

# Auburn University at Montgomery Procedures for Public Health Service Financial Conflicts of Interest Regulations

## Introduction

The Public Health Service (PHS) has issued its final rule entitled “**Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.**” 42 CFR Part 50, Subpart F/45 CFR Part 94. These regulations are commonly referred to as the “FCOI Regulations.” The purpose of the FCOI Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under PHS grants, cooperative agreements, or contracts will be free from bias resulting from Investigator financial conflicts of interest. 42 CFR 50.601/45 CFR 94.4 An Institution applying for or that receives PHS research funding by means of a grant, cooperative agreement, or contract must be in compliance with the FCOI Regulations 42 CFR 50.602 no later **August 24, 2012.**

Auburn University at Montgomery (“the University”) has adopted a PHS Financial Conflict of Interest Policy (“PHS FCOI Policy”) to meet the requirements outlined in the FCOI Regulations. 42 CFR 50.604(a) The following related procedures supplement the PHS FCOI Policy and are not intended to substitute for compliance with the Alabama code of ethics for public officials and employees. (Code of Alabama 1975 Title 36, Chapter 25).

### 1. Definitions

**Authorized Institutional Representative** – is, for the purposes of FCOI Regulations, the Provost and Senior Vice Chancellor.

**Dean** – a college or school’s senior academic dean or counterpart.

**Disclosure Form** – a form submitted by an Investigator to the University disclosing Significant Financial Interest(s) as required by FCOI Regulations, the University’s PHS FCOI Policy, and these procedures.

**Entity** – any domestic or foreign, public or non-public (private) organization from which an Investigator (and his/her Immediate Family) receives remuneration or in which they have an ownership or equity interest.

**Financial Conflict of Interest**- a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded Research. 42 CFR 50.603

**Financial Interest** - anything of monetary value, whether or not the value is readily ascertainable. 42 CFR 50.603

**Immediate Family** – the Investigator’s spouse and dependent children. Throughout these procedures, Significant Financial Interest of the Investigator also shall include the interest of the Investigator’s Immediate Family. 42 CFR 50.603

**Institutional Responsibilities**- Investigator's professional responsibilities on behalf of the University, including activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. 42 CFR 50.603

**Investigator** – 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 the PHS, or proposed for such funding, which may include for example, collaborators or consultants. 42 CFR 50.603

**Manage** – taking action to address a Financial Conflict of Interest, which may include, reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of Research will be free from bias. 42 CFR 50.603

**Management Plan** – a written document signed by the Reviewer, Investigator, and other appropriate individuals and supervisors outlining the specific steps to be taken to address Financial Conflict of Interest.

**Mitigation Report** – a report from the University to PHS which must be submitted when bias is found during a Retrospective Review

**Public Health Service** – all PHS agencies (including, but not limited to, National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA) and the Agency for Healthcare Research and Quality (AHRQ)). Throughout these procedures, PHS will be used in reference to the respective PHS Awarding Components.

**Research** - a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in these procedures, the term 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 Act or other statutory authority. 42 CFR 50.603

**Retrospective Review** – a compliance review conducted by the University of a Financial Conflict of Interest that was not identified or Managed in a timely manner

**Reviewer** – a responsible representative of the University who reviews the Disclosure Form to determine if a Significant Financial Interest is a Financial Conflict of Interest; determines what conditions

or restrictions, if any, should be imposed by the University to Manage a Financial Conflict of Interest; conducts Retrospective Reviews; drafts Mitigation Reports; and ensures that FCOI reports are submitted as required. This individual is the Associate Provost for Graduate Studies and Faculty Services through the Office of the Provost, other individuals as appointed by the Authorized Institutional Representative, or the Provost and Senior Vice Chancellor should the Associate Provost have a Conflict of Interest associated with the issue at hand. **42 CFR 50.604(d)**

**Senior/Key Personnel** - the Project Director/Principal Investigator (PD/PI) and any other person identified as Senior/Key Personnel by the University in the grant application, progress report, or any other report submitted to PHS by the Institution as required by regulation. **42 CFR 50.603**

