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1. PURPOSE

- 1.1 The purpose of this policy is to ensure the objectivity of research at Fenway Health, to protect the safety and welfare of human research subjects, 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 Fenway Health who meet the definition of Investigator and Key Personnel, hereinafter referred to as “Investigators” and applies to all activities meeting the definition of research.
- 2.2 Designated provisions of this policy apply only to Investigators applying for or conducting research funded by the Public Health Service (including the National Institutes of Health).
- 2.3 This policy is written to include portions of, and to adhere to, the Federal regulations governing financial conflicts of interest for PHS-funded activities. This policy specifically references 42 C.F.R. Part 50, Subpart F, “Promoting Objectivity in Research.”

3. ALLOWABLE EXCEPTIONS

- 3.1 None.

4. REVISIONS FROM PREVIOUS VERSION

- 4.1 Expanding to indicate that this applies to all research at Fenway Health.
- 4.2 Update Human Subject definition for harmonization with 45 C.F.R. Part 46.102(e)(1).
- 4.3 Describing documentation processes and further clarifying chain of decision-making.

5. DEFINITIONS

- 5.1 **Entity:** An organization other than Fenway Health, whether public or private. Examples include the following: a company, partnership, professional associations, voluntary health organizations, etc.
- 5.2 **Financial Conflict of Interest (FCOI):** A Significant Financial Interest that is related to proposed Institution research (i.e., the interest reasonably

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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.

- 5.3 **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 for researchers with funding from the Public Health Service, any reimbursed or sponsored travel.
- 5.4 **Human Subject:** Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; (ii) or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- 5.5 **Institutional Responsibilities:** An Investigator’s professional responsibilities on behalf of TFI, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels.
- 5.6 **FCH IRB:** The Fenway Community Health Institutional Review Board.
- 5.7 **Investigator:** Any person, including the Project Director/Principal Investigator (PD/PI), regardless of title or position, responsible for the design, conduct, or reporting of activities related to research performed under the auspices of Fenway Health, which may or may not include non-Fenway Health collaborators or non-Fenway Health consultants.
- 5.8 **Key Personnel:** Includes the PD/PI but also includes any other personnel that are considered to be “essential to work performance” on a project. Furthermore, Fenway Health defines Key Personnel on human subject protocols as Research personnel directly involved in conducting research specific interventions with study participants, or their private identifiable information (PII), or protected health information (PHI).
- 5.9 **Manage:** To take action to address a FCOI, which includes reducing or eliminating the FCOI, to ensure that the design, conduct, and reporting of research are free from bias or the appearance of bias.

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5.10 **Public Health Service (PHS):** PHS means the Public Health Service of the U.S. Department of Health and Humans Services (DHHS) and any components of PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH) and any other sponsor who requests application of the PHS FCOI regulation to the administration of their research awards.

5.11 **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:

5.11.1 Outside payments such as consulting fees, honoraria, paid authorship, 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.

5.11.2 Equity such as stock or stock options in companies and organizations, excluding the investigator’s current institution.

5.11.3 Royalties related to intellectual property rights paid by any source other than the investigator’s current institution.

5.11.4 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 a:

5.11.4.1 Government agency;

5.11.4.2 U.S. institution of higher education or research institute affiliated with such;

5.11.4.3 Medical center; or an

5.11.4.4 Academic teaching hospital.

5.12 The following are not required to be disclosed:

5.12.1 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).

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- 5.12.2 Income from investments in mutual funds or retirement accounts, as long as the Investigator does not make the investment decisions.
- 5.12.3 Payment for services (seminars, lectures, teaching engagements, 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 designates the Director of Research Compliance (Compliance Director) to implement and enforce disclosure procedures outlined in section 8. The Compliance Director will review all *Financial Disclosure Forms* to identify potential actual and apparent financial conflicts of interests.
- 7.3 The Director will convene a Conflict of Interest in Research Committee (hereafter referred to as the Committee) to review and recommend research management plans for potential financial conflicts of interest disclosed to TFI.

