

DANA-FARBER CANCER INSTITUTE

POLICY ON CONFLICT OF INTEREST AND COMMITMENT

INTRODUCTION

The Dana-Farber Cancer Institute (DFCI) is committed to advancing the understanding, diagnosis, treatment, cure, and prevention of cancer and related diseases. To support this mission, we recognize that productive interactions between academic institutions, faculty members, scientists, and industrial partners (collectively “Outside Activities”) can be beneficial. Such relationships have the potential to facilitate important research collaborations and provide support for innovative research. They also may accelerate the development of technologies, translation of scientific developments into clinical care, dissemination of scientific knowledge, and education of researchers and clinicians-in-training. Therefore, it can be advantageous for DFCI investigators to engage in Outside Activities as long they remain consistent with the DFCI mission.

Nevertheless, DFCI also acknowledges that Outside Activities have the potential to create a Conflict of Interest (COI). A COI exists whenever an individual has financial or other personal interests that stand to benefit from his or her professional actions or influence. It is imperative that DFCI’s research and education programs are not negatively impacted by the existence of financial relationships that may lead to bias, or the perception of bias, in DFCI research, patient care, and education.

It is, therefore, DFCI’s priority to preserve the highest ethical standards in the conduct of all activities at DFCI. It is with this objective in mind that DFCI implements its Policy on Conflict of Interest and Commitment. The purpose of this Policy is to direct and inform the relationships between individuals and industry. Its guiding principle is to provide assurances to DFCI faculty and staff, as well as to the health care community and public at large, that individual relationships with industry will not negatively affect the integrity of our research and clinical services, which will continue to be conducted in a manner consistent with institutional and community values.

To this end, DFCI Faculty and members of its research staff (collectively “Covered Persons”) are expected to structure their Outside Activities, business relationships, and related financial interests in a way that prevents or minimizes any possibility that they may interfere with their ability to fulfill their obligations to DFCI and affiliated Institutions, to unduly conflict with the interests of the Institute, or to interfere with, or appear to interfere with, their ability to conduct Faculty or DFCI Activities in an unbiased manner. **All Covered Persons, whether full-time or part-time, are required to comply with all aspects of this policy.**

In the interest of preserving the public’s trust, and for the avoidance of doubt, DFCI will address actual and potential conflicts of interest equally by applying the following rules and processes.

Section I. Prohibited Activities

DFCI seeks to facilitate responsible relationships between industry and faculty and staff who conduct research. However, there are certain activities and relationships that are prohibited unless a specific exception is available in accordance with this policy. In addition, the Institutional Review Board (IRB), Office of Research, Conflict of Interest Committee, or other relevant departments have the authority to impose further management requirements.

Additional guidance on the parameters of these prohibitions may be issued from time to time. If a Covered Person is unclear as to whether an event at which he or she has been invited to presently qualifies for this prohibition, staff in the Office of Research Integrity can provide additional guidance.

A. Research Rules

Certain Financial Interests are prohibited in the context of research in order to protect against the introduction of bias or unnecessary risk in that research.

The Research Rules (outlined in this section) do not apply when the relevant Financial Interests fall below a certain monetary amount. This is based on the assumption that interests below such '*de minimis*' thresholds are unlikely to meaningfully affect the individual's judgment in a manner that creates unacceptable risk.

A1. Clinical Research Rule (The "I(a) Rule"):

Covered Persons who Participate in Clinical Research, (as defined below) and members of their Family may not have a Financial Interest (Equity or Income) in a Business whose Technology is being investigated.

It is presumed that Faculty who Participate in Clinical Research may not have a Financial Interest (Equity or Income) exceeding the *de minimis* thresholds in a Business whose Technology is being investigated. The presumption may be overcome when, in the judgment of the DFCI Committee on Conflicts of Interest and Commitment (DFCI COIC) or its designee, individuals holding presumptively prohibited Financial Interests present demonstrable, compelling justification – consistent with the rights and welfare of Clinical Research subjects – for being permitted to simultaneously hold the Financial Interest and Participate in the Clinical Research.

De Minimis Thresholds: Faculty may receive \$25,000 or less annually¹ from a

¹ The payments may be considered to be accrued by the Faculty member on the date of service or on the date of receipt of the payment so long as the Faculty member is consistent in the treatment of such payments.

Business in the form of Income Financial Interests (e.g., consulting fees or other remuneration for services) and still Participate in Clinical Research on the Business's Technology. Furthermore, Faculty may have an Equity Financial Interest of \$50,000 or less in a publicly held Business and continue to Participate in Clinical Research on the Business's Technology so long as the equity was not given in connection with the Clinical Research at issue. Holding any equity in a privately held Company is presumed to be prohibited.

