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1. PURPOSE

- 1.1. The purpose of this policy is to ensure the objectivity of research and to avoid actual or perceived conflict, by defining the process for identifying, reporting, and managing conflict of interest.

2. SCOPE

- 2.1. This policy applies to all persons at The Fenway Institute (TFI) who meet the definition of Investigator and applies to all activities meeting the definition of research.
- 2.2. Designated provisions of this policy apply only to Investigator's applying for or conducting research funded by the Public Health Service (including the National Institutes of Health).

3. ALLOWABLE EXCEPTIONS

- 3.1. None.

4. REVISIONS FROM PREVIOUS VERSION

- 4.1. Remove section 6 typographical error, and replace the Vice President's responsibilities for oversight with the Director of Administration and Planning, clarify that only insufficiently managed FCOI's will bar conduct of certain human subject research.

5. DEFINITIONS

- 5.1. **Disclosure:** An Investigator's disclosure of financial interests to the Institution related to their institutional responsibilities.
- 5.2. **Entity:** An organization other than the Institution, whether public or private. Examples include the following: a company, partnership, professional associations, voluntary health organizations, etc.
- 5.3. **Financial Conflict Of Interest ("FCOI"):** A Significant Financial Interest that is related to proposed Institution research (i.e., the interest reasonably appears to be affected by the research or is in an entity whose financial interest reasonably appears to be affected by the research) and that could directly and significantly affect the design, conduct, or reporting of research.
- 5.4. **Financial Interest:** Anything of monetary value, whether or not the value is readily ascertainable, in any one of the following categories: compensation; equity (stock, stock options or other ownership interest) in a public or private company; royalty/licensing income; a position in a non-Institute entity giving rise to a fiduciary duty such as Vice President, officer, partner, trustee, employee or any position of management; or, or

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researchers with funding from the Public Health Service, any reimbursed or sponsored travel.

- 5.5. **Human Subject:** A living individual about whom an Investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.
- 5.6. **Institution:** Fenway Health.
- 5.7. **Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of the Institute, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels.
- 5.8. **FCH IRB:** The Fenway Community Health Institutional Review Board.
- 5.9. **Investigator:** Any person responsible for the design, conduct, or reporting of research. It includes but is not limited to a Principal Investigator and a co-Investigator.
- 5.10. **Manage:** To take action to address a Financial Conflict of Interest, which includes reducing or eliminating the Financial Conflict of Interest, to ensure that the design, conduct, and reporting of research are free from bias or the appearance of bias.
- 5.11. **Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- 5.12. **Significant Financial Interest:** Anything of monetary value or potential monetary value held by an Investigator (and by the Investigator's spouse and dependent children), and that reasonably appears to be related to the Investigator's institutional responsibilities, as follows:
 - 5.12.1. Outside payments such as consulting fees, honoraria, and travel reimbursements from companies and organizations outside the investigator's current institution (TFI or Fenway Health) if the value within the past 12 months as of the date of disclosure exceeds \$5,000.
 - 5.12.2. Equity such as stock or stock options in companies and organizations, excluding the investigator's current institution.
 - 5.12.3. Royalties related to intellectual property rights paid by any source other than the investigator's current institution.

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5.12.4. Any reimbursed or sponsored travel (e.g. air and taxi fare, car rentals, etc.) paid by an entity, including non-profit organizations, but not including travel sponsored by or reimbursed by:

- 5.12.4.1. a government agency,
- 5.12.4.2. a U.S. institution of higher education or
- 5.12.4.3. a research institute affiliated with such,
- 5.12.4.4. a medical center, or an academic teaching hospital.

5.13. The following are not required to be disclosed:

- 5.13.1. Salary, royalties, or other remuneration paid to the investigator from the institution that currently employs the Investigator (Fenway Health and primary institution of TFI faculty members).
- 5.13.2. Income from investments in mutual funds or retirement accounts, as long as the Investigator does not make the investment decisions.
- 5.13.3. Payment for services (honoraria, advisory committees, review panels, etc.) or travel expenses paid by a U.S. federal, state, or local government agency, a U.S. institution of higher education or a research institute affiliated with such, a U.S. medical center or academic teaching hospital.

