

Policy for Interactions with Industry and Other Outside Entities

Table of Contents

<i>Preface, Purpose, and Administration</i>	1
P.1. Purpose of the Policy	1
P.1.1 Importance of Collaboration with Industry	1
P.1.2 Definition Of Conflict Of Interest	2
P.1.3 Purpose	2
P.2. Administration of the Policy	3
P.2.1 Committee Structure	3
P.2.2 COA Responsibilities	3
P.2.3 ERB Responsibilities	4
P.2.4 OII Responsibilities	4
P.2.5 Definition of MGB Individuals	5
P.2.6 Responsibilities of MGB Individuals	5
P.2.7 Compliance Responsibility	6
P.2.8 Policy Review and Amendment	6
<i>Researchers' Financial Interests and Outside Activities Related to Research and Financial Conflicts of Interest</i>	7
1.1. Policy Overview	7
1.1.1 Policy	7
1.1.2 Researcher Responsibilities	8
1.1.3 To Whom this Policy Section Applies	8
1.2. Policy Requirements for Interactions Related to Research	9
1.2.1 Required Reporting to MGB	9
1.2.2 Reportable Interests	10
1.2.3 Impermissible Conflicts of Interest	10
1.2.4 Interests and Activities That May Be Allowed	15
1.3. Oversight of Interactions Related to Research	16
1.3.1 MGB Authority and Responsibilities Relating to Financial Interests and Outside Activities of Researchers	16
1.3.2 Required Disclosure in Publications and Presentations	17
1.3.3 Required Disclosure to Subjects in Human Subjects Research	17
1.3.4 Additional Disclosure and Accountability Measures	17
1.3.5 Management of Financial Conflicts of Interest	18

1.3.6 Special OII Responsibilities with Respect to Public Health Service Funding.....	18
<i>Clinical Care and Interactions with Industry</i>.....	20
2.1. Policy Overview	20
2.1.1 Policy.....	20
2.1.2 Definition of Clinical Conflict of Interest	20
2.1.3 Ancillary Equipment	21
2.1.4 To Whom the Policy Applies	21
2.2. Policy Requirements.....	22
2.2.1 Evaluation of Clinical Conflicts of Interest.....	22
2.2.2 Reporting of Clinical Conflicts of Interest.....	22
2.2.3 Additional Policy Requirements Related to Clinical Care and Interactions with Industry	22
2.3. Oversight of Clinical Conflicts of Interest.....	23
2.3.1 COA’s Authority for Evaluating and Managing Clinical Conflicts of Interest	23
2.3.2 Management of Clinical Conflicts of Interest.....	23
2.3.3 Disclosure to Patients	23
2.3.4 Clinical Care and Royalties Through the Institution.....	23
<i>Industry Support Related to Education</i>.....	24
3.1 Policy Overview	24
3.1.1 Rationale and Policy Statement.....	24
3.1.2 Description of Industry Support of Education	24
3.1.3 Types of MGB Educational Activities	25
3.1.4 OII Review of Industry Support.....	25
3.2. Oversight of Industry Support Related to Education	26
3.2.1 ERB Authority to Implement, Monitor, and Enforce Policy	26
3.2.2 Requirements for ERB Review and Approval	26
3.2.3 ERB Review of MGB Educational Activities.....	26
3.2.4 ERB Oversight for Industry Support for Trainee Travel	27
3.2.5 Educational Services Arrangements.....	27
3.2.6 Exception for Merit-Based Fellowship Awards.....	27
3.3. Policy Requirements for Industry Support of MGB Educational Activities.....	28
3.3.1 Overview	28
3.3.2 Compliance with Continuing Medical or Other Healthcare Professional Education Standards	28
3.3.3 Control of Content.....	28

3.3.4 Multiple Sources of Monetary Support Required	28
3.3.5 Review and Resolution of Financial Interests.....	28
3.3.6 Disclosure of Support.....	29
3.3.7 Support to Institution, not Individuals	29
3.3.8 Selection of Participants.....	29
3.3.9 Naming of Activity/ Specific Training Position	29
3.3.10 Reports to Industry	29
3.3.11 Commercial Promotion at MGB Educational Events	29
3.3.12 Documentation	30
3.3.13 Budget Review	30
3.4. Policy Requirement for Industry Support to Presidents' Funds for Medical Education	31
3.4.1 Requirements for Industry Contributions to Presidents' Funds	31
Consulting and Other Outside Activities.....	32
4.1. Policy Overview	32
4.1.1 Policy.....	32
4.1.2 To Whom Does this Section 4 Apply?.....	33
4.2. Policy Requirements for Outside Activities	34
4.2.1 Requirements for Outside Activities	34
4.2.2 Time Limitations for Outside Activities	35
4.2.3 Prohibited Outside Activities	36
4.2.4 Fiduciary Positions Require COA Review and Approval.....	37
4.2.5 Compensation for Outside Activities	38
4.2.6 Restriction on Use of MGB Name	38
4.2.7 Competition with MGB.....	39
4.2.8 When Written Agreements Are Required	39
4.2.9 Institutional Review of Outside Activities	40
4.3. Policy Requirements for Outside Activities of Institutional Officials	41
4.3.1 Prohibition on Certain Executive Positions	41
4.3.2 Restrictions on Outside Activities.....	41
4.3.3 Required PICC Approvals.....	41
4.4.1 OII Review and Approval Required.....	42
4.4. Oversight of Agreements for Outside Activities of Medical/Professional Staff and Research Staff Members.....	42
4.4.2 Outside Activities That Do Not Require OII Review, but May Require Supervisor Review.....	43

4.4.3 Outside Activities That Require Supervisor Review and Approval	44
4.5. Oversight of Agreements for Outside Activities of Employee Members	45
4.5.1 OII Review and Approval Required.....	45
4.5.2 Time Limitations for Outside Activities	45
4.5.3 Outside Activities That Do Not Require OII Review, but May Require Supervisor Review.....	45
4.5.4 Outside Activities That Require Supervisor Review and Approval	46
4.6. Authority of Supervisors.....	48
4.6.1 Independent Supervisor Review and Authority	48
4.6.2 Considerations for Supervisor Review.....	48
4.6.3 Supervisor Conflict of Interest	48
4.6.4 COA Authority for Unresolved Issues	48
4.7. Standard Requirements for a Written Agreement.....	49
4.7.1 Time	49
4.7.2 Restriction on Use of MGB Name	49
4.7.3 Scope and Field of Services	49
4.7.4 Overlap with Field of Research.....	49
4.7.5 Restriction on Intellectual Property.....	50
4.7.6 Disclosure of Unpublished Research	50
4.7.7 Confidentiality.....	50
4.7.8 Exclusivity or Non-Compete Provisions.....	50
<i>Institutional Conflicts of Interest</i>	<i>51</i>
5.1. Policy Overview	51
5.1.1 Policy Statement.....	51
5.1.2 To Whom Does Section 5 Apply?.....	51
5.2. Policy Requirements for Certain Institutional Financial Interests	52
5.2.1 Institutional Equity Acquired Outside Treasury Investments	52
5.2.2 License Payments and Research	54
5.2.3 Oversight of Major Gifts and Research.....	55
5.2.4 Royalties and Clinical Care.....	55
5.3. Policy Requirements for Financial Interests and Outside Activities of Institutional Officials	56
5.3.1 New Outside Activities Require COA review	56
5.3.2 New Human Subjects Research	56
5.4. Policy Requirements for Financial Interests and Outside Activities of Direct Supervisors of Research.....	57
5.4.1 Conflicts of Interest for Direct Supervisors	57

5.5. Policy Requirements for Institutional Purchasing and Comparable Transactions	58
5.5.1 Conflicts of Interest in Institutional Purchasing and Comparable Transactions	58
5.5.2 Interested Individuals	58
5.5.3 Recusal Requirement for Interested Individuals	58
5.5.4 Procedures for Certain Purchasing Transactions	59
5.5.5 Procedures for Other Transactions	60
5.6. COA Oversight of Institutional Conflicts of Interest.....	61
5.6.1 COA Oversight of Institutional Conflicts of Interest	61
<i>Gifts From MGB Vendors and Potential Vendors</i>	<i>62</i>
6.1. Policy Overview	62
6.1.1 Policy on Gifts to MGB	62
6.1.2 Policy on Gifts from Vendors or Potential Vendors to a MGB Individual or to MGB for the Use or Benefit of a MGB Individual	62
6.1.3 To Whom Section 6.1.2 Applies	63
6.1.4 Scope of Policy.....	63
6.1.5 MGB Code of Conduct	63
<i>Glossary and Terms</i>	<i>64</i>
Acting in a MGB Capacity.....	64
Affiliated Institution	64
Business.....	65
Clinical Conflict of Interest.....	65
Clinical Research.....	65
COA	65
Company	65
Covered Individuals	65
ERB	65
Employee Members.....	66
Executive Position.....	66
Faculty	66
Family.....	66
Fiduciary Position	66
Financial Conflict of Interest.....	66
Financial Interest	67
HMS Conflicts Policy	67

HMS Standing Committee	67
Industry.....	67
Institutional Officials.....	67
Institutional Responsibilities	68
Interested Individual.....	68
Medical/ Professional Staff Members	68
MGB.....	68
MGB Educational Activity.....	69
MGB Individual	69
Nominal Risk Clinical Research	70
OII	70
Outside Activities	71
Outside Entity.....	71
Participate.....	71
Participate in Clinical Research	72
Policy.....	72
PICC	72
Research	72
Research Staff Members	73
Researchers.....	73
Reviewable Purchasing Transaction	73
Significant Financial Interest	74
Special Equity	75
Sponsored Research	76
Technology.....	77
Transaction	77
Written Agreement.....	77

Preface, Purpose, and Administration

P.1. Purpose of the Policy

P.1.1 Importance of Collaboration with Industry

Mass General Brigham (“MGB”), its Affiliated Institutions, their leadership, and their individuals have a long history of supporting collaborations with Industry and other Outside Entities. Preserving these relationships is essential because they advance MGB’s mission of providing, promoting, and supporting high quality and leading edge patient care, research, and medical education.

At the same time, MGB recognizes that conflicts of interest, and the appearance of conflict of interest, may arise from these interactions. These conflicts create a risk that integrity, independence, leadership, exercise of professional judgment, or the reputation of MGB may be compromised. However, in most cases these risks are manageable and the relationships are encouraged and allowed because of their importance to the advancement of MGB’s mission.

Interactions with Industry and other Outside Entities also have the potential to create conflicts of commitment, in that Outside Activities or Financial Interests may deter individuals from devoting an appropriate amount of time, energy, creativity, or other personal resources to their MGB responsibilities. Here too, these risks are generally manageable and do not prevent relationships from going forward.

To assure that these relationships are reviewed consistently with these values, MGB has adopted this ***Mass General Brigham Policy for Interactions with Industry and Other Outside Entities*** to evaluate and appropriately address these relationships.

Note: The term “MGB” refers to Mass General Brigham Incorporated and/or one or more of its Affiliated Institutions. Except for Section 1.2.3, terms in this Policy that have initial capital letters shall have the meaning specified in the Glossary. Italicized terms in Section 1.2.3 shall have the meaning specified in the HMS Conflicts Policy.

P.1. Purpose of the Policy, Continued

P.1.2 Definition Of Conflict Of Interest

For purposes of this Policy, a “conflict of interest” refers in general to “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest” (Institute of Medicine, 2009).

These circumstances include, but are not limited to, the following:

- Those where outside financial or other interests may inappropriately influence the way the individual carries out his or her MGB responsibilities, or
- Those where an individual’s outside interests may be adverse to MGB, or
- Those where an individual has the opportunity to use his or her MGB position for personal financial gain.

The determination of the existence of a conflict of interest, according to the standards specified above, is based on an evaluation of relevant facts and circumstances by the decision-making entity designated in this Policy for that particular context, as may be more specifically detailed in this Policy.

