

## **Section I: Introduction**

The Harvard University Faculty of Medicine values its role as a leader in medical education and scientific advancement. We take pride that our Faculty and researchers work on the cutting edge, pushing innovative science forward and translating discovery into therapy. We are privileged to attract top talent and to encourage, support, and protect the work of the men and women who strive to improve healthcare both in our community and around the world.

We are working in a global age of discovery. To be competitive, both financially and intellectually, bridging disciplines and industries is key. Pushing the envelope of scientific knowledge and translating it to improved clinical care requires open collaboration and synergies achieved through thoughtful partnerships. The University applauds the creative ways in which our Faculty foster relationships with fellow academics, the government agencies that support and fund research, and the companies that work to commercialize innovations and bring therapies to patients. These partnerships have great potential for innovation and success and are consistent with the mission of the Harvard Medical School (HMS) to alleviate human suffering caused by disease.

With the many positives that may flow from partnerships with industry and others comes the potential for conflicts of interest. These conflicts may arise from competing Faculty commitments and financial interests that may impact scientific endeavors. Conflicts generally are positive indicators that our Faculty members are recognized thought-leaders who have professional opportunities, government funding, and support from the companies working to translate research to the bedside. Thus, a conflict does not equate to inappropriate activity. Rather it indicates a collaborative interaction between our Faculty and outside entities where additional institutional attention is needed to safeguard the integrity of our Faculty and their research.

In structuring relationships between our Faculty and industry, protection against research risks and maintaining public trust in the Faculty's work are paramount. We take very seriously our obligation to protect against any Faculty bias that could heighten the risk of harm to human research participants or recipients of products resulting from such research. Identifying and managing conflicts transparently and appropriately is essential to ensure that conflicts do not undermine the integrity of the Faculty and its scientific endeavors. We can only be proud of our collaborations if we can represent confidently that such relationships enhance, and do not detract from, the appropriateness and reliability of our work.

For these reasons, the Harvard University Faculty of Medicine has established the following policy on conflicts of interest and commitment. The policy outlines unacceptable practices and guides our Faculty in identifying and disclosing certain relationships with outside entities. The disclosures will assist the Office of the Dean

in identifying and managing conflicts so that these important collaborations can be undertaken responsibly. We start from the premise that the vast majority of scientists seek to conduct their work honestly with the goal of ethically progressing their field. This policy aims to support Faculty in those efforts and to protect them, their work, and the ultimate beneficiaries of their innovation. With appropriate protections, our Faculty can leverage collaborative relationships to stimulate discovery without compromising integrity.

## **Section II: Prohibited Activities**

The Faculty of Medicine seeks to facilitate responsible relationships between industry and Faculty who conduct research. There are certain activities and relationships, however, that are prohibited unless a specific exception is applicable in accordance with this policy. Laid out below are rules with which Faculty are required to comply.

In addition, the Institutional Review Boards, offices of Sponsored Research, conflict of interest committees, or other relevant departments at the affiliated institutions of the University have the authority to impose further management requirements. Faculty are required to comply with the requirements of any Harvard affiliate with jurisdiction over their activities to the extent that such requirements are more stringent than this policy.

### **A. Research Rules**

Certain Financial Interests are prohibited in the context of clinical and basic research to protect against the introduction of bias or unnecessary risk in the research.

The Research Rules outlined in this section do not apply when the relevant Financial Interests fall below a certain monetary amount, on the assumption that interests below such de minimis thresholds are unlikely to meaningfully affect the Faculty's judgment in a manner that creates unacceptable risk. Such de minimis thresholds are specified where applicable and are subject to review and further restriction by the Harvard affiliates with jurisdiction over Faculty members' activities.

