BC 10.400 - DISCLOSURE OF FINANCIAL INTERESTS AND MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST FOR U.S. PUBLIC HEALTH SERVICE FUNDED RESEARCH

I. POLICY:

The conduct of research advances the mission of Baystate Health to deliver the highest quality care in a compassionate and ethical manner. It is the policy of Baystate Health to adhere to practices that comply with applicable laws, regulations, and professional and ethical standards in order to minimize the potential for financial interests to influence or bias research and scholarly activities. This policy is adopted to promote compliance with federal laws and regulations that apply when funding is received or sought from an agency of the U.S. Public Health Service ("PHS").

II. PURPOSE:

To ensure full compliance with federal requirements for disclosure, review, management, oversight, and reporting of financial interests, as required by the regulations of PHS known as "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors," 42 CFR Part 50 Subpart F and 45 CFR Part 94 commonly referred to as the Financial Conflict of Interest regulations ("FCOI Regulations").

III. SCOPE AND APPLICABILITY:

This Policy is applicable whenever Baystate applies for PHS research funding or receives PHS research funding pursuant to a Notice of Award, whether Baystate is the primary applicant or recipient, sub-applicant, subrecipient, subcontractor or collaborating institution; and is applicable to each Investigator who is participating in or planning to participate in such research. This Policy does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Program applications.

IV. DEFINITIONS:

Designated Institutional Official ("DIO") means the designated institutional official with overall responsibility to ensure compliance with the FCOI Regulations. The DIO for Baystate is the Chief Research Officer/Associate Dean for Research, who has authority and responsibility for implementing and enforcing this policy in collaboration with the FCOI Committee and its Chair, the Chief Research Compliance Officer/Research Integrity Officer (CRCO/RIO).

Financial Conflict of Interest ("FCOI") exists when Baystate reasonably determines that a Signification Financial Interest (as defined in this Policy) (1) is related to a Research project funded by a PHS Awarding Component or application for such a project and (2) could directly and significantly affect the design, conduct, or reporting of Research funded by a PHS Awarding Component or proposed for such funding.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities means the Investigator's professional responsibilities on behalf of Baystate, including research, teaching, professional practice, and committee membership or service on a panel such as the Institutional Review Board.

Investigator means the principal investigator, co-principal investigator, co- investigator, sub-investigator, project manager, or any person, *regardless of title or position*, who is responsible for the design, conduct, or reporting of research funded by a PHS Awarding Component, or proposed for such funding, which may include, for example, collaborators or consultants.

PHS Awarding Component means the organizational unit of the PHS that funds the project that is subject to this Policy, including the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control, the Food and Drug Administration, the Health Resources and Services Administration and the Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research, basic and applied research, e.g., a published article, book or book chapter, and product development, e.g., a diagnostic test or drug where funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract such as a research grant, career development award, institutional training grant, program project, or research resources award.

Senior/Key Personnel means the principal Investigator or project director and any other person identified as Senior/Key Personnel in the grant application, progress report, or any other report submitted in compliance with the FCOI Regulations.

Significant Financial Interest ("SFI") means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse, domestic partner, and dependent children) that reasonably appear to be *related to the Investigator's Institutional Responsibilities (as defined in this Policy)*:

A. For a publicly traded entity

1. Remuneration in the form of income or payment for services (including salary, and any payment for services not otherwise identified as salary, such as consulting payments, honoraria, paid authorship, or any other payments or consideration of value) received during the prior twelve months and the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds $5,000.

2. Investigators are not required to disclose Significant Financial Interest in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles.

B. For a non-publicly traded entity

1. Remuneration in the form of income or payment for services (including salary, and any payment for services not otherwise identified as salary, such as consulting payments, honoraria, paid authorship, or any other payments or consideration of value) received during the prior twelve months, and any equity interest, such as stock, stock options, or ownership interest in the entity, regardless of value, even if the value cannot be determined by reasonable measures of fair market value.

2. Investigators are not required to disclose any payments made by Baystate; or income for seminars, lectures, teaching engagements, or service on advisory committees or review panels 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.

C. Intellectual property rights and interests:

Income from each organization that exceeds $5,000 received during the previous twelve months except income from royalties received from Baystate related to patents or copyrights.

D. Travel:

1. Reimbursements of any amount received during the prior twelve months made to, or the value of travel paid on behalf of, the Investigator by a for-profit or non- profit organization.

2. Investigators are not required to disclose travel that is reimbursed or sponsored by Baystate, federal, state or local governments, 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

V. INVESTIGATOR RESPONSIBILITIES:

A. Disclosure

Every Investigator named in a grant application, progress report, or other report submitted to a PHS Awarding Component must submit an SFI disclosure in the form required by Baystate at least five (5) business days prior to the submission of an application to a PHS Awarding Component.