8. PROCEDURE

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 or within 30 days of acquiring any new or increased funding. The mechanism for SFI disclosure is the *Financial Disclosure Form* (Appendix A)

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which is distributed to investigators by the Compliance Director.

8.1.2 Annual Reports

8.1.2.1 Required Reporting: Investigators must update their *Financial Disclosure Form* annually, and provide these reports to the Compliance Director.

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 discovering or acquiring a new SFI. 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.

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

8.1.4 The Compliance Director is responsible for soliciting and reviewing all TFI *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 or at least three years from the date the final report is submitted for a research project, whichever is longer.

8.2 Additional Disclosure Provisions Applicable only to PHS-funded Research Conducted via Subaward

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- 8.2.1 The TFI Grants and Contracts team (Grants and Contracts) identifies any PHS-funded research Fenway Health plans to carry out via a subaward to a subrecipient.
- 8.2.2 Once identified, Grants and Contracts will ensure that a written agreement with the subrecipient includes terms that establish whether Fenway Health’s or the subrecipient’s policy on conflict of interest in research will apply to subrecipient Investigators. This will be documented by having the subrecipient complete a *Sub-Award Financial Conflict of Interest Compliance Certification* (Appendix B), which is updated annually. This document is filed within TFI’s grants management platform, and updated annually.
- 8.2.3 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 conflicts of interest to Fenway Health to enable Fenway Health to provide timely reports to PHS.
- 8.2.4 Alternatively, if Fenway Health’s policy on conflict of interest in research will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of SFI to Fenway Health for the Compliance Director to review. Such time periods shall be sufficient to enable Fenway Health to comply with timely review, management, and reporting obligations under the PHS regulations.
- 8.2.5 Disclosures are submitted to Grants and Contracts on the *External Financial Conflict of Interest Disclosure Form* (Appendix C), and stored with the related subaward in TFI’s grants management platform. Copies of forms that include the disclosure of an SFI are provided to the Compliance Director, and reviewed and addressed as described below.

8.3 Review of FCOI Disclosure by Compliance Director

- 8.3.1 The Compliance Director reviews all *Financial Disclosure Forms*, and makes a determination whether a potential FCOI exists.

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8.3.2 The Compliance Director makes this determination by assessing whether an Investigator’s SFI:

8.3.2.1 Could directly and significantly affect the research;

8.3.2.2 Is in an entity whose financial interest could be affected by the research; OR

8.3.2.3 Appears to do either of the above (“apparent FCOI”)

8.3.3 The Compliance Director documents this review has occurred by the entering of date each disclosure is received in the Regulatory Documentation Tracking Sheet (found on the TFI shared drive in :\\TFI Regulatory & Compliance Office\\Research Compliance\\CITI Training, CV, License, Training Log) and preparation of appropriate memoranda as follows:

8.3.3.1 For disclosure forms that disclose SFIs that are not a potential FCOI with current research, the Compliance Director prepares a memorandum to the Director outlining each SFI (Annual Disclosures Letter).

8.3.3.2 For each disclosure that the Compliance Director determines represents a potential FCOI, the Compliance Director prepares a memorandum to the Director and Committee describing the potential FCOI and suggesting strategies for elimination or mitigation.

8.3.4 Annual Disclosures Letters and FCOI Memoranda are stored on TFI shared drive (:\\TFI Regulatory & Compliance Office\\Research Compliance\\Financial Disclosures - Study Specific and Forms).

8.4 **Determination and Management of FCOI**

8.4.1 When the Director receives a memorandum indicating that a disclosure represents potential FCOI, the Director then convenes the Committee for final determination and management.

8.4.2 Administrative Structure of Committee

8.4.2.1 The Committee will be appointed by the Director.

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8.4.2.2 No member of the Committee who holds a SFI in a project may participate in the review of interest or the development of a management plan for that project.

