Proposed Amended USF System Policy

Number: 0-309

Subject: Individual Conflicts of Interest in USF System Research Projects and USF System Financial Conflict of Interest (FCOI)

Date of Origin: 08-30-96          Date Last Amended: 08-17-12          Date Last Reviewed: 08-17-12

I. INTRODUCTION-PURPOSE & INTENT

As a public institution, the University of South Florida System (USF System) has the responsibility for ensuring that all its activities, including those related to research, are carried out responsibly, and with the highest degree of integrity. An Investigator* on a USF System Research Project* may have financial interests or proprietary interests, may wish to employ a Related Person on the project, or may wish to engage in activities of an entrepreneurial nature that could pose an actual or potential Conflict of Interest* with research in which the Investigator is participating. Such conflicts are not prohibited, nor are they inherently unethical. However, these potential conflicts must be disclosed by the Investigator, reviewed by the USF System, and the conflicts managed or eliminated before the research may proceed.

The purpose of this Policy is:

(1) To implement the provisions of the Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought and Responsible Prospective Contractors (42 CFR Part 50 and 45 CFR Part 94) (“PHS Objectivity in Research Rule”) for research involving Investigators who are planning to participate in a USF System Research Project funded by the Public Health Service (PHS) or any other Federal agency or extramural sponsor that has adopted the PHS Objectivity in Research Rule (“Funded by PHS”*) (“PHS-Funded Investigators”*) (Section II); and

(2) To provide a process for ensuring that any Conflicts of Interest that an Investigator may have in connection with a USF System Research Project is fully disclosed, reviewed in accordance with established procedures, and satisfactorily resolved before the USF System Research Project is initiated, regardless of funding.
Investigators, including PHS-Funded Investigators, who have a Conflict of Interest with a USF System Research Project must comply with this policy by accessing the eCOI disclosure system at https://arc.research.usf.edu/Prod and following the procedures for disclosure of the Investigator’s interests, or those of the Investigator’s Immediate Family*.

II. INDIVIDUAL FINANCIAL RELATIONSHIPS IN USF SYSTEM RESEARCH PROJECTS FUNDED BY THE PUBLIC HEALTH SERVICE (PHS) (“USF SYSTEM FINANCIAL CONFLICTS OF INTEREST POLICY”)

A. Scope and Applicability. Section II, also known as the USF System Financial Conflicts of Interest (FCOI) Policy, applies only to PHS-Funded Investigators*. If the PHS-Funded Investigator is employed at an institution other than the USF System, or is participating in the USF System Research Project Funded By PHS* through a subcontract, subaward or other agreement, then the Investigator is a PHS-Funded Subrecipient Investigator*, and subject to Section II.C. The definition of USF System Research Project Funded By PHS, and therefore applicability of this USF System FCOI Policy (Section II), will be expanded to include other Federal Agencies and Extramural Sponsors as those entities adopt regulations that mirror the PHS Objectivity in Research Rule. See the definition of “Funded by PHS” for the current list of sponsors, in addition to all units of PHS, in connection with whose funding this USF System FCOI Policy must be applied.

B. Financial Conflict of Interest (FCOI) Policy

i. Investigator Disclosure. A PHS-Funded Investigator must fully disclose whether they PHS-Funded Investigator or their PHS-Funded Investigator’s Immediate Family* has a Significant Financial Interest* (SFI) that reasonably appears to be related to the PHS-Funded Investigator’s Institutional Responsibilities*. Such SFI disclosures must be made as follows:

1. No later than the date of submission of a proposal for a USF System Research Project Funded By PHS; and

2. Updated at the time of Notice of Award; and

3. Within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance); and

4. Annually updated during the Period of the Award* to reflect any change in the value or status of the SFI.
ii. **Investigator Training.** PHS-Funded Investigators are required to complete training with respect to the USF System FCOI Policy, their PHS-Funded Investigator's responsibilities regarding disclosure of SFI, and the PHS Objectivity in Research Rule ("FCOI Training"):  
1. *Prior to engaging in the USF System Research Project Funded by PHS*; and  
2. *At least every three years, during the Period of the Award*; and  
3. *Immediately, when any of the following circumstances apply:*  
   a. The USF System revises the USF System FCOI Policy or its associated procedures in any manner that affects PHS-Funded Investigator requirements; or  
   b. A PHS-Funded Investigator is new to the USF System; or  
   c. The USF System finds that a PHS-Funded Investigator is in noncompliance with the USF System FCOI Policy or an FCOI Management plan.  