**Significant Financial Interest** - A Financial Interest consisting of one or more of the following interests of the Investigator (and the Investigator's Immediate Family) or any reimbursed or sponsored travel that reasonably appears to be related to the Investigator's Institutional Responsibilities. **42 CFR 50.603**

Publicly Traded-Entities - 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. **42 CFR 50.603**

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 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. **42 CFR 50.603**

Non-Publicly Traded Entity - 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 Immediate Family) holds **any** equity interest (e.g., stock, stock option, or other ownership interest). **42 CFR 50.603**

Intellectual Property - Intellectual property rights and interests (e.g., patents, copyrights), upon **receipt** of income related to such rights and interests. **42 CFR 50.603**

Travel Reimbursement - Investigators must disclose the occurrence of **any** reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; in the 12 months preceding the disclosure; provided, however, that this does not apply to travel that is reimbursed or sponsored by 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. **42 CFR 50.603**

The term *Significant Financial Interest* **does not** include the following types of Financial Interests: salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties

related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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 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; or income from service on advisory committees or review panels for 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. **42 CFR 50.603**

## **2. Mandatory Investigator Training**

Each Investigator is required to complete Financial Conflict of Interest Training prior to engaging in Research related to any PHS-funded grant, cooperative agreement or contract; at least every four years thereafter; and immediately when any of the following apply: (1) the University revises its PHS FCOI Policy or these Procedures in any manner that affects the requirements of Investigators; (2) an Investigator is newly appointed at the University; or (3) the University finds that an Investigator is not in compliance with the University's PHS FCOI Policy, these Procedures, or a Management Plan. **42 CFR 50.604(b)**

## **3. Investigator Disclosure of SFI**

Each Investigator planning to participate in PHS-funded Research is required to complete a Disclosure Form which includes the Investigator's Significant Financial Interests (and those of the Investigator's Immediate Family) to the University's PHS Reviewer prior to the time of application for PHS-funded Research. **42 CFR 50.604(e)(1)**

Each Investigator participating in PHS-funded Research is required to submit an updated Disclosure Form which includes the Investigator's Significant Financial Interests (and those of the Investigator's Immediate Family) at least annually, between August 1 and August 31, during the period of the award; prior to the processing of a new award or modification to the scope of work; and within thirty days of discovering or acquiring a new Significant Financial Interest for themselves (or their Immediate Family). **42 CFR 50.604(e)(2)&(3)**

Annual disclosures from Investigators should include any information that was not disclosed initially to the University during the planning/proposal stage of the project or in a subsequent disclosure of Significant Financial Interest and shall include updated information regarding any previously disclosed Significant Financial Interest. **42 CFR 50.604(e)(2)**

## **4. Review and Determination**

Prior to the expenditure of any funds under a PHS-funded Research project, the Reviewer must review all Investigator disclosures of Significant Financial Interests. The Reviewer will determine whether an Investigator's Significant Financial Interest is a Financial Conflict of Interest. Such determination will be made when the Significant Financial Interest is reasonably related to the PHS funded Research (i.e. could

be affected by the PHS-funded Research or is in an Entity whose Financial Interest could be affected by the Research) and the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded Research. The Reviewer may involve the Investigator in the determination of whether a Significant Financial Interest is related to the PHS-funded Research or may involve consultants or others as they deem appropriate to carry out any of the Reviewer's responsibilities as described in the PHS FCOI Regulations, AUM PHS Policy, or these Procedures. 42 CFR 50.604(f) & 42 CFR 50.605(a)(1)

For travel reimbursements (reimbursement or sponsored travel), the Investigator must, at a minimum, disclose the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Reviewer will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest with the PHS-funded Research. 42 CFR 50.603

For ongoing PHS-funded Research projects, when an Investigator who is new to participating in the Research project discloses a Significant Financial Interest; an existing Investigator discloses a new Significant Financial Interest; or any situation where a Significant Financial Interest is identified that was not previously reviewed, the Reviewer must, within sixty (60) days, review the disclosure to determine whether a Financial Conflict of Interest exists in relation to PHS-funded Research. The Reviewer may determine that interim measures are necessary with regard to the Investigator's participation in the PHS-funded Research project between the date of disclosure and the completion of the Reviewers review process. 42 CFR 50.604(f) & 42 CFR 50.605(a)(3)

