Harvard University Faculty of Medicine
Policy on Conflicts of Interest and Commitment

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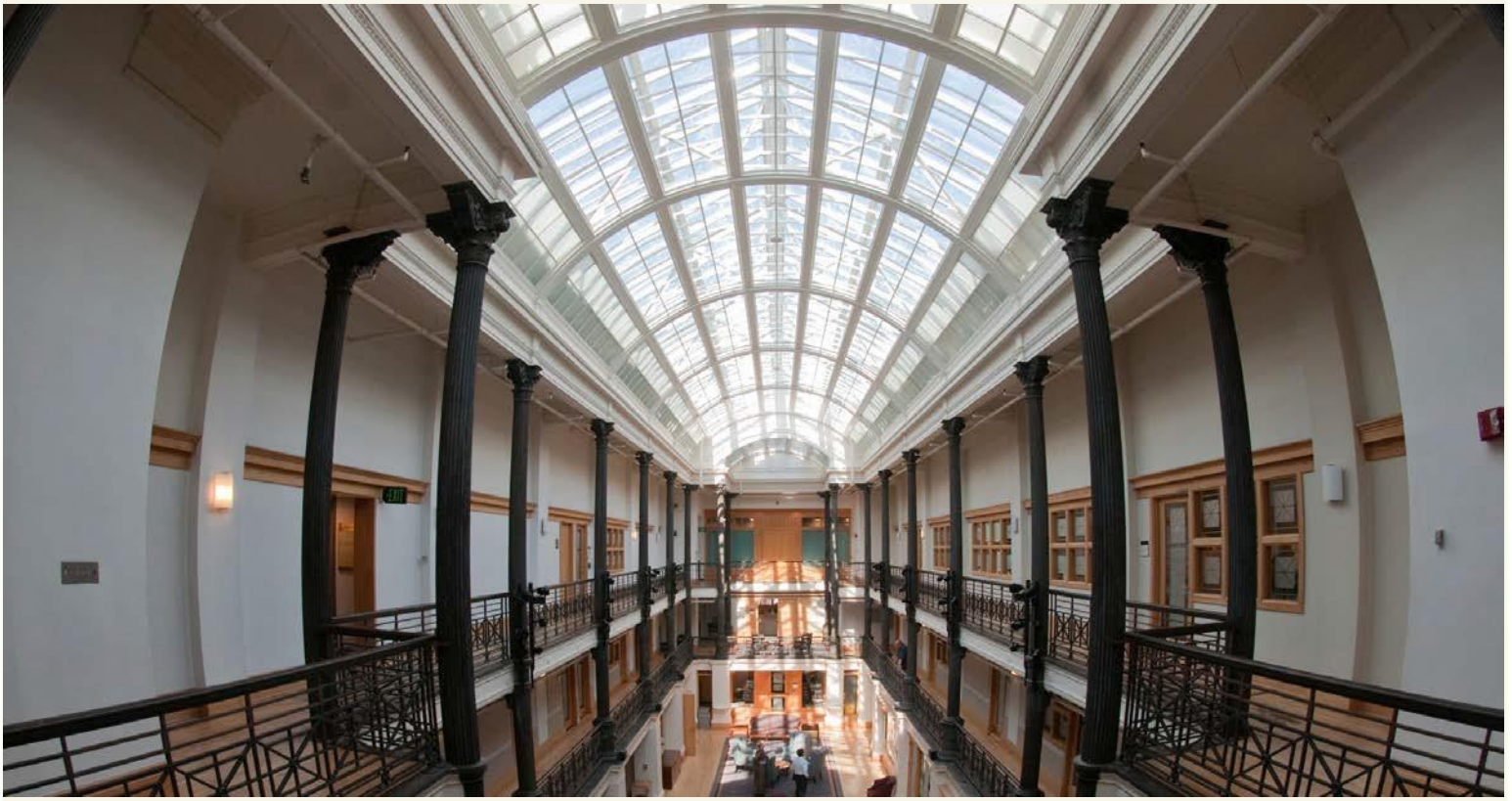

HARVARD
MEDICAL SCHOOL

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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 Dean of the

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Faculty of Medicine of Harvard University (the Dean) or the Dean's designee 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: Presumptively 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 presumed to be prohibited and others 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 may be 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"):