iii. **USF System Review and Management of SFI Disclosures, and FCOI Reporting.** The USF System, through its conflict of interest review, management, and reporting process, will:  
1. Determine, in consultation with the PHS-Funded Investigator, whether any SFI disclosed by the Investigator is related to a USF System Research Project Funded By PHS; and, if so  
2. Determine whether the SFI constitutes a Financial Conflict of Interest* (FCOI); and, if so,  
3. Take appropriate action to manage the FCOI(s), including the creation of an FCOI Management Plan*; and  
4. Report any so determined FCOIs and any associated FCOI Management Plans to the appropriate Funding Agency (in the manner directed by the Funding Agency¹), as follows:  
   a. *Prior to the expenditure of funds* for SFI determined by the USF System to be a FCOI; and  
   b. *Within 60 days* of any subsequently identified FCOI; and

¹ For example, all FCOI reports must be submitted to the NIH through the electronic Research Administration (eRA) Commons FCOI Module. See NIH Guide for Grants and Contracts, Notice No. NOT-OD-09-072.
c. *Annually* updated during the Period of the Award in the time and manner specified by the Funding Agency, specifying whether the FCOI is still being managed or explaining why the FCOI no longer exists.

In those cases where the USF System identifies an FCOI and eliminates it prior to the expenditure of funds, the USF System shall not submit an FCOI report to the Funding Agency.

iv. **USF System FCOI Monitoring.** Once an FCOI is identified per Section II.B.3, the USF System will require that the USF System Research Project Funded by PHS be monitored to ensure adherence of the PHS-Funded Investigator to the FCOI Management Plan.

v. **USF System Review of SFI's Not Timely Disclosed or Reviewed.** Whenever the USF System identifies an SFI that was not disclosed by a PHS-Funded Investigator in accordance with the timeframes specified in Section II.B.1 a.-c., or, for whatever reason, was not previously reviewed by the USF System, the USF System will, within 60 days:

1. Review the SFI and determine whether it is Related to the USF System Research Project Funded By PHS; and
2. Determine whether an FCOI exists; and, if so
3. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

vi. **USF System Retrospective Review and Determination of Bias In Design, Conduct or Reporting of Research.** If, during the course of reviewing an SFI not timely disclosed or reviewed under Section II.B.5., the USF System determines that an FCOI exists, or if the USF System finds that a PHS-Funded Investigator has failed to comply with an FCOI Management Plan, the USF System shall, within 120 days:

a. Complete a Retrospective Review of the PHS-Funded Investigator's activities and the USF System Research Project Funded By PHS to determine whether any portion of the research was biased in the design, conduct, or reporting of such research prior to the identification and management of the FCOI or during the period of the Investigator’s noncompliance of the PHS-Funded Investigator with the FCOI Management Plan; and, if so,
b. Document the Retrospective Review, including but not limited to:
   a. Project number;
   b. Project title;
   c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
   d. Name of the PHS-Funded Investigator with the FCOI;
   e. Entity with which the PHS-Funded Investigator has an FCOI;
   f. Reason(s) for the Retrospective Review;
   g. Detailed methodology used for the Retrospective Review (e.g., methodology of the Retrospective Review process, composition of the Retrospective Review panel, documents reviewed);
   h. Findings of the Retrospective Review (i.e., facts and observations); and
   i. Conclusions of the Retrospective Review (i.e., determination and recommended actions).

Depending on the nature of the FCOI, the USF System may determine that additional interim measures are necessary between the date that the FCOI or the date the Investigator’s noncompliance is determined and the completion of the Retrospective Review with regard to the PHS-Funded Investigator’s participation in the USF System Research Project Funded By PHS.

**vii. Mitigation Report.** If bias is found by the USF System during the Retrospective Review under Section II.B.6., The USF System must:

1. Notify the Funding Agency promptly; and
2. Submit a mitigation report to the Funding Agency, including but not limited to:
   a. The elements documented in Section II.B.6.b.;
   b. A description of the impact of the bias on the USF System Research Project Funded By PHS; and
   c. The USF System’s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the USF System Research Project Funded By PHS; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the USF System Research Project Funded By PHS is salvageable).

