

UC SANTA BARBARA POLICY AND PROCEDURE

POLICY ON DISCLOSURE OF FINANCIAL INTERESTS RELATED TO PHS SPONSORED PROJECTS FOR PROMOTING OBJECTIVITY IN RESEARCH

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POLICY ON DISCLOSURE OF FINANCIAL INTERESTS RELATED TO PHS SPONSORED PROJECTS FOR PROMOTING OBJECTIVITY IN RESEARCH

The following policy on *Disclosure of Financial Interests Related to Public Health Service (PHS) Sponsored Projects for Promoting Objectivity in Research* is mandated by the Department of Health and Human Services and was effective **August 24, 2012**. It applies to all investigators and institutions that apply for and receive funding from PHS agencies or other sponsors that have adopted similar federal requirements detailed in 42 CFR, Part 50, Subpart F and 45 CFR Part 94.

I. SCOPE

This policy implements the 2011 Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors (42 CFR, Part 50, Subpart F and 45 CFR Part 94). These regulations are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct and reporting of PHS funded research will be free from bias resulting from any Investigator's Financial Conflicts of Interest (FCOI).

This policy is applicable to all research funded by the PHS and other sponsors that have adopted similar federal requirements detailed in 42 CFR, Part 50, Subpart F and 45 CFR Part 94 with an award issue date of August 24, 2012, or later and to proposals for research activities submitted on or after August 24, 2012. This policy applies to the Principal Investigator (PI) and to any individual responsible for the design, conduct and reporting of proposed or funded research. This policy supplements but does not supplant the State requirements for disclosure of financial interests issued as the "University Policy on Disclosure of Financial Interests in Private Sponsors of Research" (APM-028).

On occasion, Investigators may have questions about whether proposed or on-going financial arrangements or relationships that would not require disclosure under the terms of this Policy appear to constitute an actual or potential conflict of interest (COI) with respect to a sponsored project. In such circumstances, Investigators may voluntarily choose to disclose the relationship in accordance with this Policy. Should the University subsequently determine that the voluntarily disclosed interest might reasonably appear to be directly and significantly affected by the sponsored project, the University may take steps to manage or to eliminate the conflict.

Investigators who are members of the faculty are reminded of their separate obligation, pursuant to the “University Policy on Outside Professional Activities of Faculty Members” (Academic Personnel Policy 025), to provide descriptive information regarding time and effort devoted to all outside professional activities related to their academic specialty in annual reports to department chairpersons or equivalent unit heads.

II. POLICY

Investigators seeking research funding or receiving research support from PHS, or other sponsors that follow the PHS FCOI regulations, require Investigators to submit COI disclosure statements are required to disclose Significant Financial Interests (SFI) related to their Institutional Responsibilities.

Investigators must complete a training/education program on FCOI, the Investigator’s responsibilities regarding disclosure of SFI, and the PHS regulations prior to engaging in the PHS funded research and at least every four years thereafter, and when an Investigator is not in compliance with this policy or has failed to comply with a plan to manage or mitigate a FCOI.

Collaborators from other institutions, who share responsibility for the design, conduct and reporting of the research, and who will be conducting research under a sub-award from UCSB are expected to comply with the policies and procedures of the organization at which they are employed. Sub-awards issued by UCSB will indicate that the sub-recipient organization is responsible for reviewing SFI disclosures and, if a FCOI is identified, for sending UCSB notification of their ability to manage, reduce or eliminate the FCOI, in accordance with PHS requirements. If a sub-recipient organization does not have a policy that complies with the PHS regulations, the sub-recipient’s authorized Institutional Official must agree in writing that UCSB’s policy will apply to the sub-recipient’s Investigators until such time as the sub-recipient organization implements a policy that complies with the PHS regulations. A sub-recipient organization’s failure to comply with its policy or the PHS regulations may result in the termination of the sub-award.

