Procedures

Significant Financial Interest Disclosure Review and Management Process for USF Research Projects Funded by Federal Agencies, or Certain Agencies, Foundations & Extramural Sponsors

University of South Florida
Research & Innovation
Research Integrity & Compliance
Conflict of Interest Program

USF CONFLICT OF INTEREST PROGRAM

USF Conflict of Interest Program **Disclosure Review and Management Process**	**Revision 5: March 2020**

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PART I GENERAL INFORMATION

1. Overview

A
Introduction

This is the Significant Financial Interest Disclosure Review and Management Process for USF Research Projects Funded by Federal Agencies or Certain Agencies, Foundations & Extramural Sponsors to be used by the Conflict of Interest Program (COI Program), Research Integrity & Compliance (RIC).

B
Purpose

The purpose of this document is:

- To provide guidance to the COI Administrator and administrative staff of the COI Program in the receipt, assignment, review, management, distribution and maintenance of Significant Financial Interest Disclosures of Investigators participating in USF Research Projects per USF Policy 0-309, *Individual Conflicts of Interest in USF Research Projects and USF Financial Conflicts of Interest (FCOI) Policy* ("USF Policy 0-309").

C
Use of Certain Terms

Unless otherwise noted, for ease of reference, the term "Investigator" refers for purposes of these procedures *only* to Investigators participating in USF Research Projects Funded by Federal Agencies, or PHS or Certain Agencies, Foundations & Extramural Sponsors. Additionally, the term USF Research Project will refer for purposes of these procedures *only* to USF Research Projects Funded by Federal Agencies, or PHS or Certain Agencies, Foundations & Extramural Sponsors unless otherwise noted.

2. Conflict of Interest Program & Administrator

A
Conflict of Interest Office

The Conflict of Interest Program is housed in the USF Office of Research & Innovation (ORI), Research Integrity & Compliance. The Conflict of Interest Program is responsible for implementing USF Policy 0-309, Individual Conflicts of Interest in USF Research Projects and USF Financial Conflicts of Interest (FCOI) Policy, and USF Policy 0-317, Institutional Conflicts of Interest in Research. The Conflict of Interest Program is also the home of the USF Conflict of Interest Committee ("COI Committee") and the Relatedness and FCOI Determination Committee ("RFD Committee").

B
Conflict of Interest Administrator

The Conflict of Interest Administrator is the institutional official designated by the USF to solicit and review disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in, a USF Research Project. The Conflict of Interest Administrator also has the following responsibilities:

- Oversee implementation of USF Policies 0-309 and 0-317.
- Develop proposed management plans in cooperation with the Investigator, if applicable. Gather additional information as needed.
- Handle all communications between Investigator, COI Committee, Sponsored Research (SR) and the USF Institutional Review Board (IRB) (for research involving human subjects) concerning disclosures pertaining to Investigators who are University employees or certain subcontractors on USF Research Projects.
- Create systems to monitor conflict of interest (COI) management plans for individual COI cases as required.
- Plan and organize meetings of the COI and RFD Committees and develop agenda and materials in advance of meetings.
- Provide background information on disclosures and recommendations on management controls at Committee meetings.
- Prepare minutes of Committee meetings.
- Enter COI Committee determinations in the eCOI System.
- Draft/update and distribute policies, procedures and operating guidelines for the COI and RFD Committees.
- Monitor regulatory changes/articles of interest in COI in research and communicate same to research community as needed.
- Conduct investigations of noncompliance and resolve as appropriate or communicate issues to Committee for input and resolution.
- Oversee COI aspects of the Human Research Protection Program's accreditation (i.e. accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)).
- Obtain feedback from users of COI Committee services and implement quality control and improvements to COI Program as needed.

C
Conflicts of Interest Committee

The COI Committee reviews disclosures from persons who are USF employees and who have a financial interest, relationship or external commitment related to a USF Research Project (in the broad sense). The COI Committee also reviews Significant Financial Interest disclosures from Investigators who are participating in USF Research Projects Funded by PHS or Certain Agencies, where the Significant Financial Interest has been determined to be an FCOI by the RFD Committee.

(*See* "USF COI Committee Operating Procedures", PRINCIPLES, ROLES & RESPONSIBILITIES.)

D
Relatedness and FCOI Determination Committee

The Relatedness and FCOI Determination Committee ("RFD Committee") compares the Interest Inventory of an Investigator with a proposal for a USF Research Project Funded by PHS or Certain Agencies, Foundations & Extramural Sponsors for which a Notice of Award has been received to determine whether any of the disclosed interests are related to the USF Research Project. If so, the RFD Committee determines whether the interest creates a Financial Conflict of Interest ("FCOI").

The RFD Committee will include the COI Administrator, the Chair of the COI Committee, a representative from the General Counsel's Office, and a representative from SR. *Ad hoc* participants may be invited as may be required for a complete review of an individual project.

E
Requirements Met

This section I.2 implements the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.604(d)[1].