8.4.2.3 Committee meetings are closed to the public.

8.4.3 Committee Procedures for Determination and Management of FCOI

8.4.3.1 The Committee will review the SFI and related duties/proposed research of the Investigator and make a final determination that the SFI is:

8.4.3.1.1 An FCOI;

8.4.3.1.2 An apparent FCOI; **OR**

8.4.3.1.3 Not an FCOI.

8.4.3.2 In making the final determination, 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.

8.4.3.3 The Committee will develop a management plan that specifies the actions that have been and/or must be taken to eliminate or manage the FCOI/apparent FCOI.

8.4.3.4 Management strategies may include, but are not limited to:

8.4.3.4.1 Public disclosure of the FCOI (e.g., when presenting or publishing the research);

8.4.3.4.2 For research projects involving human subjects research, disclosure of the FCOI directly to participants;

8.4.3.4.3 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 FCOI;

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- 8.4.3.4.4 Modification of the research plan;
- 8.4.3.4.5 Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- 8.4.3.4.6 Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
- 8.4.3.4.7 Severance of relationships that create actual or potential financial conflicts.

8.4.4 Specific Management Provisions Applicable to Human Subjects Research

- 8.4.4.1 Fenway Health will not permit an Investigator with an FCOI 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.
- 8.4.4.2 An FCOI is not sufficiently managed if management strategies are inadequate or monitoring plans are difficult or impossible to implement.
- 8.4.4.3 This prohibition applies to any Fenway Health staff or TFI 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.

8.5 Implementation by the Director

- 8.5.1 The Director will review the recommendation of the Committee and affirm 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 FCH IRB.

8.6 Monitoring

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8.6.1 Any management plan will be monitored by the Compliance Director on behalf of the Committee on an ongoing basis until the completion of the research project. This monitoring will be documented with a summary of the monitoring activities completed and update on plan compliance in the Annual Disclosures Letter provided to the Director.

8.7 Noncompliance

8.7.1 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.

8.7.2 Noncompliance by an Investigator in human subject research project will be promptly reported to the FCH IRB.

8.7.3 In such cases, the Investigator will be subject to appropriate sanctions consistent with Fenway Health policies relating to disciplinary policies. Fenway Health may implement a mitigation plan and require that the Investigator disclose the FCOI in each public presentation of the results of the research, and to remedy previously published presentations with an FCOI disclosure addendum. In addition, the Investigator may be subject to employment discipline including, without limitation, suspension or termination of employment. In addition, TFI may suspend an ongoing research project or halt the expenditure of funds.

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

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

8.8 Retrospective Review:

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- 8.8.1 In the event Fenway Health identifies an SFI that was not disclosed in a timely manner by an Investigator or was otherwise not previously reviewed by Fenway Health during an ongoing research project, and where the Compliance Director has determined that the undisclosed SFI constitutes a potential FCOI the Director will convene the Committee.
- 8.8.2 The Committee will review the potential FCOI, determine if the SFI constitutes an actual or apparent FCOI, and develop a management plan. Fenway Health will implement the plan for the project within 60 days of identification of that interest.
- 8.8.3 In addition, the Committee will, within 120 days of its determination of FCOI, 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, and develop a mitigation plan.
- 8.8.4 Mitigation Plan: If the Committee determines in the conduct of its retrospective review 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.
- 8.8.5 If the FCOI is related to PHS-funded research, Fenway Health will notify the PHS Awarding Component of its determination and subsequently follow up with the mitigation report for the project.

8.9 Public Access of Disclosed Significant Financial Interest

- 8.9.1 Fenway Health will make available to the public upon request information concerning any SFI disclosed to Fenway Health that meets the following three criteria:
 - 8.9.1.1 The disclosed SFI is still held by the senior/key personnel of the active PHS project;
 - 8.9.1.2 Fenway Health determines that the SFI is related to the PHS-funded research; AND
 - 8.9.1.3 Fenway Health determines that the SFI is an FCOI.

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8.9.2 The information request must be made to the Compliance Director who will respond within five (5) business days of receipt of the request.