## 5. Management of FCOI

For any Financial Conflict of Interest, the University will take necessary actions to Manage Financial Conflicts of Interest, including any related to sub-recipient Investigator(s). Management of an identified Financial Conflict of Interest is determined by the Reviewer and requires development and implementation of a Management Plan which will be monitored for compliance on an ongoing basis until the completion of the PHS-funded Research project. 42 CFR 50.604(g) & 42 CFR 50.605(a)(3) If necessary, the Reviewer will conduct a Retrospective Review and develop a Mitigation Report as described below. 42 CFR 50.604(g)

Examples of conditions or restrictions that might be imposed to Manage a Financial Conflict of Interest include, but are not limited to: public disclosure of Financial Conflicts of Interest (e.g., when presenting or publishing the Research); for Research projects involving human subjects Research, disclosure of financial conflicts of interest directly to participants; appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the Financial Conflict of Interest; modification of the Research plan; change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research; reduction or elimination of the Financial Interest (e.g., sale of an equity interest); or severance of relationships that create financial conflicts. 42 CFR 50.605(a)(1)

For ongoing PHS-funded Research projects where Significant Financial Interests are not disclosed prior to the initiation of the project or reviewed prior to the initiation of a project, the Reviewer may implement an interim Management Plan until the review process is completed and a final Management Plan or other such management actions can be established. 42 CFR 50.605(a)(2)

If the Financial Conflict of Interest is not identified or Managed in a timely manner due to the failure of the Investigator to disclose a Significant Financial Interest that is determined by the Reviewer to be a Financial Conflict of Interest; the failure of the Reviewer to review or Manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Management Plan, the Reviewer shall, within 120 days of the determination of noncompliance, complete a Retrospective Review. The Retrospective Review will determine whether any PHS-funded Research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such Research. If bias is found during the Retrospective Review, PHS will be notified promptly and a Mitigation Report submitted to PHS. Based on the results of the Retrospective Review, previously submitted FCOI reports will be updated as necessary to specify the actions that will be taken to Manage the Financial Conflict of Interest going forward. Thereafter, the Institution will submit FCOI reports annually. 42 CFR 50.605(a)(3)

Documentation of the Retrospective Review will include but not necessarily be limited to, all of the following key elements: project number; project title; Project Director/Principal Investigator (PD/PI) or contact PD/PI if a multiple PD/PI model is used; name of the Investigator with the Financial Conflict of Interest; name of the Entity with which the Investigator has a Financial Conflict of Interest; reason(s) for the Retrospective Review; detailed methodology used for the Retrospective Review (e.g., methodology of the review process, composition of the review panel, documents reviewed); findings of the Retrospective Review; and conclusions of the Retrospective Review. 42 CFR 50.605(a)(3)

The Mitigation Report will include, at a minimum, key elements documented in the Retrospective Review and a description of the impact of the bias on the Research project and University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the Research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the Research project is salvageable). 42 CFR 50.605(a)(3)

## **6. FCOI Reports to PHS 42 CFR 50.604(h)**

Prior to the expenditure of any funds under a PHS-funded Research project, the University will submit an FCOI Report to PHS regarding any Investigator's Significant Financial Interest found by the Reviewer to be conflicting. If the Reviewer identifies a Financial Conflict of Interest and eliminates it prior to the expenditure of PHS-awarded funds, an FCOI Report is not required to be submitted to PHS. 42 CFR 50.605(b)(1)

For any Significant Financial Interest that the Reviewer identifies as conflicting subsequent to the Institution's initial FCOI Report during an ongoing PHS-funded Research project (e.g., upon the participation of an Investigator who is new to the Research project), the Reviewer shall provide to PHS, within sixty (60) days, an FCOI report regarding the Financial Conflict of Interest. 42 CFR 50.605(b)(2)

