

<p><b><u>Policy Title:</u></b> FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE FUNDED PROGRAMS</p> <p><b><u>Application:</u></b> Faculty; Research Investigators</p>	<p><b><u>Policy ID No.:</u></b> 2012-</p> <p><b><u>Category:</u></b> RESEARCH</p> <p><b><u>Contact(s):</u></b> Dean of Graduate Studies and Research, Director of Research and Sponsored Programs</p>
<p><input checked="" type="checkbox"/> New Policy</p> <p><input type="checkbox"/> Revision of Existing Policy</p>	<p><b><u>Effective Date:</u></b> 08/24/2012</p>

**Policy Purpose:**

The U.S. Department of Health and Human Services (HHS) has issued revised financial conflict of interest regulations that apply to Public Health Service (PHS)<sup>1</sup>-funded sponsored projects at CSU-Pueblo. The revised regulation “promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from financial conflicts of interest,” (Specifically, compliance is required by 42 CFR Part 50, Subpart F for grants and cooperative agreements and 45 CFR Part 94 for research contracts, collectively referred to herein as the “Regulation”).

The purpose of this policy is to comply with the Regulation’s requirement that the university establish and implement policies concerning disclosures of “Significant Financial Interests” (“SFIs”) held by persons engaged in research funded by PHS agencies. Compliance is required in order for the university to maintain eligibility for federal funding from the PHS and related sponsors. The Regulation includes specific requirements for disclosing, reporting and managing FCOIs in order to “ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under NIH [or other PHS] grants, cooperative agreements, or contracts will be biased by any conflicting financial interest of an Investigator.” (“Investigator” under the Regulation is a broad term encompassing more than just the Principal Investigator—see the Definitions section below).

This policy is also intended to protect Investigators from unwarranted or erroneous charges of failing to disclose Financial Conflicts of Interest by providing an approved, institutional mechanism for objective review and approval of Financial Interests.

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<sup>1</sup> The Public Health Service of the U.S. Department of Health and Human Services includes: (1) the Agency for Healthcare Research and Quality (AHRQ), (2) the Agency for Toxic Substances and Disease Registry (ATSDR), (3) the Centers for Disease Control and Prevention (CDC), (4) the Food and Drug Administration (FDA), (5) the Health Resources and Services Administration (HRSA), (6) the Indian Health Service (IHS), (7) the National Institutes of Health (NIH), and (8) the Substance Abuse and Mental Health Services Administration (SAMHSA), and any component of such agencies to which the authority involved may be delegated.

**Application of Policy:**

This policy applies to Investigators, as defined in the Regulation, who are engaged in activities funded in whole or in part by PHS-funded grants, cooperative agreements and research contracts.

**Exemptions:**

This policy applies to all Investigators whose projects are funded, in whole or in part, by PHS agencies and their awardees (e.g., where the University is a subrecipient of PHS funds). There are no exemptions.

**Definitions:**

*Conflict of Interest Committee (COIC):* a committee (including subcommittees) with faculty and administrative membership, appointed by the Provost of the respective CSU campus. CSU-Pueblo will collaborate with CSU-Fort Collins to have the COIC on the CSU Fort Collins campus review FCOI materials originating from the CSU-Pueblo campus, as applicable, and until a time when CSU-Pueblo appoints its own COIC.

*Dependent:* An Investigator's spouse, Domestic Partner or unemancipated child(ren), including stepchildren and adoptees, under the age of 18, or anyone who receives more than one-half of his or her financial support during a year from an Investigator.

*Immediate Family Member:* A person's parents, spouse, children, siblings, parent's spouse, step children and adopted children and their spouses are included under the purview of immediate family.

*Designated Official:* A person authorized by the university to determine whether an Investigator has a Financial Conflict of Interest that requires management.

*Disclose (Disclosure):* To provide relevant information about one's financial interests to the appropriate personnel within the institution, in order to assure full awareness of potential conflicts and to foster institutional efforts to address them. A "Disclosure" is made when the person(s) whose financial interests (or those of the person's dependent or immediate family member) are concerned provides an initial written explanation of such interests to the responsible supervisor in compliance with the requirements of this policy and related Procedures. (Compare to the definition of *Report*, below).

*Equity Interest:* Any ownership interest in a company or business external to the university, including, but not limited to, partnership interests or rights, shares, stocks, stock options or warrants, membership or and similar interests.

*Financial Conflict of Interest (FCOI):* A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

*Financial Interest:* Anything of monetary value, whether or not the value is readily ascertainable.

*Institutional official:* The individual within the institution who is responsible for the solicitation and final review of disclosures of Significant Financial Interests. For the purposes of this policy, the Institutional Official is designated as the appointing authorities (Provost/VPAA, VPFA, and the President or their designee).