3. Submit FCOI reports annually, as specified in Section II.B.3.d.
C. **PHS-Funded Subrecipient Investigators.** Where any portion of a USF System Research Project Funded By PHS is carried out through a PHS-Funded Subrecipient Investigator, the USF System will incorporate terms into the written agreement (the “Subrecipient Agreement”) with the subrecipient institution (“Subrecipient Institution”) that establish whether the USF System’s or the Subrecipient Institution’s FCOI Policy will apply to PHS-Funded Subrecipient Investigators.

i. **Subrecipient Institution FCOI Policy Applies.** When the Subrecipient Agreement stipulates that the Subrecipient Institution’s FCOI Policy will apply, the USF System must receive certification from the Subrecipient Institution must also certify in the Subrecipient Agreement that its FCOI Policy complies with the PHS Objectivity in Research Rule, (“Subrecipient Certification”). The Subrecipient Agreement will further stipulate that the Subrecipient Certification must be received by the USF System designated official(s) within 10 days following the execution of the Subrecipient Agreement. Finally, the Subrecipient Agreement will stipulate that the Subrecipient Investigators will be subject to the USF System FCOI Policy unless and until such time as the Subrecipient Institution assumes responsibility for such disclosures by providing the USF System with a Subrecipient Certification.

a. **Time Periods for Subrecipients FCOI Reporting to USF System.** The written Subrecipient Agreement will further specify the time period(s) within which the Subrecipient Institution must report all identified FCOIs to the USF System, which time period(s) shall be sufficient to enable the USF System to provide timely reporting of the FCOIs to the Funding Agency per Section II. B.3.d.

b. **Requirement to Make PHS-Funded Subrecipient Investigator FCOI Information Publicly Accessible.** The Subrecipient Agreement will require the Subrecipient Institution to make FCOI information of its Investigators on the USF System Research Project publicly accessible as required by the PHS Objectivity in Research Rule.

ii. **USF System FCOI Policy Applies.** PHS-Funded Subrecipient Investigators will be subject to the USF System FCOI Policy if: 1) the USF System does not receive the Subrecipient Certification per Section II.C. 1.; 2) the Subrecipient Agreement stipulates that the Subrecipient Investigators are subject to the USF FCOI Policy; or 3) the Subrecipient Investigator is not affiliated with an institution that has an
FCOI Policy compliant with the PHS Objectivity in Research Rule. If the USF System FCOI Policy applies, the USF System will directly notify the Subrecipient Investigator(s) that the Investigator(s) is(are) subject to the USF System FCOI Policy and must disclose SFIs that are directly related to the Investigator’s work on the USF System Research Project.

a. **Time Periods for Reporting Disclosures.** If the parties elect to apply the USF System FCOI Policy, the Subrecipient Agreement will specify the time period(s) (both initially and throughout the Period of the Award) wherein PHS-Funded Subrecipient Investigators will be required to disclose their SFIs that are directly related to the Investigator’s work for the USF System via the USF System e- COI Disclosure System. Such time period(s) must be sufficient to enable the USF System to comply in a timely manner with its review, management, and reporting obligations under Sections II.B.3.

D. **Public Accessibility to FCOI Information.** The USF System will make information about FCOIs it has identified through its conflict of interest review and management process (“FCOI Information”) publicly available by responding in writing to requests for such information within five business days of receipt by the COI Administrator of such requests. Public disclosures of a PHS-Funded Investigator’s FCOI information will include the following information:

i. Name, title, and role of the PHS-Funded Investigator on the USF System Research Project;

ii. Name of the entity in which the SFI is held (if applicable); and

iii. Nature and approximate dollar value or range of the SFI, or a statement that the value cannot be readily determined.

