

**DANA-FARBER CANCER INSTITUTE  
PATIENT CARE & ADMINISTRATIVE POLICY MANUAL  
RESEARCH POLICY AND PROCEDURE MANUAL**

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 Clinical and Industry-Sponsored Research conducted at, or under the auspices of, DFCI; (ii) the safety and trust of participants in clinical 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 (“SIO”).

**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 from 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 Clinical and Industry-Sponsored Research.

*I. Policy Requirements for DFCI’s Institutional Financial Interests*

A. DFCI Equity Financial Interests

From time to time, DFCI or a DFCI-affiliated organization<sup>1</sup> will acquire equity (stock, stock options, or similar ownership interests) outside of investment and philanthropic acquisitions (“Equity Financial Interest”). In most cases this happens as a result of a license of DFCI Technology or investments relating to Technology or start-up company activities.

Institutional conflicts of interest may arise when DFCI has an Equity Financial Interest in a Relevant Business. A “Relevant Business” is a for-profit entity that:

1. provides Sponsored Research support for Clinical Research conducted at DFCI; or
2. owns, manufactures, markets or has licensed the Technology that is being

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<sup>1</sup> For the purposes of this policy, “DFCI” as used herein includes DFCI-owned entities and any DFCI-managed venture or angel financing fund.

investigated, validated, or tested in Clinical Research at DFCI.

DFCI has a rebuttable presumption that, while DFCI holds an Equity Financial Interest in a Relevant Business, DFCI may not conduct Clinical Research investigating, validating, or testing on patients the Technology of the Relevant Business. The presumption may be overcome only if

1. The DFCI Institutional Conflicts of Interest Committee (“ICOIC”) determines that there are demonstrable, compelling circumstances, consistent with the rights and welfare of human research subjects, for DFCI to conduct the Clinical Research while it or any DFCI-affiliated institution holds an Equity Financial Interest; OR
2. For non-Clinical Research or minimal risk Clinical Research, the ICOIC determines that the benefits of DFCI conducting the Clinical Research outweigh the risks.

If the presumption is overcome under (1) or (2), the Clinical Research may proceed only if the ICOIC determines that the institutional conflict of interest can be appropriately managed, pursuant to a ICOIC-approved management plan designed to protect the integrity of the Clinical Research and the care of human subjects participating in it.

Industry-Sponsored Research that is not Clinical Research, and Clinical Research that is considered by the Institutional Review Board (“IRB”) of record to be minimal risk, is not subject to the rebuttable presumption above, but may proceed pursuant to a management plan approved by the ICOIC, which authority is delegable by the ICOIC to the ICOIC-designated expedited review panel and/or the DFCI Office of Research Integrity (“ORI”).

Factors that may be relevant to the analysis of whether compelling circumstances exist to conduct the Clinical Research include, but are not limited to, the following:

- The nature of the science involved;
- A description of the Equity Financial Interest and the degree to which its value could be directly and significantly affected by the Clinical Research;
- The magnitude of the potential risks to subjects or integrity inherent in the Clinical Research;
- Study design and oversight factors that protect against bias;
- How those risks could be affected as a result of the Equity Financial Interest;
- Whether DFCI is uniquely qualified, by virtue of its attributes (e.g. special facilities or equipment, unique patient population) and its researchers, to conduct the Clinical Research;
- Whether the research will advance otherwise if DFCI does not conduct it;
- The best interests of DFCI patients; or
- The degree to which the institutional conflict of interest can be effectively managed.

Possible elements of associated management plans may include, but are not limited to, the following:

- Special oversight of human subjects involved in the Clinical Research, for example, through additional internal monitoring mechanisms or through an external IRB, external oversight by a committee comprised of members unaffiliated with DFCI, such as through an external Data Safety Monitoring Committee (“DSMC”), Data

Safety Monitoring Board (“DSMB”), External Safety Monitoring Board (“ESMB”), or biostatistician,

- Increasing or establishing firewalls or other conflicts management systems to separate financial decision-making from decision-making about the Clinical Research;
- Independent data monitoring to ensure validity, through an objective individual or individuals outside of DFCI with no ties to the Clinical Research or to the outside entity;
- Disclosure of institutional conflicts as defined in this Section 5 in all relevant settings, including to human subjects involved in the Clinical Research; or
- Modification or restriction of DFCI’s financial interest, through lock-up provisions, divestiture, or the like.