Disclosures must be updated:

- within 30 days of discovering or acquiring (e.g., through purchase, marriage, gift, or inheritance) a new SFI;
- annually during the period of the award from the PHS Awarding Component;
- when circumstances change;
- when an Investigator is added to a protocol that is funded by a PHS Awarding Component; and
- as may be required by the DIO.

B. Training

An Investigator must complete training in the requirements of this Policy:

- prior to engaging in research related to a project funded by a PHS Awarding Component
- at least every four years and
- immediately if (1) notified by Baystate that this Policy has been changed in a manner that affects Investigator requirements, (2) an Investigator is new to Baystate, or (3) Baystate finds that an Investigator is not in compliance with this Policy or a management plan.

The DIO and/or the CRCO/RIO will identify training opportunities to meet this requirement.

VI. BAYSTATE RESPONSIBILITIES:

As an institution applying for or receiving research funds from a PHS Awarding Component, the DIO will ensure that Baystate: (1) adopts and maintains an up-to-date, written, enforced policy consistent with the FCOI Regulations, (2) provides training concerning this Policy as required under the FCOI Regulations; (3) requires disclosure of SFIs and review such disclosures to determine whether an FCOI exists and, if so, develop and oversee implementation of a plan to manage the FCOI, (4) makes required reports to the PHS Awarding Component, and (5) ensures public access to required information.

A. Review of Disclosures and Management of FCOI

Prior to the expenditure of any funds received from a PHS Awarding Component, the DIO shall ensure that all Investigator disclosures of SFIs are reviewed promptly. The DIO shall be assisted in this review by

a FCOI Review Committee, chaired by the CRCO/RIO. The FCOI Review Committee will determine for each (1) whether any SFI relates to the proposed or funded research project and (2) whether an FCOI exists and if so, develop and implement a management plan that shall specify actions that have been and shall be taken to manage the FCOI.

A management plan should impose conditions or restrictions to eliminate or mitigate the effect of bias on the design, conduct or reporting of the PHS-funded project. When a management plan is imposed, the DIO in collaboration with appropriate institutional parties will ensure that Investigator compliance is monitored until the completion of the PHS-funded project.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

New Investigator. Whenever an Investigator is new to an ongoing project and discloses an SFI or whenever an existing Investigator discloses a new SFI, Baystate must, within 60 days, review the disclosure to determine whether the SFI is related to the research funded by the PHS Awarding Component, and if so, whether a FCOI exists. Where an FCOI is identified a management plan must be implemented on at least an interim basis. Depending on the nature of the SFI, Baystate may determine that additional interim measures are necessary with regard to the Investigator's participation in the research between the date of disclosure and the completion of Baystate's review.

SFI not timely disclosed. Whenever Baystate identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Baystate, Baystate must, within 60 days of the discovery of the omission, review the Investigator's disclosure to determine whether the SFI is related to the research funded by the PHS Awarding Component, and if so, whether an FCOI exists. Where an FCOI is identified a management plan must be implemented on at least an interim basis; such plan must specify the actions that have been and will be taken to manage the FCOI going forward.

FCOI not timely identified or managed. Whenever Baystate determines that an FCOI was not identified or managed in a timely manner, including because of failure of the Investigator to disclose an SFI that is determined by Baystate to be an FCOI, failure by Baystate to review or manage an FCOI, or failure of an Investigator to comply with a management plan, Baystate must, within 120 days of Baystate's determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine whether any PHS-funded project conducted during the time period of noncompliance, was biased in its design, conduct or reporting. The retrospective review will be documented as

required by the FCOI regulations. If appropriate, Baystate must update the previously submitted FCOI report. If bias is found, Baystate is required to promptly notify the PHS Awarding Component and submit a mitigation report describing the review, including the impact of the bias on the research project and Baystate's plan of action or actions taken to eliminate or mitigate the effect of bias.

B. Reporting Financial Conflict of Interest

Baystate must report an FCOI to the PHS Awarding Component

- prior to any expenditure of funds on PHS-funded research (unless the FCOI has been eliminated prior to the expenditure of funds)
- within 60 days of identification of an FCOI after Baystate's initial FCOI report during an ongoing research project funded by a PHS-Awarding Component (e.g., a determination of an FCOI for a new Investigator or the discovery that an Investigator has not timely disclosed a previously existing SFI or that Baystate failed to review a previously disclosed SFI later determined to be an FCOI)
- following a retrospective review to update a previously submitted report, and
- at least annually during the duration of the PHS-funded research project with the progress report to provide a status report on the FCOI and any changes to the management plan.

All such reports must include information required by the FCOI Regulations and the PHS Awarding Component.