E. **Procedures.**

i. All USF PHS-Funded Investigators are required to disclose whether the Investigator or the Investigator’s Immediate Family have an SFI that reasonably appears to be related to their Institutional Responsibilities (or for PHS-Funded Subrecipient Investigators, SFIs that are directly related to the PHS-Funded Subrecipient Investigator’s work for the USF System) through the eCOI Disclosure system, the procedures for which may be found at: https://arc.research.usf.edu/Prod.
ii. All PHS-Funded Subrecipient Investigators not registered with the Federal Demonstration Partnership (FDP) Clearinghouse as having a PHS-compliant COI policy are required to complete USF’s Documentation of Subrecipient Financial Conflict of Interest Policy Form A either in paper or online via the following link: http://www.research.usf.edu/dric/conflicts-of-interest/forms/form-a/. Those PHS-Funded Subrecipient Investigators that do not have a PHS-compliant COI policy and thus must follow the USF System FCOI Policy must also complete USF’s Significant Financial Interest(s) Disclosure Form B, either in paper or online.

III. INDIVIDUAL FINANCIAL RELATIONSHIPS IN USF SYSTEM RESEARCH PROJECTS (OTHER THAN USF SYSTEM RESEARCH PROJECTS FUNDED BY PHS)

A. Scope and Applicability. Section III applies to an Investigator planning to participate in a USF System Research Project (other than a USF System Research Project Funded By PHS), including Subrecipient Investigators*. If a Subrecipient Investigator is employed at an institution that has a conflict of interest review process, then that institution’s conflict of interest review policy and review process will apply and any potential conflicts will not be managed by the USF System.

B. Policy. An Investigator must fully disclose whether the Investigator or the Investigator’s Immediate Family* has a Reportable Financial Interest or Relationship* Related to a USF System Research Project*. Such disclosures must be made as follows:

i. Prior to the initiation of a USF System Research Project; and

ii. Within thirty (30) days of discovering or acquiring a new Reportable Financial Interest or Relationship (e.g., through purchase, marriage, or inheritance); and

iii. Annually updated during the Period of the Award* to reflect any change in the value or status of the Reportable Financial Interest or Relationship.

If the USF System determines that any Reportable Financial Interest or Relationship may affect the design, conduct, or reporting of the USF System Research Project, steps will be taken to manage or eliminate the conflict. If a management plan is required in order for the USF System Research Project to proceed, then the USF System Research Project may be monitored by the USF System to ensure proper adherence to the management plan.
C. Procedures. USF Investigators are required to disclose whether the Investigator or the Investigator’s Immediate Family* has a Reportable Financial Interest or Relationship* Related to a USF System Research Project* through the eCOI disclosure system, the procedures for which may be found at: https://arc.research.usf.edu/Prod.

IV. EMPLOYMENT OF RELATED PERSONS

MANAGING RELATIONSHIPS IN USF SYSTEM RESEARCH PROJECTS

A. Scope and Applicability. This section applies to all Investigators, including PHS-Funded Investigators, who intend to employ a Related Person* on a USF System Research Project.

B. Policy. Employment of a Related Person on a USF System Research Project is permitted only when such employment will not involve or create a conflict of interest. Prior to the employment of a Related Person on a USF System Research Project, an Investigator must fully disclose the proposed employment so that the proposed employment and any accompanying issues can be appropriately reviewed by the USF System to ensure that any actual or potential conflicts of interest can be managed. If it is determined that the proposed employment may affect the design, conduct, or reporting of the USF System Research Project or that it may lead to an improper personal benefit to the Investigator or the Related Person, steps will be taken to manage or eliminate the conflict before the proposed employment may occur.

C. Procedures. All USF Investigators are required to disclose proposed employment of a Related Person* on a USF System Research Project* in accordance with the provisions of this Policy through the eCOI disclosure system, the procedures for which may be found at: https://arc.research.usf.edu/Prod.

V. PURCHASING AND PROCUREMENT DECISIONS IN USF SYSTEM RESEARCH PROJECTS

All purchasing and procurement decisions made in the context of a USF System Research Project are subject to the USF System purchasing and procurement regulations, policies, and rules and must be made in accordance with the State of Florida Code of Ethics for Public Officers and Employees [F.S. Chapter 112, Part III].
VI. SANCTIONS

Failure to report as required by this Policy and the related procedures may be grounds for disciplinary action under the provisions of any applicable USF System regulation, policy, or collective bargaining agreement. Failure to comply with these Policy requirements may also result in the termination of current awards and ineligibility of the Investigator or the Investigator’s institution to receive future awards.