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 HMS Standing Committee on Conflicts of Interest and Commitment (Standing Committee) 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.[1]

De Minimis Thresholds: Faculty may receive **$25,000 or less annually**[2] 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'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.[3]

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 Standing Committee 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 Standing Committee upon petition. They are:

- *Dual-Career Family Exception*: Upon petition to the Standing Committee, Faculty may overcome the presumption that s/he may not

[1] Faculty may use this Petition form to apply to overcome this presumption. Faculty should submit the Petition form to their primary institution or to the Office for Academic and Research Integrity at outside_activities@hms.harvard.edu.

[2] 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.

[3] 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 Rule.

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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 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.

- *Institutional License/Royalty Sharing Agreement Exception:* Upon petition to the Standing Committee, 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 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 (iii) the potential conflict arising by reason of the income received through the institutional agreement can be managed through a formal management plan.

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 Standing Committee 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

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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 who have an Equity Financial Interest above the *de minimis* threshold in a Business may not receive Sponsored Research support from that Business for Research. The presumption may be overcome when, in the judgment of the Standing Committee or its designee, individuals holding presumptively prohibited Equity Financial Interests present sufficient countervailing circumstances (the benefits of the proposed Research must outweigh the risks, and the Financial Interest must be able to be appropriately managed) for being permitted to simultaneously hold the Equity Financial Interest and receive Sponsored Research support.[4]

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.

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 Business was not founded by the Faculty member, or (b) the equity was not acquire in connection with the Research at issue. Any interest exceeding 1% of the publicly traded Business's value would require an exception from the Standing Committee or its designee. **Holding any equity in a privately held Business is presumed to be prohibited**.

[4] Faculty may use this Petition form to apply to overcome this presumption. Faculty should submit the Petition form to their primary institution or to the Office for Academic and Research Integrity at outside_activities@hms.harvard.edu.

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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 Standing Committee or its Designee to Participate in Research using Sponsored Research support from the Business. *The de minimis threshold does not apply to privately held Businesses.*

Duration of Restriction: A Faculty member must be free of all Equity Financial Interests above the *de minimis* threshold from a relevant Business prior to commencing the Sponsored Research. Participation in the Sponsored Research shall apply for the entire duration of the Sponsored Research and the rule continues to apply even should one elect to terminate Sponsored Research activities.[5]

The rule shall apply until the date that is the later of (i) six (6) months following the last day that data is collected (e.g., data lock plus 6 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.

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 Equity 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.

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

Dual-Career Family Exception: Upon petition to the Standing Committee, 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 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

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

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that the Standing Committee finds, in its discretion, can be managed adequately through a formal management plan.

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. Accordingly, when the Standing Committee considers a petition to rebut the Research Support Rule, it shall consider factors which include, but are not 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 Sponsored 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); and
- Likely effectiveness of potential management strategies.

A3. External Activity Rule (The "I(d) Rule")

Faculty who serve in a fiduciary role[6] to a for-profit Business may not Participate in Clinical Research on the Business's 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.

[6] 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.

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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,[7] 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's 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 receiving Sponsored Research from that Business or from Participating in Clinical Research on the Business's 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 the Harvard University Faculty of Medicine depend on limiting inappropriate influence by industry sponsors over the content of

[7] 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.

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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 she or he has been invited to present qualifies for this prohibition, the Faculty member 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 ghostwriting 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 she or he is involved qualifies for this prohibition, the Faculty member should seek institutional guidance.[8]

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, and 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 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 (CME) provider or other professional conference or meeting organizer during the course of a CME event or other professional conference or 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.

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[8] The *Guidelines for Investigators in Scientific Research* (http://ari.hms.harvard.edu/files/integrity-academic-medicine/files/guidelines_for_investigators_in_scientific_Research_0.pdf) and the *Guidelines for Investigators in Clinical Research* (http://ari.hms.harvard.edu/files/integrity-academic-medicine/files/guidelines_for_clinical_Research.pdf) 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."

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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 biologics may be required to report the provision of such meals as part of its annual report to Medicare/Medicaid.

Other exceptions 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 appointments do 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.

