

# Financial Conflict of Interest in Research Policy

## Policy:

It is Agile Health's policy to promote objectivity in research by establishing standards and practices that:

- comply with [Title 42 Code of Federal Regulations \(CFR\), Part 50, Subpart F](#);
- compel Investigators participating in research funded under U. S. Public Health Service (PHS) grants or cooperative agreement to comply with the training, disclosure, and other requirements therein; and
- provide a reasonable expectation that the design, conduct, or reporting of funded research, grants or cooperative agreements will be free from bias resulting from Investigator's financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children).

## Scope:

This policy applies to Investigators participating in, or planning to participate in the design, conduct, reporting or proposing research. It does not apply to applications and awards supported under the Small Business Innovation Research Phase I Program or the Small Business Technology Transfer Phase I program.

If a research project involves subcontractors, subgrantees, or subawardees (collectively subrecipients), the subrecipient institution must provide written assurance that a financial conflict of interest in research policy is in effect at that institution and compliant with all applicable federal regulations. Should Public Health Service (PHS) funds be subcontracted by Agile Health to a subrecipient institution without a conflict of interest in research policy, a written agreement must state that this policy shall apply to the subrecipient.

## Definitions:

**Awardee Institution** means the organization that receives a prime award directly from PHS and under that prime award issues a subaward to a subrecipient.

**Management Plan** means the written plan developed to manage conflicts by mitigating reducing or eliminating Financial Conflicts of Interest so that the design, conduct or reporting of research is free from bias or the appearance of bias.

**Entity** means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) from which an Investigator (and/or the Investigator's spouse and/or dependent children) receives remuneration, or in which any person has an ownership or equity interest.

**Financial Interest** means anything of monetary value or potential monetary value held by the Investigator, the Investigator's spouse and/or dependent children whether or not the value is readily ascertainable

**Financial Conflict of Interest (FCOI)** means a Significant Financial Interest related to a research program or project that could directly and significantly affect the design, conduct or reporting of research.

**Institution** means any domestic or foreign, public or private, entity or organization (excluding a Federal Agency) that is applying for, or receives, PHS research funding.

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**Institutional Official** means the individual who is legally authorized to act for and on behalf of Agile Health and is responsible for implementation of this policy, including solicitation and review of disclosures of significant financial interest from research Investigators, and identification and management of Financial Conflicts of Interest on behalf of the Institution.

**Institutional Responsibilities** means an Investigator's professional responsibilities on behalf of Agile Health including, but not limited to, activities such as research, consultation, chairing or serving on committees, advisory boards, etc.

**Investigator** means the project director/principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposing of research, including persons who are subcontractors, collaborators or consultants.

**Management** means actions taken to address a financial conflict of interest, which can include reducing or eliminating the Financial Conflict of Interest, and to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**PD/PI** means the project director or principal investigator of a research project.

**Public Health Service (PHS) Awarding Component** means the organizational unit of the PHS that funds the research (e.g., National Institutes of Health).

**Research** means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research through which an investigator collects data through intervention or interaction with animal or human subjects, or from identifiable private information. The term encompasses basic and applied research and product development. The term also includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS or other statutory authority.

**Senior/Key Personnel** means the Project Director/Principal Investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

**Significant Financial Interest (SFI)** means

1. A financial interest consisting of one or more of the following interests of the Investigator (and/or of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - a. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Equity interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
  - b. With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (and/or the Investigator's spouse and/or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

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- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. For PHS-funded investigators, any reimbursed or sponsored travel related to an Investigator's institutional responsibilities, including that which is paid on behalf of the investigator so that the exact monetary value may not be readily available.
3. The term *significant financial interest* **does not include** the following types of financial interests:
  - a. Salary, royalties, or other remuneration paid by Agile Health to the Investigator if the Investigator is currently employed or otherwise appointed by Agile Health, including intellectual property rights assigned to Agile Health and agreements to share in royalties related to such rights; 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.
  - b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local 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.
  - c. Income from 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.
  - d. Travel by a PHS-funded Investigator that is reimbursed or 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.