VII. FEDERAL REQUIREMENTS

This Policy fulfills the requirements of Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors (42 CFR Part 50 and 45 CFR Part 94), published in the Federal Register on August 25, 2011, and the National Science Foundation (NSF) Investigator Financial Disclosure Policy published in the Federal Register on July 11, 1995, and as may be updated from time to time. This Policy also incorporates the requirements of the Food and Drug Administration (FDA) Regulations, “Financial Disclosure by Clinical Investigators” (21 CFR Part 54; April 1, 2002). These regulations are collectively referred to in this Policy as the Federal Regulations.

VIII. RELATED USF SYSTEM POLICIES AND REGULATIONS


USF System Regulation 10.107 “Ethical Obligations: Conflicts of Interest, Outside Employment, Employment of Relatives, Public Office.”

USF System Policy 0-027 “Florida Code of Ethics for Public Officers and Employees; Compliance and Disclosure”.

Authorized and signed by:

Paul R. Sanberg, Ph.D., D.Sc., Senior Vice President for Research & Innovation

Judy Genshaft, President
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<th><strong>Policy 0-309</strong></th>
<th><strong>DEFINITIONS</strong></th>
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<tr>
<td>*<strong>Conflicts of Interest</strong></td>
<td>Situations in which one’s financial or personal considerations either do or have the potential to compromise or bias one’s professional judgment or objectivity. In the research context, a situation could exist where an Investigator or the Investigator’s Chair or Program Leader has financial holdings or personal interests that might reasonably appear to affect or be affected by the design, conduct, reporting, review, or oversight of a USF System Research Project. It is important to note that a conflict of interest may exist whether or not the judgment of the persons listed above is actually influenced by the secondary interest.</td>
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<tr>
<td>*<strong>Exempt Organization</strong></td>
<td>A federal, state, or local government agency, an Institution of higher education as defined in 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)</td>
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<tr>
<td>*<strong>Financial Conflict of Interest (FCOI)</strong></td>
<td>A Financial Conflict of Interest exists when the USF System reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of a USF System Research Project Funded by PHS.</td>
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| ***FCOI Management Plan** | A management plan prepared by the COI Committee in the event an Investigator is determined to have a Financial Conflict of Interest per the USF System FCOI Policy. The key elements of the FCOI Management Plan report are:  
(A) The role and principal duties of the conflicted PHS-Funded Investigator in the USF System Research Project Funded By PHS;  
(B) Conditions of the management plan;  
(C) How the management plan is designed to safeguard objectivity in the USF System Research Project Funded By PHS;  
(D) Confirmation of the PHS-Funded Investigator’s agreement to the management plan; |
(E) How the management plan will be monitored to ensure the PHS-Funded Investigator’s compliance; and

(F) Other information as needed.

| **Funded By PHS** | A USF System Research Project where the Funding Agency is an organizational unit of the Public Health Service (PHS) or any other Federal agency or extramural sponsor that has adopted the PHS Objectivity in Research Rule. The PHS units are the National Institutes of Health (NIH); Food and Drug Administration (FDA); Centers for Disease Control (CDC); Agency for Healthcare Research and Quality (AHRQ); Agency for Toxic Substances and Disease Registry (ATSDR); Health Resources and Services Administration (HRSA); Indian Health Services (IHS); Substance Abuse and Mental Health Services Administration (SAMHSA). The other Federal agencies or extramural sponsors that have adopted the PHS Objectivity in Research Rule are the Administration for Children and Families (ACF), the Alliance for Lupus Research (ALR), the American Heart Association, the American Cancer Society, the American Lung Association (ALA), the Arthritis Foundation (AF), the California Breast Cancer Research Program (CBCRP), the California HIV/AIDS Research Program (CHRP), the Centers for Medicare and Medicaid Services (CMS), the Juvenile Diabetes Research Foundation (JDRF), the Lupus Foundation of America (LEA), the Susan G. Komen Foundation, and the CurePSP Foundation for PSP | CBD and Related Brain Diseases. This definition will be expanded as needed to comply with the official requirements imposed by additional federal agencies and extramural sponsors. |
| **Immediate Family** | Spouse, domestic partner, and each dependent child. |
| **Institutional Responsibilities** | An Investigator’s professional responsibilities on behalf of the USF System, including but not limited to teaching, research, research consultation, professional practice, and USF System committee memberships. |
| **Investigator** | Means the project director or principal investigator and *any other person*, (faculty, staff, students, and collaborators or consultants outside of the USF System), regardless of title or position, who is responsible for the design, conduct, or reporting of a USF System Research Project. “Design, conduct or reporting” includes, but is not limited to:

- Designing, conducting, and/or directing a USF System Research Project.
- Applying, on behalf of the USF System, for grants or awards to perform the USF System Research Project.
- Serving as the principal investigator/program director, co-investigator, or sub-investigator.
- Enrolling research subjects (including obtaining informed consent, if applicable) or making decisions related to eligibility for enrollment.
- Analyzing, reporting, presenting, or publishing research data.

All key personnel listed on a submission for the USF System Research Project to the USF Institutional Research Board (IRB) or any other institutional review board, the USF Institutional Animal Care and Use Committee (IACUC), or the applicable Sponsored Research office are Investigators. *Also, any Investigator working on a USF System Research Project as a sub-grantee, contractor, or collaborator via a subcontract, sub-award, or other agreement is an Investigator for purposes of this definition.* |

| **Period of the Award** | The time frame of the USF System Research Project as stated in the award document, including any extensions. |

| **PHS-Funded Investigator** | An Investigator who is participating or planning to participate in a USF System Research Project Funded by Public Health Service (PHS). *See the definition of “Funded by PHS” for a complete list of sponsors.* |

| **PHS-Funded Subrecipient Investigator** | An Investigator who is participating in a USF System Research Project Funded by Public Health Service (PHS) through a subcontract, sub-award, or other agreement. *See the definition of “Funded by PHS” for a complete list of sponsors.* |
| **Related to a USF System Research Project** | A Reportable Financial Interest or Relationship or a Significant Financial Interest will be considered to be Related to the USF System Research Project in question if the Reportable Financial Interest or Relationship or Significant Financial Interest:
1. Could be affected by the USF System Research Project; or
2. Is in an entity whose financial interest could be affected by the USF System Research Project. |
| **Related Person** | Persons related to each other in one of the following ways: husband; wife; parent; child; brother; sister; spouse of a child, brother, sister, or parent; or parent, child, brother, or sister of spouse; grandparent; grandchild; aunt, uncle, first cousin, niece or nephew. Related Person also includes a person who is engaged to be married to an employee or who otherwise holds himself or herself out as or is generally known as the person whom the employee intends to marry or with whom the employee intends to form a household, or any other person having the same legal residence as the USF System employee. |
| **Remuneration** | Salary and any form of payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), including equity interests (e.g., stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value). |
| **Reportable Financial Interest or Relationship** | An opportunity for the Investigator (or his/her Immediate Family) for economic gain or an external commitment that relates to, or could be reasonably affected by, the outcome of the proposed or current USF System Research Project. Examples include:
- Anything of monetary value, or a potential value that cannot readily be determined, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria) that is paid or given to the Investigator (or the Investigator’s Immediate Family), directly or indirectly, as support for the activities of the Investigator exclusive of the costs of conducting the clinical |
study or other clinical studies (e.g., a grant to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation or honoraria), or in trust by any other means.

- A proprietary interest in the USF System Research Project, including an issued (e.g. a patent, trademark, copyright, or licensing agreement in the test article or method). A proprietary interest is considered to be present as soon as protection is sought (e.g. upon submission of an Invention Disclosure Form to the USF Technology Transfer Office, upon filing of a patent application, etc.).

- A position as director, officer, partner, trustee, or member of board of directors of any entity related to the USF System Research Project.

- A consulting, advisory, employment, ownership/equity, or any other interest or relationship in any entity related to the research (including interests in a non-publicly traded corporation, the value of which interests cannot be readily determined through reference to public prices).

- Any other financial interest or external commitment that the Investigator believes may interfere with his or her ability to protect human research participants.

