I. PURPOSE & INTENT

As a public institution, the University of South Florida (USF) 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 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 USF, and the conflicts managed or eliminated before the research may proceed.

The purpose of this Policy is:

• 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 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 (“PHS-Funded Investigators”);

• To implement the provisions of the National Science Foundation’s (NSF) Grantee Standards regarding conflict of interest policies; and

• To provide a process for ensuring that any Conflict of Interest that an Investigator may have in connection with a USF Research Project is fully disclosed, reviewed in accordance with established procedures, and satisfactorily resolved before the USF Research Project is initiated, regardless of funding.
Investigators who have a Conflict of Interest with a USF 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 FEDERALLY-FUNDED USF RESEARCH PROJECTS

A. Scope and Applicability. Section II applies only to Investigators engaging in or proposing to engage in federally-funded research (“Federally-Funded Investigators**”), including Investigators engaging in research funded by agencies and extramural sponsors that have adopted the U.S. Public Health Service (PHS) Objectivity in Research Rule. If the Investigator is employed at an institution other than USF, or is participating in the Federally-Funded USF Research Project* through a subcontract, subaward or other agreement, then the Investigator is a federally-funded subrecipient investigator, and subject to Section II.C.

B. Policy.

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

   a. No later than the date of submission of a proposal for a Federally-Funded USF Research Project; and
   
   b. Updated at the time of Notice of Award; and
   
   c. Within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance); and
   
   d. Annually updated during the Period of the Award* to reflect any change in the value or status of the SFI.

2. Investigator Training. Federally-Funded Investigators are required to complete training with respect to the USF COI Policy, their responsibilities regarding disclosure of SFIs, and the PHS Objectivity in Research Rule (“COI Training”):

   a. Prior to submitting a proposal for a Federally-Funded USF Research Project; and
   
   b. At least every three years, during the Period of the Award; and
   
   c. Immediately, when any of the following circumstances apply:
i. USF revises the COI Policy for Federally-Funded Investigators or its associated procedures in any manner that affects Federally-Funded Investigator requirements; or

ii. A Federally-Funded Investigator is new to USF; or

iii. USF finds that a Federally-Funded Investigator is in noncompliance with the USF COI Policy for Federally-Funded Investigators or a Financial Conflict of Interest (FCOI) Management Plan*.

3. **USF Review and Management of SFI Disclosures, and FCOI Reporting.** USF, through its conflict of interest review, management, and reporting process, will:

   a. Determine, in consultation with the Investigator, whether any SFI disclosed is related to a USF Research Project; and, if so

   b. Determine whether the SFI constitutes a FCOI; and, if so,

   c. Take appropriate action to manage the FCOI(s), including the creation of an FCOI Management Plan; and

   d. For PHS-funded projects, 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:

   i. Prior to the expenditure of funds for SFI s determined by USF to be a FCOI; and

   ii. Within 60 days of any subsequently identified FCOI; and

   iii. 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 USF identifies an FCOI related to a PHS-funded project and eliminates it prior to the expenditure of funds, USF shall not submit an FCOI report to the funding agency.

c. For NSF-Funded Projects*, if a FCOI cannot be managed, reduced or eliminated, and the related research will proceed without the imposition of conditions or restrictions, USF will report the FCOI to the NSF Office of General Counsel in the manner directed by the funding agency.

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1 For example, for PHS-funded research, 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.
4. **USF FCOI Monitoring.** Once an FCOI is identified, USF will require that the project be monitored to ensure adherence of the Investigator to the FCOI Management Plan.

5. **USF Review of SFI Not Timely Disclosed or Reviewed.** Whenever USF identifies an SFI that was not disclosed by a Federally-Funded Investigator in accordance with the timeframes specified in Section II.B.1., or, for whatever reason, was not previously reviewed by USF, USF will, within sixty (60) days:
   a. Review the SFI and determine whether it is Related to the USF Research Project*; and
   b. Determine whether an FCOI exists; and, if so
   c. 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.