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 UCSB should be identified as Investigators by the Principal Investigator and must complete the UCSB disclosure forms. If, upon review, UCSB determines that a consultant’s SFI is a FCOI, the consultant will be expected to comply with a management plan to eliminate, reduce or manage the FCOI. Failure of a consultant to comply with a management plan may result in the termination of the consulting agreement.

III. RESPONSIBILITIES

- A. The Vice Chancellor for Research or their designee is responsible for implementing this policy, for the final decisions regarding the acceptability of disclosures, and for approval of any management plan.

- B. Investigators are responsible for disclosing their financial interests and completing training as defined by this policy. Investigators who are collaborators at sub-recipient institutions are responsible for disclosing their financial interests in accordance with the arrangement agreed upon between UCSB and the sub-recipient institution prior to submission of a proposal to the PHS and/or in accordance with the terms and conditions of the sub-award issued by UCSB. Investigators who are not UCSB employees and not a collaborator at a sub-recipient institution are subject to this policy as if they were UCSB employees. Principle Investigators are responsible for ensuring that all Investigators provide their disclosures in a timely manner and in accordance with this policy.
- C. The Conflict of Interest Committee (COIC) is responsible for reviewing financial disclosures of Investigators, making recommendations and proposing management plans to the Vice Chancellor for Research or their designee.
- D. The Office of Research staff are responsible for receiving disclosures and additional information, conducting administrative reviews of disclosures, supporting the COIC in regular and ad hoc meetings, maintaining the COI website, providing advice and information on policies and procedures, reporting information about FCOI and how such interests are being managed to PHS, and responding to public requests for information regarding FCOI.
- E. Non-UCSB collaborators, consultants or subcontractors who share responsibility for the design, conduct and reporting of the research, and who will be conducting research under a sub-award from UCSB must comply with the policies and procedures for disclosure and review of SFIs at the institution at which they are employed, or, if their institution does not have a conflict of interest policy that is compliant with the PHS regulations, they must comply with this policy and campus procedures for disclosure and review of SFIs related to PHS-sponsored awards.
- F. These Investigators must comply with all requirements of their institution's (or UCSB's) policy that pertain to Investigators, including completing NIH-compliant training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded contract and at least every 4 years thereafter, while receiving PHS research funding.

If a sub-recipient organization does not have a policy that complies with the PHS regulations, the sub-recipient's authorized Institutional Official must agree in writing that UCSB's policy will apply to the sub-recipient's Investigators until such time as the sub-recipient organization implements a policy that complies with the PHS regulations. A sub-recipient organization's failure to comply with its policy or the PHS regulations may result in the termination of the sub-award.

IV. PROCEDURES

DISCLOSURE FORMS AND DISCLOSURE PROCESSES

- A. **Identifying Investigators on the proposed or awarded project:** PIs are required to fully identify every individual on a project that meets the definition of Investigator. For proposals to PHS or other sponsors that have adopted similar federal requirements, the PI identifies all individuals, paid or unpaid, meeting the definition of Investigator. These Investigators are required to submit an electronic disclosure detailing any SFIs related to their Institutional Responsibilities.
- B. **PHS – Annual Disclosure Form of Financial Interests (Electronic Disclosure for PHS or Other Sponsors Adopting Federal Requirements):** PIs and all Investigators are required to submit an electronic disclosure annually, reporting any personal SFI related to their Institutional Responsibilities. Disclosure is required:
- a. no later than at the time of proposal submission,
 - b. annually with non-competing continuation funding,
 - c. as new Investigators are added to the project,
 - d. as Investigators' financial interests change (within 30 days of those changes).

It is the responsibility of the PI to complete the electronic disclosure, along with any other Investigators, in sufficient time to allow for COIC review of projects in which an Investigator has disclosed an SFI. The COIC review must be completed and the award deemed acceptable by the Vice Chancellor for Research or their designee prior to the acceptance of the award and any expenditure of funds.