Duration of Restriction: A Faculty member must be free of all Financial Interests above the *de minimis* thresholds from a relevant Business prior to commencing the Clinical Research. Participation in Clinical Research shall apply for the entire duration of the Clinical Research and the rule continues to apply even should the Faculty member elect to terminate Clinical Research activities.²

The rule shall apply until the date that is the later of (i) six (6) months following the last day that a human study participant completes the Clinical Research (e.g., data lock plus 6 months), or (ii) the first Publication of data derived from the Clinical Research, or a decision not to publish the data derived from the Clinical Research.

Previous Policy Exceptions: Pursuant to the previous version of this policy, the DFCI COIC considered requests for exceptions in certain situations. For sake of clarity, those exceptions have not been eliminated in this version of the policy, but rather will continue to be considered by the DFCI COIC upon petition. They are:

Dual-Career Family Exception: Upon petition to the DFCI COIC, Faculty may overcome the presumption that s/he may not Participate in Clinical Research or receive Research support if (i) the conflict arises solely by virtue of the career pursuits of the Faculty member's spouse or domestic partner, (ii) the DFCI COIC determines, in its discretion, that strict application of one or both of the rules under the circumstances would unduly inhibit scientific progress, and (iii) any potential conflict of interest is one that the DFCI COIC finds, in its discretion, can be managed adequately through a formal management plan.

Institutional License/Royalty Sharing Agreement Exception: Upon petition to the DFCI COIC, Faculty may overcome the presumption that s/he may not Participate in Clinical Research or receive Research support if (i) the conflict arises solely because of income received through an institutional license or royalty sharing agreement, (ii) the DFCI COIC determines, in its discretion, that strict application of the rule under the circumstances presented is unduly restrictive after weighing the merits of allowing the Research to go forward and the risks of the potential conflict of interest, and (iii) the potential conflict arising by reason of the income received through the institutional agreement can be managed through a formal management plan.

² Faculty may petition for relief from the application of the Clinical Research Rule to the entire period set forth here. If granted, however, the expectation is that Participation has been surrendered for the duration of the Clinical Research.

Research that involves human study participants is subject to heightened scrutiny. This is because the ramifications of bias, or the appearance of bias, in Clinical Research are more immediate and can directly impact the safety and welfare of Clinical Research participants.

Accordingly, when the DFCI COIC considers a petition to rebut the Clinical Research Rule, it shall consider factors which may include, but are not to be limited to, the following:

- Nature of the proposed Research;
- Anticipated role in the proposed Research;
- Nature of the Financial Interest and relationship with the Business;
- How closely the Financial Interest is related to the proposed Research;
- The degree to which the Financial Interest may be affected by the proposed Research;
- The degree to which the proposed Research may be affected by the Financial Interest;
- Reasons for the Faculty with the Financial Interest to be involved in the Research;
- Impact on trainees;
- If applicable, role in developing intellectual property for Technology to be studied;
- If applicable, whether the Clinical Research is on Technology subject to an institutional license or royalty sharing agreement, and if so, the type of license/royalty sharing income received (i.e., one time signing fee, success based milestone, non-success based milestone);
- The best interests of study participants who could benefit from the Clinical Research; and
- Likely effectiveness of potential management strategies.

A2. Research Support Rule (The “I(b) Rule”)

It is presumed that Faculty (and the members of their Family) who have an Equity Financial Interest in a Business may not receive Sponsored Research support from that Business for Research. Faculty holding a presumptively prohibited financial interest may request the DFCI COIC or its designee to grant an exception. Requests will be reviewed on a case-by-case basis.

Research must be protected from bias to ensure that the results of the Research are valid and can be relied on in the development of medical therapies and in furtherance of scientific knowledge. Concerns about the ultimate impact of financial conflicts on end-users of the Research and research integrity exist in all Research.

Sponsored Research includes Research, training, and instructional projects involving funds, personnel, certain proprietary materials or Technology, or other compensation from outside sources that (i) the institution classifies as a sponsored award in accordance with institutional policy or (ii) gives the donor or an identifiable third party designated by the donor preferred access to or ownership rights over the Research or the products of the Research, e.g. raw data, scientific developments, or intellectual property. Provision of periodic general reports and copies of publications shall not be considered preferred access.

Sponsored Research does include gifts that are made solely for the support of the Faculty member's Research or that of the Faculty member's laboratory. Additionally, Sponsored Research includes the provision of proprietary material or Technology which is proposed to be the subject of the Research in question and where the Business is granted the right to intellectual or tangible property created in or resulting from the use of the Material in the proposed Research.

Duration of Restriction: This Rule, when triggered, shall apply until the date that is the later of (i) twelve (12) months following the last day that data is collected (data lock plus 12 months), or (ii) the first publication of data derived from the Sponsored Research or a decision not to publish the data derived from the Sponsored Research. If a Faculty member Participates in the Sponsored Research such participation shall be considered to apply for the entire duration of the study (one cannot elect to terminate participation prior to the end of the study). A Faculty member must be free of all Equity Financial Interests from a relevant Business prior to commencing the Research.