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[1] § 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.
Each Institution shall:
(d) Designate an institutional official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

PART II INTEREST INVENTORY

3. Interest Inventory

A
Interest Inventory

The disclosure review process begins with an Investigator submitting an Interest Inventory in the eCOI System. The Interest Inventory is a disclosure of all of the Investigator's Significant Financial Interests (as defined in USF Policy 0-309) that are related to the Investigator's Institutional Responsibilities. The Interest Inventory is not tied to any specific research project.

B
Time to File Interest Inventory

Each Investigator should file an Interest Inventory upon becoming aware of funding or a potential for funding by a Federal Agency, including PHS or Certain Agencies, Foundations & Extramural Sponsors. Additionally,

- *Submission of Proposal.* An Investigator must have an Interest Inventory on file at the time of application for the USF Research Project (submission of a proposal for funding) if the Investigator is listed as an Investigator on the proposal. [USF Policy 0-309, section II.B.1.a.]
- *At Notice of Award.* If the Investigator's Significant Financial Interests have changed since the proposal was submitted, the Investigator must update his/her Interest Inventory at the time of Notice of Award for the USF Research Project. [USF Policy 0-309, section II.B.1.b.]
- *During Period of Award*. Any Investigator who is added to the USF Research Project after Notice of Award must file an Interest Inventory *before* beginning work on the Project, if the Investigator does not already have a current Interest Inventory on file. An Investigator must update the Interest Inventory on file within thirty (30) days of acquiring a new Significant Financial Interest related to the Investigator's Institutional Responsibilities. [USF Policy 0-309, section II.B.1.c.]
- *Annual Updates*. The Investigator must update the Interest Inventory annually to reflect any change in the value or status of the Investigator's Significant Financial Interests. Such update shall include any information that was not disclosed initially to USF at the time of the proposal submission or in an Interest Inventory update during the period of award. [USF Policy 0-309, section II.B.1.d.]

C **Status of Interest Inventory**	An Investigator's Interest Inventory will remain in the eCOI System indefinitely and can be updated by the Investigator at any time as new Significant Financial Interests are acquired or previously disclosed Significant Financial Interests change.
D Annual Renewal	The procedures in this section II.3 implement the following requirements of the PHS Objectivity in Research Rule, 42 CFR §50.604(e)(1)-(3)[2], and the NSF Grantee Standards regarding conflicts of interest set forth in the NSF Proposal and Awards Policies and Procedures Guide (PAPPG).
E Requirements Met	The procedures in this section also implement USF Policy 0-309, Section II.B.1.

[2] § 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.
Each Institution shall:
(e)(1) Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.
(2) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
(3) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

PART III FINANCIAL CONFLICT OF INTEREST (FCOI): NEW AWARDS FROM FEDERAL AGENCIES OR CERTAIN AGENCIES, FOUNDATIONS & EXTRAMURAL SPONSORS

4. Proposal for Funding for a USF Research Project Funded by a Federal Agency or Certain Agencies, Foundations & Extramural Sponsors

A
Proposal for Funding

Sponsored Research (SR) in the USF Office of Research & Innovation (ORI) receives all proposals for funding for submission to funding agencies and extramural sponsors. Accordingly, all proposals for funding, including proposals for Federally- and PHS-funded USF Research Projects, will be directed to SR and received in the SR office.

B
Communication of Proposal to COI Program

After submitting a proposal to a Federal Agency or Certain Agencies, Foundations & Extramural Sponsors, SR will promptly forward

- the proposal or statement of research; and
- the Internal Form (or a link to the Internal Form) ("Proposal Package") to the COI Administrator.

5. Notice of Award of a USF Research Project Funded by a Federal Agency or Certain Agencies, Foundations & Extramural Sponsors

A
Notice of Award

Sponsored Research (SR) also has the responsibility of communicating with funding agencies and extramural sponsors regarding USF Research Projects. Accordingly, notification to the USF of an award by a sponsor of a USF Research Project will be directed to SR and received in the SR office.

B
Communication of Notice of Award to COI Program

Upon receipt of a Notice of Award for a USF Research Project, SR will promptly notify the COI Administrator.

6. Identification by COI Program of a USF Research Project Funded by a Federal Agency or Certain Agencies, Foundations & Extramural Sponsors

A Identification of USF Research Project Funded by a Federal Agency or Certain Agencies, Foundations & Extramural Sponsors	Upon receipt of a Notice of Award for a USF Research Project (in the broad sense), the COI Administrator will review the Notice of Award to determine whether the funding is from a Federal Agency, or Certain Agencies, Foundations & Extramural Sponsors.

7. Comparison to Interest Inventory

A Comparing the Notice of Award to the Interest Inventory	If a Notice of Award reveals that the USF Research Project is funded by a Federal Agency or Certain Agencies, Foundations & Extramural Sponsors, the COI Administrator will identify the Investigators listed on the proposal or Internal Form, and will determine whether all listed Investigators have an Interest Inventory on file in the eCOI System.
B Final Notification to Investigators to Complete Interest Inventory	If no Interest Inventory is identified for a listed Investigator, the COI Administrator will promptly contact the listed Investigator to request that the Investigator complete an Interest Inventory.