P.1.3 Purpose

The purpose of the *Mass General Brigham Policy for Interactions with Industry and Other Outside Entities* is to

- Maintain the highest standards of integrity and professionalism in all MGB activities and affairs
 - Support principled relationships with Industry and other Outside Entities that advance patient care, research, and medical education consistent with these standards, and
 - Preserve public confidence that these standards are and will be maintained.
-

[To Table of Content](#)

P.2. Administration of the Policy

P.2.1 Committee Structure

The MGB Board of Directors has established the Professional and Institutional Conduct Committee (PICC), and the Chief Executive Officer of MGB has established the Committee on Outside Activities (COA), the Educational Review Board (ERB), and the Office for Interactions with Industry (OII). In accordance with their charges, these committees and OII are responsible for overseeing, implementing, monitoring, and enforcing the ***Mass General Brigham Policy for Interactions with Industry and Other Outside Entities*** and for resolving individual cases. In carrying out their responsibilities, these committees and OII may delegate specific responsibilities to other institutional committees, offices, or individuals.

P.2.2 COA Responsibilities

Subject to certain reserved authorities of PICC, COA handles matters that arise in connection with the Outside Activities and interests of MGB and MGB Individuals that present issues under this MGB Policy, including conflicts of interest. COA reviews and resolves matters that present potential conflicts of interest by applying, interpreting, and articulating conflict-related policy, except for matters that are the responsibility of the ERB.

In performing its functions, COA has the authority to develop, adopt, and oversee implementation of policy within existing policy framework; to address issues of academic and institutional integrity that arise in matters involving conflicts; to develop, adopt and oversee implementation of appropriate resolution of such matters, including approval of plans to manage conflicts, and where appropriate, to prohibit certain activities or actions; to develop, adopt, and oversee implementation of such policies as are necessary for compliance with applicable laws pertaining to individual and institutional conflicts of interest; to refer any case or issue to PICC; and to take whatever actions are necessary to implement this Policy or are consistent with its formal charge or other authority delegated to it.

[To Table of Content](#)

P.2. Administration of the Policy, Continued

P.2.3
ERB
Responsibilities Subject to certain reserved authorities of PICC, ERB oversees industry support for MGB educational activities. ERB reviews and approves all industry-support for MGB educational activities by applying, interpreting, and articulating policies related to industry-supported education.

In performing its functions, ERB has the authority to develop, adopt, and oversee implementation of details of policies for review of industry support for educational activities; to review and act on industry support proposals; to ensure compliance with applicable internal and external policy requirements; to ensure the appropriate level of content review for industry-supported educational activities; to review relevant financial relationships of individuals providing content for such programs or soliciting/spending gifts to support such programs; to establish monitoring programs and work with COA and relevant officials on appropriate sanctions of policies; to develop, adopt, and oversee implementation of such policies as are necessary for compliance with applicable laws; to refer any case or issue to PICC; and to take whatever actions are necessary to implement this Policy or are consistent with its formal charge or other authority delegated to it.

P.2.4
OII
Responsibilities OII assists PICC, COA, ERB, and their delegates with the administration of this Policy.

- OII has the authority to refer matters to COA or ERB, as appropriate, or to their respective delegates for assessment and action required by this Policy.
- OII has the authority to develop procedures, guidelines, forms, and tools it considers necessary and appropriate to fulfill its responsibilities under this Policy.
- OII has the authority to take appropriate actions to address personal Financial Interests and Outside Activities consistent with the authority delegated to it.

[To Table of Content](#)

P.2. Administration of the Policy, Continued

P.2.5 Definition of MGB Individuals

MGB Individuals are responsible for complying with this Policy. MGB Individuals include specifically

- Any trustee, director, officer, executive, full- or part-time Medical/Professional Staff Member, Research Staff Member, or Employee Member of a MGB Affiliated Institution (other than MGB CP);
 - Any member of a MGB committee;
 - Any consultant, independent contractor, student, trainee, sponsored staff, researcher, or other individual Acting in a MGB Capacity;
 - The following people affiliated with MGB CP
 - o MGB CP Trustees, officers, executives, and members of MGB CP committees with board-delegated powers
 - o Physicians and non-physicians employed by MGB CP
 - o Physicians who have an appointment to the professional staff of a hospital owned or controlled by MGB
 - o Other physicians and non-physicians, who, in the judgment of the Chief Executive Officer of MGB CP, have significant MGB CP-related management responsibilities.
-

P.2.6 Responsibilities of MGB Individuals

MGB Individuals are required to:

- Conduct their MGB activities and obligations, as well as their Outside Activities, in strict compliance with this Policy at all times;
- Remain impartial in exercising professional judgment and leadership and in advancing MGB's best interests;
- Provide such information as is required by MGB in connection with the implementation of this Policy on or through any applicable MGB disclosure process. Such information shall be shared with those responsible for the administration and enforcement of this Policy.

MGB Individuals must also fully comply with

- The MGB Code of Conduct
- All other applicable MGB policies, and
- All applicable laws and regulations.

MGB Individuals who have faculty appointments at Harvard Medical School (HMS) must also fully comply with all applicable HMS policies.

[To Table of Content](#)

P.2. Administration of the Policy, Continued

P.2.7 Compliance Responsibility

Failure to comply with MGB policy or to fully, accurately, and according to prescribed timetables disclose required information, including making incomplete, erroneous or misleading disclosures, and failure to comply with disclosure and accountability requirements and management plans constitute violations of this Policy and will be addressed and adjudicated within applicable disciplinary policies and procedures of MGB and its Affiliated Institutions.

P.2.8 Policy Review and Amendment

PICC shall review this ***Mass General Brigham Policy for Interactions with Industry and Other Outside Entities*** periodically in light of changes in policies of governmental entities, other comparable academic medical centers, and other relevant circumstances, and may revise, supplement, or otherwise amend this Policy from time to time. The ***Mass General Brigham Policy for Interactions with Industry and Other Outside Entities*** may also be amended by the MGB Board of Directors.

[To Table of Content](#)

Section 1

Researchers' Financial Interests and Outside Activities Related to Research and Financial Conflicts of Interest

1.1. Policy Overview

1.1.1 Policy

Collaborations between MGB and its Researchers and Industry and other Outside Entities are critical to the success of the MGB research mission and to advancing science and patient care. However, such relationships must be carefully managed to ensure that they do not affect the design, conduct, or reporting of MGB research, or raise issues of transparency or other concerns that should be addressed.

Note: The term “MGB” refers to Mass General Brigham Incorporated and/or one or more of its Affiliated Institutions. Except for Section 1.2.3, terms in this Section 1 that have initial capital letters shall have the meaning specified in the Glossary.

[To Table of Content](#)

1.1. Policy Overview, Continued

1.1.2

Researcher Responsibilities

All MGB Researchers must

- Comply with this Section 1;
- Report Financial Interests and Outside Activities, including Significant Financial Interests that reasonably appear to be related to their Institutional Responsibilities, defined as research, clinical care, education, administration, and other MGB activities, as required by MGB;
- Comply with MGB and, as applicable, HMS prohibitions on situations determined to be impermissible in the research context;
- Comply with MGB and, as applicable, HMS requirements imposed to otherwise manage Financial Conflicts of Interest;
- Comply with any applicable training requirements; and
- Comply with any other requirements determined to be needed by MGB and, as applicable, HMS to assure transparency or to address other issues relating to Financial Interests and Outside Activities as they pertain to MGB research activities.

Important: MGB Researchers may be subject to additional requirements, including those of the

- MGB Human Research Committee (including MGB or other applicable IRBs);
 - Embryonic Stem Cell Research Oversight Committee;
 - Animal Care and Use Committees;
 - Institutional Biosafety Committee; and
 - Other required reviews and approvals.
-

1.1.3

To Whom this Policy Section Applies

This Section 1 applies ONLY to MGB Researchers.

Researchers are MGB Individuals who are project directors or principal investigators of any MGB research activity, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of MGB research activities, including collaborators or consultants. The term “Researchers” is not limited to principal investigators.

[To Table of Content](#)

1.2. Policy Requirements for Interactions Related to Research

1.2.1 Required Reporting to MGB

Researchers are required to disclose their Financial Interests, including but not limited to Significant Financial Interests, and other Outside Activities with Industry or other Outside Entities that reasonably appear to be related to their Institutional Responsibilities, including reporting in the following ways:

- Researchers are required to complete the annual MGB disclosure statement when requested.
- In addition, in forms and formats at different times as specified by MGB, researchers are also required to disclose requested information, including Significant Financial Interests. Examples include but are not limited to submission of human subjects research protocols, submissions for research funding from any source, or new consulting or other Outside Activities.
- Researchers applying for and conducting research funded by the Public Health Service are required to update their disclosures within 30 days of discovering or acquiring a new Significant Financial Interest.
- Researchers applying for and conducting research funded by the Public Health Service must disclose the occurrence of reimbursed or sponsored travel as required by MGB, including but not limited to the purpose of the travel, the identity of the sponsor/organizer, the destination, and the duration.
- Researchers applying for and conducting research funded by foundations or other entities that require that MGB apply Public Health Service standards to that research must also follow those standards.

Note: Institutional Responsibilities include research, clinical care, education, administration, and other MGB activities.

[To Table of Content](#)

1.2. Policy Requirements for Interactions Related to Research,

Continued

1.2.2

Reportable Interests

Reportable Interests

Interests that are disclosable under this section 1.2.2 include, but are not limited to, Significant Financial Interests as defined in federal regulations 42 CFR Part 50 and 42 CFR Part 54, 60 FR 35811 (and as they may be subsequently modified) that would reasonably appear to be related to the researcher's Institutional Responsibilities with respect to

- any research supported by U.S. Public Health Service, and
- any other research as designated by COA.

1.2.3

Impermissible Conflicts of Interest

MGB and HMS policies state that the following activities are impermissible.

Note: This section (1.2.3) is intended to conform to the current HMS Policy on Conflicts of Interest and Commitment (HMS Conflicts Policy), except that Sections 1.2.3. A1, A2, and A3 extend these HMS Conflicts Policy requirements to all Researchers, regardless of whether they have an HMS appointment, and Section 1.2.3.B extends the HMS requirements to Researchers who are also Institutional Officials, regardless of whether they have an HMS appointment. Any changes in the HMS Conflicts Policy automatically apply to HMS faculty who are subject to the HMS Conflicts Policy. COA shall decide whether to extend any such change in the HMS Conflicts Policy to MGB Individuals who are not otherwise covered by the HMS Conflicts Policy.

Note: Sections 1.2.3. A1, A2, and A3 apply to research conducted at MGB and to all other research in which MGB is considered to be “engaged,” as determined by the MGB IRB.

Continued on Next Page

[To Table of Content](#)

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 MGB Researchers	A1. Clinical Research Rule (The “I(a) Rule”): It is presumed that Researchers 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. De Minimis Thresholds: Researchers may receive \$25,000 or less annually¹ from a Business in the form of Income (e.g., consulting fees or other remuneration for services) and still Participate in Clinical Research on the Business's Technology. Furthermore, Researchers 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 Researcher 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 Researcher elect to terminate Clinical Research activities.² The rule shall apply until the date that is the later of (i) six (6) months following the last day that a human study participant completes the Clinical Research (e.g., data lock plus 6 months), or (ii) the first Publication of data derived from the Clinical Research, or a decision not to publish the data derived from Clinical Research.

Continued on Next Page

[To Table of Content](#)

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

² A Researcher 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.

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 MGB Researchers, continued	Dual-Career Family Exception: 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. Institutional License/Royalty Sharing Agreement Exception: 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.
All MGB Researchers	A2. Research Support Rule (The "I(b) Rule"): It is presumed that Researchers 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. De minimis Threshold for Researcher's Equity Financial Interest in Publicly Traded Business: A Researcher 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 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.

Continued on Next Page

[To Table of Content](#)

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 MGB Researchers, continued	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 Researcher 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 rule continues to apply even should one elect to terminate Sponsored Research activities.³ 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) 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.