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

**Faculty 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.**

A Faculty member "Participates in Clinical Research" if he or she falls within 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 [<http://hms.harvard.edu/content/authorship-guidelines>] and ICMJE Authorship Guidelines [<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>], 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.<sup>1</sup> There may be more than one primary author, and this rule applies to all primary authors of a publication. Moreover, in situations where investigators are not subject to the Clinical Research Rule but will be authors, those investigators must fully disclose in presentations and publications related Financial Interest(s) and should include a statement regarding the Faculty member's role on the study.<sup>2</sup>

Research that involves human study participants or samples is subjected to higher scrutiny with respect to the potential for financial conflicts of interest. This is because the ramifications of bias in Clinical Research are more immediate and directly impact the safety and welfare of Clinical Research participants. This rule guards against bias, or the appearance of bias, that might occur if a Faculty member

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<sup>1</sup> For purposes of this rule, the first, last, and corresponding authors are considered to be primary authors unless the first, last, or corresponding author demonstrates to the satisfaction of the HMS Standing Committee on Conflicts of Interest and Commitment that he or she should not be considered a primary author.

<sup>2</sup> This statement may include a clarification that the individual was prohibited under HMS policy from involvement in the IRB-approved study reported within the publication.

conducted Clinical Research in which she or he had a financial stake in the outcome or allegiance to the funding company. Such a conflict might cause the Faculty member to alter his or her study design, conduct, or reporting of the Research in some way, whether consciously or unconsciously, or it may cause the public to lose trust in the reliability of the research outcomes.

*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 a human study participant completes the Clinical Research (e.g., data lock plus 12 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. If a Faculty member Participates in Clinical 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 Financial Interests from a relevant Business prior to commencing the Clinical Research.

*De Minimis Threshold:* Faculty may receive **\$10,000 or less annually** from a 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' Technology. Furthermore, Faculty may have an **Equity Financial Interest of \$30,000 or less** in a publicly held Business and continue to Participate in Clinical Research on the Business' Technology so long as the equity was not given in connection with the Clinical Research at issue. **The de minimis threshold for equity does not apply to privately held companies.**

*Dual-Career Family Exception:* If a member of the Faculty will be in violation of either the Clinical Research Rule or the Research Support Rule solely by virtue of the career pursuits of the Faculty member's spouse or partner, the Faculty member may petition the Standing Committee for an exception. The Standing Committee has the authority, in its discretion, to grant a limited exception to the Clinical Research Rule or the Research Support Rule if the following circumstances are found to exist: (i) the Faculty member is subject to either or both of the Rules solely by virtue of the career pursuits of his or her spouse or partner; (ii) the Standing Committee 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 Standing Committee finds, in its discretion, can be managed adequately through a formal management plan. The Standing Committee may issue additional guidance on this topic in the future to reduce and/or eliminate the formal petition process as a condition to grant of an exception. Check the website of the Office of Academic and Research Integrity for updates.

*Institutional License/Royalty Sharing Agreement Exception:* Faculty Members shall continue to disclose all financial interests, including income received through institutional license agreements and institutional royalty sharing agreements (as defined by the policy). The Standing Committee on Conflicts of Interest and Commitment shall have the authority to grant limited exceptions to the Clinical Research Rule if:

(1) A faculty member is subject to the Clinical Research Rule solely because of income received through an institutional license or royalty sharing agreement;

(2) The Standing Committee 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

(3) The potential conflict arising by reason of the income received through the institutional agreement can be managed through a formal management plan.

Such exceptions are subject to case-by-case assessment by the Standing Committee following a formal petition by the individual faculty member. The faculty member must first petition his or her primary institution. The Standing Committee strongly encourages the faculty member to petition prior to an executed institutional license or royalty sharing agreement. If, however, such an agreement is reached prior to or during the Standing Committee Petition period, the institution may establish an escrow account for the faculty member where the income can be held pending determination of the Standing Committee. Following an initial trial period not to exceed two years, the Standing Committee may review and recommend to the Dean of the Faculty of Medicine specific changes and/or clarifications to this limited exception.