*Investigator:* The Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding, including Investigators working for subgrantees, contractors, subcontractors, and collaborators.

**“Investigator” includes post-doctoral associates, research associates, graduate students, and other university employees involved in the sponsored project, as well as collaborators and consultants.**

*Investigator’s Institutional Responsibilities:* An Investigator's professional responsibilities on behalf of the Institution, including, but not limited to: research, research consulting, teaching, professional practice, institutional committee memberships, and service on panels such as an Institutional Review Board.

*Management Plan:* A written plan for taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

*PHS Addendum Form to Conflict of Interest Disclosure Form:* A form approved by the Institutional Official for use by PHS-funded Investigator to disclose SFIs.

*Procedures:* The guidelines, procedures, and forms adopted by the university pursuant to this policy, including pertinent sections of the Principal Investigator’s Manual.

*Remuneration:* salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, equity interests, and certain intellectual property rights as further set forth in the Procedures).

*Report:* To provide information to appropriate officials external to the university, e.g., to a PHS agency, concerning a person’s disclosed or undisclosed external commitments and financial interests, in order to meet an obligation imposed by law or policy. (Compare with *Disclose*).

*Research:* A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research, including (but not limited to) basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug), and any such activity for which research funding is available from a PHS grant, cooperative agreement, or contract.

*Senior/Key Personnel:* The Project Director or Principal Investigator, and any other person identified as senior/key personnel by the university in the grant application, progress report, or other report submitted to the PHS agency.

*Significant Financial Interest (SFI):* Any Financial Interest of an Investigator (or of the Investigator's family member) that reasonably appears to be related to the Investigator's Institutional Responsibilities **and** meets one or more of the following:

- if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- Is income related to intellectual property rights and interests not reimbursed through the Institution.

*Significant Financial Interest* does **not** include:

- Salary, royalties, or other remuneration paid by the university to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- Intellectual property rights assigned to the university, and agreements to share in royalties related to such rights;
- 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;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, institution of higher education, or a research institute that is affiliated with an institution of higher education; or
- Income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education or research institute that is affiliated with an institution of higher education.

**Policy Statement:**

Colorado State University-Pueblo is committed to the principle of conducting research in a manner that promotes the integrity of the research process and maintains the trust of the public, and of sponsors. This commitment requires the university to ensure that there is no reasonable expectation that research results may be biased by the external commitments and financial interests of persons who are responsible for the design, conduct, reporting, or direct administration of the research.

The university's conflict of interest policy is set forth in the [Faculty Handbook](#) and the [Administrative/Professional Handbook](#), sections 2.7.1.1 and 2.4, respectively, and is managed under disclosure processes, under the direction of the respective Institutional Official. For PHS-funded projects, the same policy and procedures will be followed, as supplemented by this policy and the specific procedures for PHS-funded projects, to be developed by the Office of Research and Sponsored Programs and published in the Principal Investigator's Manual (University Policies section).

The university will not accept or enter into agreements, contracts, gifts or purchases that give rise to a FCOI unless the conflict can be eliminated or appropriately managed to protect the interests of the university.

CSU-Pueblo will comply with all reporting responsibilities imposed by state or federal laws or regulations with respect to Financial Interests that have been disclosed, while protecting the personal privacy of affected employees to the extent permissible under applicable law or policy.

Pursuant to this policy and the procedures promulgated for its implementation, Investigators will report their external commitments and financial interests in a timely manner, and real and apparent Financial Conflicts of interest of research personnel will be identified and responsibly managed.

## **Responsibilities and Procedures**

### **1. Duty to Disclose Significant Financial Interests:**

a. An Investigator must make timely, accurate, and specific Disclosures of all of his or her Significant Financial Interests in accordance with the Procedures, and must assist the university in managing or eliminating such conflicts in order to fully comply with the Regulation, all other applicable laws, and university policies. Required disclosures include:

(i). Completion of the Institutional Conflict of Interest Disclosure form (see Faculty Handbook and/or Administrative/Professional Handbook), with the PHS Addendum, upon submission of an application for PHS-funded research;

(ii). Completion of a new Institutional Conflict of Interest Disclosure form (see Faculty Handbook and/or Administrative/Professional Handbook), with the PHS Addendum, within 30 days after the Investigator knows of a new SFI that has arisen that has not previously been fully and accurately disclosed; and

(iii). Reporting sponsored travel reimbursements prospectively or within 30 days after beginning travel (see section 4 below).

b. Every Principal Investigator (including a Co-PI) is responsible for identifying the persons involved in a project as an "Investigator" in order to assure that disclosure and management procedures are timely implemented and followed by that person.

c. Investigators are responsible for completing the required training on FCOI policies and procedures. Training shall be required:

- (i). Prior to engaging in research related to any PHS-funded grant;
- (ii). At least once every 4 years; and
- (iii). Immediately, if:
  - o The university revises this policy in a way that affects requirements of Investigators;
  - o The Investigator is new to the university; or
  - o The Investigator is not in compliance with the policy or a Management Plan concerning a FCOI – including failure to make timely disclosure as required herein.

