

Policy:	Financial Conflict of Interest
Type of Policy:	<input checked="" type="checkbox"/> Administrative <input type="checkbox"/> Clinical
Policy Cross Reference(s):	PP 322 Dual Relationships/Conflicts (Applies To All Research, Consulting, Training And Publishing Staff) PP 700 - Principle Seven: Research, Consultation, Training and Publishing PP 710 Compliance with Laws and Standards PP 720 Planning Research PP 730 Institutional Approval PP 740 Informed Consent PP 745 Competency Of Staff PP 750 Research Integrity PP 760 Misconduct, Reporting And Whistleblower Retaliation PP 775 Training
Citation(s):	42 CFR chapter I, subchapter D, part 50, and 42 CFR subtitle A, subchapter A, Part 94

1. Statement of Background and Purposes

The United States Department of Health and Human Services (“DHHS”) has amended its regulations (set forth in 42 CFR chapter I, subchapter D, part 50, and 42 CFR subtitle A, subchapter A, Part 94) (the “Amended Regulations”) to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (“PHS”) grants or cooperative agreements, or performed under PHS contracts will be free from bias resulting from investigator financial conflicts of interest.

This policy details how Chestnut Health Systems, Inc. (“Chestnut”) identifies and addresses potential Financial Conflicts of Interests. It applies to all Chestnut Associates who participate in research funded by the Public Health Service (PHS) agencies and/or hold certain management positions.

2. Definitions

2.1 Associate means all Regular and Term Employees.

2.2 Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

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

2.4 Healthcare-Related Entities include any organization or entity (including both publicly traded and private companies) that provides healthcare-related products or services, including but not limited to:

1. Healthcare providers, including hospitals and clinics
2. Healthcare insurance companies
3. Healthcare research or service organizations
4. Health information technology companies
5. Medical device and equipment manufacturers and distributors

6. Medical technology companies
7. Pharmaceutical companies
8. Other organizations that could be impacted by healthcare-related research, including alcohol, tobacco, or food products companies
9. Any other entity, publicly-traded or private, that could be materially affected by the conduct or results of PHS-funded Research.

2.5 Institutional Responsibilities means an Investigator's professional responsibilities relating to seeking (by submission of proposals for the award of contracts or grants) or conducting PHS-funded Research, including but not limited to: research; peer review; editing, publication, and dissemination of research; service on the Research Integrity Committee; and relevant work performed in administrative or support functions including the General Counsel.

2.6 Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants. For purposes of this policy, the following individuals at Chestnut are considered Investigators when they are responsible for the design, conduct, or reporting of research funded by PHS:

1. All research professionals, regardless of title
2. Research Assistants
3. Peer reviewers
4. Research Integrity Committee members
5. Key members of the administrative staff, including the Chief Operating Officer and General Counsel, Chief Financial Officer, and Director of Lighthouse Institute.

2.7 PHS means the Public Health Service of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health. The PHS includes the agencies listed below:

1. Agency for Healthcare Research and Quality (AHRQ)
2. Agency for Toxic Substances and Disease Registry (ATSDR)
3. Administration on Children, Youth, and Families (ACYF)
4. Centers for Disease Control and Prevention (CDC)
5. Food and Drug Administration (FDA)
6. Health Resources and Services Administration (HRSA)
7. Indian Health Service (IHS)
8. National Institutes of Health (NIH)
9. Office of the Assistant Secretary for Health (OASH)
10. Office of the Assistant Secretary for Preparedness & Response (ASPR)
11. Office of Global Affairs (OGA)
12. Substance Abuse and Mental Health Services Administration (SAMHSA)

2.8 Research means a systematic investigation, study, or experiment designed to develop or contribute to the generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). The term includes any such activity for which research funding is available from PHS.

2.9 Significant Financial Interest (SFI) is described in Section 5.1 below.

3. Overview and Responsibilities

3.1 The United States Department of Health and Human Services has issued regulations pertaining to financial conflicts of interest. The regulations require that all individuals who participate in the design, conduct, or reporting of research funded by the Public Health Service (PHS) agencies complete training on financial conflicts and disclose personal financial interests that could give rise to an actual conflict of interest or the appearance of a conflict. See the full text of the regulations and the final rule implementing the regulations published in the Federal Register for more information.

As detailed in this document, all Chestnut research professionals, including full-time, part-time, will be required to complete training, submit a financial conflict of interest screening form, and disclose relevant Financial Interests if they worked on a PHS-funded project in the preceding year, if they expect to work on a PHS-funded project in the upcoming year, or at any time they are named in a proposal for a PHS-funded project. Key members of management and certain administrative and support department staff also will be required to complete the training and the screening form and provide relevant disclosures, if they are responsible for the design, conduct, or reporting of research funded by the PHS.

The requirements of this Policy should be read in conjunction with Chestnut's Conflict of Interest Policy, which provides general instruction on preventing, recognizing, and mitigating conflicts of interest.

3.2 Responsibilities

- a. **Investigators** are responsible for completing all required training, disclosing all Financial Interests relating to PHS Research, for mitigating risks associated with Significant Financial Interests, and for assisting with the management of any identified FCOI.
- b. The **General Counsel** is responsible for reviewing all disclosed Financial Interests to identify any Significant Financial Interests to determine if they may represent an FCOI. All disclosed Financial Interests shall be reviewed by the General Counsel, and the General Counsel shall provide guidance to the Investigator and to Chestnut management with respect to Significant Financial Interests that may give rise to FCOI. Upon identification of potential FCOI related to a project funded by PHS, the General Counsel will work with the Investigator and the relevant research division or corporate manager to manage the FCOI (Section 5.2 below).
- c. **Management** is responsible for identifying any potential FCOI related to an Investigator's participation in a Research project funded by PHS. Management is also responsible for taking reasonable steps to ensure that subcontractors comply with the Department of Health and Human Services Financial Conflict of Interest regulations.
- d. All **Chestnut Associates** will comply with regulatory requirements relating to our Institutional Responsibilities, including certification of compliance, maintenance of records, responses to requests for information, and reporting requirements.

4. Reporting and Training Requirements

4.1 Requirements

As detailed in Section 4.2 below, all Chestnut Investigators must:

- a. Disclose all Financial Interests relating to Chestnut Research funded by PHS via the Chestnut conflict of interest screening and disclosure form (Section 4.2 below), and
- b. Complete the related conflict of interest training program at least every four years (Section 4.4 below).

Failure to accurately and timely complete the training and the disclosure and to provide updates as required by this policy could result in disciplinary action, up to and including termination.

4.2 Screening & Disclosure Form

The Chestnut conflict of interest screening and disclosure form is available in Chestnut's learning management system. All Investigators must fully and accurately complete the disclosure within the time allotted depending on the circumstances giving rise to the need for disclosure.

- a. **Proposals & Projects.** Investigators named in a proposal for a project funded by PHS must complete the training and the online disclosure before the proposal is submitted. Investigators who were not named in a proposal and who participate in the design, conduct, or reporting of PHS-funded work must complete the training and the online disclosure before beginning any work on a project funded by PHS.
- b. **Continuing Obligation to Update.** All Investigators must update and certify the online disclosure form at least annually. If a financial conflict of interest arises between annual reviews, Investigators must notify Chestnut's General Counsel via email immediately, but no later than 10 days after discovery. For example, changes in a Financial Interest could include (but are not limited to) purchase or inheritance of stock or a change in a spouse/domestic partner's employment. All employees covered by the PHS regulations are expected to recognize their continuing obligation to timely disclose relevant Financial Interests to ensure Chestnut's compliance with the reporting and certification requirements of the PHS regulations.

4.3 Disclosure Thresholds

Chestnut is required to comply with different regulatory and contractual requirements relating to conflicts of interest that require different disclosure thresholds. Because of the variability among the regulatory schemes that apply to Chestnut, and because of the potential for enactment of changes in the disclosure thresholds, Chestnut has not set a minimum threshold for disclosure. This eliminates the need for staff to resubmit disclosures if thresholds are changed and reduces the potential for confusion about the threshold that applies in a particular situation. Investigators therefore are required to disclose the Financial Interests listed in Section 5.2 below, regardless of the value of such Financial Interests.

4.4 PHS Conflict of Interest Training

As part of completion of the disclosure, Investigators are required to certify, at least every four years, completion of all training required by the Investigator's work on Department of Health and Human Services projects.

5. Identifying Significant Financial Interests

5.1 Significant Financial Interests

The General Counsel will review all disclosed Financial Interests and identify any Significant Financial Interests. Generally, a significant Financial Interest is a Financial Interest that is likely to have a material effect on the Research. In the context of PHS research, Significant Financial Interest means a Financial Interest of an Investigator (including the Investigator's spouse or domestic partner, dependent child, or other member of the Investigator's household) in any Healthcare-Related Entity consisting of one or more of the interests identified in Section 5.2 below (Relevant Financial Interests) if:

1. the Financial Interest reasonably appears to be related to the Investigator's Institutional Responsibilities at Chestnut, and
2. the aggregate value of all interests held in a particular Healthcare-Related Entity exceeds \$5,000.

5.2 Relevant Financial Interests

The following Financial Interests may potentially qualify as Significant Financial Interests:

- a. **Remuneration** (including salary, wages, consulting fees, honoraria, and any other fee for services)
- b. **Defined benefit pension payments** or other post-employment payments
- c. Service in a **management position** such as a board member, director, officer, partner, or trustee of a Healthcare-Related Entity

- d. Ownership of an **equity interest** (including stock, stock options, bonds, or any other ownership interest)
- e. Holdings in a **healthcare sector-oriented mutual fund**
- f. **Intellectual property rights** (e.g., patents or copyrights) from which income is received
- g. **Gifts** of more than nominal value (more than \$20) from clients, vendors, or Healthcare-Related Entities
- h. Reimbursed or sponsored **travel** related to an Investigator's Institutional Responsibilities
 1. Sponsored travel means travel expenses paid on behalf of an Investigator (or relevant family member) rather than paid by reimbursement
 2. Travel reimbursed or sponsored by the following is excluded: federal, state, or local government agencies; institutions of higher education; academic teaching hospitals; medical centers; and research institutes affiliated with institutions of higher education.
 3. Investigators will be required to provide the following information with respect to any reimbursed or sponsored travel: name of entity that sponsored or reimbursed any expenses associated with the trip; purpose of the trip; destination; date and duration of the trip; and amount of reimbursement received.

5.3 Excluded Financial Interests

The following Financial Interests do not give rise to Significant Financial Interests and therefore need not be disclosed:

- a. Salary, wages, and remuneration paid by Chestnut
- b. Travel expenses paid or reimbursed by Chestnut
- c. Income from mutual funds and retirement accounts (other than healthcare sector-oriented funds, see Section 5.2(e) above), as long as the Investigator does not directly control the investment decisions made by the funds
- d. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education
- e. Service on advisory committees or review panels for a federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education

6. Review and Evaluation of Disclosed Financial Interests for FCOI

6.1 Identifying FCOI

A disclosure of a Financial Interest does not, by itself, create an impermissible conflict of interest. Each Financial Interest disclosure will be reviewed by the General Counsel. The General Counsel is responsible for determining when an actual or potential conflict of interest exists in a given situation - that is, when a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research - and for taking action as necessary to address and manage such conflicts of interest, including development and implementation of a management plan (see Section 6.2 below). This responsibility will be exercised in cooperation with the relevant research division or corporate manager and with full participation by the Investigator. A variety of criteria may be considered in determining whether a particular Financial Interest creates a conflict of interest with respect to a particular project funded by PHS.

6.2 Managing FCOI

Chestnut will take appropriate steps to address and manage FCOI to ensure that the design, conduct, and reporting of Chestnut's research is free from bias or the appearance of bias. As described in the PHS regulations, some examples of how financial conflicts of interest may be addressed and managed include:

- a. Public disclosure of an Investigator's Significant Financial Interests; disclosures will only occur after notice to and consultation with the Investigator
- b. Disclosure of FCOI directly to participants in Research projects involving human subjects
- c. Monitoring of Research projects by reviewers who do not have FCOI and who are capable of implementing measures to protect the design, conduct, or reporting of the Research against bias arising from identified FCOI
- d. Modification of the research plan, including, for example, change of personnel or personnel responsibilities with respect to particular tasks
- e. Disqualification of personnel from participation in all or a portion of a Research project funded by PHS
- f. Reduction or elimination of a Significant Financial Interest (e.g., sale of stock)
- g. Severance of relationships (e.g., consulting activities) that create actual or potential conflicts.