8.9.3 The Compliance Director will provide SFI information to the extent required by applicable regulation and law.

8.10 Ongoing Research

8.10.1 When in the course of an ongoing research project, an Investigator new to the project discloses an SFI or an existing Investigator discloses a new or changed SFI, and where the Compliance Director has determined that the disclosed SFI constitutes a potential FCOI subject to management under this policy, the Committee will review the disclosure and Fenway Health will implement a management plan for the project within 60 days of the submission of the disclosure to Fenway Health.

8.10.2 Depending on the nature of the FCOI, Fenway Health 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 Fenway Health's management plan.

8.10.3 The Principal Investigator is responsible for reporting the SFI and any institutionally implemented interim measures to FCH IRB.

8.10.4 FCH IRB will address and implement any interim measures as necessary for the protection of human participants in any ongoing research.

8.11 Reporting

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

8.12 Records

8.12.1 Records relating to all Investigators disclosures of SFI, and Fenway Health's review and management of such

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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.

8.13 **Inquiries**

8.13.1 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:

Director 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 Regulatory Documentation Tracking Sheet
- 9.2 *Financial Disclosure Form*
- 9.3 *Sub-Award Financial Conflict of Interest Compliance Certification*
- 9.4 *External Financial Conflict of Interest Disclosure Form*

10. **TRAINING**

10.1 Prior to engaging in any research project, all Investigators subject to this policy must complete training on the Investigators obligations under this policy (CITI Financial Conflict of Interest Training Module), and submit their CITI completion report to the Compliance Director. Completion Report dates are tracked in the Regulatory Documentation Tracking Sheet are stored in: \TFI Regulatory & Compliance Office\Research Compliance\CITI Training Certifications, COIs, and CVs – Unlicensed; and \TFI Regulatory & Compliance Office\Research Compliance\CITI Training Certifications, COIs, and CVs – Licensed.

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;

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10.2.2 if an Investigator is new to Fenway Health; OR

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

10.3 This training shall also be repeated if the Compliance Director determines that an Investigator is not compliant with this policy, a management plan, or a mitigation plan.

11. REFERENCES

11.1 Federal Conflict of Interest Regulations

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/cfcr/CFRSearch.cfm?CFRPart>

11.1.4 42 C.F.R Part 50, Subpart F, “Promoting Objectivity in Research”

NOTE: All printed copies of Standard Operating Procedures are UNCONTROLLED. Please ensure that you are working with the most up to date version of this document, available online. All original signed copies are stored in The Fenway Institute’s Regulatory and Compliance Office.

APPENDIX A

Financial Disclosure Form

Financial Conflict of Interest Disclosure Form

INSTRUCTIONS: This form must be completed by all TFI workforce members annually and within 30 days of any change in responsibilities or disclosures. Please fill out this form in and return to TFI Compliance and Quality. The form can be completed by one of the following three methods:

- Print, sign and date, OR
- Utilize an application that creates a digital signature (uses a digital ID to verify the signer’s identity, binds the signature to the document with encryption, and includes a time stamp), OR
- Utilize an application that allows you to e-sign (mimics a “wet ink” signature).

STAFF INFORMATION

NAME (FIRST, MIDDLE INITIAL, LAST, DEGREE): Click here to enter text.
FENWAY TITLE: Click here to enter text.
OTHER INSTITUTIONAL APPOINTMENTS: Click here to enter text.
DATE OF STATEMENT: Click here to enter text.

