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1.2. Policy Requirements for Interactions Related to Research,

Continued

1.2.3 Impermissible Financial Conflicts of Interest Continued

To Whom It Applies	Policy Requirements
All Partners Researchers, continued	<p><i>Dual-Career Family Exception:</i> Upon petition to the Standing Committee, a Researcher 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 Researcher’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.</p> <p><i>Institutional License/Royalty Sharing Agreement Exception:</i> Upon petition to the Standing Committee, a Researcher 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.</p>
All Partners Researchers	<p>A2. Research Support Rule (The “I(b) Rule”):</p> <p>It is presumed that Researchers who have an Equity Financial Interest above the <i>de minimis</i> 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.</p> <p><i>De minimis Threshold for Researcher’s Equity Financial Interest in Publicly Traded Business:</i> A Researcher may have an Equity Financial Interest of one percent or less in a <i>publicly traded Business</i> and Participate in Research using Sponsored Research support from the Business so long as (a) the Business was not founded by the Researcher, or (b) the equity was not acquired in connection with the Research at issue. Any interest exceeding 1% of the publicly traded Business’s value would require an exception from the Standing Committee or its designee. Holding any equity in a privately held Business is presumed to be prohibited.</p>

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1.2. Policy Requirements for Interactions Related to Research,

Continued

1.2.3 Impermissible Financial Conflicts of Interest Continued

To Whom It Applies	Policy Requirements
<p>All Partners Researchers, continued</p>	<p><i>Review of Faculty Equity Financial Interest in a Privately Held Business:</i> 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. <i>The de minimis threshold does not apply to privately held Businesses.</i></p> <p><i>Duration of Restriction:</i> A Researcher must be free of all Equity Financial Interests above the <i>de minimis</i> 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 rule continues to apply even should one elect to terminate Sponsored Research activities.³</p> <p>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.</p> <p><i>SBIR/STTR Exception:</i> 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) Program⁴, the involved Researcher 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 Researcher, 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.</p>

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³ A Researcher may petition for relief from the application of the Research Support Rule to the entire period set forth there. If granted, however, the expectation is that Participation has been surrendered for the duration of the Sponsored Research.

⁴ 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.

1.2. Policy Requirements for Interactions Related to Research,

Continued

1.2.3 Impermissible Financial Conflicts of Interest Continued

To Whom It Applies	Policy Requirements
All Partners Researchers, continued	<p><i>Dual-Career Family Exception:</i> Upon petition to the Standing Committee, a Researcher 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 Researcher'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.</p>
All Partners Researchers	<p>A3. External Activity Rule (The “I(d) Rule”):</p> <p>Researchers who serve in a fiduciary role⁵ to a for-profit Business may not Participate in Clinical Research on the Business's Technology nor receive Sponsored Research support from the Business.</p> <p><i>SBIR/STTR Exception:</i> 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) Program⁶, the involved Researcher 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 Researcher, 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.</p>

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⁵ 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.

⁶ The HMS Standing Committee 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.

1.2. Policy Requirements for Interactions Related to Research,

Continued

1.2.3 Impermissible Financial Conflicts of Interest, Continued

To Whom It Applies	Policy Requirements
<p>1. ONLY Partners Researchers who are ALSO Full-Time Faculty at Harvard Medical School, AND 2. Partners Researchers who are also Partners Institutional Officials</p>	<p>B. Executive Position Rule (the “I(c) Rule”)</p> <p>Researchers who are also Full-Time Faculty at Harvard Medical School and Researchers who are also Partners Institutional Officials may not hold an Executive Position in a for-profit Business engaged in commercial or Research activities of a biomedical nature. Researchers 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.</p>

1.2.4 Interests and Activities That May Be Allowed

All other [Financial Interests](#) and Outside Activities will be reviewed and may be determined by Partners to be allowable subject, where appropriate, to Partners requirements for transparency or accountability, and in the case of a determination of Financial Conflict of Interest, a management plan.

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1.3. Oversight of Interactions Related to Research

1.3.1 Partners Authority and Responsibilities Relating to Financial Interests and Outside Activities of Researchers

Partners, acting through its designated officials and Committees, has the authority to and is responsible for:

- Reviewing reported Significant Financial Interests that reasonably appear to be related to Researchers' Institutional Responsibilities;
 - Determining whether any reported Significant Financial Interests are related to any of a Researchers' research;
 - Determining whether any reported related Significant Financial Interests constitute Financial Conflicts of Interest; a Financial Conflict of Interest exists where Partners reasonably determines that a disclosed Financial Interest could directly and significantly affect the design, conduct, or reporting of the research;
 - Evaluating and resolving identified Financial Conflicts of Interest in research, including how identified Financial Conflicts of Interest must be managed, reduced, or eliminated;
 - Providing appropriate oversight of identified Financial Conflicts of Interest and any related management plans, with other Partners officials and offices as circumstances require;
 - Taking any other appropriate actions to address Significant Financial Interests and Outside Activities to the extent in their judgment necessary; and
 - Evaluating Financial Interests and Outside Activities that do not constitute Significant Financial Interests and/or do not constitute Financial Conflicts of Interest and taking such actions as determined to be needed by Partners to achieve transparency, to assure accountability, or to address other issues relating to those Interests and Activities insofar as they pertain to Partners research activities.
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Business	<p><i>(HMS definition)</i> Any legal entity organized for profit or non-profit purposes.</p> <ul style="list-style-type: none"> • 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). <p style="text-align: right;"> → A1 Clinical Research Rule → A2 Research Support Rule → A3 External Activity Rule → B Executive Position Rule </p>
Clinical Conflict of Interest	<p>A clinical conflict of interest may exist when a Partners Individual covered by Section 2 of this Policy has a personal Financial Interest or Outside Activity with a manufacturer of a drug, device, or other products for use in patient care, according to thresholds that may be established from time to time by COA, which could influence or be perceived as influencing his/her clinical decision-making or interactions with his/her patients.</p>
Clinical Research	<p><i>(HMS definition)</i> 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.”</p> <p style="text-align: right;"> → A1 Clinical Research Rule → A2 Research Support Rule → A3 External Activity Rule </p>
COA	Committee on Outside Activities
Company	A for-profit outside entity
Covered Individuals	Medical/Professional Staff Members, Research Staff Members, and Employee Members
ERB	Education Review Board

Employee Members	Administrative staff, nurses, support personnel, and other full- or part-time employees of Partners or a Partners-affiliated Corporation who are not Medical/Professional Staff Members or Research Staff Members.
Executive Position	<p><i>(HMS definition)</i> Any position that is responsible for a material part of the operation or management of a Business.</p> <p>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.</p> <p style="text-align: right;"><i>→ B Executive Position Rule</i></p>
Faculty	<p><i>(HMS definition)</i> Any person possessing an academic appointment in the Faculty of Medicine [of Harvard Medical School]. 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 [Harvard] 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”.</p> <p style="text-align: right;"><i>→ B Executive Position Rule</i></p>
Family	Spouse, domestic partner, and dependent children
Fiduciary Position	A fiduciary position is a position in which one has a legal responsibility of care for the assets or rights of another entity or person. Members of a Board of Directors of a company have fiduciary positions. Other types of fiduciary positions include serving as an officer or executive of a company, such as the CEO or COO, which positions require high-level responsibility for the day-to-day management of the business.
Financial Conflict of Interest	A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest	<p><i>(HMS definition)</i> 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.</p> <ul style="list-style-type: none"> • 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/her 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, Postmarket Royalties. <p style="text-align: right;"> → A1 Clinical Research Rule → A2 Research Support Rule → A3 External Activity Rule → 1.2.4 </p>
HMS Conflicts Policy	The formal Conflicts of Interest policy document of the Harvard Medical School, as it may be revised from time to time. As of the date of this version of the Partners Policy, the formal Harvard Medical School document is the Harvard University Faculty of Medicine Policy on Conflicts of Interest and Commitment, available at http://ari.hms.harvard.edu/files/integrity-academic-medicine/files/final_hms_coi_policy_10.11.2016_0.pdf
HMS Standing Committee	The HMS Standing Committee on Conflicts of Interest and Commitment
Industry	A for-profit Outside Entity
Institutional Officials	<ul style="list-style-type: none"> • Presidents and Chief Executive officers • Officers and executives at and above the Vice President level • Service/Department Chiefs/Chairs • Other senior officials designated by the President/CEO of Partners and each Affiliated Corporation
Institutional Responsibilities	Institutional Responsibilities include research, clinical care, education, administrative, and other Partners activities.

Sponsored Research, Continued	<p>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.</p> <p style="text-align: right;">→ A2 Research Support Rule → A3 External Activity Rule → B Executive Position Rule</p>
Technology	<p>(HMS definition) Any compound, drug, device, diagnostic, medical or surgical procedure intended for use in health care or health care delivery.</p> <ul style="list-style-type: none"> • 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, <u>or</u> (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. <p style="text-align: right;">→ A1 Clinical Research Rule → A3 External Activity Rule → B Executive Position Rule</p>
Transaction	<p>Any contract, agreement, transaction or act of Partners</p>
Written Agreement	<p>A written agreement between a Covered Individual and an Outside Entity setting forth the terms of an arrangement relating to an Outside Activity</p>