Continued on Next Page

[To Table of Content](#)

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 MGB Researchers, continued	Dual-Career Family Exception: 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.
All MGB Researchers	A3. External Activity Rule (The "I(d) Rule"): 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. 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) 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.

Continued on Next Page

[To Table of Content](#)

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
1. ONLY MGB Researchers who are ALSO Full-Time Faculty at Harvard Medical School, AND 2. MGB Researchers who are also MGB Institutional Officials	B. Executive Position Rule (the “I(c) Rule”) Researchers who are also Full-Time Faculty at Harvard Medical School and Researchers who are also MGB 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 .

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 MGB to be allowable subject, where appropriate, to MGB requirements for transparency or accountability, and in the case of a determination of Financial Conflict of Interest, a management plan.

[To Table of Content](#)

1.3. Oversight of Interactions Related to Research

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

MGB, 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 MGB 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 MGB 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 MGB to achieve transparency, to assure accountability, or to address other issues relating to those Interests and Activities insofar as they pertain to MGB research activities.
-

[To Table of Content](#)

1.3. Oversight of Interactions Related to Research, Continued

1.3.2 Required Disclosure in Publications and Presentations

Obligation of Researchers to Disclose Certain Financial Interests

In addition to any disclosure requirement of the publisher, a Researcher who is publishing, formally presenting research results, or providing expert commentary on a subject must simultaneously disclose any Financial Interest in an Outside Entity that owns or has a contractual right to the technology being reported or discussed or that sponsors the research being reported or discussed.

1.3.3 Required Disclosure to Subjects in Human Subjects Research

Disclosure to Subjects in Human Subjects Research

The existence of all material financial interests of institutions and researchers in a human research study that are related to the research being performed shall be disclosed to the subjects in the study. Standards for "material" and "related" shall be established by the COA, guided by the Public Health Service regulations.

The precise wording of disclosure in the consent form should be determined by the IRB, but should include an explanation of the fact that the financial interest in question has been reviewed and the research allowed to go forward by the IRB.

At a minimum, the document or statement by which disclosure is made must include a clear reference to the presence of the financial interest, an indication that additional information is available regarding the details of the financial interest and how it is being addressed, and how that information can be readily obtained by those to whom the disclosure is made.

1.3.4 Additional Disclosure and Accountability Measures

Required Additional Measures

For any research, MGB may require researchers to disclose certain information regarding interests in connection with a research study to assure transparency and may require other actions as necessary to assure accountability and integrity.

[To Table of Content](#)

1.3. Oversight of Interactions Related to Research, Continued

- 1.3.5 Management of Financial Conflicts of Interest**
- When a Financial Conflict of Interest is determined to exist, MGB shall develop and implement a management plan that specifies actions that have been taken and/or will be taken to manage the Financial Conflict of Interest.
- In addition to the actions specified in Sections 1.3.2, 1.3.3, and 1.3.4, examples of actions that may be taken to manage an identified Financial Conflict of Interest include but are not limited to the following:
- Public disclosure of the Financial Conflict of Interest
 - Disclosure to the research team
 - Modification of the research plan
 - Independent oversight of the research, including appointment of an independent monitor
 - Change of personnel or personnel responsibilities
 - Disqualification from participation in the research
 - Reduction or elimination of the Financial Conflict of Interest, or severance of the relationship that creates the Financial Conflict of Interest.
-

- 1.3.6 Special OII Responsibilities with Respect to Public Health Service Funding**
- Prior to the expenditure of any Public Health Service funding to support research at MGB, MGB, acting through its designated Institutional Officials, Committees, and Offices, shall:
- Ensure that any impermissible conflicts are eliminated;
 - Ensure that any other identified Financial Conflicts of Interest are managed, as determined by MGB's designated Institutional Officials, Committees, and offices;
 - With respect to funds from the Public Health Service, notify the Public Health Service of the existence of any Financial Conflict of Interest and ensure that a management plan has been implemented; and
 - Comply in all other respects with applicable requirements for Public Health Service-funded research.
-

Continued on Next Page

[To Table of Content](#)

1.3. Oversight of Interactions Related to Research, Continued

1.3.6 Special OII Responsibilities with Respect to Public Health Service Funding Continued

For any Financial Conflict of Interest that MGB identifies after Public Health Service funding for the research at MGB has commenced, OII shall, within sixty days of the identification:

- Ensure that any impermissible Financial Conflicts of Interest are eliminated;
 - With respect to any other identified Financial Conflicts of Interest, ensure that a management plan has been implemented, at least on an interim basis, and take any additional interim measures deemed necessary;
 - Notify the Public Health Service regarding the Financial Conflict of Interest;
 - In addition, with respect to failure by a Researcher to disclose in a timely manner a Significant Financial Interest that is determined by MGB to constitute a Financial Conflict of Interest, or failure by MGB to review or manage in a timely manner such a Financial Conflict of Interest, or failure by a Researcher to comply with a Financial Conflict of Interest management plan, complete a retrospective review and, to the extent required by federal regulation, submit a mitigation report to the Public Health Service; and
 - Comply in all other respects with applicable requirements for Public Health Service-funded research
-

[To Table of Content](#)

Section 2

Clinical Care and Interactions with Industry

2.1. Policy Overview

2.1.1 Policy

Collaborations between MGB Individuals providing patient care and Industry present unique opportunities to improve and advance patient care. However, these collaborations must be carefully managed to avoid improper influence and inducements in clinical care. MGB encourages such collaborations, subject to the requirements of this Section 2.

MGB Individuals subject to this Section 2 are responsible for compliance with this Section.

Note: The term “MGB” refers to Mass General Brigham Incorporated and/or one or more of its Affiliated Institutions. Other terms in this Section 2 that have initial capital letters shall have the meaning specified in the Glossary.

2.1.2 Definition of Clinical Conflict of Interest

A clinical conflict of interest may exist when a MGB Individual covered by this Section 2 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.

A clinical conflict of interest may arise when MGB receives royalties derived from the sales of a particular drug, device, or other technology and, under institutional royalty-sharing policies, a MGB Individual subject to this Section 2 shares in those royalties according to thresholds that may be established from time to time by COA and uses the drug, device, or other technology in his/her clinical practice at MGB.

2.1. Policy Overview, Continued

2.1.3 Ancillary Equipment

Conflicts of interest that may arise in connection with the purchase of ancillary equipment (e.g., equipment whose use does not require active selection by a MGB Individual as part of a specific clinical procedure, such as standard hospital equipment like scissors, sutures, and skin staples) for use at MGB patient care facilities are addressed in Section 5 of this Policy. Accordingly, this Section 2 does not address the use of ancillary equipment, even though the equipment may be utilized during a patient's medical treatment.

2.1.4 To Whom the Policy Applies

Section 2 applies to any MGB Individual who is a licensed caregiver and who, in the course and scope of his/her MGB responsibilities, provides to patients the care for which he/she is licensed.

[To Table of Content](#)

2.2. Policy Requirements

2.2.1 Evaluation of Clinical Conflicts of Interest	Financial Interests or other Outside Activities in a manufacturer of a drug, device, or other products for use in patient care of MGB Individuals subject to this Section 2 that exceed thresholds established by COA may constitute clinical conflicts of interest and will be evaluated as provided in Section 2.3.
2.2.2 Reporting of Clinical Conflicts of Interest	MGB Individuals covered by this Section 2 are required to report their Financial Interests and Outside Activities, as required by MGB, including completing the MGB disclosure statement and such other disclosure processes when requested.
2.2.3 Additional Policy Requirements Related to Clinical Care and Interactions with Industry	In addition to the provisions of Section 2, MGB Individuals covered by this Section 2 must abide by all other applicable provisions in the Mass General Brigham Policy for Interactions with Industry and Other Outside Entities, including specifically the provisions in Section 4 on Consulting and Other Outside Activities, the provisions in Section 5 on Institutional Purchasing and Comparable Transactions, and the provisions in Section 6 on Gifts from MGB Vendors and Potential Vendors, as well as provisions of policies of Affiliated Institutions regarding Vendor Access and Pharmaceutical Samples.

[To Table of Content](#)

2.3. Oversight of Clinical Conflicts of Interest

2.3.1 COA's Authority for Evaluating and Managing Clinical Conflicts of Interest

COA shall review and, where appropriate, manage those Financial Interests and Outside Activities that are deemed clinical conflicts of interest, according to thresholds established by COA.

2.3.2 Management of Clinical Conflicts of Interest

Because of the special circumstances associated with the physician-patient relationships and the exigencies of clinical care situations, management of any clinical conflict of interest shall be tailored to fit individual circumstances. Possible management mechanisms for clinical conflicts of interest shall be determined by COA. They may include but are not limited to one or more of the following:

- Disclosure of the interest or activity, in accordance with the provisions of Section 2.3.3;
 - Corroboration through a disinterested process of any prescription involving a product or device of a Company in which the clinical conflict of interest exists;
 - Review of practice patterns;
 - Reduction or elimination of the conflict; and
 - Transfer of clinical care to an alternate clinician.
-

2.3.3 Disclosure to Patients

COA may determine in particular cases that clinical conflicts of interest, according to thresholds established by COA, warrant individualized patient disclosure before a MGB Individual covered by this Section 2 prescribes or uses that Company's medical device, pharmaceutical, or medical care-related product in connection with the care of his/her individual patients.

2.3.4 Clinical Care and Royalties Through the Institution

License agreements under which MGB technology is licensed to a Company must state, as an exception to any requirement that the Company pay royalties to MGB, that the Company will not pay royalties derived from the sales of a particular drug or device to MGB, unless COA approves an arrangement under which all such royalties will be donated to a specific non-MGB charitable organization.

[To Table of Content](#)

Section 3

Industry Support Related to Education

3.1 Policy Overview

3.1.1 Rationale and Policy Statement

Industry support for MGB Educational Activities helps to further MGB ability to carry out its educational mission. However, these situations need to be carefully managed to ensure that such support does not introduce bias into the content of MGB Educational Activities. MGB encourages such support, subject to the requirements of this Section 3.

All MGB Educational Activities supported by Industry must comply with the policy requirements imposed by the Education Review Board (ERB), as described in more detail in this Section 3.

Note: The term “MGB” refers to Mass General Brigham Incorporated and/or one or more of its Affiliated Institutions. Other terms in this Section 3 that have initial capital letters shall have the meaning specified in the Glossary.

Note: These policy requirements do not cover the participation of MGB Individuals in Industry-funded external educational activities not put on or sponsored by MGB. Such activities are covered by *Section 4 Consulting and Other Outside Activities*, and *Section 6 Gifts*, below.

3.1.2 Description of Industry Support of Education

Industry support may be provided through:

- Monetary support, or
- In-kind support.

These two types of support may be directed to a specific MGB Educational Activity so long as such support is accepted in compliance with Section 3.3. Additionally, monetary support may be directed to a President’s Fund for Medical Education so long as such support is accepted in compliance with Section 3.4.

[To Table of Content](#)

3.1. Policy Overview, Continued

3.1.3

Types of MGB Educational Activities

MGB Educational Activities include:

- Clinical training programs, such as residencies and fellowship programs that involve a significant component consisting of direct patient care;
- Educational events, including continuing medical education programs or other professional health care education programs that involve conferences or lectures or other forms of verbal presentations, regardless of whether the participants receive credit;
- Educational tools and resources, including MGB newsletters and web sites designed to distribute educational information to healthcare practitioners, patients, and the public, even if such information pertains to research;
- Educational service arrangements, whereby an Industry entity seeks to have a MGB hospital provide a training or educational program for its employees or other physicians with a specified focus or content (these may include observerships, preceptorships, and other similar arrangements); and
- Other educational programs that are put on, or sponsored, by any MGB entity.

3.1.4

OII Review of Industry Support

All Industry support for MGB Educational Activities must be reviewed by the MGB Office for Interactions with Industry (OII).

