

CAMBRIDGE HEALTH ALLIANCE Title: Conflict of Interest in Public Health Service Funded Research	Policy Number: A-COM-0015 Policy Type: Administrative Effective Date: 08/24/2012
Replaces (supersedes): Title:	Policy Chronicle: Date Original Version of Policy was Effective: August 24, 2012 Most Recent Review (month/year): August 2012 Reviewer: _____ Date: 08/24/24 Print Name: J. Glover Taylor Title: Chief Compliance Officer Previous Reviews: _____ month _____ year Previous Reviews: _____ month _____ year Previous Reviews: _____ month _____ year
Area of Operation(s): Sponsored Research Administration Corporate Compliance General Counsel	
Regulatory Agency: Public Health Service (PHS)	THIS POLICY HAS BEEN REVIEWED AND APPROVED ELECTRONICALLY: Chief Compliance Officer: J. Glover Taylor Chair, Institutional Review Board: Lior Givon, MD General Counsel: Paul Allison Chief Executive Officer: Patrick Wardell
Keyword(s):	Conflict of Interest, Research, Significant Financial Interest

I. Purpose:

This policy establishes the definition of conflict of interest involving research funded by the PHS conducted by Cambridge Health Alliance (CHA) or by CHA investigators. This policy defines requirements for research staff in structuring their relationships with industry and other outside ventures in view of their responsibilities for the ethical conduct of research.

II. Personnel:

All CHA employees, collaborators, or contractors, regardless of title or position, who are responsible for the design, conduct, or reporting of research activities which are funded by the PHS, and any of its components, including National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and Centers for Disease Control (CDC), funding by means of a grant or cooperative agreement.

III. Policy:

A Financial Conflict of Interest exists when it can be reasonably determined that an investigator's financial interests could directly and significantly influence the design, conduct or reporting of research activities. Investigators are required to report any significant financial interests in a timely manner.

The CHA Office of Sponsored Research will determine if a financial conflict of interest exists and develop a proposed resolution. The CHA Conflicts Committee will make final determinations on the resolution of financial

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conflicts of interest. The CHA Institutional Review Board retains authority to make final determinations to disapprove research involving human subjects based on the existence of financial conflicts of interest.

Investigators conducting research funded by the PHS, or any of its components, including the NIH, are subject to agency specific regulations. These regulations set forth the obligations of investigators, sponsors and institutions for research involving significant financial interests or other conflicts of interest, and affected parties are advised to review the relevant regulations prior to submissions of a research proposal or application.

IV. Procedure:

- A) Who is Covered? Investigator means the Principal Investigator/Project Director, Co-principal Investigators, and any other key personnel, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research. In this context, the term "Investigator" also includes the Investigator's spouse and dependent children.

Subrecipients on PHS-funded awards must certify that their policy complies with PHS regulations [42 CFR 50, subpart F](#), Promoting Objectivity in Research. If a subrecipient does not produce this certification, the subrecipient investigators will be covered by this policy.

Recipients of Phase I Small Business Innovative Research (SBIR) or Small Business Technology Transfer applications (STTR) are not covered by this policy.

- B) What is Covered? "Significant Financial Interests" are financial interests that reasonably appear to be related to the investigator's institutional responsibilities. Institutional responsibilities include all the official responsibilities of the individual to CHA (examples include research, research consultation, teaching, professional practice, institutional committee memberships).

1. Significant financial interest in a publicly traded entity occurs when the aggregate of all forms of remuneration from the entity over the past 12 months and the value of any equity interests in the entity exceeds \$5,000. Remuneration includes salary, consulting fees, honoraria, paid authorship, and/or gifts received from the entity within the past 12 months.
2. Significant financial interest in a non-publicly traded entity occurs when the aggregate of all forms of remuneration from the entity over the past 12 months exceeds \$5,000, or when the investigator (or spouse or dependent children) hold any equity interest in the entity.
3. Significant financial interest occurs when the investigator holds intellectual property rights and interests (patents, copyrights) upon receipt of income from those rights.
4. Significant financial interest occurs when the investigator receives reimbursement for or sponsorship of travel related to institutional responsibilities.

"Significant Financial Interest" does not include:

1. Salary, royalties, or other remuneration from CHA.
2. Income from seminars, lectures, or teaching engagements sponsored by government agencies, an institution of higher education, or an academic teaching hospital.
3. Income from services on advisory committees or review panels for government agencies, an institution of higher education, or an academic teaching hospital.
4. Income from investment vehicles, such as mutual funds or retirement accounts, as long as the investigator does not control the investment decisions made in the vehicle.
5. Reimbursed or Sponsored Travel related to institutional responsibilities when reimbursed or sponsored by government agencies, an institution of higher education, or an academic teaching hospital.

- C) When Must A Significant Financial Interest be Disclosed? Each Investigator shall disclose all significant financial interests that would reasonably appear to be related to the investigators institutional responsibilities:

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1. When applying for any PHS funded research, no later than at the time of application for the PHS funded research. This includes applications to transfer PHS funded research to CHA.
2. When participating in PHS funded research, no later than 30 days after acquiring or discovering a new significant financial interest.
3. When participating in PHS funded research, annually when requested by CHA.

D) How Should it be Disclosed?

1. Disclosure upon application for funding: A CHA "Financial Interest Disclosure Form for Federally Funded Research Application" must be completed and submitted along with an application for PHS funding to the CHA Office of Sponsored Research. Investigators are prohibited from expending any PHS funding until after the review of their disclosure and approved resolution of any financial conflicts of interests.