- C. **Disclosure of Economic Interests: Addendum (electronic disclosure addendum):** The Addendum is to be completed at the request of the COI Coordinator by Investigators who have disclosed an SFI. The Addendum should be completed in the Office of Research electronic Conflict of Interest Disclosure system. The form solicits additional facts from the Investigator to facilitate review by the COIC. Investigators complete a separate Addendum for each entity in which they have an SFI.

DISCLOSURE REVIEW PROCESS

Under supervision of the Director of Research Integrity, the COI Coordinator is responsible for reviewing all disclosures and the list of Investigators to ensure completeness and perform an initial analysis of the disclosed information. The COI Coordinator also confirms the necessity for review under this policy.

One or more Designated Official(s) shall determine whether any of the disclosed SFIs relate to the PHS-funded research. SFI(s) that are deemed related shall be reviewed by the COIC to determine whether the SFI could directly and significantly impact the design, conduct, or reporting of the PHS-funded research and creates a FCOI. A direct impact occurs when the project results would be directly relevant to the development,

manufacturing, or improvement of the products or services of the organization in which the Investigator has a financial interest, or when the organization is a proposed subcontractor or participant in the project. A significant impact on the financial interest is one which will materially affect the value of the organization, its earnings, or the sales of its product, or when the organization is a proposed subcontractor or participant in the project.

On the basis of its evaluation, the COIC forwards a recommendation to the Vice Chancellor for Research indicating one of the following outcomes:

- a. the SFI is not related to the PHS-funded research,
- b. the financial interests pose little or no probability for bias in objectivity in the sponsored project, or
- c. the FCOI requires management, elimination, or reduction.

Plans for managing an identified FCOI will be monitored for compliance until the completion of the PHS-funded research. Each management plan will specify;

- role and principal duties of the conflicted Investigator,
- conditions of the management plan,
- how the management plan will safeguard objectivity in the research,
- confirmation of the Investigator's agreement to the management plan, and
- How the management plan will be monitored to ensure compliance.

The Vice Chancellor for Research, acting within authority delegated by the Chancellor, reviews the recommendations from the COIC and determines whether to accept the recommendations. The Vice Chancellor for Research is responsible for the final decision.

The COI Coordinator prepares the Vice Chancellor's communications to the Investigators regarding each disclosure, and messages to Sponsored Projects staff who serve as the official communication link with the sponsors.

MANAGEMENT, REDUCTION, OR ELIMINATION OF CONFLICTS OF INTEREST

Under certain circumstances, the COIC or the Vice Chancellor may recommend special conditions or restrictions to manage, reduce or eliminate the effect of the financial interests on the design, conduct, or reporting of the project. Examples of conditions or restrictions that may be imposed upon the Investigator include the following:

- a) public disclosure of the related financial interest(s),
- b) monitoring of the project by independent reviewers appointed by the Vice Chancellor,
- c) modification of the research or project plan,
- d) disqualification from participation in all or a portion of the project,
- e) divestiture of the related financial interest,
- f) severance of relationships that create actual or potential conflicts.

Adoption of conditions or restrictions to manage or eliminate the FCOI must be agreed to in writing by the Investigator and the Vice Chancellor prior to the expenditure of any funds under the award.

Alternatively, if the COIC determines that an Investigator's financial interests could be directly and significantly affected by the sponsored project or could affect the sponsored project and the conflict cannot be managed, the COIC may recommend to the Vice Chancellor that the project not proceed.

TRAINING

Every Investigator must complete the online training/education program on Financial Conflicts of Interest. This training must be completed:

- a) before engaging in PHS research activities, and
- b) when an Investigator engaging in PHS research activities is new to the Institution, and
- c) at least every four years thereafter while continuing to engage in PHS research activities or receive PHS funding, and
- d) whenever the Institution revises its FCOI policy in a way that affects requirements of Investigators, and
- e) whenever an Investigator is found to be out of compliance with this policy or has failed to comply with a plan put in place to manage or mitigate a Financial Conflict of Interest.