6. **USF Retrospective Review and Determination of Bias In Design, Conduct or Reporting of Research for PHS-Funded Projects.** If, during the course of reviewing an SFI not timely disclosed or reviewed, USF determines that an FCOI exists for a PHS-funded project, or if USF finds that a PHS-Funded Investigator* has failed to comply with an FCOI Management Plan, USF shall, within 120 days:
   a. Complete a Retrospective Review* of the Investigator's activities and the project 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 with the FCOI Management Plan; and, if so,
   b. Document the Retrospective Review, including but not limited to:
      i. Project number;
      ii. Project title;
      iii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
      iv. Name of the Investigator;
      v. Entity with which the Investigator has an FCOI;
      vi. Reason(s) for the Retrospective Review;
      vii. Detailed methodology used for the Retrospective Review (e.g., methodology of the Retrospective Review process, composition of the Retrospective Review panel, documents reviewed);
      viii. Findings of the Retrospective Review (i.e., facts and observations); and
      ix. Conclusions of the Retrospective Review (i.e., determination and recommended actions).
Depending on the nature of the FCOI, USF may determine that additional interim measures are necessary between the date that the FCOI is identified or the date the Investigator’s noncompliance is determined and the completion of the Retrospective Review with regard to the Investigator’s participation in the USF Research Project.

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

   a. Notify the funding agency promptly;

   b. Submit a mitigation report to the funding agency, including but not limited to:
      
      i. The elements documented in Section II.B.6.;
      
      ii. A description of the impact of the bias on the USF Research Project; and
      
      iii. USF’s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the USF Research Project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the USF Research Project is salvageable); and

   c. Submit FCOI reports annually, as specified in Section II.B.3.d.

C. **Federally-Funded Subrecipient Investigators.** Where any portion of a Federally-Funded USF Research Project is carried out through a Federally-Funded Subrecipient Investigator*, the terms of this Section II.C. will apply.

1. Where a Federally-Funded USF Research Project is funded, in whole or in part, by a PHS agency, an entity that has adopted the PHS Objectivity in Research Rule, or by the NSF, USF will incorporate terms into the written agreement with the subrecipient institution that establish whether USF’s or the subrecipient institution’s COI Policy will apply to the Subrecipient Investigators.

   a. **Subrecipient Institution COI Policy Applies.** When the subrecipient agreement stipulates that the subrecipient institution’s COI Policy will apply, the subrecipient institution must also certify in the subrecipient agreement that its COI Policy complies with either the PHS Objectivity in Research Rule or the NSF’s Grantee Standards, whichever is applicable based on the prime sponsor of the USF Research Project.

      i. **Time Periods for Subrecipients’ FCOI Reporting to USF.** If the USF Research Project is PHS-Funded, the written subrecipient agreement will further specify the time period(s) within which the subrecipient institution must report all identified FCOIs to USF, which time period(s) shall be sufficient to enable USF to provide timely reporting of the FCOIs to the funding agency per Section II. B.3.

      b. **USF FCOI Policy Applies.** PHS- and NSF-Funded Subrecipient Investigators will be subject to the USF COI Policy if: 1) the subrecipient agreement stipulates that the Subrecipient Investigators are subject to the USF COI Policy; or 2) the Subrecipient
Investigator is not affiliated with an institution that has a COI Policy compliant with the PHS Objectivity in Research Rule or the NSF’s Grantee Standards, whichever is applicable based on the prime sponsor of the project. If the USF COI Policy applies, USF will directly notify the Subrecipient Investigator(s) that the Investigator(s) is(are) subject to the USF COI Policy and must disclose SFIs that are directly related to the Subrecipient Investigator’s work on the USF Research Project.

i. Procedures.

a) All PHS-Funded subrecipients not registered with the Federal Demonstration Partnership Clearinghouse as having a PHS-compliant policy are required to complete USF’s Documentation of Subrecipient Financial Conflict of Interest Policy Form A, either in paper or online. Those PHS-Funded subrecipients that do not have a PHS-compliant COI policy and thus must follow the USF COI Policy must also complete USF’s Significant Financial Interest(s) Disclosure Form B, either in paper or online.

b) All NSF-Funded subrecipients who are subject to the USF COI Policy are required to complete USF’s Documentation of Subrecipient Financial Conflict of Interest Policy Forms A and B, either in paper or online.

ii. Time Periods for Reporting Disclosures. If PHS- or NSF-Funded Subrecipient Investigators are subject to the USF COI Policy, the subrecipient agreement will specify the time period(s) (both initially and throughout the Period of the Award) wherein the Subrecipient Investigators will be required to disclose their SFIs that are directly related to the Investigator’s work for USF. Such time period(s) must be sufficient to enable USF to comply in a timely manner with its review, management, and reporting obligations under Section II.B.