OII works with the ERB, as appropriate, to ensure compliance with MGB policies and procedures.

3.2. Oversight of Industry Support Related to Education

3.2.1 ERB Authority to Implement, Monitor, and Enforce Policy

Subject to the reserved authority of PICC as referenced in Section P.2.3, the Education Review Board (ERB) has the authority to implement and enforce the MGB policy requirements for this section of the ***Mass General Brigham Policy for Interactions with Industry and Other Outside Entities***, including the authority to:

- Review and approve any Industry support, whether made directly or indirectly through intermediaries;
Determine appropriate conditions for Industry support;
Monitor and enforce compliance pertaining to Industry support of MGB Educational Activities; and
- Make exceptions both in particular cases and to general policy requirements.

The ERB may delegate specific responsibilities to other institutional committees, offices, or individuals.

3.2.2 Requirements for ERB Review and Approval

The ERB must review and approve all support from Industry for any MGB Educational Activity.

The ERB has the authority to determine the conditions or restrictions for receipt of in-kind Support.

If other institutional approval is required, such approval is required prior to the ERB's review. For example, all clinical fellowships must be approved by the MGB Education Committee (PEC) prior to ERB review.

3.2.3 ERB Review of MGB Educational Activities

In addition to the requirements the ERB sets for Industry support of MGB Educational Activities, the ERB reviews the contractual documentation, budget, and Financial Interests related to all MGB Educational Activities supported by Industry. Additionally, the ERB may review the content of any MGB Educational Activity supported by Industry.

[To Table of Content](#)

3.2. Oversight of Industry Support Related to Education, Continued

3.2.4 ERB Oversight for Industry Support for Trainee Travel	The ERB has the authority to determine the terms under which Industry support for trainee travel to attend professional meetings, conferences, or other training programs is acceptable.
3.2.5 Educational Services Arrangements	In recognition that educational services arrangements present special factors, the ERB shall have the authority to implement special criteria for them, including permitting such arrangements to be funded by a single Industry entity under certain, limited circumstances as defined by the ERB.
3.2.6 Exception for Merit-Based Fellowship Awards	ERB review and approval is not required for merit-based fellowship awards funded by Industry where awardees are selected by a nationally-recognized professional or scientific association through a selection committee composed predominantly of members who do not represent an Industry entity.

[To Table of Content](#)

3.3. Policy Requirements for Industry Support of MGB Educational Activities

3.3.1 Overview	All MGB Educational Activities with Industry support are subject to the following requirements as well as any additional requirements as deemed appropriate by the Education Review Board (ERB).
3.3.2 Compliance with Continuing Medical or Other Healthcare Professional Education Standards	All MGB Educational Activities with Industry support for which medical or other healthcare professional educational credit is offered through an accredited provider (whether CME or other credit) must comply with the standards for accreditation in the respective professional field. All MGB Educational Activities with Industry support for which professional medical or other healthcare education credit is not offered must still meet the Industry-support standards for accreditation in the respective professional field (e.g., a program designed for physicians must meet ACCME Standards for Commercial Support, a program designed for nurses must meet the American Nurses Credentialing Center's Commission on Accreditation standards). For programs in fields for which there are no such standards, standards will apply as established by the ERB.
3.3.3 Control of Content	Industry may not control the selection of speakers or content of the MGB Educational Activity.
3.3.4 Multiple Sources of Monetary Support Required	Industry support for a specific MGB Educational Activity must come from more than one Industry entity, in accordance with conditions imposed by the ERB and subject to exceptions granted by the ERB. Generally, no one Industry entity can provide more than 70% of the total commercial support.
3.3.5 Review and Resolution of Financial Interests	All program/course directors, speakers, moderators, panelists, others as determined by the ERB must report their Financial Interests and Outside Activities that are related to the MGB Educational Activity, as required on any applicable forms or other disclosure processes, and must be resolved by ERB prior to the educational activity start date.

[To Table of Content](#)

3.3. Policy Requirements for Industry Support of MGB Educational Activities, Continued

3.3.6 Disclosure of Support	Industry support for a MGB Educational Activity must be disclosed to participants. For educational events, disclosure must be made prior to the beginning of the event.
3.3.7 Support to Institution, not Individuals	Industry support must be directed to an administrative unit of a MGB Affiliated Institution, not to a MGB Individual.
3.3.8 Selection of Participants	The supporting Industry entity cannot be involved in reviewing or selecting participants in the supported activity. Industry representatives may attend a MGB educational event so long as such attendance is compliant with guidance issued by the ERB.
3.3.9 Naming of Activity/ Specific Training Position	A MGB Educational Activity may not be named after the Industry entity supporting the activity. In the case of a training program, the specific training position in that program may not be designated as Industry-supported training position in the program.
3.3.10 Reports to Industry	No identifying information about participants in Industry-supported MGB Educational Activities may be disclosed to the supporting Industry entities without ERB approval.
3.3.11 Commercial Promotion at MGB Educational Events	Commercial exhibits, advertisements, and other promotional opportunities associated with MGB Educational Activities must comply with the ACCME Standards for Commercial Support and any other guidance issued by the ERB. Exhibits at MGB Educational Events may not be located in the same room as the educational activity, nor in an obligate path to the room.

[To Table of Content](#)

3.3. Policy Requirements for Industry Support of MGB Educational Activities, Continued

3.3.12 Documentation Any agreement (or other appropriate documentation as determined by ERB) for Industry support of a MGB Educational Activity must be in writing, and specify the terms, conditions, and purposes of the Industry support. As stated in Section 3.1.4, all agreements for Industry support of a MGB Educational Activity shall be processed through OII.

Additionally, agreements for educational events and/or educational tools and resources must be signed prior to commencement of the event or publication of the tool/resource. Agreements for clinical training programs must be signed prior to the completion of the program.

No Industry funds may be spent until there is a signed agreement (or other appropriate documentation as determined by the ERB), and the MGB Educational Activity has secured funding from a second commercial supporter.

3.3.13 Budget Review The program/course director must submit a budget to the Office for Interactions with Industry (OII) and obtain ERB approval for the proposed Industry-supported MGB Educational Activity.

[To Table of Content](#)

3.4. Policy Requirement for Industry Support to Presidents' Funds for Medical Education

3.4.1 Requirements for Industry Contributions to Presidents' Funds

Industry entities may contribute to the support of the MGB' educational mission through the President's Fund(s) for Medical Education at each of the MGB hospitals. These funds are used to support the healthcare educational mission and activities of MGB. The requirements listed below apply to Industry contributions to a President's Fund(s) for Medical Education.

- A company's contributions to any President's Fund(s) for Medical Education must not be targeted or directed to any specific MGB Educational Activity.
 - MGB may not identify any activity supported by the President's Fund as being supported by a specific Industry entity. MGB may separately acknowledge all Industry supporters who have contributed to the President's Fund.
 - The President of each hospital has sole discretion to distribute the President's Fund(s) for Medical Education for that hospital to any of its MGB Educational Activities.
 - To the extent the President's Fund(s) for Medical Education in any hospital is distributed to a clinical training program, the program must be reviewed and approved by the MGB Education Committee (PEC) prior to receiving funds from the President's Fund for Medical Education to support the program.
-

[To Table of Content](#)

Section 4

Consulting and Other Outside Activities

4.1. Policy Overview

4.1.1 Policy

Consulting and other Outside Activities between MGB Individuals and Industry and other Outside Entities provide opportunities for productive collaboration, and foster the exchange of knowledge and information that leads to advances in science and patient care. However, these collaborations must be overseen to ensure that they do not affect the way in which MGB Individuals conduct their MGB responsibilities and do not result in a misuse of MGB assets. Therefore, MGB encourages such relationships, subject to the requirements of this Section 4.

All MGB Individuals subject to this Section 4 are responsible for compliance with this Section 4.

Subject to the reserved authority of PICC as referenced in Section P.2.2, COA has the authority to implement and enforce the MGB Policy requirements for this Section 4 of the Mass General Brigham Policy for Interactions with Industry and Other Outside Entities, including the authority to:

- Monitor and enforce compliance pertaining to Outside Activities; and
- Make exceptions both in particular cases and to general Policy requirements.

Note: The term “MGB” refers to Mass General Brigham Incorporated and/or one or more of its Affiliated Institutions. Other terms in this Section 4 that have initial capital letters shall have the meaning specified in the Glossary.

[To Table of Content](#)

4.1. Policy Overview, Continued

4.1.2 To Whom Does this Section 4 Apply?

Section 4, Consulting and Other Outside Activities, applies to Covered Individuals including Medical/Professional Staff Members, Research Staff Members, and Employee Members, all as reflected in the chart below. In addition, Sections 4.2.1, 4.2.3, 4.2.5, 4.2.6, and 4.2.7 also apply to all MGB Individuals while Acting in a MGB Capacity (except outside Trustees, Directors, and committee members).

Covered Individuals	Description
<i>Medical/Professional Staff Members</i>	Individuals who are members of the medical or professional staffs of any MGB hospital and who • have full-time or part-time faculty appointments at Harvard Medical School, or • are Service/Department Chiefs/Chairs at MGB or an Affiliated Institution, or • are employed full- or part-time by MGB or an Affiliated Institution. Exceptions: The following individuals are considered Medical/Professional Staff Members only when they are at a MGB site or otherwise Acting in a MGB Capacity: • individuals who are members of the medical or professional staff of any MGB hospital and who have an HMS faculty appointment, but • are neither employed by MGB or an Affiliated Institution, nor are Service/Department Chiefs/Chairs, and • who have a medical/professional staff appointment at a non-MGB but HMS affiliated hospital, which is their primary job location.
<i>Research Staff Members</i>	Individuals who have full-time or part-time non-faculty appointments at Harvard Medical School and • who are not Medical/Professional Staff Members, and • who are participating in research activity under the administrative authority of MGB or an Affiliated Institution Exception: Individuals who meet the criteria for Research Staff Members above, but whose primary affiliation is at a non-MGB but HMS affiliated hospital, are considered Research Staff Members only when they are at a MGB site or otherwise Acting in a MGB Capacity.
<i>Employee Members</i>	Administrative staff, nurses, support personnel, and other full-time or part-time employees of MGB or a MGB-Affiliated Institution who are not Medical/Professional Staff Members or Research Staff Members.

[To Table of Content](#)

4.2. Policy Requirements for Outside Activities

4.2.1 Requirements for Outside Activities

Outside Activities of Covered Individuals, whether full-time or part-time, and any other MGB Individual while Acting in a MGB Capacity (except outside Trustees, Directors, and committee members) must meet all of the requirements listed below.

- They must not involve the performance of services that, in the judgment of the supervisor, compete or overlap inappropriately with the individual's obligations to MGB.
 - They must be performed outside the individual's regular service period at MGB, and must be within allowable time limits for Outside Activities as specified in Section 4.2.2.
 - They must not involve use of MGB or HMS students or trainees. They must not involve the use of institutional funds or substantial use of institutional personnel, premises, equipment, or facilities. Minimal use of office resources is not considered a substantial use.
 - They must not result in the individual's engaging in promotional activity for the Outside Entity.
 - They must be conducted so that the time and creative energy devoted to the Outside Activity does not, in the judgment of the appropriate supervisor, compromise or interfere with the Individual's responsibilities at MGB.
-

4.2. Policy Requirements for Outside Activities, Continued

4.2.2 Time

Limitations for Outside Activities

The table below describes the time limits that different groups of full-time Covered Individuals can spend on Outside Activities.

Full-Time Covered Individuals	Time Limits
• Full-time Medical/Professional Staff Members with Harvard Medical School Faculty Appointments	Maximum allowable amount of time that may be spent on Outside Activities is 20 percent of the member's professional effort, not to exceed the equivalent of one working day per seven-day week. Supervisors may further limit the allowable amount of time.
• Full-time Medical/Professional Staff Members without Harvard Medical School Faculty Appointments • Full-time Research Staff Members	Individuals in this category may spend such time on Outside Activities as is permissible by the policies of their institutions and as approved by their supervisors.
• Full-time Employee Members	Individuals in this category are generally expected to devote their full professional time, energy, loyalty, and commitment to MGB. A limited amount of time for outside research, teaching, and other activities may be allowable as determined by their supervisors.