The Standing Committee will consider the following factors:

- Nature of the clinical research;
- Whether the clinical research is on the technology subject to the institutional license or royalty sharing agreement;
- Type of license/royalty sharing income received (i.e. one time signing fee, success based milestone, non-success based milestone);
- Role in institutional negotiations;
- Role in development of the intellectual property;

- Nature of the business licensing the technology including business size, diversity of product areas, corporate structure (private vs. public), and market share;
- Terms of the license or royalty sharing agreement including but not limited to factors such as total commitment of resources by the Business to technology development and percentage of total entity research budget.

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

### **Faculty and the members of their Family may not have an Equity Financial Interest in a Business providing Sponsored Research support for Research.**

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<sup>i</sup> 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.

*De Minimis Threshold:* Faculty may have an **Equity Financial Interest of \$30,000 or less** in a publicly held Business and continue to Participate in Research using Sponsored Research support from the Business so long as the equity was not given in connection with the Research at issue. The de minimis threshold does not apply to privately held companies; any amount of equity in such companies providing Sponsored Research support violates the Research Support Rule.

*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,<sup>3</sup> 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:* If a member of the Faculty will be in violation of either the Clinical Research Rule or the Research Support Rule solely by virtue of the career pursuits of the Faculty member's spouse or partner, the Faculty member may petition the Standing Committee for an exception. The Standing Committee has the authority, in its discretion, to grant a limited exception to the Clinical Research Rule or the Research Support Rule if the following circumstances are found to exist: (i) the Faculty member is subject to either or both of the Rules solely by virtue of the career pursuits of his or her spouse or partner; (ii) the Standing Committee 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 Standing Committee finds, in its discretion, can be managed adequately through a formal management plan. The Standing Committee may issue additional guidance on this topic in the future to reduce and/or eliminate the formal petition process as a condition to grant of an exception. Check the website of the Office of Academic and Research Integrity for updates.

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<sup>3</sup> The Standing Committee on Conflicts of Interest and Commitment or an affiliate 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.

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

**Faculty who serve in a fiduciary role<sup>4</sup> 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 Faculty member’s leadership role in a commercial company, even where unpaid, raises the risk that the Faculty’s 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; service on SABs 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,<sup>5</sup> the involved Faculty 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 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.

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

**Full-time Faculty may not hold an Executive Position in a for-profit Business engaged in commercial or Research activities of a biomedical nature. Faculty with part-time appointments may hold approved Executive Positions at for-profit Businesses but may not Participate in Clinical Research on the Business’ Technology nor receive Sponsored Research support from the Business.**

A Faculty member’s leadership role in a commercial company servicing the biomedical market, even where unpaid, raises the risk that the Faculty’s 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 Harvard. This is an absolute prohibition for full-time Faculty. Faculty with part-time appointments may hold an Executive Position at a Business but are prohibited from

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<sup>4</sup> 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.

<sup>5</sup> The Standing Committee on Conflicts of Interest and Commitment or an affiliate 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.



receiving Sponsored Research from that Business or from Participating in Clinical Research on the Business' Technology.

### **C. Prohibition of Industry Control over Academic Content**

**Faculty must retain intellectual independence over the content of any educational material they present. Faculty 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.**

The integrity and validity of the work of Harvard University Faculty of Medicine depend on limiting inappropriate influence by industry sponsors over the content of publications, presentations, and academic opinions. 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 Faculty and their work. This is an absolute prohibition for Faculty. Additional guidance on the parameters of this prohibition may be issued from time to time. If a Faculty member is unclear as to whether an event at which the Faculty has been invited to present qualifies for this prohibition, the Faculty should seek institutional guidance.