An FCOI Report fulfilling the requirements as stated above will include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's Management Plan. The report shall include, at a minimum, the project number; Project Director/Principal Investigator (PD/PI) or Contact PD/PI if a multiple PD/PI model is used; name of the Investigator with the Financial Conflict of Interest; name of the Entity with which the Investigator has a Financial Conflict of Interest; nature of the Financial Interest (e.g., equity, consulting fee, travel reimbursement, honorarium); value of the Financial Interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000;

amounts above \$100,000 by increments of \$50,000), 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; a description of how the Financial Interest relates to the PHS-funded Research and the basis for the University's determination that the Financial Interest conflicts with such Research; and a description of the key elements of the 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. [42 CFR 50.605\(b\)\(3\)](#)

For any Financial Conflict of Interest previously reported by the Institution with regard to an ongoing PHS-funded Research project, the Institution shall provide to PHS an Annual FCOI Report that addresses the status of the Financial Conflict of Interest and any changes to the Management Plan for the duration of the PHS-funded Research project (including extensions with or without funds). The Annual FCOI report shall specify whether the financial conflict is still being Managed or explain why the Financial Conflict of Interest no longer exists. [42 CFR 50.605\(b\)\(4\)](#)

In addition to FCOI Reports to PHS, see Section 5 "Management of FCOI" for information on reporting Retrospective Reviews and Mitigation Reports to PHS.

## **7. Appeals Process**

Within one week of notification of the Reviewer's decision, the Investigator must acknowledge, in writing, agreement to comply with any required Management Plan or submit a written request for reconsideration to the Authorized Institutional Representative who may recommend to the Reviewer that they delete a requirement. The Authorized Institutional Representative may not alter or remove a requirement. The Authorized Institutional Representative may add requirements to a Conflict Management Plan at his or her discretion. Based upon a response from the Reviewer, the Authorized Institutional Representative will issue a final binding decision on the appeal. The Investigator has the right for a timely decision by all parties in the process. The time from submission of a written request from the Investigator for reconsideration to final resolution by the Authorized Institutional Representative should not exceed 30 days.

## **8. Sub-recipient Compliance & Reporting**

When the University carries out PHS-funded Research through a sub-recipient (e.g., subcontractors or consortium members), the University will take reasonable steps to ensure that any sub-recipient Investigator complies with the FCOI Regulations. The sub-recipient Institution may elect to have sub-recipient Investigator(s) governed by the their Financial Conflict of Interest Policy and Procedures provided they are in compliance with FCOI Regulations or the sub-recipient Institution may elect to have sub-recipient Investigator(s) governed by the University's PHS FCOI Policy and these Procedures. The subcontract must include a statement clarifying whether the sub-recipient Institution or the University's PHS FCOI Policy and these Procedures will govern the sub-recipient Investigator(s). [42 CFR 50.604\(c\)](#)

If the sub-recipient Investigator(s) will be governed by the sub-recipient's Financial Conflict of Interest Policy and Procedures, the Sub-recipient must certify in the subcontract that their Financial Conflict of Interest Policy and Procedures comply with the FCOI Regulations. The subcontract shall specify the time period(s) for the sub-recipient to report all identified Financial Conflicts of Interest(s) to the University.



Such time period(s) shall be sufficient to enable the University to provide timely FCOI reports, as required, to PHS. [42 CFR 50.604\(c\)](#)

If the sub-recipient cannot provide such certification or elects to have the sub-recipient Investigators governed by the University's PHS FCOI Policy and Procedures, the subcontract shall state that sub-recipient Investigators are subject to the PHS FCOI Policy and Procedures of the University for disclosing Significant Financial Interests that are directly related to the sub-recipient's work for the University. The subcontract shall specify time period(s) for the sub-recipient to submit all Investigator disclosures of Significant Financial Interests to the University. Such time period(s) shall be sufficient to enable the University to comply timely with its review, management, and reporting obligations to PHS. [42 CFR 50.604\(c\)](#)

Regardless of the governing Financial Conflict of Interest Policy and Procedures for sub-recipient Investigators, the University will be responsible for providing FCOI reports to PHS regarding all Financial Conflicts of Interest of all sub-recipient Investigators, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI. [42 CFR 50.604\(c\)](#)