2. Where a Federally-Funded USF Research Project is funded by an entity other than a PHS agency, an entity that has adopted the PHS Objectivity in Research Rule, or the NSF, the Subrecipient Investigator’s institution’s conflict of interest policy and review process will apply and any potential conflicts will not be managed by USF.

D. Public Accessibility to FCOI Information for PHS-Funded Projects. For PHS-funded projects, USF will make information about FCOIs it has identified through its conflict of interest review and management process 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:

1. Name, title, and role of the Investigator on the USF Research Project;

2. Name of the entity in which the SFI is held (if applicable); and
3. Nature and approximate dollar value or range of the SFI, or a statement that the value cannot be readily determined.

E. Procedures. All Federally-Funded USF 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 through the eCOI disclosure system, the procedures for which may be found at: https://arc.research.usf.edu/Prod.

III. INDIVIDUAL FINANCIAL RELATIONSHIPS IN NON FEDERALLY-FUNDED USF RESEARCH PROJECTS

A. Scope and Applicability. Section III applies to an Investigator planning to participate in a non Federally-Funded USF Research Project.

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

1. Prior to the initiation of a non Federally-Funded USF Research Project; and

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

3. Annually updated during the Period of the Award to reflect any change in the value or status of the Significant Financial Interest or Relationship.

If USF determines that any Significant Financial Interest or Relationship may affect the design, conduct, or reporting of the non Federally-Funded USF Research Project, steps will be taken to manage or eliminate the conflict. If a management plan is required in order for the non Federally-Funded USF Research Project to proceed, then the non Federally-Funded USF Research Project may be monitored by USF 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 Significant Financial Interest or Relationship Related to a USF Research Project through the eCOI disclosure system, the procedures for which may be found at: https://arc.research.usf.edu/Prod.

IV. STATE FINANCIAL INTEREST DISCLOSURE REQUIREMENTS

A. Scope and Applicability. Any USF Employee* engaged in the design, conduct, or reporting of research.
B. **Policy.** Any **USF Employee** engaged in the design, conduct, or reporting of research must disclose their **Financial Interests** and receive a determination that their **Financial Interests** do not affect the integrity of USF in accordance with Florida Statutes §1012.977.

C. **Procedures.** Any **USF Employee** engaged in the design, conduct, or reporting of research must disclose their **Financial Interests** as follows:

i. Disclose any **Significant Financial Interests** in the eCOI system as described in this policy. This system is administered by the Conflict of Interest Program in Research Integrity & Compliance.

ii. Disclose all **Financial Interests** not disclosed in the eCOI system in the eDisclose system. This system is administered by the Office of Compliance & Ethics. See **USF Policy 0-027** for more details.

V. **MANAGING RELATIONSHIPS IN USF RESEARCH PROJECTS**

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

B. **Policy.** Employment of a Related Person on a USF 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 Research Project, an Investigator must disclose the proposed employment so that it and any accompanying issues can be appropriately reviewed by USF 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 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 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](https://arc.research.usf.edu/Prod).

VI. **PURCHASING AND PROCUREMENT DECISIONS IN USF RESEARCH PROJECTS**

All purchasing and procurement decisions made in the context of a USF Research Project are subject to USF 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].
VII. 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 regulation, policy, or collective bargaining agreement. Failure to comply with 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.

Any USF Employee* engaged in the design, conduct, or reporting of research who has failed to disclose any outside activity or financial interest in accordance with Florida Statutes §1012.977* will be suspended without pay pending the outcome of an investigation which shall not exceed 60 days. Upon conclusion of the investigation, USF may terminate a USF Employee* for failing to meet the requirements of Florida Statutes §1012.977*.

VIII. FEDERAL AND STATE REQUIREMENTS

This Policy fulfills the following federal disclosure and review requirements, collectively referred to in this Policy as the “Federal Regulations”:


- **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 fulfills State of Florida financial interest disclosure requirements under Florida Statutes §1012.977*.