Review of Faculty Equity Financial Interest in a Privately-Held Business: Any Equity Financial Interest in a privately held Business will require an exception from the DFCI COIC, or its designee to Participate in Research using Sponsored Research support from the Business. The *de minimis* threshold does not apply to privately held companies.

De Minimis Threshold for Faculty Equity Financial Interest in Publicly Traded Business: Faculty may have an Equity Financial Interest of one percent or less in a publicly traded Business and Participate in Research using Sponsored Research support from the Business so long as (a) the company was not founded by the investigator, or (b) the equity was not acquired in connection with the Research at issue. Any interest exceeding 1% of the publicly-traded Business's value would require an exception from the DFCI COIC or its designee. The *de minimis* threshold does not apply to privately held companies.

SBIR/STTR Exception: If the anticipated Sponsored Research support that will violate the Research Support Rule will be through a subgrant under the Small Business Innovation Research (SBIR) Program or the Small Business Technology Transfer (STTR) Program, the involved Faculty may conduct the Research notwithstanding the Financial Interest if the institution that will be responsible for administering the SBIR/STTR subgrant determines that any potential conflict of interest held by the Faculty, given his or her equity interest in the small Business, may be managed effectively with an institutional management plan. This exception does not apply to Clinical Research. This exception is subject to additional restriction and/or prohibition based on applicable federal law and institutional policy.

Dual-Career Family Exception: Upon petition to the DFCI COIC, Faculty may overcome the presumption that s/he may not Participate in Clinical Research or receive Research support if (i) the conflict arises solely by virtue of the career pursuits of the Faculty member's spouse or domestic partner, (ii) the DFCI COIC determines, in its discretion, that strict application of one or both of the rules under the circumstances would unduly inhibit scientific progress, and (iii) any potential

conflict of interest is one that the DFCI COIC finds, in its discretion, can be managed adequately through a formal management plan.

A3. External Activity Rule (The “I(d) Rule”)

Covered Persons who serve in a fiduciary role³ to a for-profit Business may not Participate in Clinical Research on the Business’ Technology nor receive Sponsored Research support from the Business.

As with Financial Interests, a Covered Person’s leadership role in a commercial company, even where unpaid, raises the risk that the affiliation with, and allegiance to, the company may influence his or her judgment with respect to related research activities. Scientific Advisory Boards (SABs) are not fiduciary Boards of Directors; as a result, service on an SAB is not subject to the External Activity Rule.

SBIR/STTR Exception: If the anticipated Sponsored Research support that will violate the External Activity Rule will be through a subgrant under the Small Business Innovation Research (SBIR) Program or the Small Business Technology Transfer (STTR) Program,⁴ the involved Covered Person may conduct the basic Research notwithstanding the Financial Interest if the institution that will be responsible for administering the SBIR/STTR subgrant determines that any potential conflict of interest held by the Covered Person, given his or her equity interest in the small Business, may be managed effectively with an institutional management plan. This exception does not apply to Clinical Research. This exception is subject to additional restriction and/or prohibition based on applicable federal law and institutional policy.

B. Executive Position Rule (the “I(c) Rule”)

Covered Persons employed full-time by DFCI may not hold an Executive Position in a for-profit Business engaged in commercial or Research activities of a biomedical nature.

A Covered Person’s leadership role in a commercial company servicing the biomedical market, even where unpaid, raises the risk that his or her affiliation with and allegiance to the company may influence his or her judgment with respect to his or her teaching, clinical care, research and other responsibilities at DFCI. This is an absolute prohibition for full- time DFCI faculty and research staff.

³ A fiduciary role includes but is not limited to 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.

⁴ The DFCI Faculty COI Committee may determine that other grant programs of a similar structure and aim to the SBIR/STTR programs warrant consideration under this exception and may grant these exceptions following review.

C. Industry-Funded Interactions

The integrity and validity of the work of DFCI Faculty and research staff depend on limiting inappropriate influence by industry sponsors over the content of publications, presentations and academic opinions. All Outside Activities must be done in accordance with the mission and values of DFCI, and may not call into question the intellectual integrity of the Institute and its research activities, clinical care, or staff.

C1. Participation in Industry Marketing Activities

Covered Persons are prohibited from engaging in Outside Activities that are intended to be used for the purpose of endorsing or marketing specific pharmaceutical products.

While Covered Persons are encouraged to participate in accredited continuing medical education (CME) activities, which may receive funding from industry, Covered Persons are discouraged from participating in speaking engagements or media activities where they are paid directly by industry and where the purpose of the activity is solely to market or endorse specific products, treatments, or technologies.