[To Table of Content](#)

4.2. Policy Requirements for Outside Activities, Continued

4.2.3 Prohibited Outside Activities

Consulting and other Outside Activities undertaken by MGB Individuals are encouraged and in most cases allowable according to the provisions of this Section 4. These provisions establish oversight requirements and minimize the possibility of inappropriate considerations affecting the exercise of MGB responsibilities. However, for a limited variety of Outside Activities, the potential for negative impact on the integrity of MGB missions is high, and accordingly, certain Outside Activities are prohibited.

A. Certain Company or Other Outside Entity Speaking and Training Engagements

Many speaking and training engagements for Companies or Other Outside Entities are encouraged, including CME presentations sponsored by accredited CME providers. However, other engagements may compromise the independence and the reputation of the speaker and of MGB to such an extent that they are not allowed. These engagements are described below.

Neither a Covered Individual, nor any other MGB Individual who is Acting in a MGB Capacity (except outside Trustees, Directors, and committee members), may participate in:

- Any arrangement or speaking engagement that is termed a “Speakers Bureau”; or
- Any speaking engagement for which a Company or Other Outside Entity has the contractual right to control what the individual says or otherwise has the final right of approval for content and edits of the individual’s presentation materials; or
- Any arrangement between an individual and a Company or Other Outside Entity
 - under which an agreement indicates that the speaker’s name will be on a list of speakers or potential speakers; or
 - under which the individual will be engaged in promotional activity for the Company or Other Outside Entity; or
- Any other exceptional circumstances as determined by the Committee on Conflicts of Interest (COA), including but not limited to excessive frequency of, or excessive compensation for, speaking engagements.

Continued on Next Page

[To Table of Content](#)

4.2. Policy Requirements for Outside Activities, Continued

4.2.3 Prohibited Outside Activities continued

Note: This section is not intended to prohibit a MGB Individual from entering into an agreement with a Company or Other Outside Entity, other than a pharmaceutical, device, or biomedical Company, that acts as an agent or broker to fill national and internationally-based requests for speaking services for prominent figures in government, foreign service, education, science, medicine, and the like, provided the arrangement has the approval of OII and does not violate the intent of this Section 4.2.3.A.

B. Ghostwriting

A Covered Individual, or any other MGB Individual who is Acting in a MGB Capacity, may not be listed as an author on an article written by Industry representatives or others unless:

- The individual has met all standards for academic authorship as defined in the HMS Authorship Guidelines, and
- All others who contributed to the work such that their contribution merits authorship (to the knowledge of the individual) are also listed as authors.

C. Executive Positions

A Medical/Professional Staff Member with a full-time faculty appointment at Harvard Medical School is prohibited under the HMS Conflicts Policy from holding an Executive Position in a for-profit Business engaged in commercial or research activities of a biomedical nature.

An Institutional Official is prohibited from holding an Executive Position in a for-profit Business engaged in commercial or research activities of a biomedical nature. COA may grant exceptions to this prohibition for Institutional Officials who do not hold full-time HMS appointments.

Note: Individuals who are researchers are subject to additional categories of impermissible activities. See *Section 1, Researchers' Financial Interests and Outside Activities with Industry Related to Research*.

4.2.4 Fiduciary Positions Require COA Review and Approval

A full-time Medical/Professional Staff Member, Research Staff Member, or Employee Member may not accept a new position on a Board of Directors or any other position with a fiduciary responsibility in a biomedical Company without prior review and approval by the COA.

4.2. Policy Requirements for Outside Activities, Continued

4.2.5 Compensation for Outside Activities

A. Fair Market Value

Compensation received by a Covered Individual for consulting or other Outside Activities may not exceed fair market value for the services provided by the Covered Individual. In the event that a question concerning fair market value arises, the Committee on Outside Activities (COA) has the authority to resolve the issue.

B. Set In Advance

The aggregate compensation or the compensation methodology for consulting or other Outside Activities must be set in advance.

C. Arms Length

All agreements must be negotiated at “arms-length” and must not take into account the volume or value of referrals or other business generated between or among MGB, the Covered Individual and the Outside Entity.

4.2.6 Restriction on Use of MGB Name

A Covered Individual and any other MGB Individual while Acting in a MGB Capacity must conduct his or her Outside Activities so as to prevent any Outside Entity from using, without the prior written approval of the MGB entity involved, the name or logo of any MGB entity in any:

- Advertising,
- Promotional, or
- Other public or printed material.

An individual subject to this Section is responsible for informing the Outside Entity of this restriction.

Allowed Usage of MGB Entity Name

An Individual subject to this Section **may** use the name of a MGB entity to identify the Individual’s position or title at MGB, so long as the use does not imply MGB endorsement or responsibility for the Outside Activity, the Outside Entity, or the Outside Entity’s product or services.

COA may further restrict the use of the name of a MGB entity under appropriate circumstances.

4.2. Policy Requirements for Outside Activities, Continued

4.2.7 Competition with MGB

Neither a Covered Individual nor any other MGB Individual while Acting in a MGB Capacity may engage in competition with MGB. Exceptions may be made by the Covered Individual's supervisor provided that the activity is unlikely to and in fact does not adversely affect the interests of MGB or the ability of the Covered Individual to carry out his or her MGB responsibilities, and is otherwise acceptable. The supervisor may impose restrictions or limitations as deemed appropriate in his or her judgment.

This Section 4.2.7 is not intended to apply to consulting or other Outside Activities or to research collaborations with other health care providers entered into by MGB and that involve Researchers, provided they comply with this Section 4 and other applicable institutional policies. COA may provide for additional exceptions to this Section 4.2.7.

4.2.8 When Written Agreements Are Required

A Written Agreement is required when an Outside Activity is with a pharmaceutical, medical device, or biotechnology Company or other Company that provides, has provided, or is likely to provide goods or services to MGB.

Examples: Examples of entities that may provide goods or services to MGB include:

- Companies that sell or distribute medical or pharmaceutical equipment, supplies or services, and/or
- Companies that provide non-medical goods and services, including clerical supplies, computer hardware and software, kitchen supplies, office equipment, as well as legal, financial, accounting, advertising, consulting, or real estate brokerage services.

Notes:

- Written Agreements must conform to the standard requirements for Written Agreements, as described in Section 4.7.
- Covered Individuals are strongly encouraged to enter into Written Agreements for all Outside Activities in order to protect their own interests, including private liability considerations, and to avoid disputes. However, Written Agreements are only required in the circumstances described in this Section 4.2.8.

Continued on Next Page
[To Table of Content](#)

4.2. Policy Requirements for Outside Activities, Continued

4.2.8 When Written Agreements Are Required Continued

Special rules for certain speaking and training agreements: A speaking or training engagement with any Company that provides, has provided, or is likely to provide goods or services to MGB requires a Written Agreement, **unless:** CME credit is given and the engagement is hosted by an ACCME-accredited provider, or comparable entity as determined by COA.

No Written Agreement is required if the engagement is paid for and hosted by an academic institution or professional or scientific organization.

Note: Expert witness agreements: No Written Agreement is required for expert witness services, but supervisor review is required pursuant to Sections 4.4.3 and 4.5.4.

4.2.9 Institutional Review of Outside Activities

Institutional reviews of certain Outside Activities are required to ensure that institutional interests are adequately addressed when Covered Individuals engage in Outside Activities.

This review is not conducted on behalf of Covered Individuals; they are encouraged to have their private attorneys or other advisors review all agreements on their personal behalf.

[To Table of Content](#)

4.3. Policy Requirements for Outside Activities of Institutional Officials

4.3.1 Prohibition on Certain Executive Positions	An Institutional Official is prohibited from holding an Executive Position in a for-profit Business engaged in commercial or research activities of a biomedical nature. COA may grant an exception to this prohibition for Institutional Officials who do not have full-time HMS appointments.
4.3.2 Restrictions on Outside Activities	Institutional officials may not accept any new Outside Activities (whether fiduciary or not) with any biomedical Company, or any other Company that does (or is reasonably likely to do) significant business with any MGB entity, without prior review and approval by COA.
4.3.3 Required PICC Approvals	Certain consulting and other Outside Activities of Institutional Officials require final approval by PICC.

[To Table of Content](#)

4.4. Oversight of Agreements for Outside Activities of Medical/Professional Staff and Research Staff Members

4.4.1 OII Review and Approval Required

Every Medical/Professional Staff member and Research Staff Member is required to submit to the Office for Interactions with Industry (OII) every proposed Written Agreement for an Outside Activity; to obtain OII's review and approval of such Agreement; and to ensure that the Written Agreement complies with OII's requirements prior to being signed or accepted. This requirement to obtain OII's review and approval applies even if the Outside Activity was not required to have a Written Agreement.

Exceptions to OII review:

The following agreements do not require OII review:

- Written Agreements described in Section 4.4.2 (supervisor review and approval may be required);
 - Non-disclosure Written Agreements in which no intellectual property is transferred and which protect only confidential information of the disclosing party with no obligations other than to keep such information confidential;
 - Written Agreements for expert witness services (supervisor review is required);
 - Written Agreements for non-research personal consulting for a governmental entity (supervisor review is required);
 - Written Agreements for speaking engagements if
 - CME credit is given and the engagement is hosted by an ACCME-accredited provider, or comparable entity, as determined by COA, or
 - The engagement is paid for and hosted by an academic institution or professional or scientific organization.
-

[To Table of Content](#)

4.4. Oversight of Agreements for Outside Activities of Medical/Professional Staff and Research Staff Members,

Continued

4.4.2 Outside Activities That Do Not Require OII Review, but May Require Supervisor Review

Outside Activities described in the table below do not need to be submitted to OII for review and approval even if they involve a Written Agreement.

However, Medical/Professional Staff Members and Research Staff Members are required to obtain their supervisors' review and approval for the Outside Activities described below. Supervisors shall have the authority to decide that such review is not necessary for any of the Outside Activities described in the table below, except for those that exceed the compensation threshold in Section 4.4.3, which Outside Activities must be reviewed by the applicable supervisor.

Additionally, Medical/Professional Staff Members and Research Staff Members are required to obtain their supervisor's approval for any Outside Activity that the supervisor determines that he/she wishes to review. A supervisor has the prerogative to refer any matter to COA.

Activity Type	Description
Academic Publication Activity	Outside Activity relating to authorship/editing of academic media, such as: • Textbooks • Editorships
"Moonlighting" Activity	Outside Activity relating to clinical work within the institution or another healthcare institution that is: • Optional • Not part of a Medical/Professional Staff Member's or Research Staff Member's institutional duties, and • Separately paid.
Medical Malpractice Review Activity	Outside Activity relating to medical malpractice review
Certain Activity involving a governmental entity	Outside Activity for non-research personal consulting for a governmental entity

[To Table of Content](#)

4.4 Oversight of Agreements for Outside Activities of Medical/Professional Staff and Research Staff Members,

Continued

4.4.3 Outside Activities That Require Supervisor Review and Approval

In addition to the Outside Activities listed in Section 4.4.2 that require supervisor review unless waived by the supervisor, the following Outside Activities must be reviewed and approved by the supervisor in advance of undertaking the activity. This supervisor review and approval is in addition to OII review and approval where that is required.

The table below describes those situations where supervisor review is required.