## **2. Responsibilities of Deans and Department Heads:**

a. As further set forth in the Procedures, disclosures of Financial Interests are initially made by the Investigator to his or her supervisor. Deans and Department Heads are responsible for assuring that Investigators and their supervisors are made aware of these requirements, and for assisting with the development and management of FCOIs in accordance with a Management Plan or other action by the university in response to an identified conflict or potential conflict of interest. It is the responsibility of each Dean to determine, for all departments within the college, the extent to which Department Heads will be delegated the authority and responsibility for managing FCOIs affecting employees in their departments. A Dean, or an Associate Dean appointed by the Dean, shall manage a FCOI of a Department Head. The Institutional Official shall manage a FCOI of a Dean.

b. Deans and Department Heads are responsible for assuring that Investigators within their colleges and departments have completed the required training on FCOIs before any expenditure of project funds is made after adoption of this policy.

c. Deans and Department Heads are responsible for determining when a Disclosure indicates the existence of a SFI, and providing all such Disclosures to the Conflict of Interest Committee in accordance with the Procedures.

## **3. Responsibilities of University Administrators External to the College:**

a. The Institutional Official is ultimately responsible for managing FCOIs that have been disclosed, and for maintaining the reports and records that are required for compliance with the Regulation.

b. The Conflict of Interest Committee, under the authority and within the scope of its charge by the Provost and the Vice President for Research, is responsible for reviewing SFI Disclosures

identified by the responsible Dean or Department Head under this Policy. Those Disclosures that have been identified by a Dean or Department Head as indicating a SFI must be reviewed by the COIC, and a recommendation shall be made by the COIC to the Institutional Official as to whether or not a FCOI exists and how the matter should be managed.

c. The Institutional Official shall review each Disclosure as to which the COIC has recommended a finding of a FCOI, shall make the final determination regarding the existence of a FCOI, and shall approve the Management Plan for each FCOI.

#### **4. Travel Reimbursement Reporting**

Investigators must also disclose to their supervisors, for themselves and their family members, any travel related to CSU-Pueblo duties that is sponsored by or reimbursed by an external entity other than a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education or the government. For all such travel, the employee must disclose, and keep a record of, the purpose of trip, the sponsor/organizer, destination, and the duration. This disclosure may be made prospectively when the travel is planned, or, if not made prospectively, must be made within 30 days after the trip begins. The supervisor shall review such disclosure and make an initial determination as to whether the value of the travel (or reimbursement for travel) could directly and significantly affect the design, conduct, or reporting of PHS-funded research. Travel disclosures indicating that such circumstances may exist shall be forwarded to the Dean and handled in the same manner as for other SFI disclosures.

#### **5. Reporting FCOIs**

Each FCOI subject to a Management Plan must be reported in accordance with the Regulation and as further set forth in the Procedures. At a minimum, CSU-Pueblo shall, for any federal research funding subject to the Regulation:

(a). Report FCOIs to the awarding component of the funding agency at the time the FCOI is determined to exist, and at least annually thereafter while the FCOI continues to exist; and

(b). Maintain records related to Investigator Disclosures and the institution's review of, and response to, such Disclosures and all actions under this policy, for at least three years from the date of the final expenditure report (unless a different time period is specified in 45 CFR 74.53(b) and 92.42(b), where applicable).

#### **6. Subrecipient Requirements**

The university shall include in each subaward agreement subject to the Regulation terms that establish whether this policy or that of the subrecipient will apply to the subrecipient's Investigators, and shall provide FCOI reports regarding subrecipient Investigators to the awarding federal funding agency.

## 7. Public Accessibility Requirements

This policy, the Procedures, and certain Disclosures made pursuant to the policy shall be made publicly accessible. With respect to the Disclosures subject to such requirement, the university will either (i) publish those Disclosures on a publicly-accessible website *prior to* the expenditure of any funds under a PHS-funded research project, or (ii) provide a written response, within five business days, to any request for information concerning an SFI that was disclosed, and is still held, by the Senior/Key Personnel for the affected research project, if the SFI was determined to be a FCOI.