REPORTING TO PHS

Initial reports of FCOIs must be made to PHS prior to UCSB's expenditure of any funds under a PHS-funded research project. Additional FCOI reports must be submitted to PHS under the following circumstances:

- A. At least annually throughout the lifetime of an award. When during the course of an ongoing PHS-funded research a FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.
- B. Within sixty (60) days of determining that a FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing PHS funded research project.
- C. Within sixty (60) days of determining that a FCOI exists for an Investigator who joins an ongoing PHS funded research project.

However, if FCOIs are eliminated before research funds are expended, UCSB is not required to submit a report to PHS.

RETROSPECTIVE REVIEW

During the course of an ongoing PHS research project, if UCSB identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, a Designated Official(s) will review the SFI within sixty (60) days to determine whether it is related to the PHS-funded research 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.

Whenever a FCOI is not identified or not managed in a timely manner (regardless of whether the Investigator did not disclose an SFI that was later determined to be a FCOI, or UCSB failed to review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan) UCSB must complete a retrospective review of the Investigator's activities and the PHS-funded research project within 120 days of the determination of non-compliance. The purpose of the retrospective review is to determine if the ongoing PHS-funded research project conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research. Based on the results of the retrospective review, any previously submitted FCOI report must be updated to specify the actions that UCSB will take to manage the identified FCOI.

If bias was found during the retrospective review, UCSB will promptly notify PHS and will draft a mitigation report that, at a minimum, documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines UCSB's plans to eliminate or mitigate the effect of the bias.

In any case in which the Department of Health and Human Services determines that a PHS-funded research 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 an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to:

- a) disclose the FCOI in each public presentation of the results of the research, and
- b) request an addendum to previously published presentations.

RECORDS ACCESS AND RETENTION

The disclosure and addendum information are open to the public and subject to the Federal Freedom of Information Act (FOIA) and the California Public Records Act (CPRA). UCSB is required to respond within five (5) business days to any request for information about SFIs held by Investigators when UCSB has determined that the disclosed SFIs are related to the PHS-funded research and constitute FCOIs.

UCSB's response to the requestor shall include, at a minimum, the following:

- a) the Investigator's name,
- b) the Investigator's title and role with respect to the research project,

- c) the name of the entity in which the significant financial interest is held,
- d) the nature of the significant financial interest, and
- e) 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.

Records of financial disclosures, Designated Official's determinations, COIC recommendations, and University action regarding management of a FCOI will be retained 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.

SANCTIONS

Failure to complete the Disclosure or the Addendum or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy will be grounds for discipline pursuant to the Policy on Faculty Conduct and the Administration of Discipline (Academic Personnel Manual, APM-016) and/or all other applicable employee disciplinary policies. In addition, UCSB is required to report violations of this policy to the PHS and other applicable federal regulatory oversight agencies and/or offices. Sponsors may suspend or terminate an award and/or debar/suspend an Investigator from receipt of future awards in the event an Investigator fails to comply with the PHS regulations. Finally, an Investigator's failure to disclose may also subject the Investigator to civil or criminal legal action.

V. REFERENCES

- 1) Public Health Services (PHS) – “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors” Code of Federal Regulations (42 CFR Part 50, Subpart F and 45 CFR Part 94)
- 2) University of California, Office of the President – Business and Finance Bulletin G-39, Conflict of Interest Policy and Compendium of Specialized University Policies, Guidelines, and Regulations Related to Conflict of Interest
- 3) University of California, Office of the President – Policy on Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Services Research Awards
- 4) University of California, Office of the President – Conflict of Commitment and Outside Activities of Faculty Members, APM-025
- 5) University of California, Office of the President – University Policy on Faculty Conduct and the Administration of Discipline, APM-016
- 6) University of California, Office of the President – Disclosure of Financial Interest in Private Sponsors of Research, APM-028