8. Relatedness Review Process

A Relatedness Determination by COI Administrator

Once Interest Inventories have been submitted for all Investigators listed on a Notice of Award, the COI Administrator will review each Interest Inventory to determine whether it qualifies for a Relatedness Determination by the COI Administrator. The Relatedness Determination may be performed by the COI Administrator if:

- The Interest Inventory does not disclose any Significant Financial Interests related to the Investigator's Institutional Responsibilities; or
- The Significant Financial Interest(s) disclosed is/are obviously not related to the USF Research Project.

If there is any question about the qualification of the Interest Inventory for a Relatedness Determination by the COI Administrator under this Section 8.A., the COI Administrator will proceed as follows:

- For projects funded by a Federal Agency other than a PHS office/agency or an entity that has adopted the PHS Objectivity in Research Rule and for PHS-funded projects in which disclosed interests do not meet the threshold of a SFI as defined in the PHS Objectivity in Research Rule, the COI Administrator will gather additional information from the Investigator about the relationship of the disclosed interest to the project and will determine whether the interest is related to the project. If it is not clear whether the interest is related to the project, the COI Administrator will confer with the COI Committee Chairperson to determine whether the interest is related. If the interest is related, it will be reviewed and managed in the same manner as financial interests associated with non-federally funded projects (*see* Disclosure and Review and Management Process for USF Research Projects (General)). If the project is NSF-funded, the NSF Grantee Standards will be utilized to determine whether the interest must be reported to the NSF's Office of General Counsel.
- For PHS-funded projects for which the disclosed interest meets the PHS Objectivity in Research Rule's definition of a Significant Financial Interest, the COI Administrator will assign the Interest Inventory to the formal Relatedness Determination process as described in Sections 8.B and C.

B Assignment to Formal Relatedness Determination Process

The COI Administrator will promptly convene the RFD Committee to review any Interest Inventories associated with a Notice of Award that do not qualify for a Relatedness Determination by the COI Administrator under section 8.A.

C Relatedness Determination by RFD Committee

For each USF Research Project Funded by PHS or Certain Agencies, Foundations & Extramural Sponsors for which USF has received a Notice of Award that does not qualify for a Relatedness Determination by the COI Administrator, the RFD Committee will review the details of the project and determine whether the Investigator disclosed a Significant Financial Interest in the Investigator's Interest Inventory that is related to the USF Research Project. A Significant Financial Interest will be considered to be related if the Significant Financial Interest: (1) could be affected by the USF Research Project; or (2) is in an entity whose financial interest could be affected by the research.

In order to make the appropriate determination of relatedness, the RFD Committee may:

- Request that a scientist from a related field participate with the RFD Committee in making the relatedness determination;
- Request that an independent scientist read the specific aims of the research protocol or grant and determine whether a company's product is a tool used to study an aim (and thus incidental to the aim) or is the actual subject of the research;
- Determine whether any company sponsor or manufacturer listed in the grant or protocol is a wholly owned subsidiary or direct competitor of a company listed in an Investigator's Interest Inventory;
- If only drug compounds are listed (without an associated manufacturer), determine whether those compounds reflect a drug that is marketed or licensed by a company that is represented on an Investigator's Interest Inventory;
- Coordinate with the Technology Transfer Office, Patents &Licensing to determine whether the research, as described in the protocol or grant, would impact any existing intellectual property rights or create any new intellectual property rights that might be impacted by the research; and
- Seek clarifying information from the Investigator as necessary throughout the relatedness determination process.

D Documenting Relatedness Determination by RFD Committee

The relatedness determination of the RFD Committee and the rationale for the Committee's decision will be documented in the minutes of the RFD Committee and kept on file within the COI Program.

E Requirements Met	The procedures in this Section III.8 implement the requirements of the PHS Objectivity in Research Rule, 42 CFR §50.604(f), (i)[3], and the NSF Grantee Standards regarding conflicts of interest set forth in the NSF Proposal and Awards Policies and Procedures Guide (PAPPG). The procedures in this section also implement USF Policy 0-309, Section II.B.3.

[3]§ 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.

9. FCOI Determination Process

A
Analysis and FCOI Determination Subsequent to Relatedness Determination

If the RFD Committee determines that a Significant Financial Interest is related to a USF Research Project funded by the PHS or Certain Agencies, Foundations & Extramural Sponsors pursuant to the process in Section III.8.C., then the RFD Committee will immediately thereafter make an initial determination as to whether the SFI rises to the level of a Financial Conflict of Interest. An SFI will be considered an FCOI if, in the opinion of the RFD Committee, the SFI could *directly and significantly affect* the design, conduct or reporting of the USF Research Project.

Direct effect occurs where the outcome of the research will be directly relevant to the development manufacturing or improvement of products or services of the business entity (secondary interest).

Significant impact occurs where the value of the business entity, its earnings or the sales of its products (or its proposed subcontractor or participant in the federally funded project) will be materially affected by the outcome of the research.

Example: a direct effect/significant impact should be presumed in circumstances where the purpose of the research is to test the safety or efficacy of a product or invention in which the Investigator has a stake either as the inventor of the product or as an owner or investor in the business entity licensing or manufacturing the product.

