

**IMPLEMENTATION OF THE FINANCIAL CONFLICT OF INTEREST POLICY
FOR PHS SPONSORED PROJECT
Effective August 24, 2012, PHS sponsored research projects**

I. Purpose & Scope

The purpose of this policy is to implement the 2011 Public Health Services (PHS) regulations on Promoting Objectivity in Research and is applicable to all PHS Research Activities with an award issue date of August 24, 2012, or later, and to proposals for research activities submitted to PHS on or after August 24, 2012.

PHS Research Activities that are ongoing as of August 24, 2012, will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, proposal for supplemental funding, or through approval of a no-cost time extension. This Policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are have or share responsibility for the design, conduct, or reporting of a PHS Research Activity.

The Policy is applicable to all research activities supported by PHS and by other sponsors and programs that specifically request review consistent with the PHS regulations on objectivity in research.

Eight agencies are designated components of the U.S. Public Health Service (PHS):

- (1) Agency for Healthcare Research and Quality (AHRQ),
- (2) Agency for Toxic Substances and Disease Registry (ATSDR),
- (3) Centers for Disease Control and Prevention (CDC),
- (4) Food and Drug Administration (FDA),
- (5) Health Resources and Services Administration (HRSA),
- (6) Indian Health Service (IHS),
- (7) National Institutes of Health (NIH)
- (8) Substance Abuse and Mental Health Services Administration (SAMHSA)

Other agencies which have adopted PHS guidelines:

- (1) Alliance for Lupus Research (ALR)
- (2) Alpha-1 Foundation
- (3) American Asthma Foundation (AAF)
- (4) American Cancer Society (ACS)
- (5) American Heart Association (AHA)
- (6) American Lung Association (ALA)
- (7) Arthritis Foundation (AF)
- (8) California Institute for Regenerative Medicine (CIRM)
- (9) Cure PSP
- (10) Juvenile Diabetes Research Foundation (JDRF)
- (11) Lupus Foundation America (LFA)
- (12) Patient-Centered Outcomes Research Institute (PCORI)
- (13) Susan G. Komen for the Cure
- (14) University of California, Office of the President (UCOP) Special Programs:

- University AIDS Program
- California Breast Cancer Program
- Tobacco-Related Disease Research Program

II. **Definitions**

University Conflict of Interest Committee:

The University Conflict of Interest Committee is established according to [UPS 610.000. IV Conflict of Interest Policy for Externally Funded Proposals](#)

Investigator:

Investigator means the project director or principal investigator and any other person, regardless of title or position, who has responsibility, or shares responsibility with the Principal Investigator, for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding. This includes but is not limited to individuals identified as Key Personnel in the contract or grant proposal. It may also include collaborators who are identified as consultants and/or subcontractors where the foregoing definition may apply.

Key Personnel:

A PHS research Project Director, Principal Investigator and any other personnel considered essential to work performance and identified as Key Personnel in the contract or grant proposal.

Principal Investigator:

An Investigator (normally an academic appointee) who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a sponsored project.

PHS Research Activity(ies):

Any award for which research funding is available from PHS including research contracts, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards and conference grants. Only Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) awards programs are excluded.

Outside Activity:

Any professional or remunerative activity undertaken by CSUF faculty or other professional personnel that is outside the scope of their designated University duties.

Financial Interest:

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Financial Conflict of Interest:

For the purposes of this policy, financial conflict of interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research. A conflict exists when it has been determined that:

- (a) an outside activity or economic interest undertaken or held by an Investigator (including economic interests of the Investigator's spouse/domestic partner and dependent children) does-- or appears to-- compete, interfere, or otherwise adversely affect the Investigator's professional obligations to the University, the CSUF Auxiliary Corporation (ASC) and/or a designated external sponsor;
- (b) when entities in which economic interests are held would be directly and significantly affected by the research or educational activities of the Investigator such that reasonable questions might be raised as to whether such actions are determined primarily by considerations of personal financial gain; or
- (c) when a significant financial interest could directly and significantly affect the design, conduct or reporting of funded research or educational activities.

Institutional Responsibilities:

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards and Data and Safety Monitoring Boards.

Significant Financial Interest (SFI):

Anything of monetary value that:

- meets the PHS thresholds (see Section III.C below) for reporting received by the Investigator, and except for travel, received by the Investigator's spouse or registered domestic partner, and dependent children for the following categories; *and*
- reasonably appears to be related to or is in the same field of expertise as the Investigator's Institutional Responsibilities.

III. Statement of PHS Regulations:

The PHS regulations on Objectivity in Research (revised in August 2011) are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct and reporting of PHS Research Activities will be free from bias resulting from any Investigator's Financial Conflicts of Interest.

Each institution applying for or receiving research support from PHS must comply with the regulations by putting in place a policy to ensure the following:

A. Investigators complete a training/education program:

1. Before engaging in PHS Research Activities and at least every 4 years thereafter while receiving PHS research funding, and
2. Whenever an Investigator is not in compliance with this Policy or has failed to comply with a plan put in place to manage or mitigate a Financial Conflict of Interest

B. Investigators disclose Significant Financial Interests at the following times:

1. Initial disclosures must be made by all Investigators planning to participate on a proposed PHS Research Activity before the application for funding is submitted.
2. CSUF Investigators who are engaged in PHS Research Activities have an ongoing

- responsibility to update their disclosures throughout the period of PHS support:
- Within 30 days of acquiring or discovering any new SFI; and
 - At least annually
3. New Investigators must complete an initial disclosure of SFIs before joining an ongoing PHS Research Activity

C. Investigators disclose to CSUF SFIs that meet the following thresholds:

1. For a *publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months and the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds \$5,000.

[Investigators are not required to disclose SFI in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles]

2. For a *non-publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months that exceeds \$5,000, or equity interest of any amount, including, but not limited to stock, stock options, or ownership interest in the entity.

[Investigators are not required to disclose (a) payments made by CSUF, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from CSUF; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education] so long as they do not involve contractual obligations that would conflict with the researcher's obligations as an CSUF employee under the terms of the University's patent, copyright or other intellectual property policies.

3. *Intellectual property rights and interests*: Income received during the previous 12 months that exceeds \$5,000 for such rights and interests.
4. *Travel*: The occurrence of any sponsored or reimbursed travel must be disclosed whether payment is made to the Investigator directly, or expenses are paid on behalf of the Investigator by a for-profit or non-profit organization:
- a. Either prospectively, by listing all travel that the Investigator anticipates will be sponsored or reimbursed during the next 12 months, or

- b. Within 30 days of the occurrence if the trip wasn't reported prospectively.
[Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education]

IV. Disclosures by Collaborators

Collaborators from other institutions, who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subaward from CSUF or CSUF Auxiliary Corporation (ASC), are expected to comply with the policies and procedures of the organization at which they are employed. Subawards issued by CSUF/CSUF ASC will indicate that the subrecipient organization is responsible for reviewing SFI disclosures and, if FCOI are identified, for sending CSUF/CSUF ASC notification of their ability to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.

Collaborators who share responsibility for the design, conduct, and reporting of research results, and who will participate in research under an independent consulting agreement issued by CSUF/CSUF ASC should be identified as Investigators by CSUF/CSUF ASC PI and must complete the CSUF disclosure forms. If, upon review, SDSU determines that an SFI could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, these collaborators will be expected to adhere to the mitigation plans put in place to eliminate, reduce or manage the identified conflicts of interest.

The Associate Vice President for Research and Sponsored Projects (AVP ORSP) will report to the PHS funding agency any FCOI which is identified by any sub-recipient to the University in the manner required under the FCOI Regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

V. Review and Evaluation of Research Investigator Financial Interest Disclosure Statements

The Investigator will forward completed disclosures to the Office of Grants and Contracts for administrative review by AVP ORSP. If a disclosure reveals a significant financial interest based on defined criteria and determined to be related to the Investigators' institutional responsibilities, the Investigator will be asked to complete an addendum to the disclosure for use in further evaluation. Copies of the completed disclosure, the addendum, and proposal will then be forwarded to members of the University Conflict of Interest Committee for review by the convened Committee.

The Committee shall review the information provided by the Investigator through the disclosure form and addendum statement, evaluate the disclosure to determine whether the financial interest could significantly affect the conduct or reporting of the project, and determine what, if any, conditions or restrictions should be imposed on the Investigator or research protocol in order to manage, reduce or eliminate conflicts that are identified. The Committee may also evaluate whether the financial interest has the potential to improperly influence financial expenditures, personnel decisions, or facilities usages, or has potential to limit or influence the teaching and research environment of the University. The Committee may consult with the Investigator, faculty, administrators or other University personnel, as appropriate, in developing a plan to resolve any real or apparent conflict of interest issues.

The Committee shall report recommendations on all cases considered to the President, the Provost, Executive Director, CSUF ASC, and the affected college Dean when conditions or restrictions are implemented to manage the potential conflict. An annual summary report shall also be provided to the University Faculty Research Committee.

VI. Actions of the Conflict of Interest Committee

Acting in a timely manner so as not to unduly delay the conduct of the research, the Committee shall conclude that the University take one of the following actions: (1) approval of acceptance of the project award; (2) withdrawal of the proposal or disapproval of acceptance of the project award; or (3) approval of acceptance of the project award subject to implementation of recommendations for modifications in either the project proposal or in the external affiliations or economic interests of the Investigator. Recommended actions to resolve conflicts of interest may include but are not limited to the following:

- Public disclosure of significant financial Interests
- Monitoring of research by independent reviewers
- Modification of the research plan subject to sponsor approval
- Disqualification from participation in the portion of the research that would be affected by the significant financial interests
- Divestiture of significant financial interests
- Severance of relationships that create actual or potential conflicts

VII. Decision and Appeal Process

The conclusions of the University Conflict of Interest Committee, along with any recommended modifications in the project or the significant financial interests of the Investigator shall be promptly communicated to the Investigator, the CSUF ASC and the AVP ORSP. If the Committee proposes such modifications and the Investigator agrees with the conclusions of the Committee, the Investigator will provide the Committee with appropriate documentation sufficient to verify that any such modifications have been made. If the Investigator is dissatisfied with the conclusions of the Committee, the Investigator may appeal to the President. Acting on behalf of the President, the Provost or AVP ORSP, may investigate and make appropriate recommendations to the President regarding the disposition of the matter. In such cases, the decision of the President shall be final.

VIII. Enforcement Mechanisms and Sanctions

The CSUF ASC shall withhold access to awards from designated external sponsors when the disclosure statement has not been completed by the investigator and reviewed. Grants and/or contracts designated for research purposes will not be available to the Investigator until the disclosure has been submitted and reviewed.

Alleged violations of the policy or procedures used to implement the policy shall be investigated by the AVP ORSP, who may, after consultation with the President or designee, suspend or terminate the research project or the Investigator's involvement in the research.

Substantive violations of this policy, such as instances of falsification or willful concealment of significant financial interests, or failure to implement or maintain necessary modifications required by the University Conflict of Interest Committee and agreed to by the Investigator, may also constitute violations of the research integrity. In such cases, the [UPS 630.000 "Policy for Investigating Instances of Possible Research Misconduct"](#), will be invoked.

In any cases in which it has been determined that a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with a conflicting interest that was not disclosed or managed as required by this research Investigator conflict of interest policy, the University will require disclosure of the conflicting interest in each public presentation of the results of the research.

IX. Notification of External Sponsor

Initial, annual (i.e. ongoing) and revised FCOI reports must be made to PHS at the following times:

1. Prior to the expenditure of funds;
2. Within 60 days of the identification of an Investigator who is newly participating in the project;
3. Within 60 days for new, or newly identified, FCOIs for existing Investigators;
4. At least annually (at the same time as when the University is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
5. Following a retrospective review to update a previously submitted report, if appropriate.

When identified conflicts of interest are eliminated before research funds are expended, no report need be submitted.

If a Significant Financial Interest (SFI) is identified during the course of an ongoing project that was not previously disclosed or reviewed, the University Conflict of Interest committee will review the SFI within sixty (60) days to determine whether it is related to research activities and whether a FCOI exists. If a FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis (see section VI).

If the University determines that a FCOI exists that was not previously identified or managed in a timely manner, the University will complete a retrospective review of the Investigators' activities. This retrospective review must occur (or "be completed") within 120 days of the determination of non-compliance. The purpose of this retrospective review is to determine if the ongoing research activity was biased in its design, conduct or reporting.

Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that the University will take to manage the identified FCOI. If bias was found during the retrospective review, the University will promptly notify the external funding source

and will draft a mitigation report that at a minimum document the key elements of the retrospective review, describes the impact of the bias on the research, and outlines the institution's plans to eliminate or mitigate the effect of the bias.

XI. Maintenance of Records

The Office of AVP ORSP shall maintain records of all disclosure statements and of all actions taken to resolve conflicts of interest for at least three (3) years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained. Copies of all financial disclosures of University employees may also be kept by The Center for Human Resources in a manner consistent with other conflict or disclosure statements by University personnel. The CSUF ASC may also retain copies of such records for its employees.

XII. Public Disclosure

As required by PHS, any disclosed significant financial interest(s) of investigators as defined in this policy, and any resulting management plan(s) will be made publicly available within five (5) days of a lawful request for such information. General public disclosure laws and regulations may require disclosure of other conflict of interest documents and findings.

XIII. Training

As required by PHS, all investigators as defined in this document on PHS/NIH grants and sub-recipient awards will be required to complete Conflict of Interest training prior to beginning work on PHS/NIH funded research and every four years thereafter. Please refer to our Research Compliance website for additional guidance [FCOI training plan](#).

XIV. Review and revision of policy

This policy will be reviewed annually by the Conflict of Interest committee. The committee shall develop and, as required, amend specific guidelines for the implementation of the provisions of this policy. These guidelines will be submitted for approval to the AVP ORSP.