C2. Prohibition of Industry Control Over Academic Content

Covered Persons must retain intellectual independence over the content of any educational material they present, and are prohibited from being compensated to participate in “speakers bureaus” or any other “educational” or informational event sponsored by a for-profit Business at which the Business exerts undue influence or control over the content, tone, or views presented.

Events for which a company compensates physicians to speak about the company’s product in a manner scripted by the company, sometimes known as “speakers bureaus”, have earned a reputation for being forums where companies exert undue control over the content of the conversation and promote the benefits of their product without balanced views. Rather than open exchanges of information, such events have the appearance of company marketing and, as such, are inappropriate venues for Covered Persons and their work.

While these activities are typically no longer called “speaker’s bureaus” they are identifiable by attempts by the company to limit the speaker’s control over the content and manner of presentation. Frequently, these engagements involve written contracts or agreements that require the use of company-provided presentation materials, including slide decks, or that allow the company (or its agent, such as an educational management company) to review and edit materials prepared by the speaker. Covered Persons may not participate in any activity in which his or her ability to provide an unbiased presentation is limited or curtailed in any way. It is expected that in all public speaking engagements, Covered Persons will present a fair, accurate, and unbiased view of the subject matter. To that end, Covered Persons may not use presentation materials, scripts, or “talking points” provided by the company, or allow the company to make any revisions or changes to materials

created by the speaker. **This is an absolute prohibition.**

C3. Ghostwriting Rule

Covered Persons are required to make significant intellectual or practical contributions if identified as an author.

Covered Persons are expected to be responsible for the work they do and to claim and accept credit when appropriate. The practice of “ghostwriting” or “honorary authorship”, in which a manuscript is developed principally by a for-profit Business directly or through a third party vendor such as a medical education company and then attributed to an academic researcher who did not contribute meaningfully, contradicts the principles of intellectual credit outlined in the Harvard Medical School Authorship Guidelines. This is an absolute prohibition. If a Faculty member is unclear as to whether a publication in which the Faculty member is involved qualifies for this prohibition, staff in the Office of Research Integrity can provide additional guidance.

C4. Prohibition of Industry Sponsored Gifts/Meals/Travel

Covered Persons are prohibited from soliciting or accepting any Personal Gifts, meals, or fees for professional meeting registration and/or related travel (whether paid directly on their behalf or reimbursed) from a pharmaceutical, medical device or biotechnology manufacturing or supply company.

Even modest gifts can sometimes instill a sense of obligation or duty in the recipient. To protect the independence of healthcare providers, Federal and State laws restrict pharmaceutical and medical device manufacturers from giving gifts and meals to healthcare practitioners. The concerns that gave rise to these laws apply equally to non-practitioners as they do to practitioners. This rule ensures that Covered Persons are not unduly influenced by for-profit companies, which may sponsor their research and/or engage in other business with DFCI.

Contractually Required Meetings Exception: If a Covered Person is required, pursuant to the terms of a negotiated contract, to attend a meeting, the following exceptions to this prohibition may be available:

- Covered Persons may accept modest meals while attending a meeting of a SAB or Board of Directors of a pharmaceutical, medical device or biotechnology manufacturing or supply company if their attendance at the meeting is required by the terms of their consulting agreement with the company;
- Covered Persons may accept reasonable fair market reimbursement or payment for registration and travel fees from a for-profit sponsor or organizer of a professional or trade meeting for attendance at such a meeting if they have formally agreed to serve as a speaker, panelist or other presenter at the meeting;

- Covered Persons may accept reasonable fair market reimbursement or payment for the costs associated with their attendance at “Users Group” meetings or similar training sessions to learn how to use a technical device already purchased by DFCI or another HMS affiliate if their compensated attendance at the meeting is incorporated into a written agreement (whether purchasing or other) between the manufacturer and DFCI or the affiliate;

Education Exception: Covered Persons are permitted to accept meals offered by a Continuing Medical Education provider or other professional conference/meeting organizer during the course of the CME event or other professional conference/meeting if the meals are offered across the board to all participants out of the event’s budget at the discretion of the organizer and are not directly provided or earmarked for such purpose by a pharmaceutical, medical device or biotechnology manufacturing or supply company;

Research Collaboration/Funding Request Exception: In general, Covered Persons should pay for the cost of his or her own meal when meeting with industry representatives. They may, however, accept modest meals from medical and device manufacturers when discussing potential Research collaborations and funding opportunities with non-sales/marketing industry representatives if it is not reasonably feasible for the Covered Person to pay for his or her own meal. Covered Persons should be aware that under the Physician Payments Sunshine Act, manufacturers of drugs, medical devices, and biologicals may be required to report the provision of such meals as part of its annual report to Medicare/Medicaid.

Other exceptions that may be granted from time to time by the DFCI Faculty Committee on Conflicts of Interest, at the Committee’s discretion.