Are you responsible for the design, conduct, or reporting of results for research conducted at Fenway Health? **NOTE: “Research” in this context includes all activities receiving funding from a PHS Awarding Component (e.g., center grants, infrastructure grant, institutional training grants).**

- YES (FILL OUT ENTIRE FORM)**
- NO (COMPLETE ONLY THE ‘NOTHING TO DISCLOSE’ CERTIFICATION BOX BELOW)**

CONFLICT OF INTEREST

Please disclose the following **significant financial interests** for yourself, your spouse/partner, and children (“family”):

1. **Outside payments** such as salary consulting fees, honoraria, and travel reimbursements from other than your current institution if the value within the past 12 months from the date of disclosure exceeds \$5,000. Disclosure of payment for services from 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 is not required
2. **Equity** such as stock or stock options in companies and organizations, excluding your current institution, with an aggregate fair market value over \$5,000 or more than 5% ownership interest. Disclosure of income from mutual funds or retirement accounts for which you do not make the investment decisions is not required.
3. **Royalties** related to intellectual property paid by any source other than your current institution.
4. Any **reimbursed or sponsored travel** paid for by any company/institution/organization other than a government agency; U.S. institution of higher education/research institute affiliated with such; a medical center or academic teaching hospital.

NOTHING TO DISCLOSE

My family and I have NO present/imminently pending significant financial interest to disclose.

Initials: _____

OR COMPLETE THE DISCLOSURE TABLES ON PAGE 2.

FINANCIAL INTEREST DISCLOSURES

List any outside payments, equity, or royalties/honoraria qualifying as significant financial interests below. Please append additional sheets if more space is required. **If none, state “none.”**

COMPANY/INSTITUTION/ORGANIZATION	TYPE OF INTEREST	DESCRIPTION & MONETARY VALUE OF INTEREST
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.

REIMBURSED OR SPONSORED TRAVEL DISCLOSURES

List any qualifying sponsored or reimbursed travel that occurred in the last 12 months or planned for the next 12 months. Please append additional sheets if more space is required. **If none, state “none.”**

SPONSOR OF TRAVEL	DESTINATION/DURATION	PURPOSE
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

CERTIFICATION AND SIGNATURE

I CERTIFY THE FOLLOWING:

- I understand that I must update Financial Disclosure Form of any new SFI (including sponsored/reimbursed travel) **within 30 days** of identification or change in responsibility.
- I certify that I have read and agree to comply with the Fenway Health Financial Conflict of Interest policy and procedures, consistent with 42 C.F.R. Part 50, Subpart F, "Promoting Objectivity in Research."
- I give my permission to disclose this information to appropriate officials at Fenway Health.

By signing below, I certify that I have completed this form truthfully and to the best of my knowledge.

Signature

Date

Print Name

APPENDIX B

Sub-Award Financial Conflict of Interest Compliance Certification

Sub-Award Financial Conflict of Interest Compliance Certification

INSTRUCTIONS: The United States Public Health Service (PHS) 42 C.F.R. Part 50, Subpart F, “Promoting Objectivity in Research” mandates that Fenway Health determine if a subrecipient has a PHS-compliant financial conflict of interest policy and also requires the subrecipient to disclose certain information should a financial conflict of interest be present. Fenway Health will collect this information prior to issuing a subaward and then annually at the time of renewal.

SUB-AWARD INFORMATION

Grant Name:	Click here to enter text.
Grant Number:	Click here to enter text.
Budget Period:	Click here to enter text.
Fenway PI or Program Director:	Click here to enter text.
Subrecipient PI:	Click here to enter text.
Subrecipient Institution:	Click here to enter text.

