



# Abington Health

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## Purpose

This Policy is intended to promote objectivity in research and comply with the requirements of 45 C.F.R. § 50, Subpart F. This Policy applies to investigators performing, or planning to perform, federally funded research at Abington Health (“AH”).

## Policy

In order to determine whether a Financial Conflict of Interest exists, Investigators must disclose certain interests (Significant Financial Interests and Sponsored Travel) to Abington Health. Then, the Chief Compliance Officer (the “Designated Official”) will determine whether the disclosed interest is related to the federally funded research that the Investigator is or plans on performing. If the disclosed interest is related to the research, Abington Health will determine whether that disclosed interest could directly and significantly affect the design, conduct, or reporting of the research. If that is the case, a Financial Conflict of Interest exists and must be managed and reported to the appropriate awarding agency.

## Definitions

**Exempt Entity** - means 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.

**Financial Conflict of Interest (“FCOI”)** - means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of federally funded research.

**Family** - means an Investigator’s spouse and/or dependent children.

**Institutional Responsibilities** - means an Investigator’s professional responsibilities while working at AH or performing research at AH.

**Investigator** - means individuals who are responsible for the design, conduct, analysis, or reporting of research funded by the Public Health Service (“PHS”).

**Research** - means a systemic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.

**Senior/Key Personnel** - means the Principal Investigator (“PI”) and any other person identified as senior/key personnel by AH in the grant application, progress report, or any other report submitted to the appropriate awarding agency.

**Significant Financial Interests** - means remuneration received by an Investigator and his or her Family. The Significant Financial Interest may include:

- With regard to any publicly traded entity, when the value of any remuneration (salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest (stock, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value) in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.
- With regard to any non-publicly traded entity, when the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or any equity interest.
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests (aggregate income must exceed \$5,000).
- Examples of Significant Financial Interests:
  - Consulting fees paid to an Investigator by a publically or non-publically traded pharmaceutical company over the last year that total over \$5,000.
  - ANY stock in a non-publically traded medical device manufacturing company owned by an Investigator or their family.
  - Salary and consulting fees paid over the last year to an Investigator's spouse by a biotechnology company that total, in aggregate, over \$5,000.
- Examples of Interests that are not Significant Financial Interests:
  - Salary, royalties, or other remuneration paid by AH to the Investigator if the Investigator is currently employed or otherwise appointed by AH;
  - Intellectual property rights assigned to AH and agreements to share in royalties related to such rights;
  - Salary from or ownership interest in a private physician practice if that practice is the Investigator's primary employer and place of practice.
  - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
  - Income from seminars, lectures, or teaching engagements sponsored by an Exempt Entity;
  - Income from service on advisory committees or review panels for an Exempt Entity.

**Sponsored Travel** – means sponsored or reimbursed travel with a value over \$5,000 related to the Investigator's Institutional Responsibilities. Travel sponsored or reimbursed by an Exempt Entity does not have to be disclosed.

### Procedure

1. Disclosure of Significant Financial Interests of Investigators at Abington Health
  - a) Investigators must disclose Significant Financial Interests that reasonably appear to be related to the Investigator's Institutional Responsibilities:
    - i. No later than at the time of application for federally funded research;
    - ii. Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
    - iii. At least annually during the period of award.

- b) Investigators must disclose any Sponsored Travel related to the Investigator's Institutional Responsibilities.
  - i. The following information related to Sponsored Travel must be disclosed: (1) the purpose of the trip; (2) the identity of the sponsor; (3) the destination; and (4) the duration.

2. Review of Disclosed Significant Financial Interests and Sponsored Travel.

- a) The Designated Official will review the disclosed Significant Financial Interests and Sponsored Travel for each Investigator and determine whether they are related to the federally funded research.
  - i. A Significant Financial Interest or Sponsored Travel is related to the federally funded research if it is reasonably determined that the interest could be affected by the research, or if it is in an entity whose financial interest could be affected by the research.
  
- b) If the Significant Financial Interest or Sponsored Travel is determined by the Designated Official to be related to the research, the Designated Official, in conjunction with a sub-committee of the Institutional Review Board, will then determine whether a Financial Conflict of Interest exists by considering the following:
  - i. The nature and magnitude of an Investigator's Disclosed Interest;
  - ii. The nature and scope of an Investigator's role in the proposed Research;
  - iii. The extent to which the Disclosed Interest could affect or be affected by the research activities;
  - iv. The degree of risk to research participants;
  - v. Whether a conflict of interest can be effectively managed;
  - vi. An Investigator's unique or unusual qualifications to conduct the research; and
  - vii. Whether the research could be conducted as safely or effectively without the Investigator's contributions.

3. Managing Financial Conflicts of Interest.

- a) After it is determined that a Financial Conflict of Interest exists, AH will take such actions as necessary to manage it. The Designated Official, working with a subcommittee of the Institutional Review Board and the Center for Clinical Research will work to develop a management plan. Conditions or restrictions imposed in order to manage, reduce or eliminate conflicts of interest might include the following:
  - i. Public disclosure of the relationships;
  - ii. Prior scientific evaluation and ongoing monitoring of the Research project by independent reviewers;
  - iii. Modification of a Research project;
  - iv. Exclusion of the Investigator from all or part of a Research project; or
  - v. Divestiture or severance of a financial relationship that creates a potential, perceived or actual conflict.