Note that A CHA "IRB Conflict of Interest Disclosure Form" must also be completed and submitted to the IRB along with an IRB Application and Research Proposal.

2. Disclosure upon identification of new significant financial interest: A CHA "Financial Interest Disclosure Form for Federally Funded Research New SFI" must be completed and submitted to the CHA Office of Sponsored Research no later than 30 days after acquiring or discovering the new significant financial interest. In addition, any time there is a significant change in an Investigator's institutional responsibilities, whether in relation to PHS funding or not, the Investigator is to assess whether his/her SFI disclosures are affected.

3. Annual Disclosure: Investigators must submit a Conflict of Interest Disclosure Form annually to the CHA Office of Sponsored Research Administration.

If you are a Harvard Medical School (HMS) Faculty member, you are required to submit a Disclosure Form annually to HMS. Submission of the HMS Disclosure form satisfies the CHA annual disclosure requirement. HMS will forward your completed Disclosure form to the CHA Office of Sponsored Research Administration for review and resolution of any conflicts. HMS will contact you directly each year with the procedures and deadlines for submission.

If you are not a HMS Faculty member, you must submit the CHA Annual Conflict of Interest Form annually to the Office of Sponsored Research Administration. The CHA Office of Sponsored Research Administration will notify you of the procedures and deadlines each year.

E) What Happens to the Disclosure? The CHA Office of Sponsored Research Administration will review each Investigator's disclosure to determine if the significant financial interest might influence the design, conduct, or reporting of the research.

The Office of Sponsored Research Administration will seek input from the Investigator in determining whether a significant financial interest is related to the research. The significant financial interest will be determined to be related to the research if either the significant financial interest could be affected by the research or if the significant financial interest is in an entity whose financial interest could be affected by the research.

When a significant financial interest is determined to be related to the research, the Chief Compliance Officer, in conjunction with CHA Legal Counsel, will determine whether the significant financial interest constitutes a Financial Conflict of Interest. A financial conflict of interest exists if it is determined that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the research. If a financial conflict of interest exists, the Chief Compliance Officer, in conjunction with CHA Legal Counsel, will take the necessary steps to manage the financial conflict of interest, including development, implementation and ongoing monitoring of a management plan, and if necessary, a retrospective review and mitigation report.

The Office of Sponsored Research will make required reports to the PHS. Financial conflicts of interest that require resolution must be resolved prior to the expenditure of related grant funds from PHS. For significant

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financial interests identified during ongoing PHS funded research, or that were not previously disclosed or reviewed in a timely manner, within 60 days of the disclosure, the Chief Compliance Officer will determine whether a financial conflict of interest exists, and if so, implement a management plan.

The Conflict of Interest disclosure form and records of all further actions related to such disclosure will be maintained in the Office of Sponsored Research Administration for three (3) years following submission of the final expenditure report to PHS for the relevant award.

F) Confidentiality of the Conflict of Interest: All disclosures and information provided by an Investigator for the purpose of disclosure and management and all official records of disclosure and management shall be considered confidential, except for disclosures required by law or the PHS regulations. Any information disclosed by an Investigator as required by this policy shall be used solely for the purpose of administering this policy and may not be used for any other purpose, unless required by law. However, CHA has the right to use and share any information for the sole purpose of evaluating, auditing, resolving, and reporting conflict of interest issues.

G) Public Access to information: Upon written request, CHA will disclose within five (5) business days, to the requester financial conflicts of interests related to PHS-funded research and involving Senior/Key personnel for the research project. The information disclosed will include: the investigator's name, title and role in the project; the name of the entity in which the financial interest is held; the nature of the financial interest and the approximate dollars value, or a statement that the value cannot be readily determined through reasonable measures of fair market value.

H) What happens if a Disclosure is not made in time, or if a management plan is not implemented in time?
If an investigator does not disclose a significant financial interest in a timely manner and that interest is determined to create a financial conflict of interest, or if a management plan for a financial conflict of interest is not implemented in a timely manner, the Chief Compliance Officer, in conjunction with CHA Legal Counsel, will develop and implement a management plan at least on an interim basis within 60 days of discovery of the unmanaged financial conflict of interest. In addition, the Chief Compliance Officer, within one hundred twenty (120) days, will complete a retrospective review of the research to determine if the research was biased in the design, conduct or reporting of the research. If bias is found, the Office of Sponsored Research will develop and submit to PHS a mitigation report.

I) Training: The Office of Sponsored Research will provide training to investigators on this policy. Investigators are required to complete training prior to engaging in PHS-funded research. Additionally, investigators must complete training every four years, if CHA revises this policy in a manner that affects the requirements of Investigators, or CHA finds that an Investigator is not in compliance with CHA's financial conflicts of interest policy or management plan.

J) Compliance:

There are serious consequences for not following CHA policies and Federal regulations when conducting research. Failure to properly disclose relevant financial interests or to adhere to conditions or restrictions imposed by the Office of Sponsored Research Administration will be considered a deviation from accepted standards of conducting research at CHA.

Alleged violations of this policy will be investigated by the Office of Sponsored Research Administration. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous, or misleading disclosure forms; or failure to comply with a management plan. If the Office of Sponsored Research Administration determines that the policy has been violated, sanctions may be imposed. Sanctions could include, but are not limited to, termination of the research project; a letter to the investigator's personnel file; and suspension of the privilege to conduct future research at CHA. Violations that result in bias in the design, conduct or reporting of research will be reported to the PHS funding entity.