B
Determination of No FCOI

If the RFD Committee determines that an SFI related to a USF Research Project is not an FCOI, then the Investigator will be instructed by the COI Administrator to complete a project-specific disclosure through the eCOI System and the SFI will be reviewed and managed in the same manner as financial interests related to other federally funded USF Research Projects.

Each Institution shall:
(f) Provide guidelines consistent with this subpart for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research.
(i) Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

C Determination of FCOI

If the RFD Committee initially determines that an SFI related to a USF Research Project is an FCOI, then the Investigator will be asked to complete a PHS-funded project-specific disclosure through the eCOI System and, if the COI Committee agrees with the RFD Committee's determination, the SFI will be reviewed and managed in accordance with Section III.10.

D Requirements Met

The procedures in this Section III.9 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.604(f)[4].

The procedures in this section also implement USF Policy 0-309, Section II.B.3.

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[4] § 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.
Each Institution shall:
(f) Provide guidelines consistent with this subpart for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

10. FCOI Management Process

A
Receipt of Project Specific Disclosure in eCOI System

If an initial determination of an FCOI has been made per Section III.9.C., then the COI Administrator will instruct the Investigator to complete a PHS-funded project-specific disclosure through the eCOI System. The COI Administrator will be alerted that the project-specific disclosure for the study has been completed when the disclosure appears in the COI Administrator's inbox in the eCOI System.

B
COI Administrator Review of Project Specific Disclosure and Preparation of FCOI Management Plan

The COI Administrator will review the PHS-funded project-specific disclosure and the proposal or statement of research and will prepare a proposed FCOI Management Plan for presentation to the COI Committee, consulting the Investigator in this process as may be required.

C
Elements of the FCOI Management Plan

The FCOI Management Plan prepared by the COI Administrator will include, at a minimum, the following specific elements, which elements shall also be included in the FCOI Report to the PHS or Certain Agencies, Foundations & Extramural Sponsors as required under Section III.11., below:

(i) Project Number;

(ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;

(iii) Name of the Investigator with the FCOI;

(iv) Name of the entity with which the Investigator has an FCOI;

(v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

(vi) 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;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for USF's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of USF's management plan, including:

(A) Role and principal duties of the conflicted Investigator in the research project;

(B) Conditions of the Management Plan;

(C) How the Management Plan is designed to safeguard objectivity in the research project;

(D) Confirmation of the Investigator's agreement to the Management Plan;

(E) How the Management Plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

D
Assignment of FCOI Management Plan to COI Committee

In the eCOI System, the COI Administrator will assign the PHS-funded project-specific disclosure and associated FCOI Management Plan to the next scheduled meeting of the COI Committee.

E
Review and Management of FCOI by COI Committee

At its next scheduled meeting, *and prior to USF's expenditure of any funds under a USF Research Project Funded by PHS or Certain Agencies, Foundations & Extramural Sponsors,* the COI Committee will review the PHS-funded project-specific disclosure and associated FCOI Management Plan and determine 1) whether it concurs with the RFD Committee's assessment that the SFI represents an FCOI; and 2) whether the FCOI Management Plan is sufficient to maintain objectivity of the research.

Examples of conditions or restrictions that the COI Committee might impose to manage an FCOI include, but are not limited to:

(i) *Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

(ii) *For research projects involving human subjects, disclosure of financial conflicts of interest directly to participants;

(iii) 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;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.

Additionally, the COI Committee may require that the interest be reduced or eliminated and may impose the following conditions prior to allowing the research to proceed:

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

*NOTE: *Disclosure alone is not sufficient to manage an FCOI.*

F
Documentation of COI Committee Action

Following a COI Committee meeting at which an FCOI Management Plan has been reviewed, the COI Administrator will document the actions taken by the COI Committee and if the FCOI Management Plan was approved, upload it into the eCOI System.

G
Monitoring Required

Whenever the COI Committee implements an FCOI Management Plan pursuant to Section III.10, the COI Committee shall monitor Investigator compliance with the Management Plan on an ongoing basis until the completion of the USF Research Project.

H Requirements Met

The procedures in this Section III.10 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.604(g); § 50.605 (a)(1),(4)[5].

The procedures in this section also implement USF Policy 0-309, Section II.B.3.

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[5] §50.604
Each Institution shall:
(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section.
…
§ 50.605 Management and reporting of financial conflicts of interest.
(a) Management of financial conflicts of interest.
(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with § 50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research); (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants; (iii) 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; (iv) Modification of the research plan; (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or (vii) Severance of relationships that create financial conflicts.
…
(4) Whenever an Institution implements a management plan pursuant to this subpart, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

11. FCOI Reporting Process

A **Reporting of FCOIs to the Funding Agency by the COI Administrator**	*Prior to USF's expenditure of any funds under a USF Research Project Funded by PHS or Certain Agencies, Foundations & Extramural Sponsors*, the COI Administrator shall provide to the PHS or Certain Agencies, Foundations & Extramural Sponsors an FCOI report regarding any Investigator's FCOI found by USF to be conflicting according to Sections III.8-9. In cases in which USF identifies an FCOI and eliminates it prior to the expenditure of funds, the COI Administrator shall not submit an FCOI report to the PHS or Certain Agencies, Foundations & Extramural Sponsors. For National Science Foundation-funded USF Research Projects, the COI Administrator will notify the NSF Office of General Counsel if required by the NSF Grantee Guidelines.
B **Required Elements in an FCOI Report**	The COI Administrator will include the elements identified in Section III.10. C. in any FCOI report to PHS or Certain Agencies, Foundations & Extramural Sponsors. In all instances, the FCOI report shall include sufficient information to enable the PHS or Certain Agencies, Foundations & Extramural Sponsors to understand the nature and extent of the financial conflict, and to assess the appropriateness of USF's Management Plan.
C **Manner and Timing of FCOI Report**	For new awards, the COI Administrator will submit the FCOI report to the PHS or Certain Agencies, Foundations & Extramural Sponsors in the manner directed by such sponsor prior to the expenditure of funds.

D Requirements Met

The procedures in this Section III.11 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.604(h); §50.605 (b)(1),(3)[6].

The procedures in this section also implement USF Policy 0-309, Section II.B.3.

[6] § 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.
Each Institution shall:
(h) Provide initial and ongoing FCOI reports to the PHS as required pursuant to § 50.605(b).
…
§50.605 (b) Reporting of financial conflicts of interest.
(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this subpart. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.
…
(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following: (i) Project number; (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used; (iii) Name of the Investigator with the financial conflict of interest; (iv) Name of the entity with which the Investigator has a financial conflict of interest; (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium); (vi) 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;
(vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and (viii) A description of the key elements of the Institution's management plan, including:
(A) Role and principal duties of the conflicted Investigator in the research project;
(B) Conditions of the management plan;
(C) How the management plan is designed to safeguard objectivity in the research project;
(D) Confirmation of the Investigator's agreement to the management plan;
(E) How the management plan will be monitored to ensure Investigator compliance; and
(F) Other information as needed.

PART IV FINANCIAL CONFLICT OF INTEREST (FCOI): ONGOING AWARDS FROM FEDERAL AGENCIES OR CERTAIN AGENCIES, FOUNDATIONS & EXTRAMURAL SPONSORS

12. USF Review of Disclosure

A **Disclosure by Investigator New to a USF Research Project**	Whenever, in the course of an ongoing USF Research Project funded by a federal agency or by Certain Agencies, Foundations & Extramural Sponsors, *an Investigator who is new to participating in the research project* completes an Interest Inventory, the COI Administrator shall, within sixty (60) days complete the procedures set forth in Section III.8-9 in order to determine whether any SFIs disclosed are related to the USF Research Project and if so, whether an FCOI exists.
B **Disclosure of New SFI by Existing Investigator on a USF Research Project**	Whenever, in the course of an ongoing USF Research Project funded by a federal agency or Certain Agencies, Foundations & Extramural Sponsors, *an existing Investigator updates an Interest Inventory with a new SFI*, the COI Administrator shall, within sixty (60) days complete the procedures set forth in Section III.8-9 in order to determine whether the SFI is related to the USF Research Project and if so, whether an FCOI exists.
C **SFI Not Disclosed/ Reviewed Timely**	Whenever, in the course of an ongoing USF Research Project funded by a federal agency or Certain Agencies, Foundations & Extramural Sponsors, USF identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by USF (e.g., was not timely reviewed or reported by a subrecipient), the COI Administrator shall, within sixty (60) days complete the procedures set forth in Section III.8-9 in order to determine whether the SFI is related to the USF Research Project and to determine whether an FCOI exists.
D **Requirements Met**	The procedures in this Section IV.12 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.605 (a)(2)[7]. The procedures in this section also implement USF Policy 0-309, Section II.B.5.

[7] §50.605 (a) Management of financial conflicts of interest.
(2) Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research [and] determine whether a financial conflict of interest exists[.]

13. Interim Management Plan

A Interim Management Plan	If an FCOI is found in connection with the review in Section IV.12, the COI Administrator and/or COI Committee shall implement, on at least an interim basis, a Management Plan that shall specify the actions that have been, and will be, taken to manage the FCOI. Depending on the nature of the SFI, the COI Administrator and/or COI Committee may determine that additional interim measures are necessary with regard to the Investigator's participation in the USF Research Project between the date of disclosure and the completion of USF's review.
B Requirements Met	The procedures in this Section IV.13 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.605 (a)(2)-(3)[8]. The procedures in this section also implement USF Policy 0-309, Section II.B.5.

14. Ongoing FCOI Reporting Process

A Subsequent FCOI Reports	For any SFI that the RFD Committee identifies as conflicting per Section III.9 subsequent to the initial FCOI report submitted under Section IV.11 during an ongoing PHS-funded USF Research Project, the COI Administrator shall provide to PHS or Certain Agencies, Foundations & Extramural Sponsors, within *sixty (60) days*, an FCOI report regarding the FCOI and ensure that USF has implemented an FCOI Management Plan.
B Requirements Met	The procedures in this Section IV.14 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.605 (b)(2)[9]. The procedures in this section also implement USF Policy 0-309, Section II.B.3.

[8] §50.605 (a) Management of financial conflicts of interest.
(2) …[If] a financial conflict of interest exists…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 financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional 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 Institution's review.

[9] §50.605 (b) Reporting of financial conflicts of interest.
(2) …For any significant financial interest that the Institution 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 Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this subpart.

PART V RETROSPECTIVE REVIEW OF PROJECTS FUNDED BY PHS OR CERTAIN AGENCIES, FOUNDATIONS & EXTRAMURAL SPONSORS

15. Retrospective Review

A Retrospective Review: Triggering Events

If an FCOI is found in connection with the review in Section IV.12 for a PHS- or Certain Agencies, Foundations & Extramural Sponsors-funded USF Research Project, and it is determined by the COI Administrator that the FCOI was not identified or managed in a timely manner including, but not limited to:

(i) failure by the Investigator to disclose the SFI that was determined by USF to be an FCOI; or
(ii) failure by USF to review or manage such FCOI; or
(iii) failure by the Investigator to comply with an FCOI Management Plan,

then the COI Committee shall, within one hundred and twenty (120) days of such determination by the COI Administrator, complete a Retrospective Review of the Investigator's activities and the USF Research Project to determine whether any research funded by PHS or Certain Agencies, Foundations & Extramural Sponsors, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research.

B Retrospective Review: Documentation/ Key Elements

The COI Administrator will document the Retrospective Review. Such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Project number;

(2) Project title;

(3) PD/PI or contact PD/PI if a multiple PD/PI model is used;

(4) Name of the Investigator with the FCOI;

(5) Name of the entity with which the Investigator has a financial conflict of;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review.

C **Update FCOI Report**	Based on the results of the Retrospective Review, if appropriate, the COI Administrator shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
D **Requirements Met**	The procedures in this Section V.15 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.605 (a)(3)[10]. The procedures in this section also implement USF Policy 0-309, Section II.B.6.

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[10] §50.605 (a) Management of financial conflicts of interest.
(3) Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:
(i) 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 financial conflict of interest going forward;
(ii)(A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to 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.
(B) The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements: (1) Project number; (2) Project title; (3) PD/PI or contact PD/PI if a multiple PD/PI model is used; (4) Name of the Investigator with the FCOI; (5) Name of the entity with which the Investigator has a financial conflict of interest; (6) Reason(s) for the retrospective review; (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (8) Findings of the review; and (9) Conclusions of the review.
(iii) Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

PART VI MITIGATION REPORT FOR PROJECTS FUNDED BY PHS OR CERTAIN AGENCIES, FOUNDATIONS OR EXTRAMURAL SPONSORS

16. Mitigation Report

A
Mitigation Report

If bias is found in connection with the Retrospective Review conducted under Section V.15, the COI Administrator will notify the PHS or Certain Agencies, Foundations & Extramural Sponsors promptly and will submit a mitigation report to the sponsor. The mitigation report must include, at a minimum, the key elements documented in Section V.15.B. and a description of the impact of the bias on the USF Research Project and USF'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).

B
Interim Measures

Depending on the nature of the FCOI, USF may determine that additional interim measures are necessary with regard to the Investigator's participation in the USF Research Project between the date that the FCOI (or the Investigator's noncompliance) is determined and the completion of the COI Committee's retrospective review.

C
Annual FCOI Reports

Following completion of the procedures in this Section VI.16, the COI Administrator will submit FCOI reports annually, as provided in Section III.11.

D
Requirements Met

The procedures in this Section VI.16 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.605 (a)(3)(iii)[11].

The procedures in this section also implement USF Policy 0-309, Section II.B.7.

[11] §50.605 (a) Management of financial conflicts of interest.
(3)(iii) …If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution'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). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this subpart.

17. Remedies for Noncompliance

A **Notification to PHS or Certain Agencies, Foundations & Extramural Sponsors Where Bias is Found Due to Noncompliance**	If the failure of an Investigator to comply with USF FCOI Policy or an FCOI Management Plan (hereinafter "noncompliance") appears to have biased the design, conduct, or reporting of the USF Research Project, the COI Administrator shall promptly notify the PHS or Certain Agencies, Foundations & Extramural Sponsors of the corrective action taken or to be taken.
B **Training Requirement**	Upon discovery of an Investigator's noncompliance, the COI Administrator will require the Investigator to submit to training as required by Section VIII.20.
C **Sanctions**	Noncompliance of an Investigator, including a PHS subrecipient Investigator, will be referred to the COI Committee for appropriate handling in accordance with the Operating Procedures for the COI Committee. [*See* "USF COI Committee Operating Procedures", INTERESTED PERSON NONCOMPLIANCE.]
D **Requirements Met**	The procedures in this Section VI.17 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.604(k) and §50.606 (a)[12]. The procedures in this section also implement USF Policy 0-309, Section II.B.2.c.iii.

[12] §50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.
Each Institution shall:
(k) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
…
§ 50.606 Remedies.
(a) If the failure of an Investigator to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Institution shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.

PART VII PUBLIC ACCESSIBILITY OF INFORMATION REGARDING PROJECTS FUNDED BY PHS OR CERTAIN AGENCIES, FOUNDATIONS & EXTRAMURAL SPONSORS

18. Written Response to Requestors

A
Public Request for Information Concerning an SFI

Within *five (5) business days* of receiving a written request, the COI Administrator shall respond to a written request for information concerning any SFI disclosed to USF for an Investigator acting as Senior/Key Personnel on a USF Research Project funded by PHS or Certain Agencies, Foundations & Extramural Sponsors that meets the following three criteria:

(A) The SFI was disclosed and is still held by the Investigator;

(B) USF has determined that the SFI is related to the USF Research Project; and

(C) USF has determined that the SFI is an FCOI.

B
Information Included in Response

The information that the COI Administrator makes available to any requestor shall include, at a minimum, the following:

(i) the Investigator's name;

(ii) the Investigator's title and role with respect to the USF Research Project;

(iii) the name of the entity in which the SFI is held;

(iv) the nature of the SFI;

(v) and the approximate dollar value of the SFI (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.

The COI Administrator will note in the written response 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 USF's identification of a new FCOI, which should be requested subsequently by the requestor.

C
Retention Period for FCOI Information

Information concerning the SFIs of an Investigator will available for at least three (3) years from the date that the information was most recently updated.

D Requirements Met	The procedures in this Section VII.18 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.605(a)(5)[13]. The procedures in this section also implement USF Policy 0-309, Section II.D.

[13] §50.605 (a) Management of financial conflicts of interest.
(5)Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and

(C) The Institution determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: 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.

(iii) …If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response 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 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv)Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

19. Response to Request from PHS or Certain Agencies, Foundations & Extramural Sponsors

A **PHS or Certain Agencies, Foundations & Extramural Sponsors Request for Information Concerning an SFI**	Promptly upon request by PHS or Certain Agencies, Foundations & Extramural Sponsors, the COI Administrator will make information available relating to any Investigator disclosure of financial interests and USF's review of, and response to, such disclosure, whether or not the disclosure resulted in a determination of an FCOI.
B **Retention Period for FCOI Information**	Information concerning the SFIs of an Investigator will available for at least three (3) years from the date that the information was most recently updated.
C **Requirements Met**	The procedures in this Section VII.19 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.604(k)(4)[14].

[14]§ 50.604 Responsibilities of Institutions regarding Investigator financial conflicts of interest.
Each Institution shall:
(k) Certify, in each application for funding to which this subpart applies, that the Institution:
…
(4) 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[.]

PART VIII INVESTIGATOR TRAINING

20. Training: Content & Timing

A Investigator Training: Content

The COI Administrator shall inform each Investigator of USF FCOI Policy, the Investigator's responsibilities regarding disclosure of SFIs, and of the PHS Objectivity in Research Rule (collectively "training").

B Investigator Training: Timing

The COI Administrator/USF will require each Investigator to complete training:

(1) prior to engaging in a USF Research Project funded by a federal agency or by Certain Agencies, Foundations & Extramural Sponsors; *and*
(2) at least every three (3) years; *and*
(3) *immediately* when any of the following circumstances apply:

a. USF revises its USF FCOI Policy or procedures in any manner that affects the requirements of Investigators;
b. an Investigator is new to the USF; or
c. USF finds that an Investigator is not in compliance with USF FCOI Policy or an FCOI Management Plan.

C Requirements Met

The procedures in this Section VIII.20 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.604(b)(5)[15].

The procedures in this section also implement USF Policy 0-309, Section II.B.2.

[15] §50.604. Responsibilities of Institutions regarding Investigator financial conflicts of interest.
Each Institution shall:
(b) Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

(1) The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

(2) An Investigator is new to an Institution; or

(3) An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

PART IX SUBRECIPIENTS

21. Subrecipients

A
USF Responsibility for Subrecipients

If USF carries out a USF Research Project Funded by the National Science Foundation or by PHS or Certain Agencies, Foundations & Extramural Sponsors through a subrecipient (e.g., subcontractors or consortium members), USF is responsible for ensuring subrecipients' compliance with the National Science Foundation's Grantee Standards or the PHS Objectivity in Research Rule, as appropriate according to the source of funding.

B
USF Subrecipient Policy/Procedure

As soon as a USF department/unit research administrator or Investigator becomes aware of a proposed subrecipient, the department/unit research administrator or Investigator must confirm whether the subrecipient entity has a PHS or NSF-compliant COI policy (as is appropriate according to the funding source). PHS subrecipients listed on the FDP Clearinghouse List of Compliant Institutions and Entities are not required to complete USF Subrecipient Conflict of Interest Disclosure Form A. PHS subrecipients not listed on the FDP Clearinghouse and all NSF subrecipients must complete USF Subrecipient Conflict of Interest Disclosure Form A. Those PHS subrecipients whose institutions have a PHS-compliant COI policy must follow that policy.

If the proposed subrecipient indicates on Subrecipient COI Disclosure Form A that it does not have a PHS or NSF-compliant COI policy and as such will follow USF's FCOI Policy, 0-309, each subrecipient Investigator must also complete USF Subrecipient COI Disclosure Form B. Documentation of the completion of Forms A and B should be included in the proposal package sent to SR.

C Management and Reporting of PHS Subrecipient FCOIs

For PHS-funded subrecipient Investigators following their own institution's COI policy who have an FCOI pursuant to their institutional official's determination, an FCOI report must be submitted to the USF COI Program Administrator according to the following:

1) For new awards, prior to execution of the subagreement;
2) For disclosures made during the course of an award, within forty-five (45) days of the subrecipient institution's receipt of the Investigator's disclosure.

For subrecipient Investigators following USF's FCOI Policy who disclose an SFI that is directly related to the Investigator's work for USF, the USF Conflict of Interest Administrator will prepare a Proposed Management Plan for presentation to the USF COI Committee, consulting the Investigator as necessary. The USF COI Administrator will assign the Management Plan to the next COI Committee Meeting, at which the Committee will review the Management Plan and determine whether it is sufficient to maintain objectivity of the research. Following a COI Committee meeting at which a subrecipient's FCOI Management plan has been reviewed and approved, the COI Administrator will draft a Final Management Plan and provide a copy to the USF Principal Investigator and the subrecipient.

For all PHS-funded subrecipient Investigators deemed to have an FCOI (whether by their own institutional official or by the USF COI Committee), *prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI,* the COI Administrator will provide FCOI reports to the PHS Awarding Component or to the Certain Agency, Foundation or Extramural sponsors sponsoring the project.

D Retrospective Review and Mitigation of Subrecipient FCOIs	The COI Administrator will follow the procedures in Section V and VI under the following circumstances: (i) failure by the subrecipient Investigator to disclose a SFI that was determined by USF to be an FCOI; or (ii) failure by USF to review or manage such FCOI; or (iii) failure by the subrecipient Investigator to comply with an FCOI Management Plan.
E Requirements Met	The procedures in this Section IX.21 implement the following requirements of the PHS Objectivity in Research Rule: 42 CFR §50.604(c), (g)[16]. The procedures in this section also implement USF Policy 0-309, Section II.C.

[16] §50.604. Responsibilities of Institutions regarding Investigator financial conflicts of interest.
Each Institution shall:

(c) If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this subpart;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this subpart.
…
(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section.

Exhibit 1. List of Acronyms

A List of Acronyms

The table below contains the list of acronyms used in this guide and the term referred to by each acronym.

Acronym	Term
CFR	Code of Federal Regulations
COI	Conflict of Interest
DRIC	Division of Research Integrity & Compliance
DSR	Division of Sponsored Research
FCOI	Financial Conflict of Interest
NSF	National Science Foundation
ORI	Office of Research and Innovation
PD	Project Director
PHS	Public Health Service
PI	Principal Investigator
RFD	Relatedness and FCOI Determination
SFI	Significant Financial Interest
USF	University of South Florida

Exhibit 2. Glossary of Terms

A Glossary of Terms

The table below contains a glossary of terms used in this guide.

***Denotes that the term first appears in the context of another definition.**

Term	Definition
Conflicts of Interest	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.
***Exempt Organization**	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).
Financial Conflict of Interest (FCOI)	A Financial Conflict of Interest exists when USF reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of a Federally-Funded USF Research Project.
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 FCOI Policy.
Funded by PHS or Certain Agencies, Foundations & Extramural Sponsors	A USF 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. For a current list of entities that have adopted the PHS Objectivity in Research Rule, please reference the FDP Clearinghouse website.
***Immediate Family**	Spouse, domestic partner, and each dependent child.
Institutional Responsibilities	An Investigator's professional responsibilities on behalf of USF, including but not limited to teaching, research, research consultation, professional practice, and USF committee memberships.
Investigator	Means the project director or principal investigator and *any other person* (faculty, staff, students, and collaborators or consultants outside of USF), regardless of title or 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. Also, any Investigator working on a USF 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.
PHS Objectivity in Research Rule	42 CFR Part 50 Subpart F-Objectivity in Research
***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 of a project funded by the PHS or Certain Agencies, Foundations & Extramural Sponsors, which is conducted by USF upon determining 1) that an SFI not timely disclosed or reviewed is an FCOI or 2) that an Investigator has failed to comply with an FCOI Management Plan. The Retrospective Review will consist of a review of the Investigator's activities and the USF Research 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 noncompliance of the 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 Investigator with the FCOI; e. Entity with which the 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).
Senior/Key Personnel	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.
Subrecipient Investigator	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.
USF Research Project	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 the 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: • 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.

***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); II. 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; III. 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 the University. 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.). IV. 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. V. 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 the 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 Exempt Organization*. 42 CFR §50.603(1), (2), and (3).

Exhibit 3. Table of Authority

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Table of Authority

The table below lists the statutes and regulations that render authority for the provisions of this guide.

No.	Authority
1	*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")
2	USF Policy 0-309, *Individual Conflicts of Interest in USF Research Projects and USF Financial Conflict of Interest (FCOI)*
3	National Science Foundation's Proposal and Awards Policies and Procedures Guide