IX. RELATED USF POLICIES AND REGULATIONS

- USF HRPP Policies
- USF Policy 0-027 “Florida Code of Ethics for Public Officers and Employees; Compliance and Disclosure.”
*Current Responsible Office: Research & Innovation

*Refer to the appropriate Responsible Office website for a current name of the Vice President or other Responsible Officer.

History: New 8-30-96, Amended 2-11-05, 1-23-09, 4-4-11, 8-17-12, 5-19-14, 1-29-15, 4-13-17, 4-1-20 (technical), 3-4-21 (technical), 11-2-21 (technical).
<table>
<thead>
<tr>
<th><strong>Policy 0-309</strong></th>
<th><strong>DEFINITIONS</strong></th>
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<tr>
<td><em>Conflicts of Interest</em></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 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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<td><em>Exempt Organization</em></td>
<td>A U.S. federal, state, or local government agency, a U.S. Institution of higher education as defined in 20 U.S.C. 1001(a), a U.S. academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education. 42 CFR §50.603(2), NIH Notice NOT-OD-18-160</td>
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<tr>
<td><em>Federally-Funded Investigator</em></td>
<td>An Investigator who seeks or receives funding from a federal agency.</td>
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<tr>
<td><em>Federally-Funded USF Research Project</em></td>
<td>A USF Research Project for which funding is sought or received from a federal agency.</td>
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<td><em>Financial Interest</em></td>
<td>Anything of value not provided by USF. [Florida Statute §1012.977]</td>
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<tr>
<td><em>Financial Conflict of Interest (FCOI)</em></td>
<td>A Financial Conflict of Interest exists when USF reasonably determines that a Significant Financial Interest could <em>directly and significantly</em> affect the design, conduct, or reporting of a Federally-Funded USF Research Project.</td>
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<tr>
<td><em>FCOI Management Plan</em></td>
<td>A management plan prepared by the COI Committee in the event an Investigator is determined to have a Financial Conflict of Interest per this USF Policy.</td>
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<tr>
<td><em>Immediate Family</em></td>
<td>Spouse, domestic partner, and each dependent child.</td>
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<tr>
<td><em>Institutional Responsibilities</em></td>
<td>An Investigator’s professional responsibilities on behalf of USF, including but not limited to teaching, research, research consultation, professional practice, and USF committee memberships.</td>
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<tr>
<td><em>Investigator</em></td>
<td>The project director or principal investigator and <em>any other person</em> (faculty, staff, students, and collaborators or consultants outside of USF), regardless of title or role.</td>
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**DEFINITIONS**

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<th>Position, who is responsible for the design, conduct, or reporting of a USF Research Project. “Design, conduct or reporting” includes, but is not limited to: ● Designing, conducting, and/or directing a USF Research Project. ● Applying, on behalf of USF, for grants or awards to perform the USF 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 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.</th>
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<tr>
<td><em>NSF-Funded Investigator</em></td>
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<td><em>NSF-Funded Project</em></td>
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<td><em>Period of the Award</em></td>
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<td><em>PHS-Funded Investigator</em></td>
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<td><em>PHS-Funded Subrecipient Investigator</em></td>
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<tr>
<td><em>Related to a USF Research Project</em></td>
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<td>Policy 0-309</td>
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<td>(2) Is in an entity whose financial interests could be affected by the USF Research Project.</td>
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**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 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).

**Retrospective Review**

The review conducted by USF of a PHS-funded project 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 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:

i. Project number;

ii. Project title;

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

iv. Name of the PHS-Funded Investigator with the FCOI;
### DEFINITIONS

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<td>v.</td>
<td>Entity with which the PHS-Funded Investigator has an FCOI;</td>
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<td>vi.</td>
<td>Reason(s) for the Retrospective Review;</td>
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<td>vii.</td>
<td>Detailed methodology used for the Retrospective Review (e.g., methodology of the Retrospective Review process, composition of the Retrospective Review panel, documents reviewed);</td>
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<td>viii.</td>
<td>Findings of the Retrospective Review (i.e., facts and observations); and</td>
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<td>ix.</td>
<td>Conclusions of the Retrospective Review (i.e., determination and recommended actions).</td>
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### *Florida Statutes §1012.977*

Requirements of Florida Statutes § 1012.977 are as follows:

1. Any person employed by a state university or entity engaging in research which was created or authorized pursuant to part II of chapter 1004 consents to the policies of the university or entity, the regulations of the Board of Governors, and the laws of this state. At a minimum, such policies shall require employees engaged in the design, conduct, or reporting of research to disclose and receive a determination that the outside activity or financial interest does not affect the integrity of the state university or entity.