F. Prohibition on Engagement with Tobacco Companies

Covered Individuals are prohibited from participating in any Outside Activities conducted with or on behalf of tobacco companies.

Section II. Conflicts of Commitment

A Conflict of Commitment (COC) occurs when a Covered Person’s time commitment to Outside Activities interferes with his or her ability to fulfill his or her obligations to DFCI, or when the Outside Activity otherwise negatively impacts an Institutional interest (e.g., reputation, intellectual property ownership, or publication rights).

A. Primary Obligation to DFCI

When an individual accepts a full-time appointment or position at DFCI, that individual is expected to devote his or her primary professional loyalty, time, and energy to teaching, research, patient care and administrative responsibilities at DFCI. Accordingly, the individual should arrange any Outside Activities and Related Financial Interests so they do

not interfere with the primacy of these commitments, and further should restrict their Outside Activities to those for which the benefits of the interaction outweigh the potential for conflicts with the interests of the Institution.

B. Allowable Amount of Time

1. **Full-Time DFCI Faculty:** Full-time DFCI Faculty may engage in Outside Activities with the approval of their Department Chair. However, no more than twenty percent (20%) of his or her total professional effort may be directed to outside work, not to exceed the equivalent of one working day per calendar week. In the event that the Faculty Member's Outside Activities compromise his or her ability to conduct Faculty Activities in an unbiased fashion, are compromising his/her professional performance at DFCI, or result in an unacceptable conflict with the interest of DFCI, the Faculty Member can be required to terminate an Outside Activity.

2. **Full-time Research Staff:** DFCI recognizes that non-faculty members of the Research Staff may have legitimate interest in engaging in Outside Activities. A limited amount of such activities might be allowable, so long as it is subject to review and approval by his or her supervisor, and by the Office of Research Integrity, and is conducted outside their regular working hours at DFCI.

3. **Part-time Faculty and Research Staff:** Members of the Faculty and Research Staff whose appointments are less than full-time are expected to devote professional loyalty, time, and energy to their teaching, research, patient care, and administrative activities, in accordance with their agreed-upon time commitments.

C. Use of Institutional Materials

Outside Activities should not involve use of institutional funds or material use of institutional resources, equipment or facilities, and should not, in the judgment of the Individual's supervisor, compromise or interfere with the Individual's responsibilities at DFCI.

Section III: Mentors Obligations to Mentees

The relationship between trainees (medical students, graduate students and post-doctoral fellows) and those Covered Persons assigned to mentor them is one that DFCI views as central to the success of medical and scientific training and must be fostered in a way that benefits both the mentor and those mentored. It is recognized that mentors and their trainees may not have equivalent information, given their relative positions. Furthermore, trainees' research projects may be dictated, in part, by their mentors' interests and areas of focus, and they may not be privy to their mentors' various relationships with industry. As a result, a risk exists that trainees may not have the information or leverage to recognize projects designed to enhance their mentor's Financial Interests, or object to their own involvement in projects in which a potential financial conflict of interest exists. Because DFCI aspires for a culture where open conversation and communication is paramount and without retribution, trainees should never be forced to choose between challenging a

mentor and resigning themselves to involvement in research about which the trainee has concerns. For these reasons, this policy seeks to ensure that trainees are provided with complete information about any Financial Interests their mentor may have in a research project and a neutral process through which the trainee's interests may be protected.

Disclosure by Covered Persons of Relevant Financial Interests:

Frequently, Covered Persons serve as mentors, and are responsible for ensuring that those with whom they conduct research do so with full information about the nature of their relationships with industry that may be impacted positively or negatively by the work.

General Disclosure to all Trainees: Covered Persons must disclose to all individuals whose job description includes assisting with their research work any Financial Interests (whether Income or Equity) held in any Business that (i) provides Sponsored Research support to the research or (ii) whose Technology is being investigated in the research. The individuals to whom such disclosure must be made may include, but are not limited to, students, trainees, and other research staff members. Such disclosure must be made prior to or at the time an individual is offered a position or collaboration with the mentor's research team or research laboratory, or any other job that may encompass assisting with the mentor's research work.

Project Specific Disclosure: Before a trainee may be involved in any specific research project, Covered Persons must provide a clear description of the following to the trainee:

- The source of funding of the specific research project (industry or otherwise);
- Any Financial Interest (whether Income or Equity) held by the Covered Person in a Business that provides Sponsored Research support to the project;
- Any Financial Interest (whether Income or Equity) held by the Covered Person in a Business whose Technology is being investigated in the project;
- Any restrictions that may be imposed on the timing of the scientific communication of data.