SUBRECIPIENT FINANCIAL CONFLICT OF INTEREST POLICY INFORMATION

Please select #1 or #2 and complete relevant additional details.																					
<input type="checkbox"/> 1	<p>My organization HAS a PHS-compliant Financial Conflict of Interest (FCOI) policy and my organization will rely on this policy and associated procedures to comply with PHS FCOI regulation. My organization will provide information related to any identified FCOI to Fenway Health prior to the execution of the subagreement, or in cases where disclosure is made during the course of the subaward, within 30 days of receiving the pertinent Investigator disclosure, and will include information listed in Appendix 1.</p> <p>Project Specific FCOI Information</p> <p>→ <input type="checkbox"/> Our institution and study staff have NO FCOI related to this protocol requiring disclosure at this time. OR</p> <p>→ <input type="checkbox"/> YES, there are conflicts of interest to be disclosed. For each of the investigators on this project with a positive FCOI, please provide the data requirements listed in Appendix 1.</p>																				
<input type="checkbox"/> 2	<p>My organization does not have a conflict of interest policy at least as rigorous as that mandated by the NIH at 42 CFR Part 50, Subpart F or 45 CFR Part 94 that will apply to the budgeted activities. My organization agrees to rely on The Fenway Institute, Fenway Health FCOI policy and procedures to comply with PHS Conflict of Interest regulations. The following listed individuals, including the Project Director and/or Principal Investigator, are responsible for the design, conduct, or reporting of the budgeted activities.</p> <p>Subrecipient Study Staff Information</p> <p>Please list all individuals responsible for the design, conduct, or reporting of the budgeted activities. Append additional pages if more space is required.</p> <table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 50%;">Name (First, Last, Degree), Title</th> <th style="width: 50%;">Name (First, Last, Degree), Title</th> </tr> </thead> <tbody> <tr><td>Click here to enter text.</td><td>Click here to enter text.</td></tr> <tr><td>Click here to enter text.</td><td>Click here to enter text.</td></tr> <tr><td>Click here to enter text.</td><td>Click here to enter text.</td></tr> <tr><td>Click here to enter text.</td><td>Click here to enter text.</td></tr> <tr><td>Click here to enter text.</td><td>Click here to enter text.</td></tr> <tr><td>Click here to enter text.</td><td>Click here to enter text.</td></tr> <tr><td>Click here to enter text.</td><td>Click here to enter text.</td></tr> <tr><td>Click here to enter text.</td><td>Click here to enter text.</td></tr> <tr><td>Click here to enter text.</td><td>Click here to enter text.</td></tr> </tbody> </table> <p><input type="checkbox"/> I confirm that each individual listed above has reviewed Fenway Health’s FCOI policy, completed Fenway Health’s FCOI training, and has completed and returned the External Financial Conflict of Interest Disclosure Form to The Fenway Institute’s Grants and Contract Department.</p>	Name (First, Last, Degree), Title	Name (First, Last, Degree), Title	Click here to enter text.																	
Name (First, Last, Degree), Title	Name (First, Last, Degree), Title																				
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CERTIFICATION AND SIGNATURE

By signing this document I certify that I am authorized to sign on behalf of this institution/entity, the information provided above is complete and accurate to the best of my knowledge, and in compliance with all other laws and regulations applicable to my awards.

Authorized Official Signature: _____ Date: _____

Name of Authorized Official: _____

Legal Name of Organization: _____

Contact Name: _____ Title: _____

Phone: _____ Email: _____

APPENDIX 1
INFORMATION REQUIREMENTS FOR AN FCOI REPORT

Institutions with a PHS-Compliant FCOI Policy, please include the following in any FCOI Report.

1. Grant number;
2. Name of the Fenway Health Program Director or Principal Investigator;
3. Name of Investigator at Subrecipient Institution with the FCOI;
4. Name of the entity with which the Investigator has an FCOI and whether it is publicly traded or privately held;
5. Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
6. Value of the financial interest: \$0-4,999; \$5K-9,999; \$10K-19,999; amts between \$20K-\$100K by increments of \$20K; amounts above \$100K by increments of \$50K; or a statement that a value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
7. A description how the financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
8. Key elements of the Institution's management plan, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure compliance by the Investigator; and
 - Other information as necessary.

APPENDIX C

External Financial Conflict of Interest Disclosure Form

External Financial Conflict of Interest Disclosure Form

INSTRUCTIONS: All external study staff study whose institutions are relying on TFI's Financial Conflict of Interest Policy, or non-TFI staff working on TFI research at Fenway and not otherwise covered by a Financial Conflict of Interest Policy must complete this form. Please fill out this form, sign, and date.

PROTOCOL

Protocol Title/Grant Name:	Click here to enter text.
Fenway Health PI:	Click here to enter text.
Sponsor:	Click here to enter text.
Grant Number:	Click here to enter text.
Sub-Award Institution:	Click here to enter text.

