatment options for cancer and related diseases. These relationships, however, can create financial incentives that conflict with DFCI’s fundamental responsibility to protect and preserve the trust of human research participants and to maintain the integrity of research.

This policy sets the Institute’s standards for the identification, review and management of institutional conflicts of interest relating to Human Subjects research and Industry-Sponsored Non-Human Subjects Research.

1. **Identifying Material Interests Held by Senior Institutional Officials**

Each Senior Institutional Official must disclose to DFCI, and update as necessary, all financial interests related to his or her DFCI institutional role, held either individually or by a Family Member, using the system maintained and managed by the DFCI Office for Research Integrity (ORI) for annual outside activities reporting. ORI will review these disclosures to identify Material Interests. Material Interests (as defined herein) shall be reviewed by the Institutional Conflict of Interest Committee (ICOIC).

2. **Identifying Material Interests Held by the Institution**

The Belfer Office for Dana-Farber Innovations (BODFI), DFCI’s Division of Philanthropy, and other relevant departments are responsible for reporting Institutional Interests to ORI for purpose
of maintaining an accurate and current database. ORI will review the Institutional Interests to identify Material Interests. Material Interests shall be reviewed by the ICOIC for management (See Part IV Assessing Material Interests below).

III. Limitations on Royalties Paid to DFCI

In all cases, license agreements pursuant to which DFCI licenses a Technology, exclusively or non-exclusively, to a Business must state that the Business will not pay royalties to DFCI that are based on DFCI’s own purchase of products incorporating the Technology. If circumstances warrant, the ICOIC may approve an arrangement under which all such royalties will be donated to a charitable organization unaffiliated with DFCI.

IV. Assessing Material Interests for ICOI

The ICOIC shall determine on a case-by-case basis whether a Material Interest constitutes an ICOI. In making such a determination, the ICOIC shall give particular consideration to the potential risk to (i) human research participants and (ii) the integrity of the research study. Additionally, the ICOIC shall consider:

A. In the case of a Material Interest of a Senior Institutional Official:
   1. The degree of authority, if any, that the Senior Institutional Official has over the relevant research and research personnel;
   2. Whether the value of the Material Interest could be directly and significantly affected by the research; and
   3. Whether the financial interests of the Relevant Business could be directly and significantly affected by the research.

B. In the case of a Material Interest of DFCI:
   1. Whether the value of the Material Interest could be directly and significantly affected by the research; and
   2. Whether the financial interests of the Relevant Business could be directly and significantly affected by the research.

V. Determining Prevention and/or Management Measures

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. If the ICOIC concludes that the research may be conducted at, or under the auspices of DFCI, the ICOIC shall, in its sole discretion, establish a management plan which will identify the necessary steps required to manage the ICOI, which may include the following:

1. Modification of the research plan;
2. Modification of the Material Interest, for example through the divestment of an Equity Financial Interest, or the termination of a conflicted SIO’s consulting relationship;

3. Formal recusal of the conflicted Senior Institutional Official from the chain of authority. If the Senior 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 place of a conflicted Senior Institutional Official in the case of purchasing or supply contracts or other financial transactions related to the relevant research;

5. Disclosure of the ICOI to all faculty, staff, and trainees/students under the conflicted Senior 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. Establish a firewall to separate the conflicted Senior Institutional Official and his/her role from the relevant research;

7. Use of an external oversight or monitoring committee comprised of members unaffiliated with DFCI, which may include an external IRB, DSMC/DSMB/ESMB, or biostatistician;

8. In the case of human subjects research, disclosure of the ICOI to research participants in the informed consent form or through other mechanisms approved by the Institutional Review Board (IRB) of record for the research;

9. Disclosure of the ICOI to other investigators on the research study and, in the case of human subjects research, to the other investigators who Participate in the Clinical Research at all other sites if the research is being conducted at multiple sites where DFCI is the lead site;

10. Disclosure of the ICOI in any public presentation, publication, and to any other participating research site (in the case of a multi-center trial), and/or

11. Require a secondary review of institutional spending under a Significant Investigator Gift made solely for the support of a named individual’s research or his/her laboratory who, in the case of human subjects research, Participates in the Clinical Research.

VI. Compliance and Oversight

A. In the case of a Material Interest of a Senior Institutional Official: It is the responsibility of a conflicted Senior Institutional Official to maintain compliance with his or her ICOI management plan.

B. In the case of a Material Interest of DFCI: It is the responsibility of the DFCI principal investigator and/or DFCI site principal investigator to maintain compliance with an ICOI management plan applicable to his/her study.
C. ORI shall be responsible for monitoring compliance with ICOIC management plans and for reporting instances of noncompliance to the ICOIC. The ICOIC has wide discretion to recommend a variety of actions in the event of noncompliance with a management plan developed under this policy. These may include, but are not limited to:

1. Suspension or termination of the relevant research study.
2. Modification or revised management of the research study.
3. An external audit or review of the research study.
4. Individual admonition or sanction.
5. Ineligibility to apply for IRB approval for research on a Technology of the Relevant Business.
6. Any other restriction, limitation or, as appropriate, sanction determined by the ICOIC to be warranted by the circumstances.