Trainee Right to Raise Concerns Confidentially: All trainees shall have the right to raise concerns regarding participation in research that is sponsored by a Business or research investigating a Technology of a Business in which a co-investigator or mentor holds a Financial Interest (whether Income or Equity). Concerns should be raised to and addressed by the appropriate Department Chair or the Office of Research Integrity. Additionally, concerns about compliance with this or any other DFCI policy can be made to the Compliance Hotline at 1-800-451-0659.

Section IV: The DFCI Conflicts of Interest Committee

The DFCI Conflicts of Interest Committee (DFCI COIC) is comprised of representatives from both the clinical and preclinical Faculty. The Committee is charged with the interpretation and implementation of this policy. It has discretion and authority to issue interpretive guidance as it deems necessary to assist Covered Persons in their understanding of and

compliance with the rules contained herein. In the event of any dispute over appropriate application of this policy, the Committee is the primary arbiter.

The Committee shall approve the procedures through which compliance with the Policy is effectuated, monitored, and enforced. This will include development of the procedures through which information related to conflicts is disclosed, conflicts are identified and managed, and non-compliance is uncovered, investigated and sanctioned. Part of this responsibility includes assuring that the policy is applied in a consistent manner across all Covered Persons.

The Office of Research Integrity shall refer specific issues to the Committee for evaluation. Following review of a specific issue, the Committee will make formal determinations as to how the matter should be resolved or managed.

In the event that a Covered Person requests that the Committee invoke an exception under this policy that requires Committee pre-approval, whether prospectively or in response to an alleged violation of the policy, it will be within the Committee's discretion to determine whether or not to grant such a request. Notwithstanding the facts of any given case, the Committee may decline a request for an exception. In the event that the Committee grants the request for exception based on specific circumstances, it will not serve as precedent for or apply to future research undertaken by the Covered Person who is making the request or any other Covered Person by reference. Furthermore, the Committee may rescind an exception at any time.

In order to ensure that the Policy reflects current best practices and requirements, the Committee will undertake or commission on an on-going basis the review of similarly situated institutions' policies, relevant professional guidance documents, available academic literature and applicable laws and government guidance documents and recommend periodic changes to the policy as appropriate.

Section V: Compliance Responsibility

Mandatory Review and Approval of Outside Activities: Covered Persons who wish to participate in Outside Activities must do so by way of a written agreement that outlines the terms and conditions of the activity, and specifies the scope of work and any financial compensation. All agreements must be reviewed by staff in the Office of Research Integrity to ensure compliance with applicable Institute policies. Agreements can be sent to Consulting@dfci.harvard.edu for review, and will be reviewed in the order in which they are received.

Institutional Disclosure of Outside Activities: Covered Persons are required to disclose in a timely manner all required information to DFCI to facilitate the identification of existing conflicts of interest. The applicable disclosure process will be prescribed by the Office of Research Integrity and the Committee, and outlined in more detail in standard operating procedures and guidelines, which may be amended from time to time. Covered Persons are responsible for understanding and following the currently applicable disclosure process. As a general rule, this process will involve annual disclosure of all Outside Activities and

Financial Interests as directed by the Office of Research Integrity. Covered Persons are responsible for amending the disclosure information on file with the Office of Research Integrity during the annual reporting period to the extent a material change occurs (for example, a new interest or activity that might create a conflict of interest, or a change that eliminates a previously existing conflict of interest). Covered Persons are also expected to comply with reporting requirements outlined in the DFCI Policy on Financial Conflicts of Interest in Sponsored Research, as well as specific disclosure policies of all other funding sources, affiliated institutions, professional associations, and the like.

After information is received by the Office of Research Integrity, it will be reviewed in order to determine whether any identified external activity or Financial Interest violates the rules outlined applicable policies.

The information disclosed by a Covered Person will be treated confidentially to the extent possible; however, information may be used and shared as necessary to facilitate the purposes of this policy. For example, information may be shared with affiliated institutions with jurisdiction over the Covered Person for review when warranted, as well as with department chairs or supervisors.

Covered Persons are required to participate in any required training programs related to compliance with this policy, whether at the direction of the DFCI, HMS, or any other affiliated institutions.

Public Disclosure Obligations

Covered Persons are required to disclose Outside Activities and Financial Interests in related outside entities and sources of support related to a presentation or publication of Research results, the provision of expert testimony on a subject, or if members of an audience would give weight to those interests in assessing the opinions, advice, or work they are receiving. This includes the disclosure of a Financial Interest in a Business which owns or has a contractual relationship to the Technology being reported or discussed or which sponsors the Research being reported or discussed.

Training

Covered Persons are required to Participate in any required training programs related to compliance with this policy whether at the direction of DFCI or its affiliated institutions.

