

Title:	Institutional Conflicts of Interest
Department:	Human Research Affairs
Policy Type:	Mass General Brigham System-wide
Applies to:	Employees, Professional Staff or Other Agents of Mass General Brigham
Approved by:	Chief Academic Officer
Original Approval Date:	December 1, 2020
Original Effective Date:	December 1, 2020
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Current Revision Effective Date:	N/A
Next Review Date:	January 15, 2022
Contact Person:	Director, Human Research Office

KEYWORDS:

Institutional Conflict of Interest, Institutional Official, Outside Activities

PURPOSE:

This policy establishes the process to identify institutional financial interests that may create an institutional conflict of interest (ICOI) for Mass General Brigham or its affiliated entities.

DEFINITIONS:

See Definitions in Human Subjects Research

POLICY STATEMENT:

Review of human subject research by the Mass General Brigham IRB must take into consideration institutional financial interests that may be relevant to the conduct of the research. Collaborations between Mass General Brigham and industry provide opportunities for productive collaboration and advances in patient care. However, financial interests of Mass General Brigham or Mass General Brigham institutional officials cannot be allowed to compromise, or appear to compromise, the safety or integrity human subject research.

PROCEDURES:

An institutional conflict of interest may exist when any of the following might affect the design, conduct or reporting of the research:

1. Investments of the institution;
2. Payments from licenses, including royalties;

3. Major gifts to the institution; or
4. Interests of Mass General Brigham institutional officials.

The Mass General Brigham Office for Interactions with Industry (OII) is responsible for maintaining a list of financial holdings and financial interests or fiduciary duties of institutional officials that may create an ICOI (the “entity list”). OII will periodically, but no less frequently than annually, provide the Human Research Office (HRO) with a copy of the entity list. HRO staff will utilize the entity list when conducting intake and screening of applications submitted via Insight to identify studies for which there may be a related ICOI. The following situations may create an institutional conflict of interest:

1. Mass General Brigham human subject research is sponsored by an entity on the entity list;
2. Mass General Brigham human subject research is evaluating an investigational drug or device manufactured by an entity on the entity list.

When HRO staff identify a study with which there is a potential ICOI, they will notify the Director, HRO or designee, who will in turn notify OII. OII will conduct an assessment to determine whether, pursuant to the Policy for Interactions with Industry and Other Entities and applicable OII standard operating procedures, there is an ICOI that must be managed.

In the event that OII determines there is an ICOI related to human subject research submitted to the IRB for review, OII will provide to the IRB documented controls for managing the ICOI, which may include that the research will not be reviewed by the Mass General Brigham IRB, or confirmation that management is not required. The IRB application will not be assigned to a Chair or to an agenda for review by the convened Board prior to the IRB receiving the documented management strategies or confirmation that management is not required. The Chair, designee or convened Board will ratify the documented management controls and may add additional management controls to ensure the protection of subjects. The Chair, designee or convened Board may not remove any management controls required by OII.

OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES:

Mass General Brigham Policy for Interactions with Industry and Other Outside Entities

REFERENCES:

N/A

DEVELOPMENT AND CONSULTATION:

Human Research Office
Office for Interactions with Industry