### **D. Ghostwriting Rule**

**Faculty are required to make significant intellectual or practical contributions if identified as an author.**

The Faculty of Medicine Authorship Guidelines set forth detailed requirements for being an author on a biomedical publication. These standards are consistent with the Recommendations of the International Committee of Medical Journal Editors and clarify that honorary or guest authorship is not acceptable. Faculty members 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 Authorship Guidelines. This is an absolute prohibition for Faculty. As such, Faculty participation in industry ghost writing or honorary authorship violates this policy and is subject to review and possible sanction by the Standing Committee on Conflicts of Interest

and Commitment. If a Faculty member is unclear as to whether a publication in which the Faculty member is involved qualifies for this prohibition, the Faculty should seek institutional guidance.<sup>6</sup>

### **E. Prohibition of Industry Sponsored Gifts/Meals/Travel**

**Faculty 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 to the Faculty member) 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. As a result, the restrictions apply to all members of the Faculty. This rule ensures that Faculty members are not unduly influenced by for-profit companies which may sponsor their Research and/or engage in other business with Harvard University or its affiliated institutions.

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

- Faculty are permitted to accept modest meals while attending a meeting with a pharmaceutical, medical device or biotechnology manufacturing or supply company if their attendance at the meeting is included in the terms of their agreement with the company;
- Faculty are permitted to 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 the Faculty member has formally agreed to serve as a speaker, panelist, or other presenter at the meeting;
- Faculty are permitted to accept reasonable fair market reimbursement or payment for the costs associated with their attendance at “Users Group” meetings or similar training sessions to

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<sup>6</sup> The Guidelines for Investigators in Scientific Research (<http://hms.harvard.edu/about-hms/integrity-academic-medicine/hms-policy/faculty-policies-integrity-science/guidelines-investigators-scientific-research>) and the Guidelines for Investigators in Clinical Research (<http://hms.harvard.edu/about-hms/integrity-academic-medicine/hms-policy/faculty-policies-integrity-science/guidelines-investigators-clinical-research>) reiterate that the only reasonable criterion for authorship is significant intellectual or practical contribution. As stated in those policies, “[t]he concept of ‘honorary authorship’ is deplorable.”

learn how to use a technical device already purchased by Harvard or its affiliate if their compensated attendance at the meeting is incorporated into a written agreement (whether purchasing or other) between the manufacturer and Harvard or its affiliate;

*Education Exception:* Faculty 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, Faculty should pay for the cost of his or her own meal when meeting with industry representatives. Faculty 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 Faculty to pay for his or her own meal. Faculty 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 Standing Committee upon request and at the Standing Committee's discretion.

### **Section III: Conflicts of Commitment**

As pioneers in medical and scientific advancement, the Harvard University Faculty of Medicine recognizes that its Faculty may have professional opportunities beyond the commitments they make to Harvard and its affiliated institutions. These external pursuits are often an advantage to the advancement of science, to Harvard, and to the individual Faculty member. Harvard encourages its Faculty to engage in meaningful ancillary work that complements their professional portfolios and Harvard Medical School's mission of intellectual curiosity and rigor.

Nonetheless, full-time appointments in the Faculty of Medicine demand a primary and substantial commitment to the patient care, teaching, Research, and administrative responsibilities shared by the Faculty. When Faculty accept such appointments, they agree to prioritize their responsibilities to Harvard and its affiliated institutions. As with financial conflicts of interest, this policy seeks to guard against external commitments undermining or overwhelming a Faculty

member's core obligations in a way that threatens Harvard's standards of excellence. The loyalty expected of full-time Faculty, while not exclusive, counsels that outside activities and Financial Interests should be arranged so as not to compete with the primacy of the Faculty's commitments to Harvard. Faculty should recognize that their appointment does not include a guaranteed right to pursue other interests on Harvard time; these pursuits are always subject to review and restriction and then supported where appropriate. As a general rule, **no more than twenty percent (20%) of a full-time Faculty member's total professional effort may be directed to outside work.** Members of the Faculty whose appointments are less than full-time are expected to devote professional loyalty, time, and energy to their patient care, teaching, Research, and administrative responsibilities in accordance with their agreed-upon time commitments.