Section VI: Noncompliance and Sanctions

Noncompliance may occur in varying degrees and along a continuum of intention. Such a continuum may encompass deliberate acts in violation of this policy, reckless disregard of applicable requirements, negligent behavior resulting in a violation, and even inadvertent or technical violations for which there exist a reasonable explanation. The totality of the facts and circumstances of an incident of noncompliance, along with the individual's prior history of compliance, will be considered when assessing appropriate sanctions. Each case will be analyzed individually with careful consideration of factual nuances and any mitigating factors. Although prior cases may serve as an internal point of reference for the Committee when deciding what sanctions should be meted out, strict comparisons

between cases and their outcomes are usually unproductive given the extremely fact-specific nature of the analysis.

The DFCI COIC has wide discretion to recommend a variety of sanctions in the event of noncompliance with this policy by any Covered Person.

Upon finding noncompliance with this policy, sanctions recommended by the Committee may include, but will not be limited to, the following:

- Formal admonition;
- The inclusion in the Covered Person's file of a letter from the Office of the President calling into question the individual's good standing as a member of the Faculty or research staff;
- Ineligibility of the Covered Person to submit grant applications, apply for Institutional Review Board (IRB) approval of research, or supervise graduate students in research activities;
- Non-renewal of the individual's Faculty appointment or employment;
- Dismissal from the Institution; or
- Any other restriction, limitation or punishment determined by the Committee to be warranted by the circumstances.

Section VII: Definitions

Business: Any legal entity organized for profit or non-profit purposes.

- This term includes, but is not limited to: corporations, partnerships, sole proprietorships, associations, organizations, holding companies, and business or real estate trusts.
- A Business is considered to be "non-profit" if it is legally organized for charitable purposes (e.g., 501(c)(3) and equivalents), unless it is principally organized, funded, and/or managed by one or more for-profit entities engaged in commercial or Research activities of a biomedical nature.
- Not included in this term are Harvard University, including Harvard Medical School, and the institutions formally affiliated with Harvard Medical School (for example, the Harvard teaching hospitals).

Clinical Research: Any Research that is subject to IRB approval and requires an investigator who is responsible for the design, conduct, or reporting of such Research to meet either of the criteria listed in *either* paragraph 1 or 2 below:

1. Faculty who are responsible for the design, conduct, or reporting of an IRB-approved study (excluding those studies determined to be Nominal Risk Clinical Research by an IRB or COI Committee) 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 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.

2. Faculty who serve as the primary author, or one of the primary authors, of a publication reporting the results of an IRB-approved study (excluding those studies determined to be Nominal Risk Clinical Research by an IRB or COI Committee). A primary author of a publication is the individual who, in compliance with [HMS Authorship Guidelines](#) and [ICMJE Authorship Guidelines](#), takes primary responsibility for the integrity of the work as a whole even if he or she does not have an in-depth understanding of every part of the work.

Nominal Risk Clinical Research is determined by the Institutional Review Board and/or the HMS or an affiliate institution Conflict of Interest Committee. Nominal Risk Clinical Research includes Clinical Research that is:

- 1. minimal risk (as that term is defined in 45 CFR Part 46⁵) and
- 2. falls within one or more of the following categories:
 - a. Use of bodily fluids, secretions, or other biospecimens, (excluding such materials obtained for clinical care purposes, which are covered in b. below) that are obtained through non-invasive, routine, and established collection procedures from a healthy, non-pregnant individual who is not a member of a vulnerable population (as defined in 45 CFR part 46) and provided that the samples cannot be linked to any individually identifiable person by any Faculty member who Participates in the Nominal Risk Research;
 - b. Use of excess bodily fluids, secretions, or other biospecimens, which may be linked by a Faculty member who Participates in the Nominal risk Research to an individually identifiable patient, where the samples are otherwise obtained during the course of clinical care by an individual who (1) does not Participate in the Nominal Risk Clinical Research; (2) is not under the direction or control of any individual who Participates in the Nominal Risk Clinical Research; and (3) is not supervising any individual who Participates in the Nominal Clinical Risk Research;

⁵ Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

- c. Medical records review, including collection of coded identifiable data, provided, however, that the protocol ensures that, after collection of the data, any Faculty who Participate in the Nominal Risk Research cannot link it to an individually identifiable patient;
- d. Non-sensitive survey Research on individuals or group characteristics or behavior, provided that if the subjects are considered members of a vulnerable population as defined by 45 CFR Part 46, the institution's conflicts of interest committee and/or Institutional Review Board may, on a case by case basis, conclude that the Research is not Nominal Risk Clinical Research; or
- e. Such other categories of Research activities as may from time to time be designated by the Faculty of Medicine DFCI COIC on Conflicts of Interest.

Executive Position: Any position that is responsible for a material part of the operation or management of a Business. This term specifically includes, but is not limited to, the following positions: Chief Executive Officer, Chief Operations Officer, Chief Scientific Officer, Chief Medical Officer, Scientific Director, and Medical Director.