C. Records

Baystate must maintain records relating to all Investigator disclosures and all related records of its review of and responses to such disclosures pursuant to this Policy and the FCOI Regulations for a period of three (3) years from the date of submission of the final expenditures report to the PHS Awarding Component or, for Federal awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, respectively, as reported to the HHS awarding agency or pass-through entity in the case of a subrecipient. These retention periods may differ in the event of: litigation, claim or audit; upon request of the HHS awarding agency; for indirect cost rate proposals and cost allocations plans; and for program income transactions as specified in 45 CFR 75.361. Contact the CRCO if applicable.

D. Public Access

1. Access to the Policy

This Policy is available to the public on the Baystate website, www.baystatehealth.org.

2. Information about Significant Financial Interests

Prior to its expenditure of any funds under a research project sponsored by a PHS Awarding Component, Baystate must ensure that information will be publicly available in response to a written request about any SFI held by Senior/Key Personnel if: (a) the SFI was disclosed to Baystate and is still held by the Investigator; (b) the SFI is related to the PHS-sponsored project; and (c) Baystate has determined that the SFI is an FCOI.

The response must include the name of the Investigator; the Investigator's title and role in the research project; the name of the entity in which the SFI is held; the nature of the SFI; and its approximate dollar value or a statement that the value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

A written request must be sent via first class mail or hand-delivery to the Office of Research, attention: Designated Institutional Official, 3601 Main Street, 3rd Floor, Springfield, MA 01107, or via email to FCOI@baystatehealth.org. Baystate's response must be postmarked (or dated if replying electronically)

within five (5) business days of receipt of the request.

VII. SUBRECIPIENT COMPLIANCE AND REPORTING:

If Baystate carries out a PHS-funded project through one or more subrecipients Baystate must take reasonable steps to ensure that any subrecipient Investigator complies with the FCOI Regulations. Baystate will enter into a written agreement with the subrecipient that includes terms that establish whether this Policy or the FCOI policy of the subrecipient will apply to the subrecipient's Investigators.

Subrecipient's FCOI Policy Applies

If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient must certify as part of its agreement with Baystate that its policy complies with the FCOI Regulations. If the subrecipient cannot provide such a certification, the agreement shall state that the subrecipient Investigators are subject to this Policy for disclosing SFIs that are directly related to the subrecipient's work for Baystate.

The agreement between Baystate and the subrecipient must specify time period(s) for the subrecipient to report all identified FCOIs to Baystate. Such time period(s) must be sufficient to enable Baystate to provide timely FCOI reports, as necessary to the PHS Awarding Component as required by the FCOI Regulations.

Subrecipient Institution Complies with Baystate's Policy

If the subrecipient's Investigators must comply with this Policy, the agreement between Baystate and the subrecipient must specify the time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to Baystate. Such time period(s) shall be sufficient to enable Baystate to comply timely with its review, management, and reporting obligations under the FCOI Regulations.

Subrecipient Investigator Complies with Baystate's Policy

If an Investigator serving as a subrecipient is not affiliated with an institution, the Investigator must fulfill the requirements of this Policy, including submission directly to Baystate of a disclosure form and proof of FCOI training.

Baystate must report to the PHS Awarding Component any FCOI identified by any subrecipient Investigator as required under the FCOI Regulations, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

VIII. REMEDIES:

If an Investigator fails to comply with this Policy or a management plan and the non-compliance appears to have biased the design, conduct, or reporting of the PHS- funded project, Baystate must promptly notify the PHS Awarding Component of actions taken or to be taken. The PHS Awarding Component may take its own action as it deems appropriate, which may include suspension of funding, or may refer the matter to Baystate for further action, which may include directions on how to maintain the objectivity of the research.

Failure to comply with the requirements of this Policy and the FCOI Regulations may result in referral to the appropriate Baystate department or committee for corrective or other appropriate action.

IX. CLINICAL RESEARCH PROJECTS:

If the Department of Health and Human Services determines that a PHS-funded project of clinical

research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with an FCOI that was not properly managed or reported as required by the FCOI Regulations, Baystate must require the Investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts, and oral presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

X. REFERENCES:

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, 42 C.F.R. Part 50, Subpart F
Responsible Prospective Contractors, 45 CFR Part 94 http://grants.nih.gov/grants/policy/coi/
National Institutes of Health FCOI FAQs http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

APPROVALS

		Date:
Approved:	BH Policy Management Committee	12/20/2022
Policy Owner (department name)	Office of Research	
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Reviewers (Stakeholders)	Peter Friedmann, MD, MPH; CRO/ADR, Baystate Health/UMass Chan Med School-Baystate Renee Wroth, JD, CHC VP and Chief Compliance and Privacy Officer	
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