**Small Business Innovation Research (SBIR) Program** - the extramural research program for small businesses established by the awarding components of certain Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. The term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Publiclaw 102-564.

## Procedure

### A. Investigator Responsibilities

Investigators are responsible for:

- Disclosing all significant financial interests
- Providing updates to disclosed information as needed
- If acting as the PI/PD, providing a list of individuals who meet the definition of "investigator" within the required disclosure timeline
- Completing all required training and education
- Completing the annual disclosure form even if they have no financial interests to report.

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## **B. Disclosure**

Each Investigator who is planning to participate in the PHS-funded research for which Agile Health is the Awardee Institution or a subrecipient must disclose to the Institutional Official via the Disclosure of Financial Interests Form attached hereto as Exhibit A his/her significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

Each Investigator who is participating in the PHS-funded research for which Agile Health is the Awardee Institution or a subrecipient must submit an updated disclosure of significant financial interests at least annually during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution) and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Additionally, any Investigator who is participating in the PHS-funded research must submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

In each case, Investigators are required to complete the Disclosure of Financial Interests Form even if they have no financial interest to report.

## **C. Financial Conflicts of Interest**

A financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of research. Examples include, but are not limited to, the following:

- a. Investigator (and/or an Investigator's spouse and/or dependent children) entering into a paid consultancy with an outside entity that has an interest in the investigator's Agile Health-based research;
- b. Investigator (and/or an investigator's spouse and/or dependent children) receiving royalties or non-royalty payments related to ongoing research; or
- c. Investigator (and/or an investigator's spouse and/or dependent children) having an equity interest (e.g., stocks, stock options, warrants) related to ongoing research.

This policy addresses individual financial conflicts of interest; however, Agile Health may also have conflicts of interest in research whenever the financial interests of Agile Health, or of a Agile Health official acting within his or her authority on behalf of Agile Health, might affect—or reasonably appear to affect—Agile Health processes for the conduct, review, or oversight of research. If institutional conflicts of interest are identified via the process described below, they will normally be addressed in a manner that is consistent with this policy.

## **D. Review of FCOIs**

The Institutional Official will conduct reviews of all disclosures, including any SFI that has been identified in a disclosure. These interests will be compared to each research

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subaward funded under a PHS prime award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research subaward.

## Guidelines for Determining “Relatedness” and Financial Conflict of Interest

The Institutional Official will determine whether an Investigator’s SFI is related to the research under a subaward supported by a PHS prime award and, if so, whether the SFI is a financial conflict of interest. An Investigator’s SFI is related to the research under the subaward when the Institutional Official reasonably determines that the SFI: could be affected by the research conducted under the subaward; or is in an entity whose financial interest could be affected by the research. The Institutional Official may involve the Investigator in the determination of whether a SFI is related to the research supported by the subaward.

A financial conflict of interest exists when the Institutional Official reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. In determining if an Investigator’s SFI creates a FCOI, the Institutional Official will consider relevant factors including but not limited to the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, risks to rights and safety of animal and/or human research subjects, the value of the SFI in relation to the size and value of the entity, the appearance of conflict of interest and the impact on integrity of research data. If a financial conflict of interest is identified, the Institutional Official will determine whether the research can be undertaken with appropriate management.

## **E. Management of FCOIs**

If a conflict of interest exists, the Institutional Official will determine by what means the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the Institutional Official will be guided by the principles discussed in this Policy. The Institutional Official will also take into consideration whether the Investigator’s ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

For cases that require management, a Management Plan will be developed by the Institutional Official. The Management Plan will be developed collaboratively and examples of conditions or restrictions that may be employed to manage conflicts include:

- a. public disclosure of significant financial interests (e.g., when presenting or publishing the research), if appropriate;
- b. disclosure of significant financial interests directly to subjects involved in human research;
- c. appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;
- d. modification of research plan;
- e. change of personnel or personnel responsibilities or disqualification from participation in all or a portion of the research;
- f. reduction or elimination of the financial interest (e.g., sale of an equity interest);

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- g. severance of relationships that create the actual or potential conflict of interest; or
- h. If it proves impossible to reach an acceptable Management Plan, funds will be returned to the sponsor.

