

# Objectivity in Research - Conflict of Interest Policy

## Introduction:

The purpose of this Policy is to promote objectivity in Research by assuming responsibility for ensuring that the financial interests of staff members do not compromise the objectivity with which research or activity is designed, conducted, or reported. This Policy has been amended to comply with the final rule issued by the U.S. Department of Health and Human Services (HHS) amending the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). To meet the requirements of those regulations, Altarum Institute has adopted this Policy, as amended, which will continue in effect until rescinded or modified by appropriate authority.

This Policy applies to proposals made to and sponsored projects supported wholly or in part by the U.S. Public Health Service, the National Institutes of Health, the National Science Foundation, and other U.S. government agencies that announce regulations on conflict of interest (or objectivity in research).

## Policy:

It is the policy of Altarum that no proposed, awarded, or ongoing Research project at Altarum will be biased by any Significant Financial Interest of any Investigator responsible for the design, conduct, or reporting of that Research project.

## Definition of Terms:

*“Designated Official”* means the individual within the Institute that is responsible for the solicitation and review of disclosures of Significant Financial Interests related to the Investigator’s Institutional Responsibilities. For the purposes of this Policy, the Designated Official is the Director of Legal Affairs.

*“Family”* means any member of the Investigator’s immediate family, including dependent children and spouse.

*“FCOI Management Plan”* means a Financial Conflict of Interest management plan that includes, at a minimum, the following:

- a) Role and principal duties of the conflicted Investigator in the Research project;
- b) Conditions of the plan;
- c) How the plan is designed to safeguard objectivity in the Research project;
- d) Confirmation of the Investigator’s agreement to the plan;
- e) How the plan will be monitored to ensure Investigator compliance; and
- f) Other information, as needed.

*“Financial Conflict of Interest”* or *“FCOI”* means a Significant Financial Interest (or, where the Designated Official requires disclosure of other Financial Interests, a Financial Interest) that the Institute reasonably determines could directly and significantly affect the design, conduct or reporting of Institute or PHS-funded Research.

*“Financial Interest”* means anything of monetary value received or held by an Investigator or an Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to:

## Objectivity in Research – Conflict of Interest Policy (cont'd) Page 2 of 7

salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

“*Financial Interest*” does not include:

- a) salary, royalties, or other remuneration from the Institute;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

For Investigators, “*Financial Interest*” also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her Institutional Responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

“*Institution*” or “*Institute*” means Altarum Institute.

“*Institutional Responsibilities*” means the Investigator’s responsibilities associated with his or her position at the Institute, including, but not limited to, research activities, consulting activities, etc.

“*Investigator*” means any individual who is responsible for the design, conduct, or reporting of PHS-funded Research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal.

“*Public Health Service*” or “*PHS*” means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated.

“*Research*” means a systematic investigation, study, or experiment designed to contribute to 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).

“*Significant Financial Interest*” or “*SFI*” means a Financial Interest that reasonably appears to be related to the Investigator’s Institutional Responsibilities, and:

- 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 disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for

## Objectivity in Research – Conflict of Interest Policy (cont'd) Page 3 of 7

- services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; or
- 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 (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

### **Conflict of Interest:**

Altarum's expectation is that Investigators will conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. This Policy informs staff about situations that generate conflicts of interest related to Research, provides mechanisms for Investigators and the Institute to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator who applies for or receives PHS funding has an obligation to become familiar with, and abide by, the provisions of this Policy. If a situation raising questions of conflict of interest arises, an Investigator must immediately discuss the situation with the Designated Official.

### **Disclosure of Financial Interests:**

All Investigators are required to disclose their outside financial interests, as it relates to their Institutional Responsibilities, to the Institute at the time of application for PHS-funded Research, on an annual and on an as needed or required basis. In addition to the required disclosures, the Investigator should disclose any other financial or related interests that could present an actual or perceived conflict of interest. The Designated Official, or designee, is responsible for the distribution, receipt, processing, review and retention of Disclosure Forms.

#### *Initial Disclosure*

All Investigators must disclose their Significant Financial Interests to the Institute, at the time of application for PHS funding.

#### *Annual Disclosures*

All Investigators must disclose their Significant Financial Interests to the Institute, at least annually while any of their projects remain supported by PHS funding.

#### *Additional Disclosures*

In addition to the annual disclosure, certain situations may require disclosure. All Investigators must disclose their Significant Financial Interests to the Institute, through the Designated Official, within 30 days of their initial appointment.

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## Objectivity in Research – Conflict of Interest Policy (cont'd) Page 4 of 7

Prior to entering into sponsored projects or applications for sponsored projects for PHS-funded Research, where the Investigator has a Significant Financial Interest, the Investigator must submit to the Designated Official an updated disclosure of his or her Significant Financial Interests. The Institute will not submit a research proposal for PHS-funded Research unless the Investigator(s) has submitted the disclosure.

In addition, all Investigators with PHS-funded Research must submit to the Designated Official a disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring a Significant Financial Interest.

### *Travel*

Investigators must also disclose reimbursed or sponsored travel related to their employment responsibilities. A disclosure of all sponsored travel other than that specifically exempted by the FCOI rules must be submitted to the Institute when travel sponsored by a single entity or company is valued at more than \$5,000 in the 12 months preceding disclosure, or within 30 days of reaching the \$5,000 threshold. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Designated Official will determine if additional information is needed to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's PHS-funded Research.