2. (a) “Financial interest” includes anything of value other than that provided directly by the university or entity.

   (b) “Outside activity” includes anything an employee does for an organization or an individual, other than the university or entity, that is related to the employee’s expertise.

3. An employee who has failed to disclose any outside activity or financial interest as required by subsection (1) shall be suspended without pay pending the outcome of an investigation which shall not exceed 60 days. Upon conclusion of the investigation, the university or entity may terminate the contract of the employee.

Florida Statutes § 1012.977 available online here: [http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&Search_Only=&URL=1000-1099/1012/Sections/1012.977.html](http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&Search_Only=&URL=1000-1099/1012/Sections/1012.977.html)
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<td><strong>Senior/Key Personnel</strong></td>
<td>The PD/PI and any other person identified as “senior/key personnel” by USF in the grant application, progress report, or any other report submitted to a funding agency.</td>
</tr>
</tbody>
</table>
| **Significant Financial Interest** | I. An opportunity for the Investigator (or his/her Immediate Family) for economic gain or an external commitment that relates to, or could reasonably be affected by, the outcome of the proposed or current USF Research Project, including:  
   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 Investigator (or the Investigator’s Immediate Family) holds any equity interest (e.g., stock, stock option, or other ownership interest);  
   c. A position as director, officer, partner, trustee or member of board of directors of any entity related to the USF Research Project, whether or not remuneration is received for such service;  
   d. A proprietary interest in the USF Research Project (e.g., patents, trademarks, copyrights or licensing agreements in the test article or method), and royalties of any amount from such rights, including those royalties distributed by USF. A proprietary interest is considered to be present as soon as a patent is granted or an option |
or license agreement is executed (including option and license agreements for provisional patents, patent applications, etc.).

II. For PHS-Funded Investigators only, 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. USF will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI.

III. Any other financial interest or external commitment that an Investigator believes may interfere with his or her ability to oversee or participate in research without bias.

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

1. Salary or other Remuneration received from USF if the Investigator is currently employed or otherwise appointed by USF.

2. 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, except where the value of the equity in one publicly-traded company related to the research exceeds $50,000;

3. Income from seminars, lectures, or teaching engagements sponsored by an Exempt Organization*.

4. Income from service on advisory committees or review panels for an Exempt Organization.

5. Reimbursed or sponsored travel that is reimbursed or sponsored by an
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<tr>
<th><strong>Policy 0-309</strong></th>
<th><strong>DEFINITIONS</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>Exempt Organization.</strong>&lt;br&gt;42 CFR §50.603(1), (2), and (3).</td>
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<tr>
<td><strong>Subrecipient Investigator</strong></td>
<td>An Investigator who is not a USF employee or student and who participates in the USF Research Project through a subcontract, subaward, or other agreement.</td>
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<tr>
<td><strong>USF Research Project</strong></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 employee, student, or other person where USF is responsible for the oversight and/or administration of the activity. Activities that contribute to generalizable knowledge are those that include, but are not limited to, the following: &lt;br&gt;• attempt to make comparisons or draw conclusions from the gathered data; &lt;br&gt;• attempt to reach for generalizable principles of historical or social development; &lt;br&gt;• seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes; &lt;br&gt;• create general explanations about what has happened in the past; or &lt;br&gt;• predict the future.</td>
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<tr>
<td><strong>USF Employee</strong></td>
<td>Any individual in one of the following employee position types, as coded in GEMS, the information management system used by Human Resources: Faculty, Administration, Staff, or Temporary. The term &quot;temporary&quot; employee refers to any person occupying an OPS position type, such as OPS-Graduate Assistant, OPS-Teaching Assistant, OPS-Adjunct, etc., essentially, OPS-anything as coded in GEMS.</td>
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