6. POLICY

- 6.1. Fenway Investigators must disclose their Significant Financial Interests and certain sponsored travel so that TFI may evaluate and appropriately manage these relationships with industry and other external institutions/commitments to promote objectivity in TFI research.

7. RESPONSIBILITIES

- 7.1. This policy is overseen by TFI's Director of Administration and Planning ("Director")
- 7.2. The Director appoints the Manager of Research Integrity and Compliance ("Compliance Manager") to implement and enforce disclosure procedures outlined in section 8. The Compliance Manager will review all financial disclosure forms to identify real and perceived financial conflicts of interests.
- 7.3. The Director will appoint a Conflict of Interest in Research Committee (hereafter referred to as "Committee") to review and recommend research management plans for disclosed financial conflicts of interest to TFI.

8. PROCEDURE

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8.1. Financial Disclosure Procedures

8.1.1. Investigators are required to disclose Significant Financial Interests (“SFI”) on an annual basis and event-required basis. All disclosures must be made no later than the time of applying for research funding. The mechanism for SFI disclosure is the Financial Disclosure Form which is distributed to investigators by the Compliance Manager.

8.1.2. Annual Reports

8.1.2.1. Required Reporting: Investigator must update their report of Significant Financial Interests related to their Institutional responsibilities annually.

8.1.3. Event-based Reports

8.1.3.1. New Hire: All new investigators are required to complete a Financial Disclosure Form within 30 days of hire.

8.1.3.2. Newly Assigned Responsibilities: Individuals who become newly responsible for the design, conduct, reporting, or direct administration of research are required to complete a Financial Disclosure Form within 30 days of their assumption of such responsibilities.

8.1.3.3. Material Change in Circumstances: Investigators must amend their Financial Disclosure Form within 30 days of any material changes to their responses. Material changes include but are not limited to the initiation or elimination of a reportable external commitment or financial interest for the reporter and family, a change in, or the Initiation of, a sponsor.

8.1.4. The Compliance Manager is responsible for soliciting and reviewing all Financial Disclosure Forms. These forms are maintained by TFI’s Compliance Department for at least three years from the date the final expenditure report is submitted for a research project and/or at least three years from the date the final report is submitted for a research project.

8.2. Review of FCOI Disclosure by Compliance Manager

8.2.1. The Compliance Manager reviews all Financial Disclosure Forms and determines whether an investigator's Significant Financial Interests:

8.2.1.1. could directly and significantly affect the research, or

8.2.1.2. is in an entity whose financial interest could be affected by the research

8.2.2. The Director is notified of all Significant Financial Interests held by Investigators.

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8.2.3. When the Compliance Manager determines a FCOI exists, the issue is referred to the Committee for appropriate management.

8.3. **Determination and Management of FCOI**

8.3.1. Administrative Structure of Committee

8.3.1.1. The Committee will be appointed by the Director.

8.3.1.2. No member of the Committee who holds a Significant Financial Interest in a project may participate in the review of interest or the development of a management plan for that project.

8.3.1.3. Committee meetings are closed to the public.

8.3.2. Committee Procedures for Determination and Management of FCOI

8.3.2.1. Where the Compliance Manager has determined that a Financial Conflict of Interest exists, the Committee will develop and recommend for implementation to the Director a management plan that specifies the actions that have been and/or will be taken to manage the Financial Conflict of Interest.

8.3.2.2. In so doing, the Committee will consider the nature of the research, the nature and size of the interest, the degree to which the conflict is related to the research, the extent to which the interest could be affected by the research, and any management strategies that would mitigate or eliminate the conflict.

8.3.2.3. Management strategies may include, but are not limited to:

8.3.2.3.1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

8.3.2.3.2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

8.3.2.3.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, or the appearance of bias, resulting from the Financial Conflict of Interest;

8.3.2.3.4. Modification of the research plan;

8.3.2.3.5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

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8.3.2.3.6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); and

8.3.2.3.7. Severance of relationships that create actual or potential financial conflicts.

8.3.3. Specific Provisions Applicable to Human Subjects Research

8.3.3.1. The Institution will not permit an Investigator with a Financial Conflict of Interest that has not been sufficiently managed to conduct a clinical research protocol whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment.

8.3.3.2. A Financial Conflict of Interest is not sufficiently managed if disclosure or other conflict management strategies are inadequate or monitoring plans are difficult or impossible to implement.

8.3.3.3. This prohibition applies to any TFI staff or faculty involved in the design, conduct, or reporting of the research. A Principal Investigator would thus be prohibited not only from serving in that role, but in any role in which they are responsible for the design, conduct or reporting of the study.

8.4. Implementation by the Director

8.4.1. The Director will review the recommendation of the Committee and determine the final management plan to be implemented for the research. This determination will be provided to the Investigator, who must accept the requirements of the management plan in writing before beginning work on the project. Copies of the signed management plan will also be provided to relevant Fenway Health officials and to the Institutional Review Board.

8.5. Appeal

8.5.1. Any investigator may appeal management of a finding of Financial Conflict of Interest in writing to the Director.

8.6. Non-compliance

8.6.1. Failure to file a complete and truthful disclosure as required by this policy or to comply with the management plan constitutes a violation of Institution policy and may violate state and/or federal law.

8.6.2. Non-compliance by an Investigator in human subject research project will be promptly reported to the FCH IRB.

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8.6.3. In such cases, the Investigator will be subject to appropriate sanctions consistent with Fenway Health policies relating to disciplinary policies. In addition, the Institute may suspend an ongoing research project or halt the expenditure of funds.

8.6.4. In any case in which the Investigator does not comply with any applicable conditions or restrictions imposed pursuant to this policy, the Institute will withdraw any affected applications for funding if the project cannot otherwise be completed without the services of the Investigator.

8.6.5. In the event the Institute discovers that a failure to comply with this policy has biased the design, conduct, or reporting of the research, the Institution will promptly notify the sponsor of the research as required by applicable law and describe the corrective action(s) taken or to be taken.

8.7. **Specific Provisions Applicable to PHS-funded Research**

8.7.1. In addition to the requirements of this policy outlined above, the Institute will apply the following specific provisions to research funded by PHS:

8.7.1.1. Disclosure Upon Application: Any investigators planning to participate in PHS-Funded Research must disclose any Significant Financial Interests to the Compliance Manager no later than the time of application or submission of a formal proposal for the PHS-Funded Research.

8.7.1.2. Monitoring: For PHS-funded research, the Investigator's management plan will be monitored by the Committee on an ongoing basis until the completion of the research project.

8.7.1.3. Subrecipients:

8.7.1.3.1. If the Institution carries out the PHS-funded research through a subrecipient, the Institution will incorporate as part of a written agreement with the subrecipient terms that establish whether the Institution's or the subrecipient's policy on conflict of interest in research will apply to the subrecipient Investigators.

8.7.1.3.2. If the subrecipient's policy will apply, the subrecipient will certify as part of the agreement that its policy complies with the PHS regulations on Objectivity in Research. Additionally, the agreement shall specify time period(s) for the subrecipient to report all identified financial

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conflicts of interest to the Institution to enable the Institution to provide timely reports to PHS.