### **Review and Decision of the Designated Official:**

If the Disclosure Form reveals a Significant Financial Interest, it will be reviewed promptly by the Designated Official for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Designated Official will take action to eliminate, reduce, or manage the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Designated Official determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded Research. If the Designated Official determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written FCOI Management Plan before any related PHS-funded Research proceeds. The affected Investigator is responsible for developing and submitting a proposed management plan, in consultation with the Designated Official.

To address complex situations, committees may be established by the Designated Official to periodically review the ongoing activity, to monitor the conduct of the activity, to ensure open and timely dissemination of the Research results, and to otherwise oversee compliance with the FCOI Management Plan.

### **Subrecipient Requirements:**

Subrecipient requirements will be established through a written agreement between the Institute and the subrecipient, and will address whether the subrecipient will follow this Policy, the Financial Conflict of Interest policy of the PHS prime awardee, or the Financial Conflict of

## Objectivity in Research – Conflict of Interest Policy (cont'd) Page 5 of 7

Interest policy of the subrecipient. If the latter, the subrecipient will certify that the subrecipient's Financial Conflict of Interest policy complies with the regulation, and will provide any additional information that may be necessary to allow the prime awardee to fulfill their reporting obligations to PHS.

### **Reporting to PHS and the PHS Prime Awardee:**

In the event of an FCOI on a Research project, the Designated Official will prepare FCOI Reports for PHS and the PHS Prime Awardee, as applicable, which include the following information:

- Agreement number and title
- Name of project manager
- Name of Investigator with an FCOI
- Name of the entity with which the Investigator has an FCOI
- Nature of the Significant Financial Interest
- Value of the Significant Financial Interest
- Description of how the Significant Financial Interest relates to the Research project, and the basis for the Designated Official's determination that the Significant Financial Interest constitutes an FCOI
- Description of the Institute's FCOI Management Plan, including role and principal duties of the Investigator with the FCOI; how the FCOI Management Plan is designed to safeguard objectivity in the Research project; confirmation that Investigator agrees with the FCOI Management Plan; and how the FCOI Management Plan will be monitored

The FCOI Reports will be made initially and on an annual basis, as well as within 60 days of identifying a new FCOI. Should any reported conflict or non-compliance require reporting to PHS, the Designated Official, or designee, will report in accordance with PHS regulations. If the funding for the Research is made available from a PHS prime awardee, such reporting will be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

### **Enforcement and Sanctions:**

#### *Disciplinary Action*

In the event of an Investigator's failure to comply with this Policy, the Designated Official may pursue suspension of all relevant Research activities or pursue other disciplinary action, following established Institute procedures, until the matter is resolved or other action deemed appropriate by the Designated Official is implemented.

The Designated Official's decision to pursue sanctions on, or pursue other action against, an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Designated Official, will be described in a written explanation of the decision to the Investigator, and other administrative areas of the Institute, and will notify the individual of the right to appeal the decision.

## Objectivity in Research – Conflict of Interest Policy (cont'd) Page 6 of 7

### *Retrospective Review*

If the Designated Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with an approved management plan for a Financial Conflict of Interest, the Designated Official will, within 60 days, review the SFI, determine if an FCOI exists, report the FCOI to PHS, and implement an interim FCOI Management Plan, if needed. If the funding for the Research is made available from a PHS prime awardee, such reporting will be made available to the prime awardee such that they may fulfill their reporting obligations to PHS. The Designated Official will complete a full retrospective review of the Investigator's activities and the Research project to determine whether the Research conducted during the period of non-compliance was biased in the design, conduct or reporting of the Research.

This retrospective review will be completed and documented within 120 days of the retrospective review and will include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Designated Official, or designee, will update any previously submitted report to the PHS or the prime PHS awardee relating to the Research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, PHS and the PHS prime awardee, if any, will be notified immediately, and a report submitted containing a mitigation report in accordance with the PHS regulations, including the key elements of the review, a description of the impact of the bias on the Research project, and the plan of action to eliminate or mitigate the effect of the bias. Thereafter, FCOI reports will be submitted annually.

### **Training:**

Each Investigator must complete training on this Policy prior to engaging in Research funded by PHS, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Designated Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this Policy or with an FCOI Management Plan related to their activities.

### **Record Retention:**

The Designated Official will maintain records of all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to PHS or to the PHS prime, or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

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## Objectivity in Research – Conflict of Interest Policy (cont'd) Page 7 of 7

### **Confidentiality:**

To the extent permitted by law, all Disclosure Forms, FCOI Management Plans, and related information will be confidential. However, the Institute may make such information available to an agency funding Research, to a requestor of information concerning FCOIs related to PHS funding, or to the PHS prime awardee, if required. If the Institute is requested to provide Disclosure Forms, FOIC Management Plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

### **Public Accessibility:**

The Institute will respond to a requestor, as required by law, within five business days of the request, concerning a Significant Financial Interest that meets the following criteria:

- The Significant Financial Interest was disclosed and is still held by the Investigator;
- A determination has been made that the Significant Financial Interest is related to PHS-funded Research; and
- A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

In the event of an SFI, the Designated Official will prepare a Public Financial Conflict of Interest Disclosure Form, including the following information, for reported FCOIs such that it can be made publicly available upon request:

- Investigator's name;
- Investigator's title and role with respect to the Research project;
- Name of the entity in which the relevant SFI is held;
- Nature of the relevant SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.); and
- Approximate dollar value of the relevant SFI (dollar ranges are permissible: \$5,000-\$9,999; \$10,000-\$19,999; etc.).

### **Regulatory Authority:**

This Policy implements the requirements of 42 CFR 50 and 45 CFR 94. In the event of substantive differences between this Policy and the requirements, the requirements will take precedence.