Faculty: Any person possessing an academic appointment at DFCI. This includes individuals who are on sabbatical or other paid leave. Faculty who, alone or together with one or more members of their Family, exercise a controlling interest in any trust, organization, or enterprise other than the University or any Harvard affiliated institution, will be evaluated under this policy based on any income or equity held by the entity in which the controlling interest is held. Such entities are viewed, for purposes of this policy, as extensions of the term "Faculty".

Family: The "Family" of a Faculty member includes his or her spouse or domestic partner and dependent children.

Financial Interest: 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").

- Equity Financial Interests may include any type of ownership interest, such as owning stock or stock options, but excludes equity that arises solely by reason of investment in a Business by a mutual, pension, or other institutional investment fund over which the Faculty member does not exercise control.
- Income Financial Interests may take the form of various types of compensation and may be paid either by the Business or by an agent or other representative of the Business on its behalf. Examples of income that might be paid or owed by a Business to a Faculty member include, but are not limited to, consulting fees, salary, or other payments for various services, interests in real or personal property, dividend payments, payments derived from the licensing of Technology, and

forgiveness of debt. The term explicitly excludes, however, Post-market Royalties.

Participate: To be responsible for the design, conduct, or reporting of Research, regardless of title or position.

- This term assumes that the individual may have the opportunity to influence or impact the results. It is not intended to apply to individuals who provide primarily technical support to a Research study or who act in a purely advisory capacity with no direct access to the study data, unless such individuals are nonetheless in a position to influence or impact the study's results or have privileged information as to its outcome.
- If a Faculty member Participates in Research pursuant to this definition, such participation shall be considered to be for the entire duration of the study (one cannot elect to terminate participation prior to the end of the study).

Personal Gifts: Anything of value that is received by an individual for which the recipient has not paid fair market value.

Postmarket Royalties: Royalties received by a Faculty member directly or under an institutional royalty-sharing agreement as a result of the sale of a Technology invented by the Faculty member in the public market (e.g., if applicable, post-FDA approval). This term does not include license fees, annual maintenance fees, milestone payments, or other income that may become due under a license prior to market approval of the Technology.

Research: Systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic, Sponsored, and Clinical Research, including applied research and product development.

Sponsored Research: Research, training, and instructional projects involving funds, personnel, certain proprietary materials, or Technology, or other compensation from outside sources under an agreement that (i) the institution classifies as a sponsored award in accordance with institutional policy or (ii) gives the donor, or an identifiable third party designated by the donor, preferred access to or ownership rights over the Research or the products of the Research, e.g. raw data, scientific developments, or intellectual property. Provision of periodic general reports and copies of publications shall not be considered preferred access.

- Notwithstanding the forgoing, Sponsored Research shall not incorporate the following agreements:
 1. Gifts: Agreements that an institution classifies as a gift in accordance with institutional policy except as specifically set forth below:
 - a. Faculty members who hold equity in the donor company are prohibited from receiving gifts that are made solely for the support of the Faculty member's Research or that of the Faculty member's

laboratory.

2. Certain Material Transfer Agreements: Agreements that provide for the provision of tangible materials, including equipment (“Material”) from an outside source pursuant to a material transfer or other agreement provided each of the following factors are met:
 - a. The proposed protocol does not consist of Research on the Material in question, either directly or indirectly (e.g., the primary usefulness of the Material in the proposed protocol is as a research tool to achieve scientific aims distinct from the donor company’s business aims and not as a potential product or integral component of such product);
 - b. The proposed agreement does not grant to the Business any rights to intellectual or tangible property created in or resulting from the use of the Material in the proposed Research, except:
 - i. Options to negotiate (even if such options are exclusive) a license to intellectual property made in and derived directly from the use of the Material in the Research; or
 - ii. A non-exclusive license for Research purposes to intellectual property made in and derived directly from the use of the Material in the Research.
 - c. The agreement otherwise meets with the approval of designated University/Hospital institutional officials who may impose additional prohibitions and/or restrictions in view of potential conflicts, as deemed warranted.

Technology: Any compound, drug, device, or diagnostic, medical, or surgical procedure intended for use in health care or health care delivery. A Technology “belongs” to a Business in a way that would implicate the Clinical Research Rule if the Business (i) manufactures the Technology (or contracts with another entity to manufacture the Technology under its direction) or (ii) owns or has licensing rights to the Technology. An exception to this general rule, however, may be granted if the Conflict of Interest Committee at the Institution approving the IRB Protocol determines, after a review of the specific facts, that a Technology is (i) off-patent and manufactured as a generic, (ii) non-exclusively licensed to multiple companies, or (iii) manufactured by multiple companies; and , as a result, there is a sufficiently dilutive market for the Technology to conclude that the Technology does not belong to any one Business.

Questions? Contact the Office of Research Integrity at 617-632-4557