Factor	Description
High Compensation	Any Outside Activity that contains substantial monetary or equity compensation Thresholds Relevant thresholds are: • Cash compensation that exceeds \$30,000 per year, or • Equity compensation valued at more than \$30,000 per year or consists of more than 1% of the equity in a Company. COA may revise these thresholds from time to time. Supervisors have the authority to set lower thresholds for supervisor review of agreements for Covered Individuals reporting to them.
Fiduciary Obligation or Scientific Advisory Board (Committee) Service	Any Outside Activity that contains a fiduciary obligation to the Outside Entity or that calls for membership on the Outside Entity's Scientific Advisory Board or Scientific Advisory Committee. Such agreements may also require COA review.
Expert Witness Activity	Any Outside Activity relating to serving as an expert witness in a legal or administrative proceeding
Online Medical Opinion Activity	Any Outside Activity involving the delivery of medical opinions or advice online to patients/consumers.
Other Circumstances	Any other unusual provisions or circumstances relating to an Outside Activity (including, without limitation, multiple agreements or substantial time commitments), as determined by OII or COA, may also be considered to require supervisor review.

[To Table of Content](#)

4.5. Oversight of Agreements for Outside Activities of Employee Members

4.5.1 OII Review and Approval Required

The following Written Agreements for Outside Activities of an Employee Member must be submitted to Office for Interactions with Industry (OII) for prior review and approval:

- Written Agreements that purport to involve performance of research activities, or
 - Written Agreements that purport to involve a grant or transfer of intellectual property rights to the Outside Entity.
-

4.5.2 Time Limitations for Outside Activities

Full-time Employee Members are generally expected to devote their full professional time, energy, loyalty, and commitment to MGB. A limited amount of time for outside research, teaching, and other activities may be allowable as determined by their supervisors.

4.5.3 Outside Activities That Do Not Require OII Review, but May Require Supervisor Review

Employee Members who have been designated to complete a MGB Disclosure Statement must obtain their supervisors' review and approval in advance of undertaking any Outside Activity that is with or for a pharmaceutical, medical, device, or biotechnology Company or other Company that provides, has provided, or is likely to provide goods or services to MGB. Supervisors shall have the authority to decide that such review is not necessary for any such Outside Activities except for those that are described in Section 4.5.4, which Outside Activities must be reviewed and approved by the applicable supervisor.

Additionally, Employee Members are required to obtain their supervisor's approval for any Outside Activity the supervisor determines that he/she wishes to review.

A supervisor has the prerogative to refer any matter to the COA.

[To Table of Content](#)

4.5. Oversight of Agreements for Outside Activities of Employee Members, Continued

4.5.4 Outside Activities That Require Supervisor Review and Approval

In addition to the Outside Activities described in Section 4.5.3 that require supervisor review unless waived by the supervisor, the following Outside Activities must be reviewed and approved by the supervisor in advance of undertaking the activity. This supervisor review and approval is in addition to OII review and approval where that is required.

The table that follows describes those situations where supervisor review is required.

Factor	Description
High Compensation	An Outside Activity that contains substantial monetary or equity compensation Thresholds Relevant thresholds are • cash compensation that exceeds \$30,000 per year, or • equity compensation valued at more than \$30,000 per year or consists of more than 1% of the equity in a Company. COA may revise these thresholds from time to time. Supervisors have the authority to set lower thresholds for supervisor review of agreements for Covered Individuals reporting to them.
Fiduciary Obligation or Scientific Advisory Board (Committee) Service	Any Outside Activity that contains a fiduciary obligation to the Outside Entity or that calls for membership on the Outside Entity's Scientific Advisory Board or Scientific Advisory Committee. Such agreements may also require COA review.
Financial Consulting (including "Expert Networks")	Any Outside Activity with an Outside Entity or individual • involved in the investment or financial services industries, or • where the consulting involves providing analysis or advice for investment or similar purpose (including consulting through "expert networks")
Expert Witness Activity	Any Outside Activity relating to serving as an expert witness in a legal or administrative proceeding.
Online Medical Opinion Activity	Any Outside Activity involving the delivery of medical opinions or advice online to patients/consumers.

Continued on Next Page

[To Table of Content](#)

4.5. Oversight of Agreements for Outside Activities of Employee Members, Continued

4.5.4 Outside Activities That Require Supervisor Review and Approval Continued

Other Circumstances	Any other unusual provisions or circumstances relating to an Outside Activity (including, without limitation, multiple agreements or substantial time commitments), as determined by OII or COA, may also be considered to require supervisor review.
------------------------	---

[To Table of Content](#)

4.6. Authority of Supervisors

4.6.1 Independent Supervisor Review and Authority

Supervisors have the right to review any and all Outside Activities, whether or not covered by a Written Agreement, of Covered Individuals who report to them.

Supervisors have the right and authority to disapprove any Outside Activity if, in the supervisor's judgment, the amount of time, compensation, or other factors would interfere with the Covered Individual's MGB responsibilities.

4.6.2 Considerations for Supervisor Review

In reviewing and deciding whether to approve an Outside Activity, supervisors may take into account any relevant factors, including the Covered Individual's:

- Level of seniority
- Authority, and
- Administrative responsibilities.

For example, supervisors may limit the amount of time devoted to Outside Activities or the amount of compensation received.

4.6.3 Supervisor Conflict of Interest

If a supervisor has a personal Financial Interest above thresholds established by COA in a matter for which he or she has supervisory responsibility pursuant to this Section 4, the supervisor must recuse himself or herself from acting on the matter and shall refer the matter to his or her supervisor.

4.6.4 COA Authority for Unresolved Issues

If any issue reviewed by a supervisor is not resolved in the normal course of business, the COA has the authority to resolve the issue.

4.7. Standard Requirements for a Written Agreement

4.7.1 Time	Each Written Agreement must contain sufficient evidence that the committed time will be within allowable limits, preferably by specifying the maximum number of days committed through that Written Agreement.
4.7.2 Restriction on Use of MGB Name	Except for minimal risk circumstances approved by the OII, every Written Agreement must state that Outside Entities do not have the right to use the logo or name of any MGB entity in any form in any advertising, promotional or other public material without the prior written approval of the MGB entity involved. • A Covered Individual may use the name of a MGB entity (in connection with an Outside Activity) to identify the Individual's position or title at MGB, so long as the use, in the judgment of COA, does not imply MGB endorsement or responsibility for the Outside Activity, the Outside Entity, or the Outside Entity's product or services, unless otherwise restricted by COA.
4.7.3 Scope and Field of Services	Written Agreements: • Should clearly specify all of the services, including scope and field of those services, to be provided by the Covered Individual, and • Must not provide for services that compete or overlap inappropriately with the individual's obligations to MGB.
4.7.4 Overlap with Field of Research	If the field of activity in any Outside Activity overlaps with the field of research conducted by the Covered Individual at or through MGB, then the following additional requirements apply. • If the Covered Individual's research at MGB is sponsored by the Outside Entity with which the Covered Individual is entering into the Written Agreement, the intellectual property provisions of the Written Agreement for the Outside Activity must not be so broad as to purport to grant to the Outside Entity ownership of or other rights in any intellectual property that may arise from, or relate to, the sponsored research agreement between the Outside Entity and MGB.

Continued on Next Page

[To Table of Content](#)

4.7. Standard Requirements for a Written Agreement, Continued

4.7.4 Overlap with Field of Research Continued	OII may determine that it is acceptable in the Written Agreement to grant the Outside Entity a more limited scope of rights to intellectual property arising solely out of consulting activities. These consulting activities must be specifically and clearly distinguishable from the MGB-based research conducted under the sponsored research agreement.
4.7.5 Restriction on Intellectual Property	Written Agreements must not purport to grant to any Outside Entity the rights to intellectual property that are assigned or assignable to MGB under its Intellectual Property Policy, except as MGB determines appropriate, consistent with its Intellectual Property Policy.
4.7.6 Disclosure of Unpublished Research	Written Agreements must not give an Outside Entity any priority or advantage in gaining access to any unpublished MGB research information or any intellectual property that arises from activities performed by the Covered Individual or others at or through MGB.
4.7.7 Confidentiality	- Written Agreements must not limit or restrict a Covered Individual's ability to use or publish the results of research, education, patient care or other activities performed at or through MGB. - Written Agreements may impose confidentiality obligations on: - Information, data, and other results generated by the Covered Individual under the Written Agreement, and - Information provided to the Covered Individual by the Outside Entity, provided that the language must not cover any information created or acquired in connection with the individual's MGB responsibilities and that there is a pre-defined period of confidentiality.
4.7.8 Exclusivity or Non-Compete Provisions	The requirements listed below apply to exclusivity or non-compete provisions. - Written Agreements must not restrict the ability of the Covered Individual to conduct research, education, patient care, or administrative activities at or through MGB. - A Covered Individual is free to accept restrictions limiting his or her right to undertake other activities for another Outside Entity. It must be clear that those restrictions do not apply to activities supported by that Outside Entity or any other Outside Entity at or through MGB.

[To Table of Content](#)

Section 5

Institutional Conflicts of Interest

5.1. Policy Overview

5.1.1 Policy Statement

Collaborations among MGB, MGB Individuals, and Industry provide opportunities for productive collaboration and foster the exchange of knowledge and information that leads to advances in science and patient care. However, MGB Financial Interests in Industry, including Financial Interests of Institutional Officials and other supervisory personnel, may result in inappropriate influence, or the appearance of inappropriate influence, on MGB charitable activities. MGB requires that these Interests receive special review and oversight, as described in this Section 5.

Note: The term “MGB” refers to Mass General Brigham Incorporated and/or one or more of its Affiliated Institutions. Other terms in this Section 5 that have initial capital letters shall have the meaning specified in the Glossary.

5.1.2 To Whom Does Section 5 Apply?

The various policy requirements of this ***Section 5 Institutional Conflicts of Interest*** apply to different MGB groups.

5.2. Policy Requirements for Certain Institutional Financial Interests apply to Mass General Brigham Incorporated and MGB Affiliated Institutions.

5.3. Policy Requirements for Financial Interests and Outside Activities of Institutional Officials apply to Institutional Officials.

5.4. Policy Requirements for Financial Interests and Outside Activities of Supervisors Whose Direct Reports Engage in Research apply to such supervisors.

5.5. Policy Requirements for Institutional Purchasing and Comparable Transactions apply to certain MGB Individuals, including outside directors and trustees, involved in institutional transactions.

5.2. Policy Requirements for Certain Institutional Financial Interests

5.2.1 Institutional Equity Acquired Outside Treasury Investments

Sometimes MGB acquires equity (stock, stock options, or similar ownership interests) outside the normal Treasury investment and Development Office acquisition processes. In most cases this happens as a result of a license of institutional technology or investments relating to technology or start-up Company activities. Such equity is referred to here as “Special Equity.”

Institutional Conflicts of Interest may arise when MGB holds Special Equity in a Company and conducts Clinical Research on or clinical validation of technology of that Company.

Accordingly, MGB adopts a rebuttable presumption that a MGB Affiliated Institution may not conduct Clinical Research on the technology of a Company, or validate or test on patients the unvalidated technology of a Company, (collectively referred to in this Section 5.2.1 as Clinical Research/Validation) if it or any other MGB Affiliated Institution simultaneously holds Special Equity in the Company.

The presumption may be overcome only if:

- (a) COA determines that there are demonstrable, compelling circumstances, consistent with the rights and welfare of clinical research subjects, for the MGB Affiliated Institution conducting the Clinical Research/Validation while it or any other MGB institution holds special equity; OR
- (b) COA determines that the Clinical Research/Validation will be conducted at a different MGB Affiliated Institution from the one that owns or stands to benefit financially from the equity, and that individuals at the Affiliated Institution that owns or stands to benefit from the equity have no significant supervisory or other authority over the Researchers in the Clinical Research/Validation; OR
- (c) COA determines that the benefits of the MGB Affiliated Institution conducting the Clinical Research/Validation outweigh the risks, and the Clinical Research/Validation has been determined by the IRB to present no more than minimal risk to the subjects participating in it.