- b) AH shall implement a management plan, on at least an interim basis, within sixty (60) days. Investigators have an obligation to abide by any management plan implemented under this Policy.

#### 4. Retrospective Reviews and Mitigation Reports.

- a) If a Significant Financial Interest was not timely disclosed by an Investigator, was not previously reviewed by AH during an ongoing research project, or the Investigator does not comply with a management plan under this Policy, the Designated Official shall, within sixty (60) days: review the Disclosed Interest; determine whether it is related to the research; determine whether a Financial Conflict of Interest exists; and, if so, implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage the Financial Conflict of Interest going forward.
- b) AH will then, within 120 days of AH's determination of noncompliance, complete a retrospective review of the Investigator's activities and the federally funded research project to determine whether any federally funded research, or portion thereof, conducted during the time period of noncompliance was biased in the design, conduct or reporting of such research. The retrospective review will be documented, and must include all of the following:
  - i. Project number;
  - ii. Project title;
  - iii. Principal Investigator or contact PI if a multiple PI model is used;
  - iv. Name of the Investigator with the Financial Conflict of Interest;
  - v. Name of the entity with which the Investigator has a Financial Conflict of Interest;
  - vi. Reason(s) for the retrospective review;
  - vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
  - viii. Findings of the review; and
  - ix. Conclusions of the review.
- c) Based on the results of the retrospective review, if appropriate, AH will update the previously submitted Financial Conflict of Interest report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, AH will notify the appropriate awarding agency promptly and submit a mitigation report to the awarding agency. The mitigation report must include the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and AH plan of action or actions taken to eliminate or mitigate the effect of the bias.

#### 5. Reporting of Financial Conflicts of Interest.

- a) AH will report Financial Conflicts of Interest to the appropriate awarding agency prior to the expenditure of any funds or, if later disclosed, within sixty (60) days of the

Investigator's disclosure. Additionally, if a Financial Conflict of Interest is reported, AH will submit annual reports to the appropriate awarding agency for the duration of the research project. Such reports will address the status of the Financial Conflict of Interest and any changes to the management plan. Financial Conflicts of Interests that are eliminated prior to the expenditure of any funds do not need to be reported.

- b) The Financial Conflict of Interest reports will include sufficient information to allow the appropriate awarding agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of AH management plan. Such reports will include the following:
    - i. Project number;
    - ii. Principal Investigator or Contact PI if a multiple PI model is used;
    - iii. Name of the Investigator with the financial conflict of interest;
    - iv. Name of the entity with which the Investigator has a financial conflict of interest;
    - v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
    - vi. Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
    - vii. A description of how the financial interest relates to the research and the basis for AH determination that the financial interest conflicts with such research; and
    - viii. A description of the key elements of AH 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 Investigator compliance; and other information as needed.
  - c) AH will report to the appropriate awarding agency if an Investigator fails to comply with this Policy, or a management plan for a Financial Conflict of Interest. AH will also take appropriate corrective action for the Investigator noncompliance.
  - d) AH will submit any other notifications or reports required by the applicable regulations.
6. AH will provide training to Investigators in order to inform them about the federal regulations, the Investigator's disclosure responsibilities, and this Policy. Investigators will need to complete this training prior to engaging in the federally funded research, and at least every four years thereafter. Additionally, Investigators will be required to complete training immediately if:
- a) AH revises this policy in a way that affects the Investigator's requirements;
  - b) An Investigator is new to AH; or
  - c) An Investigator is not in compliance with this Policy or a management plan for a

## Financial Conflict Of Interest.

7. Subrecipients. Investigators performing research at AH through a sub-award agreement of a different institution must also follow this Policy. Investigators must disclose any Significant Financial Interests or Sponsored Travel to AH. After review and potential management by AH, the prime grant awardee will be notified of the FCOI. Additionally, if AH carries out Research through sub-grantees, contractors, or collaborators, AH shall require such sub-grantee, contractor, or collaborator to agree to comply with this Policy or has its own policy on Financial Conflicts of Interest and certifies, through the sub-award agreement or other contract, that its policy complies with the applicable regulations.
8. Public Accessibility. AH shall provide any person, within five (5) days of a request, with the information about a Senior/Key Personnel as required by 45 C.F.R. § 50.605(a)(5). Additionally, this Policy shall be posted on AH's public website – [abingtonhealth.org](http://abingtonhealth.org) .
9. Records. AH shall maintain records of Investigator disclosures and all actions taken by AH during the review, management, and reporting of Financial Conflicts of Interest, for at least three years from the date of the submission of the final expenditures report, or from other dates as otherwise required by 45 C.F.R. § 74.53(b) or 45 C.F.R. § 92.42(b).
10. Enforcement. Sanctions for violation of this Policy may include suspension or termination of employment, loss of the privilege of conducting Research at or in connection with AH, loss of medical staff privileges, cessation of funding, loss of administrative, scientific and/or medical responsibilities, liability for damages and other appropriate sanctions. AH must also notify the appropriate awarding agency of any Investigator noncompliance with this Policy or a management plan for a known Financial Conflict of Interest.
11. Disclosure. If a federally funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this Policy, the Investigator(s) must disclose the conflicting interest in each public presentation of the results of the research and request an addendum to previously published presentations.
12. Compliance. This Policy is intended to comply with the requirements of 45 C.F.R. § 50, Subpart F. To the extent that this Policy conflicts with the applicable regulations, the regulations control.