## **Section IV: Mentors' Obligations to Trainees**

The relationship between trainees (medical students, graduate students, and post-doctoral fellows) and those Faculty assigned to mentor them is one that Harvard 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 Faculty 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 mentors' Financial Interests, or object to their own involvement in projects in which a potential financial conflict of interest exists. Because Harvard 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.

### Instruction and Advising of Trainees:

A Faculty member's outside activities should not adversely influence the instruction, guidance, or supervision of trainees. Academic assignments should principally serve the interests of the trainees in their academic advancement. To that end, Faculty should not assign trainees to Participate in projects that could constrain their ability to freely discuss, defend, and publish their Research. Additionally, no Faculty member may assign any trainee to any project in which the Faculty member has a Financial Interest directly or through an outside entity.

### Disclosure by Mentor of Relevant Financial Interests:

A Faculty Mentor is responsible for ensuring that those who conduct Research with him or her do so with full information about the nature of any relationships with industry that may be impacted positively or negatively by the work.

- General Disclosure to all Trainees: Faculty must disclose to all individuals whose job description includes assisting with the Faculty's Research work any Financial Interests (whether Income or Equity) held by the Faculty member in any Business that (i) provides Sponsored Research support to the Faculty's Research or (ii) whose Technology is being investigated in the Faculty's Research. The individuals to whom such disclosure must be made may include, but are not limited to, students, trainees, and other Faculty. Such disclosure must be made prior to or at the time an individual is offered a position or collaboration with the Faculty member's Research team or Research laboratory or any other job that may encompass assisting with the Faculty member's Research work.
- Project Specific Disclosure: Before a trainee may be involved in any specific Research project, the trainee's Faculty mentor 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 Faculty mentor in a Business that provides Sponsored Research support to the project;
  - any Financial Interest (whether Income or Equity) held by the Faculty member 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: A trainee shall have the right to raise concerns regarding his/her 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:

- 1) In the case of undergraduate or graduate students (A.B., Ph.D., M.D./Ph.D., M.P.H., and D.M.Sc. candidates), concerns may be brought to the Dean for Faculty and Research Integrity, the chairperson (or designated Faculty member or committee) for the undergraduate concentration or graduate program, or to the mentor's department chairperson.

- 2) In the case of postdoctoral fellows and medical and dental students (M.D. and D.M.D. degree candidates), concerns may be brought to the Dean for Faculty and Research Integrity or to the mentor's Medical School or hospital-based department chairperson.

## **Section V: Standing Committee on Conflicts of Interest and Commitment**

The Standing Committee on Conflicts of Interest and Commitment (Standing Committee) is appointed by the Dean of the Faculty of Medicine (Dean) and comprised of representatives from both the clinical and preclinical Faculty. The Standing 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 Faculty in their understanding of and compliance with the rules contained herein. In the event of any dispute over appropriate application of this policy, the Standing Committee is the primary arbiter, and the Dean shall rely on its recommendations regarding how the policy shall apply to the facts of a specific case.

The Standing 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 Faculty members.

The Office of the Dean shall refer specific issues to the Standing Committee for evaluation. Following review of a specific issue, the Standing Committee will make formal recommendations to the Dean and to the affiliated hospital with jurisdiction over the case as to how the matter should be resolved or managed. The Dean will consider the Standing Committee's recommendations prior to instituting any management plan or sanctions in accordance with this policy.

In the event a member of the Faculty requests that the Standing Committee invoke an exception under this policy that requires Standing Committee pre-approval, whether prospectively or in response to an alleged violation of the policy, it will be within the Standing Committee's discretion whether or not to grant such a request. Notwithstanding the facts of any given case, the Standing Committee may decline a request for an exception. In the event the Standing Committee grants a request for exception based on specific circumstances, it will not serve as precedent for or apply to future Research undertaken by the Faculty member making the request or any

other Faculty by reference. Furthermore, the Standing Committee may rescind an exception at any time.