#### B. DFCI Income Financial Interests

Institutional conflicts of interest may arise when DFCI has an Income Financial Interest as a result of a transfer of rights to DFCI Technology or providing support for start-up company activities. An Income Financial Interest may include, but is not limited to:

1. Upfront payments
2. Milestone payments
3. Royalties and
4. Contingent value rights.

While DFCI has an Income Financial Interest in the Relevant Business, ICOIC approval is required before DFCI may conduct Clinical Research investigating, validating, or testing on patients the unvalidated Technology of the Relevant Business or validate or test on patients the unvalidated Technology of the Relevant Business.

In performing its analysis, the ICOIC may consider any factors that it deems relevant to the analysis. Clinical Research that is considered by the IRB of record to be minimal risk, are not subject to the rebuttable presumption above, but may proceed pursuant to a management plan approved by the ICOIC, which authority is delegable by the ICOIC to an expedited review panel of the ICOIC.

The ICOIC may, from time to time, establish a de minimis threshold for reviewing a DFCI Income Financial Interest.

#### C. Gifts and Donations made to DFCI

Institutional conflicts of interest may arise when DFCI or a DFCI-affiliated organization receives or has the potential to receive a significant gift or donation from a Relevant Business. ICOIC review is required when DFCI or a DFCI-affiliated organization receives or has the potential to receive a gift from a Relevant Business that exceeds these de minimis thresholds:

1. A gift or donation from a Relevant Business, restricted to the support of a named individual’s research or that of his/her laboratory, that is equal to or exceeds \$25,000 (“Significant Investigator Gift”).
2. A gift or donation from a Relevant Business, unrestricted, that is equal to or exceeds \$1,000,000 (“Significant Institutional Gift”).

The ICOIC shall determine on a case-by-case basis whether these interests require management of

research at DFCI. The ICOIC may consider any factors that it deems relevant to the analysis.

#### D. Identifying Institutional Financial Interests of DFCI

The DFCI Office of Innovations, Office of Philanthropy, and other relevant departments are responsible for reporting DFCI institutional interests to ORI for purposes of this Policy.

#### II. *Limitations on Royalties Paid to DFCI*

In all cases, license agreements pursuant to which DFCI licenses a Technology, exclusively or non-exclusively, to an entity must state that the entity 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.

#### III. *Policy Requirements for Financial Interests and Fiduciary Roles of Senior Institutional Officials*

Institutional conflicts of interest may arise when DFCI conducts Clinical Research sponsored by, or on the Technology of, a Relevant Business in which an SIO has an Equity Financial Interest over de minimis, or a Fiduciary Role.

##### A. Reviewable Interests of Senior Institutional Officials

When DFCI proposes to conduct Clinical Research sponsored by, or on the Technology of, a Relevant Business, and that research is within the scope of the responsibilities of an SIO who holds one of the following relationships or interests in the Relevant Business, the proposed research must be reviewed and approved by ICOIC before the research begins at DFCI:

1. A Fiduciary Role at the Relevant Business; or
2. An Equity Financial Interest in the Relevant Business that exceeds \$50,000 in a publicly held Relevant Business or any equity in a privately held Relevant Business.

The ICOIC shall determine on a case-by-case basis whether these interests require management. The ICOIC may impose restrictions on and implement management mechanisms for the SIO with respect to oversight of such research. In making such a determination, the ICOIC shall consider

1. The potential risk to (i) human research participants and (ii) the integrity of the research study;
2. Whether the value of the Equity Financial Interest or Fiduciary Role could be directly and significantly affected by the research;
3. Whether the financial interests of the Relevant Business could be directly and significantly affected by the research; and
4. The degree of authority, if any, that the SIO has over the relevant research and research personnel.

##### B. Identifying Financial Interests of Senior Institutional Officials

Each SIO 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 ORI for annual outside activities reporting. ORI will review these disclosures to identify Equity Financial Interests over de minimis and Fiduciary Roles and

determine:

1. Whether the value of the Equity Financial 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
3. Whether the Fiduciary Role could directly and significantly affect the design, conduct, or reporting of the research.