## **9. Remedies**

If an Investigator fails to comply with the University's PHS FCOI Policy, these Procedures, or a Management Plan and the non-compliance appears to have biased the design, conduct, or reporting of the PHS-funded Research, the University will promptly notify the PHS of the corrective action taken or to be taken. [42 CFR 50.606\(a\)](#)

For clinical projects supported by PHS, if HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with a Financial Conflict of Interest that was not Managed as required by PHS FCOI Regulations, the University shall require the Investigator(s) involved to disclose the Financial Conflict of Interest in each public presentation of the results of the Research and to request an addendum to previously published presentations. [42 CFR 50.606\(b\)](#)

## **10. Public Disclosure**

The University is required by PHS under the PHS FCOI Regulations to provide public disclosure through a publically accessible website or through a process for responding to requests for information related to Significant Financial Interests disclosed to the institution. In response to written requests concerning any Significant Financial Interest disclosed to the University which at the time of the request is held by the Senior/Key Personnel which the Reviewer has determined is related to PHS-funded Research and constitutes a Financial Conflict of Interest, the University will respond within five (5) business days of the written request for information. [42 CFR 50.605\(a\)\(5\)](#)

The following will be disclosed pursuant to the FCOI Regulations: the Investigator's name; the Investigator's title and role with respect to the Research project; the name of the Entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; and the approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), 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. 42 CFR 50.605(a)(5)

The University will notify the requestor in writing that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty (60) days of the Institution's identification of a new Financial Conflict of Interest, which would need to be requested subsequently by the requestor. 42 CFR 50.605(a)(5)

Information concerning the Significant Financial Interests of an Investigator subject to public disclosure shall remain available, for responses to written request for at least three (3) years from the date that the information was most recently updated. 42 CFR 50.605(a)(5)

## **11. Enforcement & Sanctions**

The University is required by PHS under the FCOI Regulations to establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance. Sanctions shall apply for non-compliance with the University's PHS FCOI Policy and these Procedures. 42 CFR 50.604(j) The appropriate Deans (or designated Associate Dean) or the Provost (or designated Associate Provost) shall utilize the standard faculty or staff disciplinary procedures or other applicable University disciplinary policies or guidelines which may result in suspension, dismissal, or severance of relationship with the University. Other sanctions may be imposed, including, but not limited to:

- Withdrawal of any compromised proposal(s)
- Halt expenditures from involved funds
- Suspend ongoing Research project(s)
- Remove the non-compliant investigator from a project(s)
- Terminate the involved sponsored project(s) or other agreements
- Penalties if Conflict of Interest is determined to be in violation of the Alabama Ethics Act
- Falsification of Information may invoke the University Research Misconduct Policy

## **12. Records Maintenance**

The University, through the Authorized Institutional Representative, will maintain all Disclosure Forms, review and response documentation, and all related records of actions taken by the University with respect to disclosures of Financial Interest(s) of Investigators for a period of three (3) years from the date the final expenditures report is submitted to PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations. 42 CFR 50.604(i). The content of such records are considered confidential to the extent allowable by applicable laws and regulations.

## **13. Certifications**

The Reviewer will be required to certify that the Disclosure Form has been filed. To ensure compliance with sponsor regulations, the University will require such certification before approval for submission of the proposal is given by the Authorized Institutional Representative. The Investigator and the Reviewer will provide additional certification that any Financial Conflict of Interest has been Managed before the Authorized Institutional Representative will accept an award on behalf of the University.

The Authorized Institutional Representative shall, as appropriate, be responsible for certifying in each application for funding to PHS, that the Institution: has an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all Research projects for which funding is sought or received from the PHS; shall promote and enforce Investigator compliance with this subpart's requirements including those pertaining to disclosure of Significant Financial Interests; shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this subpart; agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of Financial Interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a Financial Conflict of Interest; and shall fully comply with the PHS FCOI Regulations. [42 CFR 50.604\(k\)](#)