Continued on Next Page

[To Table of Content](#)

5.2. Policy Requirements for Certain Institutional Financial Interests, Continued

5.2.1 Institutional Equity Acquired Outside Treasury Investments Continued

If the presumption is overcome under (a), (b), or (c), the Clinical Research/Validation may proceed only if COA determines that the equity holding can be appropriately managed, pursuant to a COA-approved management plan directed at protection of the integrity of the Clinical Research/Validation and the human subjects participating in it. PICC shall have the authority to review any decision by COA pursuant to this Section 5.2.1 that has significant financial implications for MGB.

For purposes of this section 5.2.1, Clinical Research/ Validation shall not include research that is determined by the Institutional Review Board and/ or COA to be Nominal Risk Clinical Research. Such Nominal Risk Clinical Research/ Validation is not subject to the rebuttable presumption above, but may proceed only pursuant to a management plan approved by COA, which authority is delegable by COA to OII.

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

- The nature of the science involved;
- A description of the institutional financial interest and how closely it is linked to the Clinical Research/Validation;
- The degree to which the interest may be affected by the Clinical Research/Validation;
- The magnitude of the potential risks to subjects or integrity inherent in the Clinical Research/Validation;
- How those risks could be affected as a result of the institutional financial interest;
- Whether the MGB Affiliated Institution is uniquely qualified, by virtue of its attributes (e.g. special facilities or equipment, unique patient population) and its researchers, to conduct the Clinical Research/Validation; or
- The degree to which the institutional conflict of interest can be effectively managed.

Continued on Next Page

[To Table of Content](#)

5.2. Policy Requirements for Certain Institutional Financial Interests, Continued

5.2.1 Institutional Equity Acquired Outside Treasury Investments Continued

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

- Special oversight of human subjects involved in the Clinical Research/Validation, for example, through additional internal monitoring mechanisms or through an external IRB or DSMB;
 - Increasing or establishing firewalls or other conflicts management systems to separate financial decision-making from decision-making about the Clinical Research/Validation;
 - Independent data monitoring to ensure validity, through an objective individual or individuals outside the MGB Affiliated Institution with no ties to the Clinical Research/Validation or to the outside entity;
 - Disclosure of institutional conflicts as defined in this Section 5 in all relevant settings, including to human subjects involved in the Clinical Research/Validation; or
 - Modification or restriction of the MGB Affiliated Institution's financial interest, through lock-up provisions, divestiture, or the like.
-

5.2.2 License Payments and Research

Institutional Conflicts of Interest may arise when a MGB Affiliated Institution receives or has the potential to receive significant license payments from the sale of technology that is the subject of Clinical Research conducted at that Institution. These license payments include, but are not limited to:

- Upfront payments
- Milestone payments, and
- Royalties.

Requirement for COA Review and Approval

When OII determines that a MGB Affiliated Institution proposes to conduct Clinical Research on the technology of a Company that is subject to a license or option to license from that Institution and that Institution is receiving license payments, above a threshold established by COA, from the sale of that technology, the proposed research must be reviewed and approved by COA before the research begins at that Institution. In performing its analysis, COA may take into account any factors that it deems relevant to the analysis.

[To Table of Content](#)

5.2. Policy Requirements for Certain Institutional Financial Interests, Continued

5.2.3 Oversight of Major Gifts and Research

Institutional Conflicts of Interest may arise when a MGB Affiliated Institution receives substantial gifts from a Company:

- That sponsors Clinical Research at that Institution or
- Whose technology is proposed to be studied or tested in Clinical Research at that Institution.

Requirement for COA Review and Approval

When OII determines that a MGB Affiliated Institution proposes to conduct Clinical Research sponsored by, or on the technology of, a Company from which that Institution has received substantial gifts above thresholds established by the COA, including gifts in kind, the proposed research must be reviewed and approved by COA before the research begins at that Institution. In performing this analysis, COA may take into account any factors it deems relevant to the analysis.

5.2.4 Royalties and Clinical Care

Institutional Conflicts of Interest may arise when MGB receives royalties derived from the sales of particular drugs or devices to MGB.

License agreements under which MGB technology is licensed by MGB to a Company must state that the Company will not pay royalties derived from the sales of a particular drug or device to MGB, unless the COA approves an arrangement under which all such royalties will be donated to a specific non-MGB charitable organization.

[To Table of Content](#)

5.3. Policy Requirements for Financial Interests and Outside Activities of Institutional Officials

5.3.1 New Outside Activities Require COA review

Institutional Officials may not accept any new Outside Activities (whether fiduciary or not) with any biomedical Company, or any other Company that does (or is reasonably likely to do) significant business with any MGB Affiliated Institution, without prior review and approval by the COA.

5.3.2 New Human Subjects Research

Institutional Conflicts of Interest may arise when MGB conducts Clinical Research sponsored by, or on the technology of, a Company in which an Institutional Official has a Financial Interest or Outside Activity.

Requirement for COA Review and Approval

When OII determines that MGB proposes to conduct Clinical Research sponsored by, or on the technology of, a Company, and that research is within the scope of the responsibilities of an Institutional Official who holds one of the following relationships or interests in the Company, the proposed research must be reviewed and approved by COA before the research begins at MGB:

- A fiduciary position in the Company; or
- Annual compensation or other income from the Company above a threshold established by COA; or
- Equity or other ownership interest in the Company, including stock options, above a threshold established by COA;

In performing its analysis, COA may take into account any factors it deems relevant to the analysis.

[To Table of Content](#)

5.4. Policy Requirements for Financial Interests and Outside Activities of Direct Supervisors of Research

5.4.1 Conflicts of Interest for Direct Supervisors

A conflict of interest may arise any time that a supervisor whose direct reports participate in research has Financial Interests or Outside Activities, based on thresholds established by the COA, in a Company:

- That sponsors research (or that is proposing to sponsor research) conducted by the supervisor's direct reports, or
- Whose technology is (or is proposed to be) the subject of research conducted by the supervisor's direct reports.

COA may impose restrictions on and implement management mechanisms for the supervisor with respect to oversight of such research.

- Note: A MGB Individual participating in research may request COA's review of a potential conflict of interest, as defined in this section, of his or her direct supervisor with respect to that research. COA shall have the prerogative to decide whether the relationship merits management.
 - Direct supervisors of research may request OII or COA review of any potential conflict.
 - COA can review other situations where appropriate.
-

5.5. Policy Requirements for Institutional Purchasing and Comparable Transactions

5.5.1 Conflicts of Interest in Institutional Purchasing and Comparable Transactions

Institutional Conflicts of Interest may arise when MGB enters or considers entering a transaction with any of the following:

- A MGB Individual
- A person who is a member of a MGB Individual's Family; or
- An Outside Entity in which a MGB Individual or a member of his/her Family has a Financial Interest or relationship.

The requirements in this Section 5.5 are intended to ensure the integrity of decision-making in institutional transactions.

5.5.2 Interested Individuals

A MGB Individual, including an outside director or trustee, is deemed to be an Interested Individual for a particular transaction if he/she is a party to or aware that MGB is entering (or considering entering) into a transaction with:

- A person who is a member of the MGB Individual's Family, or
- An Outside Entity in which that MGB Individual or a member of his/her Family has either a Financial Interest or relationship that exceeds thresholds established by COA.

5.5.3 Recusal Requirement for Interested Individuals

Except as stated below, a MGB Individual must not participate in discussions on or recommendations regarding, act upon, or otherwise participate in the decision-making regarding the transaction in which he/she is an Interested Individual.

Limited Allowable Participation

The Interested Individual may participate in discussions and/or recommendations about a transaction, but not in the final decision-making, provided that:

- The person with authority for final decision-making or the chairperson of a committee determines that involvement of the Interested Individual is appropriate, **and**

Continued on Next Page

[To Table of Content](#)

5.5. Policy Requirements for Institutional Purchasing and Comparable Transactions, Continued

5.5.3 Recusal Requirement for Interested Individuals Continued

- Others involved in the discussion and/or recommendation are aware of the Financial Interest or relationship held by the Interested Individual, whether by disclosure by the Interested Individual or otherwise; and
- The Interested Individual possesses particular expertise or knowledge that would be beneficial to the final decision.

Note: COA may determine additional exceptions to the recusal requirement of Section 5.5.3.

5.5.4 Procedures for Certain Purchasing Transactions

For any transaction that involves a contract to purchase Goods or Services exceeding thresholds established by COA (referred to in this section as a “Reviewable Purchasing Transaction”), the following procedures must be completed prior to entering into the transaction.

When informed of a Reviewable Purchasing Transaction, OII shall determine from submitted MGB Annual Disclosure Statements whether a MGB Individual or member of his or her Family has a Financial Interest in or relationship with the Outside Entity involved in the transaction that exceeds thresholds established by COA.

- If OII finds there is no such Financial Interest or relationship, this finding shall be documented in writing, and the transaction may be entered into.
- If OII finds there is one or more such Financial Interests or relationships, the person responsible for the transaction must make a written determination that, notwithstanding the apparent conflict, the transaction is fair and reasonable to MGB and is in the best interest of MGB. The basis for this determination must include but is not limited to:
The consideration of at least two alternative disinterested competitive proposals, or
- A determination that two such competitive proposals do not exist or that it would be impractical to solicit them, along with an explanation for why it was determined appropriate to enter into the transaction without considering such competitive proposals.

5.5. Policy Requirements for Institutional Purchasing and Comparable Transactions, Continued

5.5.5 Procedures for Other Transactions

The determination described in the fourth paragraph of section 5.5.4 must be made under either of the following circumstances:

- For a Transaction that involves the purchase of Goods or Services falling below the threshold for a Reviewable Purchasing Transaction in Section 5.5.4, and
- For any transaction other than a purchasing transaction.

But only if:

- The Transaction is with a MGB Individual or a Family Member of a MGB Individual; or
- The person responsible for the transaction is aware that a MGB Individual or a member of his or her Family:
 - Has a Financial Interest in or relationship with the Outside Entity involved in the transaction that exceeds the thresholds for Individuals established by COA (as described in Section 5.5.4), **and**
 - Meets one of the following descriptions:
 - is actually involved in the Transaction, or
 - is an Institutional Official or
 - is an outside director or trustee, or
 - has his/her MGB affiliation with the entity entering into the transaction or with a parent of that entity and the transaction is within the scope of his or her responsibilities.

The requirements of this Section 5.5.5 do not apply to transactions involving ordinary and routine research or technology transfer matters that are processed through the appropriate research and/or technology transfer office in the ordinary course of business.

5.6. COA Oversight of Institutional Conflicts of Interest

5.6.1 COA Oversight of Institutional Conflicts of Interest	Subject to the reserved authority of PICC as referenced in Section P.2.2, COA shall have overall authority and responsibility for overseeing Institutional Conflicts of Interest. COA shall review and manage or otherwise resolve all cases of potential Institutional Conflicts of Interest as described in Sections 5.2.1, 5.2.2, 5.2.3, 5.3.1, 5.3.2, and 5.4.1.
---	--

[To Table of Content](#)

Section 6

Gifts From MGB Vendors and Potential Vendors

6.1. Policy Overview

6.1.1 Policy on Gifts to MGB Gifts to MGB or its Affiliated Institutions from pharmaceutical Companies, medical device Companies, and other vendors may provide valuable resources that help MGB to carry out its charitable activities. However, such gifts may raise concerns about inappropriate influence on MGB charitable missions. Therefore, they must be overseen by appropriate MGB officials.

Gifts to MGB from pharmaceutical Companies, medical device Companies, and other vendors and potential vendors for the support of MGB Educational Activities shall be handled by OII in accordance with Section 3 of this Policy. All other gifts are the responsibility of the relevant Institution's Development Office.

Note: The term "MGB" refers to Mass General Brigham Incorporated and/or one or more of its Affiliated Institutions. Other terms in this Section 6 that have initial capital letters shall have the meaning specified in the Glossary.

6.1.2 Policy on Gifts from Vendors or Potential Vendors to a MGB Individual or to MGB for the Use or Benefit of a MGB Individual When gifts are made to or for the benefit of MGB Individuals, they have the potential to influence or create the appearance of influencing the behavior of MGB Individuals in carrying out their MGB responsibilities.