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Section IV: Mentors' Obligations to Trainees

The relationship between trainees (medical students, graduate students, residents, and postdoctoral 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 mentors may have in Research projects, and a neutral process through which trainees' 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 a Faculty member has a Financial Interest above the *de minimis* thresholds without the prior approval of the Dean or the Dean's designee.[9]

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 any Financial Interests (whether Income or Equity) held by the Faculty member in any Business related to the Faculty member's Research, teaching, or clinical care. 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 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 mentor in a Business whose Technology is being investigated in the project;
  - any restrictions that may be imposed on the timing of the communication of scientific 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, residents, 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 department chairperson.

[9] Faculty who are directly supervising Research are considered to be Participating in the Research.

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, 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 the Faculty.

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 institution 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 ongoing basis the review of similarly situated institutions' policies, relevant professional guidance documents, available academic literature, and applicable laws and government

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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), 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.

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Disclosure Obligations

Faculty are required to disclose Financial Interests in related outside entities and sources of support related to a presentation, public comment (including online), 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 the Financial Interest (by Entity name) 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 reasonable explanations. 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;

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- 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 (excluding those studies determined to be Nominal Risk Clinical Research by an IRB and/or COI Committee). Also see definition of "Participate in Clinical Research."

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 (lecturer, instructor, assistant professor, associate professor, professor) 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.

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- 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") held by the Faculty member and/or his/her Family.

- 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 and/or his/her Family 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 and/or his Family 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.

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

(i) minimal risk (as that term is defined in 45 CFR Part 46[10]) and
(ii) falls within one or more of the following categories:

[10] 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. http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

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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 Clinical 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 Risk Clinical Research;
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.

Participate: To be responsible for the design, conduct, or reporting of Research, regardless of title or position. (See also the definition for Participate in Clinical Research).

- 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

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Research even should the Faculty member elect to terminate the Research activities.

Participate in Clinical Research: Faculty who Participate in Clinical Research either:

1. **are responsible for the design, conduct, or reporting of an IRB-approved study** and, as part of that IRB-approved study:
   a. have access to information about living individuals by intervening or interacting with them for Research purposes; and/or
   b. have access to identifiable private information about living individuals for Research purposes; and/or
   c. obtain the voluntary informed consent, assent or participation of individuals to be subjects in Research; and/or
   d. study, interpret, or analyze identifiable private information or identifiable data for Research purposes; and/or
   e. have access to the study treatment assignment made through, for example, a randomization process; or
2. **serve as the** Primary Author, or one of the Primary Authors, of a Publication reporting the results of an IRB-approved study. A Primary Author of a Publication is the individual who, in compliance with HMS Authorship Guidelines [http://ari.hms.harvard.edu/files/integrity-academic-medicine/files/authorship_guidelines.pdf] and ICMJE Authorship Guidelines [http://www.icmje.org/icmje-recommendations.pdf], 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.[11]

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

Post-market 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.

[11] In situations where a Faculty member is not subject to the Clinical Research Rule but will be an author, the Faculty member must fully disclose his or her Financial Interest in related presentations and Publications and include a statement regarding the Faculty member's limited role on the study. The statement may include a clarification that the individual was prohibited under HMS Policy from involvement as described in the definition of Participation in Clinical Research.

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Primary Author: An individual who, in compliance with HMS Authorship Guidelines [http://ari.hms.harvard.edu/files/integrity-academic-medicine/files/authorship_guidelines.pdf] and ICMJE Authorship Guidelines [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. For purposes of applying the Clinical Research 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 Standing Committee or its designee that he or she should not be considered a Primary Author.

Publication: Ordinarily refers to a peer reviewed indexed manuscript or the substantial equivalent as determined by the Standing Committee or its designee. Abstracts alone will not typically meet this definition.

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[12] 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 foregoing, 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.

[12] The Harvard University Policy on Distinguishing Gifts vs. Sponsored Awards in External Funding Received by Harvard can be found at the following link: http://osp.finance.harvard.edu/gift-vs-sponsored-research-policy. 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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2. **Certain Material Transfer Agreements**: Agreements that provide for the provision of tangible materials, including equipment, 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:
        1. 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
        2. 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.
- 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 HMS Office of Academic and Research Integrity for guidance.

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