VII. Definitions

Unless otherwise defined below or in this policy, capitalized terms shall have the meaning ascribed to them in the Dana-Farber Cancer Institute Policy on Conflicts of Interest and Commitment.

Business is any legal entity organized for profit or non-profit purposes. Not included in this definition is Dana-Farber Cancer Institute.

Relevant Business is any for-profit Business that:

1. provides Sponsored Research support for research conducted at, or under the auspices of, DFCI; or
2. Owns, manufactures, markets or has licensed the Technology that is being investigated in human subject research at, or under the auspices of, DFCI.

Clinical Research means a research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. (45 CFR 46.102(b) -2018 Common Rule).

Equity Financial Interest is any equity holdings owned by DFCI in a Business, the amount of which could be impacted by the outcome of research conducted at, or under the auspices of, DFCI.

Financial Interest is any equity interest in a Business (“Equity Financial Interest”) or the receipt of, or the right or expectation to receive (except rights to future income under institutional royalty sharing agreements), any income from a Business (“Income Financial Interest”).

Human Subjects Research means research involving a living individual about whom an investigator (whether professional or student) (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or
biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102(e)(1)-2018 Common Rule).

**Industry-Sponsored Non-Human Subjects Research** means research, training, and instructional projects involving funds, personnel, certain proprietary materials, or Technology, or other compensation from a Relevant Business under an agreement that the institution classifies as a sponsored research agreement in accordance with institutional policy.

**Income Financial Interest** the expectation of DFCI to receive income derived from research activities that generate institutional interests.

**Institutional Conflict of Interest (ICOI)** refers to any Material Interest that could directly and significantly affect the design, conduct, reporting, review, or oversight of Human Subjects research and Industry-Sponsored Non-Human Subjects Research.

**Institutional Conflict of Interest Committee (ICOIC)** refers to the committee charged with responsibility to modify, interpret and implement this institutional policy and the responsibility to review and manage any actual, potential, or perceived ICOI.

**Institutional Interest** refers to:

1. the following interests of DFCI:
   a. DFCI Financial Interests derived from technology transfer activities of the Belfer Office for Dana-Farber Innovations (BODFI), including the licensing of DFCI technology and intellectual property. This may include, but is not limited to, licensing revenue, royalties, milestone payments, contingent value rights, and Equity Financial Interests;
   b. Gifts and donations made to DFCI under the following circumstances:
      i. A gift or donation from a Relevant Business equal to or exceeding $1,000,000 (“Significant Institutional Gift”).
      ii. A gift or donation from a Relevant Business (or multiple gifts in a given year) equal to or exceeding $25,000 made solely in support of a named individual’s research or that of his/her laboratory (“Significant Investigator Gift”).
   c. Equity Financial Interests held by a DFCI-managed venture or angel financing fund, if applicable at any time.

2. the Financial Interests of a Senior Institutional Official and/or his or her spouse and dependent children (collectively his or her “Family”). This includes, but is not limited to:
   a. Income Financial Interests;
   b. shares of upfront payments, milestone payments, contingent value rights, or other royalties resulting from licensing or other technology transfer activities of DFCI or the Institutional Official;
c. Equity Financial Interests;

d. fiduciary or director positions regardless of payment; or

e. significant gifts.

**Material Interest** is:

1. In the case of Human Subjects Research, any Institutional Interest in or from a Relevant Business; and

2. In the case of all other research, any Equity Financial Interests of DFCI or of a Senior Institutional Official in a Relevant Business.

**Senior Institutional Official** refers to anyone who, by virtue of his or her academic or administrative leadership position at DFCI, has oversight and/or decision-making authority over the allocation of resources, promotion, review and salary determinations, or other institutional activities that could impact the design, conduct, reporting or oversight of research conducted at or under the auspices of DFCI. This includes Department and Division Chairs, Research Administration Leadership, Belfer Office of Dana Farber Innovations (BODFI) Leadership and DFCI Leadership. The Board of Trustees Conflicts of Interest Oversight Committee has the responsibility of the review, approval and oversight of outside activities of the Dana-Farber Chief Executive Officer (“CEO”) and any Executive Vice Presidents.

**Participate in Clinical Research:** Covered Persons who Participate in Clinical Research are individuals who are responsible for the design, conduct, or reporting of an IRB-approved study and, as part of that IRB-approved study:

a. have access to information about living individuals by intervening or interacting with them for Research purposes; and/or

b. have access to identifiable private information about living individuals for Research purposes; and/or

c. obtain the voluntary informed consent, assent or participation of individuals to be subjects in Research; and/or

d. study, interpret, or analyze identifiable private information or identifiable data for Research purposes; and/or

e. have access to the study treatment assignment made through, for example, a randomization process.

**Technology** means any compound, drug, device, or diagnostic, medical, or surgical procedure intended for use in health care or health care delivery.

Questions? Contact the DFCI Office of Research Integrity at researchintegrity@dfci.harvard.edu.

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1 The specific titles of each covered position may change over time, but it is assumed that the term will cover any faculty or administrative (Vice President level or above) leadership position that meets the definition specified.
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