If the Institutional Official determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the applicable Investigator, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor.

No expenditures on a PHS award or subaward involving the Investigator will be permitted until the Investigator has complied with the disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the Institutional Official to be necessary to manage the Financial Conflict of Interest. The Institutional Official will communicate, in writing, with the PHS Award Component or the applicable Awardee Institution, and with any applicable subrecipient(s) if applicable to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the FCOI has been reported to the PHS Award Component. Agile Health or the applicable Awardee Institution will notify subrecipient(s) when expenditures may be incurred

If Agile Health identifies a SFI that was not disclosed or reviewed in a timely manner it will initiate the review process and an interim management plan will be implemented when necessary.

## **F. Monitoring**

If the Institutional Official prescribes monitoring of the activity, the Management Plan will describe what monitoring shall be performed and what records are to be kept. Investigator compliance with Management Plans will be monitored by Agile Health officials, or by an independent monitor if prescribed in the Management Plan. The frequency of monitoring will be dictated by sponsor/agency requirements and Management Plan provisions.

## **G. Maintenance of Records**

The Institutional Official will keep a record of Investigator disclosures of financial interests and the Institutional Official's review of, and response to, such disclosure and all actions under this policy. Agile Health will maintain all records related to the implementation of this policy for at least three years after:

- the date of creation;
- the date of termination or completion of a research award or contract;
- the submission of the final expenditures report; or
- the date of final resolution of any investigation, audit, or similar action involving the records.

## **H. Appeals**

Investigators may appeal in writing within 15 days of receipt of the finalized management plan or other decision of the Institutional Official. The written appeal should include details regarding circumstances which support the request for a proposed revision to a

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decision made by the Institutional Official. An Appeals Committee will be formed for purposes of investigating the appeal and making a final decision. A meeting of the Appeals Committee will be convened to review the SFI information, the Management Plan, and the appeal to make a decision. The Investigator may be invited to describe reasons for the appeal and to address further questions. The appeals process will take no more than 60 days from the date requested by the Investigator. The decision of the appeals committee is final and binding.

## **I. Confidentiality**

Financial and other information disclosed in compliance with this policy will be kept confidential and disclosed only on a need-to-know basis as required to perform appropriate review and evaluation required by the policy, except in the case of required public accessibility of identified financial conflicts of interest held by senior/key personnel (see Section N).

## **J. Enforcement**

Failure on the part of an Investigator to comply with this policy will result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the PHS Awarding Component or Agile Health.

## **K. Subrecipients**

For PHS-funded research that involves subcontractors, subgrantees or subawardees (collectively subrecipients) at other Institutions, Agile Health will require a written agreement that includes terms that establish whether the FCOI policy of the Awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. This agreement will specifically address time periods to meet disclosure and/or financial conflict of interest reporting requirements.

Subrecipient Institutions who rely on their Financial Conflict of Interest policy must certify that their FCOI policy complies with the regulations and must report identified financial conflicts of interests to the Institutional Official in sufficient time to allow the Agile Health to report the FCOI to the PHS Awarding Component as required by regulation.

Subrecipients who do not have such a conflict of interest policy will be required to follow the Agile Health FCOI in Research policy. In this case, the written agreement terms required by Agile Health will contain a provision requiring that subrecipient Investigators will report to Agile Health as the Awardee Institution and will complete and submit Disclosures to the Institutional Official in sufficient time to allow Agile Health to identify, manage and report identified FCOI to the PHS Awarding Component as required by regulation.

A subrecipient's failure to promptly comply with the Agile Health policy will be considered grounds for immediate termination by Agile Health of any applicable subcontract or subaward.

