



Financial Conflicts of Interest in Sponsored Research

Public Health Service Financial Conflict of Interest Training and Disclosure Requirements

This policy details how Astero Technologies LLC (Astero) identifies and addresses potential Financial Conflicts of Interest relating to research funded by the U.S. Department of Health and Human Services Public Health Service agencies to ensure Astero's research is free from bias or the appearance of bias. It applies to all Astero employees who participate in research funded by the Public Health Service agencies.

1. Definitions

1.1 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.

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

1.3 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, dissemination of research, and relevant work performed in administrative or support functions.

1.4 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 Astero are considered Investigators when they are responsible for the design, conduct, or reporting of research funded by the PHS:

- All research professionals, regardless of title
- Peer reviewers
- Research Programmers
- Senior members of the administrative staff

1.5 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:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)



- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Assistant Secretary for Preparedness & Response (ASPR)
- Office of Global Affairs (OGA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

1.6 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.

1.7 Significant Financial Interest (SFI) is described in Section 4.1 below.

2. Overview and Responsibilities

2.1 The U.S. 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 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 Astero employees will be required to complete training 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 staff also will be required to complete the training and provide relevant disclosures, if they are responsible for the design, conduct, or reporting of research funded by the PHS.

2.2 Responsibilities

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.



Astero's Conflict of Interest Official (COI Official) 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 COI Official, and the COI Official shall provide guidance to the Investigator and to Astero management with respect to Significant Financial Interests that may give rise to FCOI. Upon identification of potential FCOI related to a project funded by the PHS, the COI Official will work with the Investigator and Astero management to manage the FCOI (Section 5.2 below).

All Astero employees 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.

3. Reporting and Training Requirements

3.1 Requirements

As detailed in Section 3.2 below, all Astero Investigators must:

- Disclose all Financial Interests relating to Astero Research funded by the PHS via the Astero Financial Disclosure Form (Section 3.2 below), and
- Complete the related conflict of interest training program at least every four years (Section 3.3 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.

3.2 Disclosure Form

The Astero Financial Disclosure Form is available on Astero's internal form repository. All Investigators must fully and accurately complete the disclosure within the time allotted depending on the circumstances giving rise to the need for disclosure.

- **Proposals & Projects.** Investigators named in a proposal for a project funded by the PHS must complete the training and the 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 disclosure before beginning any work on a project funded by the PHS.
- **Continuing Obligation to Update.** All Investigators must update and certify the disclosure form at least annually and within 30 days of receiving, acquiring, or discovering either a new Financial Interest or additional interests from an entity previously disclosed by the Investigator. 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 Astero's compliance with the reporting and certification requirements of the PHS regulations.

3.3 PHS Conflict of Interest Training

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.

4. Identifying Significant Financial Interests

4.1 Significant Financial Interests

The COI Official 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) consisting of one or more of the interests identified in Section 4.2 below if:

- the Financial Interest reasonably appears to be related to the Investigator's Institutional Responsibilities at Astero, and
- the aggregate value of all interests held in a particular entity exceeds **\$5,000**.

4.2 Relevant Financial Interests

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

- Remuneration (including salary, wages, consulting fees, honoraria, and any other fee for services).
- Defined benefit pension payments or other post-employment payments.
- Service in a management position such as a board member, director, officer, partner, or trustee of an entity.
- Ownership of an equity interest (including stock, stock options, bonds, or any other ownership interest).
- Intellectual property rights (e.g., patents or copyrights) from which income is received.
- Gifts of more than nominal value (more than \$20) from clients, vendors, or other entities.
- Reimbursed or sponsored travel related to an Investigator's Institutional Responsibilities.
 - Sponsored travel means travel expenses paid on behalf of an Investigator (or relevant family member) rather than paid by reimbursement.



- 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. Note, however, that the exclusion does not apply to travel reimbursed or sponsored by foreign institutions of higher education, foreign government agencies, or other foreign entities.
- 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.

4.3 Excluded Financial Interests

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

- Salary, wages, and remuneration paid by Astero.
- Travel expenses paid or reimbursed by Astero.
- Income from mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made by the funds.
- 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. This exclusion does not apply to income from seminars, lectures, or teaching engagements sponsored by a foreign institution of higher education, a foreign government agency, or any other foreign entity.
- 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. This exclusion does not apply to service on advisory committees or review panels for a foreign institution of higher education, a foreign government agency, or any other foreign entity.

5. Review and Evaluation of Disclosed Financial Interests for FCOI

5.1 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 COI Official. The COI Official 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 5.2 below). This responsibility will be exercised in cooperation with Astero management 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 the PHS.

5.2 Managing FCOI

Astero will take appropriate steps to address and manage FCOI to ensure that the design, conduct, and reporting of Astero'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:

- Public disclosure of an Investigator's Significant Financial Interests; disclosures will only occur after notice to and consultation with the Investigator.
- Disclosure of FCOI directly to participants in Research projects involving human subjects.
- 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.
- Modification of the research plan, including, for example, change of personnel or personnel responsibilities with respect to particular tasks.
- Disqualification of personnel from participation in all or a portion of a Research project funded by the PHS.
- Reduction or elimination of a Significant Financial Interest (e.g., sale of stock).
- Severance of relationships (e.g., consulting activities) that create actual or potential conflicts.