In order to ensure that the Policy reflects current best practices and requirements, the Standing 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 to the Dean periodic changes to the policy as appropriate.

## **Section VI: Faculty Compliance Responsibility**

Faculty members are required to comply with all aspects of this policy, the Harvard University Policy on Individual Conflicts of Interest for Persons Holding Faculty and Teaching Appointments ([http://www.provost.harvard.edu/policies\\_guidelines/Harvard\\_University\\_fCOI\\_policy.pdf](http://www.provost.harvard.edu/policies_guidelines/Harvard_University_fCOI_policy.pdf)), the applicable policies of the affiliated institutions of Harvard University, and all applicable state and federal requirements concerning conflicts of interest.

### **Annual Reporting**

Such compliance shall include reporting in a timely manner all required information to the Office of the Dean or its affiliate designee to facilitate the identification of existing conflicts of interest. The applicable disclosure process will be prescribed by the Office of the Dean and outlined in more detail in standard operating procedures and guidelines which may be amended from time to time.

Faculty are responsible for understanding and following the currently applicable disclosure process. As a general rule, this process will involve annual reporting by Faculty of all external activities and Financial Interests to the Office of the Dean or its designee. Faculty are responsible for amending the disclosure information on file 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). After information is received, it will be reviewed in order to determine whether any identified external activity or Financial Interest violates the rules outlined in this policy.

The information disclosed by a Faculty member 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 Faculty member for review when warranted as well as with department chairs or supervisors. Furthermore, relevant information regarding a Faculty member's interests, activities, and relationships with industry may be made publicly available, such as through a website, at the

discretion of the Office of the Dean and in whatever manner the Office deems appropriate.

### **Disclosure Obligations**

Faculty are required to disclose 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**

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

## **Section VII: Noncompliance and Sanctions**

The Standing Committee on Conflicts of Interest and Commitment has wide discretion to recommend a variety of sanctions to the Office of the Dean in the event of noncompliance with this policy by a Faculty member.

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 Faculty member'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.

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 Faculty member's file of a letter from the Office of the Dean calling into question the individual's good standing as a member of the Faculty;
- Ineligibility of the Faculty member 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;
- Dismissal from the Faculty of Medicine; or
- Any other restriction, limitation, or punishment determined by the Committee to be warranted by the circumstances.

## Section VIII: 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 [<http://hms.harvard.edu/content/authorship-guidelines>] and ICMJE Authorship Guidelines [[http://www.icmje.org/ethical\\_1author.html](http://www.icmje.org/ethical_1author.html)], 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:
  - (i) minimal risk (as that term is defined in 45 CFR Part 46<sup>7</sup>) and
  - (ii) 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;

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<sup>7</sup> 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 Standing Committee 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 in the Faculty of Medicine.

- Full-time Faculty on sabbatical or other paid leave are considered full-time for the purposes of the Policy.
- Full-time Faculty on approved unpaid leave are not considered full-time for these purposes.
- 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, Postmarket 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<sup>ii</sup> 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:
    1. 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);
    2. 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:
      - a. 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
      - b. A non-exclusive license for Research purposes to intellectual property made in and derived

directly from the use of the Material in the Research.

3. 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.

- For more information on whether a Technology is being “investigated” or having Research conducted “on” it in a way that would implicate the Research Rules in this policy, please see the website of the Office of Academic and Research Integrity for guidance.

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<sup>i</sup> The Harvard University Policy on Distinguishing Gifts vs. Sponsored Awards in External Funding Received by Harvard can be found at the following link:

[http://vpf-web.harvard.edu/osp/pdfs/Gifts\\_vs\\_Sponsored\\_Awards\\_policy%206-18-11\\_.pdf](http://vpf-web.harvard.edu/osp/pdfs/Gifts_vs_Sponsored_Awards_policy%206-18-11_.pdf)

A Faculty member’s home institution may have similar policies applicable to the affiliated institution’s internal classification of gifts vs. sponsored awards.

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