## **L. Reporting**

Agile Health will provide to the PHS Awarding Component a FCOI report as outlined in the

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regulations:

Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI. Agile Health will also provide a FCOI report within 60 calendar days from the date when a new SFI disclosure for an existing investigator is determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project, or the Institution identifies a FCOI not previously disclosed. This report will include the following information:

- Grant/Contract Number
- PD/PI
- Name of Investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement or honoraria)
- 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
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
- Key elements of the Management Plan

Annual updates: to this report will be submitted to the PHS Awarding Component for the duration of the research project. The annual report will include:

- Status of the FCOI
- Changes to the Management Plan
- Justification if FCOI no longer exists

## **M. Travel Disclosure**

PHS-funded Investigators must disclose the occurrence of reimbursable or sponsored travel related to their institutional responsibilities, **regardless of the value**. At a minimum the travel disclosure must include:

- Purpose of the trip
- Identity of the sponsor/organizer
- Destination
- Length
- Monetary value, if known

The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

- 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



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- a medical center, or
- a research institute that is affiliated with an Institution of higher education

Travel disclosures will be reviewed by the Institutional Official to determine if the travel represents a FCOI with PHS-funded research. Additional information may be requested at the time of review. Disclosure of travel must occur no more than 30 days after the last day of the trip.

## **N. Public Accessibility**

This policy will be posted on the Agile Health public website [www.agilehealth.com](http://www.agilehealth.com). In addition, information concerning identified FCOIs held by senior/key personnel will be made available to requestors via an email response within five business days from when the Research Official receives the request. This information may be requested by calling Agile Health at (847) 955-1905 or emailing [research@agilehealth.com](mailto:research@agilehealth.com).

The written response will include:

- Senior/key personnel name
- Senior/key personnel's role in the research project
- Name of the entity in which the FCOI is held
- Nature of the FCOI
- Approximate dollar value of the FCOI or a statement that the value cannot be readily determined

This information will be updated annually, as well as within 60 days of a newly identified FCOI, and will remain available for three years from the date the information was most recently updated.

## **O. Training Requirements**

PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter. Training must also be completed as soon as reasonably possible under the following circumstances:

- This policy changes in a manner that affects Investigator requirements
- An Investigator is new to Agile Health and will be working on PHS-funded research
- An Investigator is found to be noncompliant with this policy or his/her approved Management Plan

In fulfillment of the training requirement, Agile Health requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at:

<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training, promptly provide the Institutional Official with a copy, and retain the original for audit purposes. Note: Subrecipient organizations can develop and/or consider other compliant training opportunities.

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## **P. Investigator/Institutional Non-Compliance**

If an SFI is not disclosed or reviewed in a timely manner, Agile Health will review the Investigator's financial interest, determine if it is related to PHS-funded research; and determine whether a FCOI exists, and if so:

- Implement a Management Plan for ongoing research, at a minimum implement an interim Management Plan;
- Complete and document a retrospective review of Investigator's activities and the PHS-funded research project within 120 days of a non-compliance finding to determine if bias was present in the design, conduct, or reporting of such research; and
- If bias/non-compliance is found, the Institution will promptly inform the PHS Awarding Component by submitting a mitigation report.

Thereafter, Agile Health shall submit FCOI reports annually to the PHS Award Component, in accordance with the regulation. If the Department of Health and Human Services determines that a PHS-funded clinical research project 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 managed or reported by Agile Health, the Investigator must disclose the FCOI in each public presentation of the results of the research and must request an addendum to previously published presentations.



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## EXHIBIT A1 Supplemental Information

Provided in addition to Disclosure of Financial Interests Form for: \_\_\_\_\_

Reporting for  self  family member:  
name: \_\_\_\_\_  
relationship: \_\_\_\_\_

Name of External Entity: \_\_\_\_\_  
Address of External Entity: \_\_\_\_\_

Type of external relationship: (check all that apply)

<input type="checkbox"/>	Consultant
<input type="checkbox"/>	Speaker
<input type="checkbox"/>	Advisory Board or Committee
<input type="checkbox"/>	Equity Holdings
<input type="checkbox"/>	Governing Board or Officer
<input type="checkbox"/>	Intellectual Property Rights
<input type="checkbox"/>	Royalty Income
<input type="checkbox"/>	Other (describe below)

Amount of compensation or financial interest in reporting period: \$ \_\_\_\_\_

If travel paid by entity:  
Destination \_\_\_\_\_  
Amount \$ \_\_\_\_\_

Comments or explanatory information: