Sponsored Programs Foundation

Financial Conflict of Interest (FCOI)

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INTRODUCTION

Humboldt State University Sponsored Programs Foundation (HSU SPF) encourages campus personnel to engage in a variety of scholarly and creative activities, including those leading to external funding or income from public agencies, private entities and individuals, and entrepreneurial ventures.

At times, such activities may create situations that lead to potential or real instances of conflict of interest. HSU recognizes the obligation of individuals and the institution to ensure that instances of conflict of interest do not improperly affect university activities, including those conducted through auxiliary organizations. Therefore, through the policies and procedures set forth herein, HSU SPF intends to identify and address potential conflicts of interest that may arise among campus personnel proposing or engaging in externally funded activities.

This policy recognizes that State of California and federal government laws and regulations, which differ, do exist. These regulations and the CSU Chancellor's Office Memo HR 2005-38 require HSU SPF to establish and maintain a conflict of interest policy and implementing procedures. The intention of the policy set forth below is to establish a uniform policy which covers state and federal laws and regulations currently in place and those anticipated and to provide the public with accountability in the institution's dealings with external organizations.

POLICY

This policy is based upon the principle that institutions of higher education operate for the common good. Advancement of this mission requires that employees avoid conflicts of interest that may impair public trust and conflicts of commitment that may compromise their performance effectiveness. HSU SPF has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest involving activities conducted under the authority of the University or its auxiliary organizations.

Each investigator, as defined below, is required to file the appropriate disclosure form and any related information as specified in this policy. In no case shall HSU SPF accept funds from an external agency or individual on behalf of an employee or project in the absence of the disclosures required in this policy and the satisfactory completion of actions required by the provisions of this policy, the applicable regulations and any findings approved by the President to manage, reduce or eliminate any conflicts of interest.

Department chairs, deans, or other administrators will disqualify themselves from approving a proposal for a project to be funded in whole or in part by a nongovernmental entity in which they have a financial interest. Also in keeping with CSU regulations, investigators will not make, participate in, or in any way attempt to use the investigator's position to influence the making of any governmental decision that



foreseeably will have a material financial effect as specified in HR 2005-38 and any subsequent regulations.

DEFINITIONS

Investigator: Any member of the campus community who is a full or part-time or temporary employee of HSU or a university auxiliary organization who is assigned the task of principal investigator(s)/project director(s), co-principal investigator (s), and any other member of the campus community who is responsible for the design, conduct, or reporting of activities proposed for funding or funded by an external source. The latter includes funds provided by grants and contracts and other means. In this context, "investigator" also includes the investigator's spouse and dependent children. For the purposes of this policy, investigators also may include subcontractors where the foregoing definition may apply.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of the Institution, including, but not limited to activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Governmental funding source: Research funded by the Public Health Service (PHS), National Science Foundation (NSF), or other sponsors that have adopted the federal requirements for financial disclosure.

Nongovernmental funding source: Entities other than those listed in the Governmental Funding Source definition identified above.

Potential conflict of interest: Occurs when a divergence develops between an individual's private interests and his or her professional obligations to the University and its auxiliary organizations such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. In particular, a financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of a sponsored project. Reviewer(s) of disclosure statements can find an actual or potential conflict of interest when it is determined that a significant financial interest of the investigator could directly or significantly affect the assigned campus activities and professional obligations of campus personnel. Each campus personnel member must disclose all financial interests that would reasonably appear to be affected by the proposed activities.

Financial interest: Anything of monetary value, whether or not the value is readily ascertainable, including but not limited to salary or other payments for services (e.g., consulting fees or honorariums), equity interests (e.g., stocks, stock options or other ownership interests), reimbursed travel under some circumstances and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

Significant Financial Interest (SFI): Defined in two ways, as follows as a result of differing state and federal regulations.

1. In relation to nongovernmental funding source(s), significant financial interest is involved and must be disclosed where a funding source has allocated to the investigator (including investigator's spouse or dependent children).



- \$500 or more in income, salary or other payment(s) for services (outside the parameters of a current or previous award conducted through the campus wherein the investigator was paid through the campus) in the last 12 months
- A gift of \$50 or more in the last 12 months, including payment for travel
- A loan(s) of \$500 or more in the last 12 months, or the investigator
- Has investment or equity interest in the non-governmental funding source of more than \$2,000
- Serves as a director, officer, partner, trustee, consultant or employee or holds any management position in the entity providing the funds.
- 2. In relation to governmental funding source(s), the National Science Foundation (NSF) and the Public Health Service (PHS)) have differing definitions of what constitutes a significant financial of interest.
- a. For the Public Health Service (PHS) significant financial interest is involved and must be disclosed when one or more of the following financial interests of the investigator (and those of the investigator's spouse or dependent children) reasonably appears to be related to the investigator's Institutional responsibilities:
- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment not otherwise identified as salary (such as consulting fees, honoraria, paid authorships). Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value. In aggregate includes any remuneration or equity interest received by the investigator's spouse or dependent children;
- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (and/or investigator's spouse or dependent children) holds any equity interest (such as stock, stock option), or other ownership interest; or
- With regard to intellectual property rights and interests (such as patents and/or copyrights), a significant financial interest exists upon receipt of income related to such rights and interests.
- In addition, for the previous 12 months and over the life of the award, investigators also must disclose any travel, regardless of the value, related to their institutional responsibilities that are reimbursed by an external entity. Exceptions to this disclosure requirement include travel unrelated to a Public Health Service (PHS) funded project, travel that is reimbursed or sponsored by a federal, state, or



local government agency, an institution of higher education as defined by 20 U.S.C.1001 (a), an academic teaching hospital, a medical center, a research institute that is affiliated with an institution of higher education or travel reimbursed through a university auxiliary organization. When disclosure is required, the investigator will disclose at a minimum the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The Director of Sponsored Programs Foundation will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest.

A reportable SFI is related to the Investigator's institutional responsibilities. The term does not include:

- Salary, royalties or other remuneration from the applicant institution;
- Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities:
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity;
- Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next funded twelve-month period.
- 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.
- b. For National Science Foundation (NSF), significant financial interests is involved and must be disclosed where one or more of the following financial interests of the investigator (and those of the investigator's spouse of dependent children) reasonably appears to be related to the investigator's Institutional responsibilities:
- A significant financial interest exists if an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of market value, and represent more than a 5% ownership interest in any single entity
- A significant financial interest exists when salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse of dependent children, have exceeded or are expected to exceed \$10,000 during any immediately preceding or following 12 month period.



For National Science Foundation (NSF), significant financial interest does not include:

- Salary, royalties or other remuneration from the applicant Institution
- Any ownership interest in the Institution, if the Institution is an applicant under the
- Small Business Innovation Program or Small Business Technology Transfer Program
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
- Income from service on advisory committees or review panels for public or nonprofit entities
- Equity interest and/or salary, royalty and other payments do not exceed the thresholds in the section regarding NSF immediately above.

Public Health Service (PHS) agencies include the following:

- National Institutes of Health (NIH)
- Food and Drug Administration (FDA)
- Centers for Disease Control and Prevention (CDC)
- Indian Health Service (IHS)
- Health Resources and Services Administration (HRSA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substance and Disease Registry (ATSDR)
- Any other sponsor who has adopted PHS FCOI financial disclosure requirements

PROCEDURES

The Investigator Disclosure and Conflict Resolution/Management Plan

HSU SPF requires that an investigator disclose any Significant Financial Interest, as defined above that may present an actual or potential conflict of interest with assigned campus Institutional responsibilities. Each investigator will complete the appropriate Conflict of Interest Disclosure Form, either a California Form 700-U for a nongovernmental funding source, or a Disclosure of Financial Interests Certification Form (NSF, PHS or other Agency Adopting the Federal Requirements) for a governmental funding



source. The appropriate form must be submitted to the HSU SPF even if the investigator believes no conflict of interest exists. In addition, each investigator must file an updated form at any time during the award period when a material change occurs that presents a conflict of interest as defined by this policy.

Investigators must disclose Significant Financial Interests at the time of proposal submission. As required by federal regulations, HSU SPF requires that investigators follow the appropriate regulations and report any findings of financial conflicts of interest to the Director of Sponsored Programs Foundation who is charged with any follow up on such disclosures that may be required to meet the federal guidelines.

Investigators who have principal responsibility for a project funded or supported, in whole or in part, by a contract, grant or gift from a nongovernmental entity, are required to report financial interests on the California Form 700-U:

- Before final acceptance of the contract, grant, or gift.
- Within 90 days after expiration of the contract/grant or after gift funds have been fully expended.

In addition to the responsibilities noted above, investigators who have principal responsibility for a project funded or supported, in whole or in part, by a contract, grant or gift from entities other than federal, state or local government agencies and their subsidiaries and nonprofit entities exempted from the financial disclosure requirement by the California Fair Political Practices Commission file a new form (California Form 700-U) within 30 days if funding is renewed from the same source.

Investigators who have principal responsibility for a project funded or supported, in whole or in part, by a contract, grant or gift from the Public Health Service (PHS), National Science Foundation (NSF), or other sponsors that have adopted the federal requirements for financial disclosure are required to report financial interests on the Disclosure of Financial Interests Certification Form:

- No later than at the time of application
- At least annually during the period of the award

Investigators must file an updated form within 30 days of discovering or acquiring a new significant financial interest when from NSF, PHS, or a nongovernmental source.

Awards or gifts cannot be accepted until any conflict of interest issues are resolved.

Grant analysts will collect all financial disclosure forms. If the disclosure form identifies any potential financial conflict, the Director of Sponsored Programs Foundation will review the financial disclosure form. A conflict of interest exists when the review reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, and reporting of the proposed activity(ies). Supporting documentation that provides details of the investigator's significant financial interest(s), relationship(s) with external entity(ies), and any other pertinent information should be attached to the form (in a sealed envelope labeled with the term "Confidential" and the investigator's name if the investigator prefers confidentiality beyond those who must review the documentation). Upon receiving a disclosure form that may disclose a potential conflict of interest, the Director will notify the investigator(s) and convene a Conflict of Interest Resolution Committee as described below.



Potential violations shall be handled by the Conflict of Interest Resolution Committee made up of the Director of Sponsored Programs Foundation, the Dean of Research and Sponsored Programs, the Compliance Officer, and the Dean of the affected investigator's College. The Conflict of Interest Resolution Committee will engage in an independent substantive review of the potential conflict(s) of interest to determine if a significant conflict of interest as defined by this policy does exist or potentially could occur. In conducting its business, the committee may confer with other individuals, including the investigator(s) involved, to gain information and discuss possible solutions to the conflict(s) of interest. If a conflict of interest is found to exist or the potential for one could occur, the committee will make recommendations as to how to manage, reduce or eliminate the potential or actual conflict(s) of interest. The committee may also conclude that the conflict(s) of interest cannot be managed, reduced or eliminated so that the award or gift may be accepted. The committee's recommendations will be reduced to writing and submitted first to the Dean of Research and Sponsored Programs for review and comment who will make the final determination as to what actions should be taken. The Dean of Research and Sponsored Programs decision(s) will be reduced to writing and presented to the Director of Sponsored Programs Foundation for dissemination to the appropriate individuals including the investigator(s) and all potentially affected faculty and units. The Dean of Research and Sponsored Programs will see that a written record is recorded throughout the process and maintained for at least three years following the Dean's decision or the end of the project, whichever occurs last. Records, upon a lawful request, will be made available to the public upon conclusion of the review process.

Committee recommendations for managing, reducing or eliminating conflict(s) of interest may include but not be limited to the following:

- Public disclosure of significant financial interests
- Monitoring of research by independent reviewers capable of taking measures to protect the
 design, conduct, and reporting of the research against bias resulting from the Financial Conflict of
 Interest.
- Modification of the research plan
- Change of personnel or personnel responsibilities, or disqualification from participation in all or the portion of the project that is affected by the Financial Conflict of Interest
- Reduction or divestiture of significant financial interests
- Severance of relationships that create actual or potential Financial Conflicts of Interest.
- For research projects involving human subjects research, disclosure of Financial Conflicts of Interest

If a resolution/management plan is required to manage, reduce or eliminate a significant conflict of interest, the plan should be reduced to writing and submitted as a report to the funding agency. Such a plan and report will include the following:

• The role and principal duties of the conflicted Investigator in the research project



- Conditions of the resolution/management plan
- How the resolution/management plan is designed to safeguard objectivity in the research project
- Confirmation of the Investigator's agreement to the resolution/management plan
- How the resolution/management plan will be monitored to ensure Investigator compliance
- Other information as needed.

The Director of Sponsored Programs Foundation will serve as the University's contact with external entities for reporting, resolving, and otherwise dealing with matters related to this policy. The Director of Sponsored Programs Foundation will report disclosure and resolution activities to agencies and funding sources as required and appropriate.

Enforcement Mechanisms and Sanctions

Instances of failure to disclose conflict(s) of interest and potential violation(s) of the Conflict Resolution/Management plan will be reported/referred to the Director of Sponsored Programs Foundation. The Director will investigate the issue(s), following campus and system wide procedures and rules for such matters. Disciplinary measures, if any, will be in keeping with campus and system wide policies and procedures and union contracts current at the time. Funding sources and other appropriate parties will be notified and kept informed as required by state and federal laws and regulations and Sponsored Programs Foundation award documents. Appropriate regulations will be followed in any such instance including further management and disclosure of financial conflicts of interest.

Documentation and Record Maintenance

HSU SPF will maintain records of all financial disclosures and of all actions taken to resolve financial conflicts of interest for at least three years beyond the termination or completion of the grant to which they relate, or until the resolution of any federal action involving those records, whichever is longer.

Ethics Training

The Director of Sponsored Programs Foundation will ensure that the campus meets any state or federal regulations regarding the provision of ethics training to investigators. PHS regulations require that each investigator complete training prior to engaging in research related to Public Health Service funding and undergo training at least every four years. Certain circumstances require training at other times as well.

Public Disclosure

As required by PHS, any significant financial interest(s) disclosed and any resulting resolution/management plan(s) will be publicly disclosed within five 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.



ROLES AND RESPONSIBILITIES

Grant Analyst

- Ensures that the appropriate conflict of interest disclosure form is completed for all projects for which they are required
- Ensures that appropriate conflict of interest documentation procedures are being followed

Compliance Officer

• Participates as a member of the Conflict of Interest Resolution Committee

Dean of Research and Sponsored Programs

- Participates as a member of the Conflict of Interest Resolution Committee
- Makes the final determination as to what actions should be taken and presents decision(s) to the Director

Director of Sponsored Programs Foundation (Director)

- Reviews and certifies all potential financial conflict of interest disclosure forms
- Develops resolution strategies with the Investigator (s) to manage, eliminate or reduce conflicts of interest
- Participates as a member of the Conflict of Interest Resolution Committee
- Serves as liaison to federal agencies regarding unresolved financial conflicts of interest
- Contacts the University Counsel when legal questions arise related to an identified conflict of interest

University Counsel

If a plan of action to address a financial conflict of interest has legal ramifications, the University Counsel coordinates with the Director to review the plan and provide assistance with any legal questions.

Principal Investigator (PI)

- Discloses any financial conflict of interest on a sponsored project by completing and submitting the appropriate disclosure form to HSU SPF;
- Notifies HSU SPF immediately of any change in disclosure;
- Assists HSU SPF in obtaining disclosure forms from key project personnel and if necessary assists with obtaining verification of disclosure forms from sub-contract personnel; and
- Works with the Director to develop a plan of action to address the conflict of interest if one exists.



College Dean

- Reviews and approves any resolution/management plan developed by the investigator (s) and the Director
- Participates as a member of the Conflict of Interest Resolution Committee

RELATED DOCUMENTS

- California Form 700 U-Statement of Economic Interest for Principal Investigators
- HSU SPF Disclosure of Financial Interests Certification Form
- 42 CFR Part 50, Subpart F (Public Health, Department of Health and Human Services, Promoting Objectivity in Research)
- 45 CFR Part 94 (Public Health, Department of Health and Human Services, Research Contract)
- California State University Policies and Procedures