STAFF INFORMATION

NAME (FIRST, MIDDLE INITIAL, LAST, DEGREE): Click here to enter text.	
INSTITUTION: Click here to enter text.	
DEPT/SERVICE: Click here to enter text.	
MAILING ADDRESS: Click here to enter text.	
E-MAIL: Click here to enter text.	PHONE: Click here to enter text.

YOUR ROLE IN THE STUDY:

PHYSICIAN (NON-PI) **CONSULTANT** **CO-INVESTIGATOR**
 DATA COORDINATOR/MANAGER **RESEARCH NURSE** **RESEARCH COORDINATOR**
 OTHER, SPECIFY: Click here to enter text.

IN THIS ROLE, ARE YOU RESPONSIBLE FOR THE DESIGN, CONDUCT, OR REPORTING OF RESULTS FOR THE RESEARCH DESCRIBED ABOVE? PLEASE NOTE THAT ALL STAFF DESIGNATED AS "KEY PERSONNEL" MEET THIS CRITERIA.

YES (FILL OUT ENTIRE FORM)
 NO (COMPLETE ONLY THE 'NOTHING TO DISCLOSE' CERTIFICATION BOX BELOW)

CONFLICT OF INTEREST

Please disclose the following **significant financial interests** for yourself, your spouse/partner, and children ("family"):

- Outside payments** such as salary consulting fees, honoraria, and travel reimbursements from other than your current institution if the value within the past 12 months from the date of disclosure exceeds \$5,000. Disclosure of payment for services from 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 is not required
- Equity** such as stock or stock options in companies and organizations, excluding your current institution, with an aggregate fair market value over \$5,000 or more than 5% ownership interest. Disclosure of income from mutual funds or retirement accounts for which you do not make the investment decisions is not required.
- Royalties** related to intellectual property paid by any source other than your current institution.
- Any **reimbursed or sponsored travel** paid for by any company/institution/organization other than a government agency; U.S. institution of higher education/research institute affiliated with such; a medical center or academic teaching hospital.

NOTHING TO DISCLOSE

My family and I have NO present/imminently pending significant financial interest to disclose.

Initials: _____

OR COMPLETE THE DISCLOSURE TABLES ON PAGE 2.

FINANCIAL INTEREST DISCLOSURES

List any outside payments, equity, or royalties/honoraria qualifying as significant financial interests below. Please append additional sheets if more space is required. **If none, state “none.”**

COMPANY/INSTITUTION/ORGANIZATION	TYPE OF INTEREST	DESCRIPTION & MONETARY VALUE OF INTEREST
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.
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Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.
Click here to enter text.	<input type="checkbox"/> Outside Payment <input type="checkbox"/> Equity <input type="checkbox"/> Royalties	Click here to enter text.

REIMBURSED OR SPONSORED TRAVEL DISCLOSURES

List any qualifying sponsored or reimbursed travel that occurred in the last 12 months or planned for the next 12 months. Please append additional sheets if more space is required. **If none, state “none.”**

SPONSOR OF TRAVEL	DESTINATION/DURATION	PURPOSE
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

CERTIFICATION AND SIGNATURE

AS A MEMBER OF THE STUDY STAFF ON THIS PROTOCOL, I CERTIFY THE FOLLOWING:

- I have reviewed this protocol and acknowledge my participation;
- I accept responsibility for assuring adherence to applicable federal and state research regulations, policies, and IRB determinations relative to the protection of the rights and welfare of subjects enrolled in this study.
- I agree to comply with the Fenway Health Financial Conflict of Interest policy and procedures, consistent with 42 C.F.R. Part 50, Subpart F, "Promoting Objectivity in Research."
- I give my permission to disclose this information to appropriate officials at Fenway Health.

By signing below, I certify that I have completed this form truthfully and to the best of my knowledge. Further, I understand that it is my obligation to update this form promptly if there is any change.

Signature

Date

Print Name