MGB Individuals may not accept any gifts (including meals and entertainment or funding for meals and entertainment), regardless of value, from pharmaceutical Companies, medical device Companies, or other vendors or potential vendors of MGB.

MGB and its Affiliated Institutions may not accept any gifts for the personal use or benefit of staff members (including meals and entertainment or funding for meals and entertainment), regardless of value, from pharmaceutical Companies, medical device Companies, or other vendors or potential vendors of MGB.

Continued on Next Page

[To Table of Content](#)

6.1. Policy Overview, Continued

6.1.2 Policy on Gifts from Vendors or Potential Vendors to a MGB Individual or to MGB for the Use or Benefit of a MGB Individual Continued	<i>Special rule for certain gifts offered to MGB Individuals:</i> If a MGB Individual is offered a non-cash gift or gratuity prohibited under this Policy and believes that it would be contrary to the best interests of MGB to decline the gift or gratuity, the MGB individual may accept the gift or gratuity and must report the matter to OII. OII, after consultation with COA and the MGB Individual's supervisor, will direct the MGB Individual to take appropriate action, which may include keeping the gift or gratuity, returning it, or donating it to an appropriate MGB entity or department.
6.1.3 To Whom Section 6.1.2 Applies	Section 6.1.2 applies to: • All full-time Covered Individuals; • All other MGB Individuals while Acting in a MGB Capacity. The provisions of this Section 6.1.2 apply to gifts, whether provided at a MGB site or off site.
6.1.4 Scope of Policy	The following are not considered gifts (but generally require Written Agreements or other documentation as determined by OII): • Reasonable compensation for providing services; and • Reimbursement of reasonable costs incurred by an individual in the performance of providing services to the entity providing the reimbursement; • Circumstances where MGB or an individual to whom this Section 6 applies provides fair market value for the item; • Other situations as determined by COA.
6.1.5 MGB Code of Conduct	Additional policies on gifts and outside remuneration are found in the MGB Code of Conduct policy on Gifts, Gratuities, and Outside Remuneration.

[To Table of Content](#)

Glossary and Terms

Note: Any Term in this Glossary that is referred to as an “HMS definition” shall have the definition provided in the HMS Conflicts Policy (and as it may be subsequently modified).

Term	Definition
Acting in a MGB Capacity	Acting in a MGB capacity means an individual is: • Engaged in an activity that constitutes or is part of his/her MGB role (for example, serving on a committee or seeing patients as a part-time member of the medical staff of a MGB hospital); or • Acting at the direction of a MGB supervisor to carry out an activity that constitutes the individual's MGB role (for example, attending an off-site meeting at the supervisor's direction); or • Engaging in any activity in which the individual identifies him/herself as associated with MGB in such a manner that a reasonable person would believe that the individual is acting on behalf of MGB or in a MGB capacity. For further explanation, see here (link only accessible to MGB Employees)
Affiliated Institution	Any of the following institutions: • The Brigham and Women’s/Faulkner Hospitals, Inc., and all affiliates • The Massachusetts General Hospital, and all affiliates • The North Shore Medical Center, Inc., and all affiliates • Newton-Wellesley Hospital, and all affiliates • Mass General Brigham Community Physicians (“MGB CP”) • Spaulding Rehabilitation, Inc. and all affiliates • Partners Harvard Medical International, Inc. • Partners International Medical Services, Inc., • AllWays Health Partners, Inc. and • other institutions and entities designated in the future as Affiliated Institutions

Business	<i>(HMS definition)</i> 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). → A1 Clinical Research Rule → A2 Research Support Rule → A3 External Activity Rule → B Executive Position Rule
Clinical Conflict of Interest	A clinical conflict of interest may exist when a MGB 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.
Clinical Research	<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.” → A1 Clinical Research Rule → A2 Research Support Rule → A3 External Activity Rule
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 MGB or a MGB-affiliated Corporation who are not Medical/Professional Staff Members or Research Staff Members.
Executive Position	<i>(HMS definition)</i> 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. <i>→ B Executive Position Rule</i>
Faculty	<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”. <i>→ B Executive Position Rule</i>
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	(HMS definition) 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/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. → A1 Clinical Research Rule → A2 Research Support Rule → A3 External Activity Rule → 1.2.4
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 MGB 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	- 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 MGB and each Affiliated Corporation

Institutional Responsibilities	Institutional Responsibilities include research, clinical care, education, administrative, and other MGB activities.
Interested Individual	A MGB Individual, including an outside director or trustee, is deemed to be an Interested Individual for a particular transaction if he/she is a party to or aware that MGB is entering (or considering entering) into a transaction with: • that MGB Individual, • a person who is a member of the MGB Individual's Family, or an Outside Entity in which that MGB Individual or a member of his/her Family has either a Financial Interest or relationship that exceeds thresholds established by COA.
Medical/ Professional Staff Members	Individuals who are members of the medical or professional staffs of any MGB hospital AND who: • Have full-time or part-time faculty appointments at Harvard Medical School, OR • Are Service/Department Chiefs/Chairs at MGB or an Affiliated Institution, OR • Are employed full-time or part-time by MGB or an Affiliated Institution Exceptions The following are considered Medical/Professional Staff Members only when they are at a MGB site or otherwise Acting in a MGB Capacity: • Individuals who are members of the medical or professional staff of any MGB hospital and who have an HMS faculty appointment, but • are neither employed by MGB or an Affiliated Institution, nor are Service/Department Chiefs/Chairs, AND • who have a medical/professional staff appointment at a non-MGB but HMS affiliated hospital, which is their primary job location.
MGB	Mass General Brigham and/or one or more of the Affiliated Institutions

MGB Educational Activity	All MGB educational endeavors designed to provide educational information to healthcare practitioners (including physicians, nurses, residents, and fellows), non-physicians, non-professional staff, patients, and/or the public, regardless of whether the participants receive credit for their participation (e.g., accredited CME, CNE, and other such accredited programs, as well as unaccredited educational courses). MGB Educational Activities include the following: • Clinical training programs, such as residencies and fellowship programs that involve a significant component consisting of direct patient care; • Educational events, including continuing medical education programs or other professional health care education programs that involve conferences or lectures or other forms of verbal presentations, regardless of whether the participants receive credit; • Educational tools and resources, including MGB newsletters and web sites designed to distribute educational information to healthcare practitioners, patients, and the public, even if such information pertains to research; and • Other educational programs that are put on, or sponsored, by any MGB entity
MGB Individual	Any trustee, director, officer, executive, full- or part-time Medical/Professional Staff Member, Research Staff Member, or Employee Member of a MGB Affiliated Institution (other than MGB CP) Any member of a MGB committee Any consultants, independent contractors, students, trainees, sponsored staff, researcher, collaborator, or other individuals acting in a MGB capacity The following people affiliated with MGB CP: • MGB CP Trustees, officers, executives, and members of MGB CP committees with board-delegated powers • Physicians and non-physicians employed by MGB CP • Physicians who have an appointment to the professional staff of a hospital owned or controlled by MGB • Other physicians and non-physicians, who, in the judgment of the Chief Executive Officer of MGB CP, have significant MGB CP-related management responsibilities.

Nominal Risk Clinical Research	(HMS definition) 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 and ii. falls within one or more of the following categories (i) 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; (ii) 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 Clinical Risk Research; (iii) 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; (iv) 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 (v) 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.
OII	Office for Interactions with Industry

Outside Activities	Any activity that is not performed as part of an individual's MGB responsibilities and either: • Draws on his or her expertise relating to his or her responsibilities at MGB, <u>or</u> • Is with an Outside Entity, the primary business activities of which relate to his or her responsibilities at MGB, <u>or</u> • Is with an Outside Entity that is a biomedical company or other vendor that does or is likely to do business with MGB, <u>or</u> • Is with an Outside Entity that provides health care related goods or services.
Outside Entity	Any for profit or non-profit corporation, foundation or other entity or organization, including any governmental entity that is not a MGB Affiliated Institution.
Participate	(HMS definition) 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 even should the Faculty member elect to terminate the Research activities. → A1 Clinical Research Rule → A2 Research Support Rule

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 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. → A1 Clinical Research Rule → A2 Research Support Rule → A3 External Activity Rule → B Executive Position Rule
Policy	The Mass General Brigham Policy on Interactions With Industry and Other Outside Entities
PICC	Professional and Institutional Conduct Committee
Research	(HMS definition) 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. → A1 Clinical Research Rule → A2 Research Support Rule → A3 External Activity Rule → B Executive Position Rule

Research Staff Members	Individuals who have full-time or part-time non-faculty appointments at Harvard Medical School and: • who are not Medical/Professional Staff Members, and • who are participating in research activity under the administrative authority of MGB or an Affiliated Institution Exception: Individuals who meet the criteria for Research Staff Members, above, but whose primary affiliation is at a non-MGB but HMS affiliated hospital, are considered Research Staff Members only when they are at a MGB site or otherwise Acting in a MGB Capacity.
Researchers	MGB Individuals who are project directors or principal investigators of a MGB research activity, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of, MGB research activities, including collaborators or consultants. The term “Researchers” is not limited to principal investigators. → A1 Clinical Research Rule → A2 Research Support Rule → A3 External Activity Rule → B Executive Position Rule
Reviewable Purchasing Transaction	Any transaction that involves a contract to purchase goods or services exceeding thresholds established by COA.

Significant Financial Interest	(1) A financial interest consisting of one or more of the following interests of the Researcher (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Researcher's Institutional Responsibilities: (i) With regard to any publicly traded entity, a <i>significant financial interest</i> exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (<i>e.g.</i>, consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; (ii) With regard to any non-publicly traded entity, a <i>significant financial interest</i> exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Researcher (or the Researcher's spouse or dependent children) holds any equity interest (<i>e.g.</i>, stock, stock option, or other ownership interest); or (iii) Intellectual property rights and interests (<i>e.g.</i>, patents, copyrights), upon receipt of income related to such rights and interests. (2) The occurrence of any reimbursed or sponsored travel (<i>i.e.</i>, that which is paid on behalf of the Researcher and not reimbursed to the Researcher so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this definition does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a) or a research institute that is affiliated with an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, or a medical center. <i>Continued on Next Page</i>
---------------------------------------	--

Significant Financial Interest, Continued	The term <i>significant financial interest</i> does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Researcher if the Researcher is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Researcher, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Researcher does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
Special Equity	Equity or other ownership interests received by MGB outside normal Treasury or Development Office stock acquisitions, for example, as a consequence of a license of institutional technology or other involvement in a start-up Company.

Sponsored Research	(HMS definition) Research, training and instructional projects involving funds, personnel, certain proprietary materials, or Technology, or other compensation from outside sources under an agreement that (i) the institution classifies as a sponsored award in accordance with institutional policy or (ii) gives the donor, or an identifiable third party designated by the donor, preferred access to or ownership rights over the Research or the products of the Research, e.g. raw data, scientific developments, or intellectual property. Provision of periodic general reports and copies of publications shall not be considered preferred access. - Notwithstanding the forgoing, Sponsored Research <u>shall not</u> incorporate the following agreements: 1. Gifts: Agreements that an institution classifies as a gift in accordance with institutional policy <u>except</u> 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, 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: - 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 - A non-exclusive license for <u>Research purposes</u> to intellectual property made in, and derived directly from the use of the material in, the Research. <i>Continued on Next Page</i>
---------------------------	--

Sponsored Research, Continued	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. → A2 Research Support Rule → A3 External Activity Rule → B Executive Position Rule
Technology	(HMS definition) Any compound, drug, device, 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, <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. → A1 Clinical Research Rule → A3 External Activity Rule → B Executive Position Rule
Transaction	Any contract, agreement, transaction or act of MGB
Written Agreement	A written agreement between a Covered Individual and an Outside Entity setting forth the terms of an arrangement relating to an Outside Activity