The following financial interests or commitments are generally recognized as not relating to or being impacted by the outcome of the research and, therefore, do NOT need to be disclosed:

1. Salary, royalties, or other remuneration received from the USF System if the Investigator is currently employed or otherwise appointed by the USF System.
2. Receipt of royalties for any published scholarly works or other writings.
3. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities (NOTE: All honoraria received from commercial entities must be disclosed).
4. Income from service on advisory committees or review panels for public or nonprofit entities.
5. Interests in commercial enterprises on the part of an Investigator that are in no way related to the Investigator’s professional role and/or obligations.

6. Any “arm’s length” financial interest (e.g., a mutual fund or employer retirement plan), where the participant has no control over the investment decision, except where the value of the equity in one publicly traded company related to the research exceeds $50,000.

**Retrospective Review**

The review conducted by the USF System upon determining 1) that an SFI not timely disclosed or reviewed is an FCOI or 2) that a PHS-Funded Investigator has failed to comply with an FCOI Management Plan. The Retrospective Review will consist of a review of the PHS-Funded Investigator’s activities and the USF System Research Project Funded By PHS to determine whether any portion of the research was biased in the design, conduct, or reporting of such research prior to the identification and management of the FCOI or during the period of noncompliance of the PHS-Funded Investigator with the FCOI Management Plan. The Retrospective Review will be documented and will include, but not be limited to:

a. Project number;

b. Project title;

c. PD/PI or contact PD/PI if a multiple PD/PI model is used;

d. Name of the PHS-Funded Investigator with the FCOI;

e. Entity with which the PHS-Funded Investigator has an FCOI;

f. Reason(s) for the Retrospective Review;

g. Detailed methodology used for the Retrospective Review (e.g., methodology of the Retrospective Review process, composition of the Retrospective Review panel, documents reviewed);

h. Findings of the Retrospective Review (i.e., facts and observations); and

i. Conclusions of the Retrospective Review (i.e., determination and recommended actions).
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<th><strong>Senior/Key Personnel</strong></th>
<th>The PD/PI and any other person identified as “senior/key personnel” by the USF System in the grant application, progress report, or any other report submitted to a Funding Agency.</th>
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| **Significant Financial Interest** | I. A **financial interest** consisting of one or more of the following interests of the PHS-Funded Investigator and those of the PHS-Funded Investigator's Immediate Family:  
   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**.  
   b. With regard to any *non-publicly traded entity*, a Significant Financial Interest exists:  
      i. if the value of any Remuneration* received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds **$5,000**, OR  
      ii. when the PHS-Funded Investigator (or the Investigator’s Immediate Family) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest); OR  
   II. **Intellectual property rights and interests** (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests. (*See Exclusion #2 below.*)  
   III. 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 the PHS-Funded Investigator’s Institutional Responsibilities. The details of the travel disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The USF System will determine if further information is needed, including a determination or |
IV. Paid authorships.

Exclusions:
The following interests are excluded from the definition of Significant Financial Interests:

1. Salary, royalties, or other Remuneration received from the USF System if the PHS-Funded Investigator is currently employed or otherwise appointed by the USF System.
2. Intellectual property rights assigned to the USF System and income from agreements to share in royalties related to such rights.
3. 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;
4. Income from seminars, lectures, or teaching engagements sponsored by an Exempt Organization*.
5. Income from service on advisory committees or review panels for an Exempt Organization*.
6. Reimbursed or sponsored travel that is reimbursed or sponsored by an Exempt Organization*.
   
42 CFR §50.603(1), (2), and (3).

<table>
<thead>
<tr>
<th>*Subrecipient Investigator</th>
<th>An Investigator who is not a USF System employee or student and who participates in the USF System Research Project through a subcontract, subaward, or other agreement.</th>
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<tr>
<td>*USF System Research Project</td>
<td>Any systematic investigation (i.e., the gathering and analysis of information), including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, whether or not it is made available to the general public, involving a USF System employee, student, or other person where the USF System is responsible for the oversight and/or administration of the</td>
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activity. Activities that contribute to generalizable knowledge are those that include, but are not limited to, the following:

- attempt to make comparisons or draw conclusions from the gathered data;
- attempt to reach for generalizable principles of historical or social development;
- seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes;
- create general explanations about what has happened in the past; or
- predict the future.