### References:

#### Public Health Service Regulations

- Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought ([42 C.F.R. Part 50. Subpart F](#))
- Responsible Prospective Contractors ([45 C.F.R. Part 94](#))
- [Summary of Major Proposed Changes to the Financial Conflict of Interest \(FCOI\) Regulations](#)

#### FDA Regulations

- [FDA Guidance: Financial Disclosure by Clinical Investigators](#)

#### Other Resources

- [NIH Financial Conflicts of Interest Page](#)
- [NIH Frequently Asked Questions Regarding PHS Funding and COI](#) (July 29, 2009)
- [NIH FCOI Web-based Tutorial](#) (July 29, 2009)
- [NIH Guide on Objectivity in Research](#) (July 14, 1995)
- [Recognizing and Managing Personal Financial Conflicts of Interest](#) (COGR – Winter 2002)
- [DHHS Office of Technology Transfer Policies and Reports](#)
- [CSU-Pueblo Faculty Handbook](#)
- [CSU-Pueblo Administrative Professionals handbook](#)

### Forms and Tools:

Forms will be provided in the Appendix of the CSU-Pueblo Principal Investigator's Manual, and the related policy referenced in the "University Policies" section.

APPROVED:  
COLORADO STATE UNIVERSITY-PUEBLO

By: \_\_\_\_\_  
Lesley Di Mare, President

Date: \_\_\_\_\_

**PHS Addendum to  
Conflict of Interest Disclosure Form**

<b>PART I. Remuneration/Consulting 42 CFR 50.604(e) (1) – (3)</b>		
<p>Have you or a member of your Immediate Family received in the past calendar year or expect to receive in this or the next calendar year any Remuneration from an entity other than CSU that reasonably appears to be related to your Institutional Responsibilities?</p> <ul style="list-style-type: none"> <li>• <b>I received or expect to receive such Remuneration</b></li> <li>• <b>A member of my Immediate Family received or expects to receive such Remuneration</b></li> </ul>	<p>Yes</p> <p>Yes</p>	<p>No</p> <p>No</p>
<b>PART II. Equity Interest 42 CFR 50.604(e) (1) – (3)</b>		
<p>Do you or a member of your Immediate Family have Equity Interest in an entity that reasonably appears to be related to your Institutional Responsibilities?</p> <ul style="list-style-type: none"> <li>• <b>I have Equity Interests</b></li> <li>• <b>A member of my Immediate Family has Equity Interests</b></li> </ul>	<p>Yes</p> <p>Yes</p>	<p>No</p> <p>No</p>
<b>PART III. Business Interest 42 CFR 50.604(e) (1) – (3)</b>		
<p>Do you or a member of your Immediate Family have a Business Interest in an entity that reasonably appears to be related to your Institutional Responsibilities?</p> <ul style="list-style-type: none"> <li>• <b>I have a Business Interest</b></li> <li>• <b>A member of my Immediate Family has a Business Interest</b></li> </ul>	<p>Yes</p> <p>Yes</p>	<p>No</p> <p>No</p>
<b>PART IV. Intellectual Property Rights 42 CFR 50.604(e) (1) – (3)</b>		
<p>Do you or a member of your Immediate Family have any intellectual Property Rights with respect to which there has been a receipt of income in excess of \$5000 related to such rights (excluding income from intellectual property assigned to CSU) that reasonably appear to be related to your Institutional Responsibilities?</p> <ul style="list-style-type: none"> <li>• <b>I have applicable Intellectual Property Rights</b></li> <li>• <b>A member of my Immediate Family has applicable Intellectual Property Rights</b></li> </ul>	<p>Yes</p> <p>Yes</p>	<p>No</p> <p>No</p>

**Part V. Travel Related Information 42 CFR 50.604(e) (1) – (3)**

**If you have any Travel Related Information to report, please do so below or on attached sheets if necessary. You may be asked to supplement this information.**

- a. the purpose of the trip;
  
- b. the identity of the sponsor/organizer;
  
- c. the trip destination; and
  
- d. the duration of the trip.

**PART VI. Public Disclosure 42 CFR 50.604(a)**

The University is required to maintain certain information associated with identified Financial and Business Interests and must provide this information in writing within five business days of any external request.

With respect to any disclosed Significant Financial Interest in connection with Remuneration (Part I), Equity Interests (Part II) , Business Interests (Part III) or Intellectual Property Rights (Part IV), please provide the following:

- the individual’s name, title, and role on the research;
- the name of the entity involved;
- the nature of the Significant Financial Interest; and
- the approximate value of the Significant Financial Interests in dollar ranges.

**PART VII. Required Training 42 CFR 50.604(b)**

Covered Individuals must complete Financial Conflict of Interest Training prior to engaging in any PHS funded grant or contract and at least every four years immediately upon the occurrence of certain circumstances.

Please identify the location/sponsor and date of your most recent Financial Conflict of Interest Training:

