FINANCIAL CONFLICT OF INTEREST MANAGEMENT PLAN

Faculty Name	
Department	
Project / Grant	
Sponsor / Funder	
Plan Date	*Review Date:*

1. Purpose and Regulatory Background

This Financial Conflict of Interest (FCOI) Management Plan has been developed in accordance with the following regulatory frameworks:

- 42 CFR Part 50, Subpart F — NIH regulations on Promoting Objectivity in Research
- 45 CFR Part 94 — PHS regulations applicable to grantee institutions
- University of San Francisco Financial Conflict of Interest Policy
- Federal Acquisition Regulation (FAR) 52.203-16 (for federal contracts, where applicable)

The purpose of this plan is to manage, reduce, or eliminate identified financial conflicts of interest that could bias the design, conduct, or reporting of research funded by a Public Health Service (PHS) agency or other applicable sponsor. The existence of a financial conflict of interest does not imply misconduct; rather, this plan establishes transparent safeguards to protect research integrity.

2. Identification of the Financial Conflict of Interest

The Investigator has disclosed the following Significant Financial Interest (SFI) that has been determined to constitute a Financial Conflict of Interest (FCOI) as defined under applicable regulations and university policy:

Field	Details
Entity Name	
Nature of Interest	

Field	Details
Annual Value	
Relationship to Research	
Date Disclosed	
FCOI Determination Date	

3. Description of the Research Project

The following research project is subject to this management plan:

Field	Details
Project Title	
Award / Grant Number	
Funding Source	
Project Period	
Role of Investigator	
Project Summary	

4. Risk Assessment

The Research Compliance Office has assessed the nature and degree of the financial interest relative to the funded research and has identified the following risk factors:

Risk Factor	Level	Notes
Investigator has decision-making authority over research design	Low	
Entity could benefit financially from research outcome	Low	
Human subjects are involved in the research	Low	
Investigator controls data collection and analysis	Low	

Risk Factor	Level	Notes
Research involves proprietary materials from entity	Low	
Publication or dissemination rights could be restricted	Low	

5. Management Conditions and Strategies

Based on the risk assessment above, the following management conditions are established and required of the Investigator. All conditions are effective immediately upon signing of this plan.

5.1 Disclosure and Transparency Requirements

- The Investigator must disclose the FCOI in all presentations, publications, and public communications arising from this research.
- Disclosure language must read: 'The author declares a financial interest in [Entity Name], which may have an interest in the results of this research.'
- A copy of this management plan must be provided to journal editors or conference organizers upon submission of any manuscript or abstract related to this work.
  - Provide disclosure in the manuscript's conflict-of-interest statement section.
  - Notify the journal of the plan upon submission via cover letter.

5.2 Research Oversight and Independent Review

- An independent monitor or oversight committee shall review the Investigator's research procedures, data, and conclusions at minimum [quarterly / semi-annually].
- The Investigator shall not serve as the sole decision-maker on key research activities. The following individuals are designated as independent overseers:

Responsible for:	Name	Title	Department
Independent Data Review			
Subject enrollment decisions (if applicable)			

- Any deviation from the approved research protocol must be reviewed and approved by the oversight committee prior to implementation.

5.3 Restrictions on Investigator Authority

- The Investigator is prohibited from making unilateral decisions regarding: subject enrollment, data collection, statistical analysis methodology, or interpretation of results without independent co-review.

- Any subcontract, purchase order, or financial arrangement with [Entity Name] in connection with this project must receive prior written approval from the Research Compliance Office.
- The Investigator may not negotiate or execute agreements with [Entity Name] relating to the research without approval from the Office of Sponsored Programs.

5.4 Data Management and Integrity

- All research data must be stored in the University's secure institutional data repository and be accessible to the oversight monitor.
- A data audit trail must be maintained for all datasets generated under this award.
- Raw data may not be shared with without prior written authorization from the Office of Sponsored Programs, and, where applicable, the institutional IRB.

5.5 Financial Arrangements

- Consulting, speaking, advisory, or other compensation from must not exceed the amounts disclosed, without updated disclosure to the Office of Sponsored Programs.
- The Investigator must not enter into new equity positions, royalty arrangements, or financial agreements with during the project period without prior written notification to and approval from the Office of Sponsored Programs.
- The Investigator's compensation from must not be contingent on the outcomes of this research.

5.6 Mandatory Training

- The Investigator must complete the University's FCOI training module within 30 days of plan execution (or prior to conducting research if not yet completed).
- Refresher training is required annually for the duration of the project.
- Training completion records must be submitted to the Research Compliance Office.

6. Monitoring and Reporting Requirements

The Research Compliance Office will conduct ongoing monitoring to ensure adherence to this management plan throughout the project period.

Activity	Frequency	Responsible Party
Investigator self-certification of compliance	Annually and upon renewal	Investigator
Independent data and protocol review	Quarterly ☐ Semi-Annually ☐	Designated Oversight Monitor
FCOI status update / re-disclosure review	Annually or upon change in SFI	Research Compliance Office
Audit of financial arrangements with entity	Annually	Research Compliance Office

Activity	Frequency	Responsible Party
Review of publications and presentations	Prior to each submission	Compliance Officer + Investigator
Full plan review and renewal	Annually or upon change in project scope	Research Compliance Office + Department Chair

The Investigator must notify the Research Compliance Office within 30 days of any material change in the financial interest, including but not limited to: changes in the value of equity, new consulting arrangements, additional roles with the entity, or termination of the financial relationship.

7. Consequences of Non-Compliance

Failure to comply with the terms of this Management Plan may result in:

- Suspension or termination of research activities under the affected award
- Notification to the sponsoring agency (e.g., NIH Office of Research Integrity), as required by 42 CFR Part 50, Subpart F
- Retroactive review of affected research data and findings
- Institutional disciplinary action in accordance with the University's Faculty Handbook and Research Misconduct Policy
- Requirement to correct or retract affected publications
- Debarment from future research funding (in cases of willful noncompliance)

Noncompliance that is not corrected within 120 days of discovery by the Investigator will be reported to the sponsoring agency in accordance with federal regulations.

8. Plan Modifications

This plan may be modified under the following circumstances:

- Material change in the nature or value of the Investigator's financial interest
- Change in the scope, aims, or direction of the funded research project
- Change in the Investigator's role or responsibilities on the project
- Acquisition of a new financial interest in any entity with relevance to the research
- Annual plan review finds current conditions insufficient

Modifications must be approved in writing by the Associate Vice Provost for Sponsored Programs. Modified versions of this plan will supersede prior versions and will be date-stamped accordingly.

9. Signatures and Acknowledgments

By signing below, each party acknowledges having read and understood this Financial Conflict of Interest Management Plan and agrees to fulfill the responsibilities assigned herein.

Investigator	Associate Vice Provost
Signature: _____	Signature: _____
Printed Name: _____	Printed Name: _____
Date: _____	Date: _____

Dean	Provost (if required)
Signature: _____	Signature: _____
Date: _____	Date: _____

Appendix A: Definitions

Term	Definition
Significant Financial Interest (SFI)	A financial interest of the Investigator (and/or their spouse/domestic partner and dependent children) that reasonably appears related to their institutional responsibilities, meeting applicable threshold criteria.
Financial Conflict of Interest (FCOI)	A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded or other sponsored research.
Investigator	The PI, co-PI, and any other person responsible for the design, conduct, or reporting of the research, regardless of title or position.
Management Plan	A written plan to manage, reduce, or eliminate the identified FCOI, developed by the institution and agreed to by the Investigator.
PHS	Public Health Service — includes NIH, CDC, FDA, AHRQ, HRSA, SAMHSA, and other component agencies of HHS.

Appendix B: Reference Regulations and Policies

- 42 CFR Part 50, Subpart F — Promoting Objectivity in Research (NIH FCOI regulations)
- 45 CFR Part 94 — Responsible Prospective Contractors
- [University Name] Financial Conflict of Interest in Research Policy — Policy No. [XXX]
- [University Name] Research Misconduct Policy
- NIH Guide Notice NOT-OD-19-116 — FCOI Reporting and Disclosure Guidance

- Federal Acquisition Regulation (FAR) 52.203-16

This document is maintained by the Office of Sponsored Programs. For questions regarding this plan, contact: grantscompliance@usfca.edu