VI. APPENDIX

DEFINITIONS

- A. **Conflict of Interest Committee (COIC):** The faculty advisory committee appointed by the Vice Chancellor for Research to review disclosures of significant financial interests related to the PHS (as defined below) funded research and determine whether any of the significant financial interests constitute a financial conflict of interest (as defined below). This group is also referred to as the Independent Substantive Review Committee in UC policies.
- B. **Designated Official:** The campus official(s) designated to solicit and review disclosures of significant financial interests. This includes the Vice Chancellor for Research, Associate Vice Chancellor for Research, Assistant Vice Chancellor for Research, conflict of interest staff in the Office of Research and COIC members.
- C. **Financial Conflict of Interest (FCOI):** A significant financial interest that is related to research (as defined below) funded by PHS (as defined below) in which the Investigator is engaged and that could directly and significantly affect the design, conduct and/ or reporting of PHS funded research.
- D. **Institutional Responsibilities:** Teaching/education, research, outreach, clinical service, and University and public service on behalf of the University of California which are in the course and scope of the Investigator's University of California appointment/employment.
- E. **Investigator:** Any individual responsible for the design, conduct, or reporting of research (as defined below) performed or to be performed with PHS (as defined below) funding, regardless of whether the Investigator receives compensation from the funding source supporting the research. Investigator includes but is not limited to the PI, Investigators and any other individual (including non-UCSB personnel) responsible for the design, conduct, or reporting of the PHS funded research.
- Note: Reporting includes authorship on publications resulting from the research. Thus, graduate and undergraduate students may be required to disclose, even if they are not paid from the project.
- F. **Principal Investigator (PI):** An Investigator who is a UCSB employee and who has primary responsibility for the scientific and technical conduct, reporting, and administrative and financial management of a sponsored research project.
- G. **PHS (PHS):** Any organizational unit, agency or entity of the Department of Health and Human Services (DHHS) designated by the DHHS as being part of the PHS, as well as any non-PHS entity adopting the PHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is Sought and Responsible Prospective Contractors.

- H. **Research:** Any activity for which research funding is available from the PHS, including but not limited to research grants, cooperative agreements, career development awards, center grants, individual fellowship awards, infrastructure awards, Institutional training grants, program projects or research resources awards, conference grants and Phase II Small Business Innovative Research (SBIR) and Phase II Small Business Technology Transfer Research (STTR) awards. Excluded from this policy, consistent with the underlying PHS regulations, are Phase I SBIR awards and Phase I STTR awards.
- I. **Significant Financial Interest (SFI):** Significant financial interests are anything of monetary value, consisting of one or more of the following interests of the Investigator or the Investigator's spouse or registered domestic partner and dependent children that reasonably appear related to the Investigator's Institutional Responsibilities:
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 received during the prior twelve months and the value of any equity interests (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.
 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 received during the prior twelve months, which when aggregated, exceeds \$5,000 or any equity interest (regardless of valuation) including, but not limited to stock, stock options, or ownership interest in the entity.
 3. Intellectual property rights and interests: Income from each organization that exceeds \$5,000 during the twelve months preceding disclosure from such rights and interests.
 4. Travel: Reimbursements greater than \$5,000 per entity received during the prior twelve months made to, or on behalf of, the Investigator by a for-profit or non-profit entity (including foreign institutions or governments). Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. **Spouses, registered domestic partners, and dependent children of Investigators are exempt from this disclosure requirement.**

Investigators do not need to disclose:

1. Financial interests in mutual funds or other investment vehicles such as retirement funds where the Investigator or the Investigator's spouse, registered domestic partner or dependent children does not directly control the investment decisions made for these investment vehicles.
2. Payments made by The Regents, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University of California.
3. Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. institution of higher education.

Please direct questions about this policy to the Office of Research, Research Integrity. For general questions or comments about this website, please contact coi@research.ucsb.edu.