- 8.7.1.3.3. Alternatively, if the Institution's policy on conflict of interest will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of Significant Financial Interests to the Institution. Such time periods shall be sufficient to enable the Institution to comply with timely review, management, and reporting obligations under the PHS regulations.
- 8.7.1.4. Retrospective Review:
 - 8.7.1.4.1. In the event the Institution identifies a Significant Financial Interest that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing research project, and where the Compliance Manager has determined that the undisclosed Significant Financial Interest constitutes a Financial Conflict of Interest related to a PHS-funded research project, the Committee will review the Financial Conflict of Interest and the Institution will implement a management plan for the project within 60 days of identification of that interest.
 - 8.7.1.4.2. In addition, the Committee will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's research activities associated with the project to determine whether the research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.
- 8.7.1.5. Mitigation Plan
 - 8.7.1.5.1. If the Committee determines in the conduct of its retrospective review of PHS-funded research that the research or any part of it was biased, the Committee will recommend a mitigation plan to the Director and the FCH IRB to address any such issues. The Institution will notify the PHS Awarding Component of its determination and subsequently follow up with the mitigation report for the project.
- 8.7.1.6. Public Access of Disclosed Significant Financial Interest

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8.7.1.6.1. The Institution will make available to the public upon request information concerning any Significant Financial Interest disclosed to the Institution that meets the following three criteria:

- 8.7.1.6.1.1. The disclosed Significant Financial Interest is still held by the senior/key personnel of the active PHS project;
- 8.7.1.6.1.2. The Institution determines that the Significant Financial Interest is related to the PHS-funded research; and
- 8.7.1.6.1.3. The Institution determines that the Significant Financial Interest is a Financial Conflict of Interest.

8.7.1.6.2. The information request must be made to the Compliance Manager who will respond within five (5) business days of receipt of the request. Disclosed information will be provided to the extent required by applicable PHS regulations and state law.

8.7.1.7. Ongoing Research

- 8.7.1.7.1. When in the course of an ongoing research project an Investigator new to the project discloses a Significant Financial Interest or an existing Investigator discloses a new or changed Significant Financial Interest, and where the Compliance Manager has determined that the disclosed Significant Financial Interest constitutes a Financial Conflict of Interest subject to management under this policy, the Committee will review the disclosure and the Institution will implement a management plan for the project within 60 days of the submission of the disclosure to the Institution.
- 8.7.1.7.2. Depending on the nature of the Financial Conflict of Interest, the Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date of disclosure and the implementation of the Institution's management plan.
- 8.7.1.7.3. FCH IRB will address and implement any interim measures as necessary for the protection of human participants in any ongoing research.

8.8. Reporting

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8.8.1. The Institution will provide initial and ongoing reports of its management of financial conflicts of interest to external sponsors of Institution research as required by law and in accordance with this policy.

8.9. Records

8.9.1. Records relating to all Investigators disclosures of Significant Financial Interests and the Institution's review and management of such disclosures, will be maintained by research for three years from the date of submission of the final expenditures report (in the case of grants and cooperative agreements) or three years from the final payment (in the case of research contracts), or as otherwise required by law.

8.10. Inquiries

8.10.1. All inquiries related to Fenway's FCOI policy or to obtain information on the Significant Financial Interests of senior/key personnel should be made to:
 Manager of Research Compliance
 The Fenway Institute, Fenway Health
 1340 Boylston Street
 Boston, MA 02215
regulatory@fenwayhealth.org
 Phone: 617-927-6031

9. MATERIALS

9.1. Materials here or 'None.'

10. TRAINING

10.1. Prior to engaging in any research project, all Investigators must complete training on the Investigators obligations under this policy.

10.2. This training must be repeated at least every four years and must be completed immediately if this policy:

10.2.1. is revised so as to affect the Investigator's obligations,

10.2.2. if an Investigator is new to the Institution,

10.2.3. or if the Institution finds an Investigator to have violated this policy or any applicable management plan.

11. REFERENCES

11.1. Federal Conflict of Interest Regulations

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- 11.1.1. NIH Public Health Service: <http://grants.nih.gov/grants/policy/coi/index.htm>
- 11.1.2. National Science Foundation: <http://nsf.gov/policies/conflicts.jsp>
- 11.1.3. Food and Drug Administration:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&>

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