#### *IV. Determining Prevention and/or Management Measures*

If the ICOIC concludes that the research may be conducted at, or under the auspices of, DFCI, the ICOIC shall establish a management plan which will identify the necessary steps required to manage the ICOI, which may include, but are not limited to, the following:

1. Modification of the research plan;
2. Modification of the interest, for example through the divestment of an Equity Financial Interest, or the termination of a conflicted SIO's Fiduciary Role;
3. Special oversight of human subjects involved in the Clinical Research, for example, through 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;
4. In the case of Clinical 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;
5. Disclosure of the ICOI to other investigators on the research study and, in the case of Clinical 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;
6. 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
7. 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 Clinical Research, participates in the Clinical Research.

Additionally, in the case of an Equity Financial Interest of a SIO, the ICOIC may also consider:

1. Termination of a conflicted SIO's Fiduciary Role;
2. Formal recusal of the conflicted SIO from the chain of authority. If the SIO 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;
3. The assignment of substitute decision-making or negotiating authority in place of a conflicted SIO in the case of purchasing or supply contracts or other financial transactions related to the relevant research;
4. Disclosure of the ICOI to all faculty, staff, and trainees/students under the conflicted SIO's supervision, including the designation of a 'safe-haven,' or a non-conflicted senior official, to whom they may address ICOI-related concerns;
5. Establishing a firewall to separate the conflicted SIO and his/her role from the relevant research.

## *V. Compliance and Oversight*

In the case of an institutional conflict of interest of DFCI, it is the responsibility of the DFCI principal investigator and/or DFCI site principal investigator to maintain compliance with the ICOI management plan applicable to his/her study.

In the case of an institutional conflict of interest of an SIO, it is also the responsibility of the conflicted SIO to maintain compliance with his or her ICOI management plan.

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.

## *VI. Definitions*

Relevant Business is any for-profit entity, or philanthropic arm of a for-profit entity, 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 Clinical Research at DFCI.

Clinical Research means any research that is subject to IRB approval (excluding those studies determined to be minimal risk clinical research by an IRB).

Equity Financial Interest is any type of ownership interest, such as owning stock or stock options, but excludes equity that arises solely by reason of investment in a Relevant Business by a mutual, pension, or other institutional investment fund over which DFCI or the SIO does not exercise control. For DFCI, it includes Equity Financial Interests held by a DFCI-managed venture or angel financing fund, if applicable at any time .

Fiduciary Role means members of the fiduciary board of directors, managers of or members of a member-managed limited liability company, and partners in a partnership or limited liability partnership, whether paid or unpaid.

Income Financial Interest means the expectation of DFCI to receive income derived from licensing activities that generate institutional interests. It may take the form of various types of compensation and may be paid either by the Relevant Business or by an agent or other representative of the Relevant Business on its behalf. This may include, but is not limited to, upfront payments, licensing revenue, milestone payments, and contingent value rights, and other royalties resulting from licensing or other Technology transfer activities of DFCI or the SIO.

Institutional Conflict of Interest Committee (ICOIC) refers to the DFCI 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. The Board of Trustees Conflicts of Interest Oversight Committee has the responsibility for the review, approval and oversight of conflicts of interest arising from the outside activities of the Dana-Farber Chief Executive Officer and any Executive Vice Presidents.

Workforce means any person who is hired, appointed, designated, selected, or otherwise associated with DFCI, including an employee, trainee, volunteer, student, visiting scientist, provider, and/or consultant, whether compensated or not, who is involved in any activities supported in whole or in part by DFCI funds, personnel, facilities, materials, and/or other DFCI resources.

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. The specific titles of each covered position may change over time, but it is assumed that the term SIO will cover any faculty or administrative (Vice President level or above) leadership position that meets the definition specified. This includes Department and Division Chairs, leadership of DFCI Research Administration and the Office of Innovations, and certain DFCI executive leadership. The Board of Trustees Conflicts of Interest Oversight Committee has the responsibility for the review, approval and oversight of conflicts of interest arising from the outside activities of the Dana-Farber Chief Executive Officer and any Executive Vice Presidents.

Industry-Sponsored Research is research supported by funds from commercial sources under an agreement that DFCI classifies as a sponsored award in accordance with institutional policy.

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

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Questions may be directed to the DFCI Office of Research Integrity at [researchintegrity@dfci.harvard.edu](mailto:researchintegrity@dfci.harvard.edu).

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