

**PHS Addendum to
Conflict of Interest Disclosure Form
(See background and definitions attached)**

PART I. Remuneration/Consulting 42 CFR 50.604(e) (1) – (3)		
<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"> • I received or expect to receive such Remuneration • A member of my Immediate Family received or expects to receive such Remuneration 	<p>Yes</p> <p>Yes</p>	<p>No</p> <p>No</p>
PART II. Equity Interest 42 CFR 50.604(e) (1) – (3)		
<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"> • I have Equity Interests • A member of my Immediate Family has Equity Interests 	<p>Yes</p> <p>Yes</p>	<p>No</p> <p>No</p>
PART III. Business Interest 42 CFR 50.604(e) (1) – (3)		
<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"> • I have a Business Interest • A member of my Immediate Family has a Business Interest 	<p>Yes</p> <p>Yes</p>	<p>No</p> <p>No</p>
PART IV. Intellectual Property Rights 42 CFR 50.604(e) (1) – (3)		
<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"> • I have applicable Intellectual Property Rights • A member of my Immediate Family has applicable Intellectual Property Rights 	<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:

Received and Reviewed _____
Dean Date

PHS Addendum to Annual Role and Responsibility Survey

Background:

In August, 2011, the U.S. Department of Health and Human Services (HHS) issued a final rule in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). An Institution applying for or receiving NIH funding from a grant, cooperative agreement, or contract must be in compliance with all of the revised regulatory requirements no later than 365 days after publication of the regulation in the Federal Register, i.e. August 24, 2012.

This regulation aims to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants, cooperative agreements, and contracts will be free from bias resulting from Investigator financial conflicts of interest.

Major changes to the previous regulations from 1995 include:

- Lower Significant Financial Interest disclosure threshold: \$5000
- New conflict of interest training requirement (every 4 years for investigators receiving PHS funds)
- New public accessibility to Significant Financial Interest disclosures
- Increased reporting requirement for travel reimbursements

Timing:

This Survey must be completed:

- No later than at the time you make application for PHS-funded research;
- At least annually during the period of time you have a PHS-funded award; and
- Within thirty days of your discovering or acquiring a new Significant Financial Interest (as defined below).

Training:

You must complete Financial Conflict of Interest Training through CSU:

- Prior to engaging in research related to any PHS-Funded grant;
- At least every four (4) years; and
- Immediately if:
 - CSU revises its Financial Conflict of Interest policy to change disclosure requirements;
 - You are new to CSU; or
 - You are found not to be in compliance with CSU's Conflict of Interest policy or any applicable Conflict of Interest Management Plan.

Definitions:

- A. **“Business Interests”** include holding any executive position in a business or membership on a board of a business entity, whether or not such activities are compensated.
- B. **“Covered Individual” (“Investigator”)** means the project director or principal investigator or **any other person, regardless of title or position**, who is responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding, including, but not limited to, visiting, full-time and part-time faculty, staff and students, collaborators or consultants.
- C. **“Equity Interest”** means any stock, stock option, or other ownership interest, with valuation to be determined through reference to public prices or other reasonable measures of fair market value.
- D. **“Financial Interest”** means anything of monetary value or potential monetary value whether or not the value is readily ascertainable.
- E. **“Immediate Family”** means a Covered Individual’s spouse or domestic partner and dependent children or stepchildren.
- F. **“Intellectual Property Rights”** means any rights or interests in intellectual property such as patent rights, copyrights, trademarks or trade secrets.
- G. **“PHS”** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the Administration for Children and Families, Administration on Aging, Centers for Disease Control and Prevention, Food and Drug Administration, Federal Occupational Health, National Institute of Health or Substance Abuse and Mental Health Services Administration.
- H. **“Remuneration”** means salary and any payment for services not otherwise identified as salary including, but not limited to, consulting fees, honoraria, paid authorship, and travel reimbursement.
- I. **“Responsible Representative”** means (i) with respect to any student, visiting faculty, or academic or research faculty or staff, the Dean of the college or his or her designee in which such Covered Individual conducts the majority of his or her University activities, (ii) with respect to any non-academic, professional or administrative staff, the Vice President to which such Covered Individual directly or indirectly reports, (iii) with respect to any Dean, the Vice President for Research and (iv) with respect to any Vice President or any other Covered Individual not covered under clauses (i) through (iii), the President of the University.
- J. **“Significant Financial Interest”** means a Financial Interest consisting of one or more of the following interests of the Covered Individual and those of the Covered Individual’s Immediate Family that reasonably appears to be related to the Covered Individual’s University Responsibilities:
 - a. with regard to any publicly traded entity, any Remuneration received from such entity in the twelve (12) months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure that, when aggregated, exceeds \$5,000;

- b. with regard to any non-publicly traded entity:
 - i. any Remuneration received from such entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds \$5,000, or
 - ii. any Equity Interest regardless of value;
- c. Intellectual Property Rights with respect to which there has been a receipt of income in excess of \$5,000 related to such rights excluding income from intellectual property assigned to CSU.

Significant Financial Interest does not include the following types of Financial Interests: (1) salary, royalties, or other Remuneration paid by the University to the Covered Individual; (2) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a); or (3) income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a).

- K. **“Travel-related information”** information related to travel related to their University Responsibilities paid for or reimbursed by a business entity which must be reported by those engaged in PHS sponsored research unless the trip was paid for or reimbursed by a governmental agency, an academic teaching hospital, medical center or a research institute that is affiliated with an institution of higher education:
 - a. the purpose of the trip;
 - b. the identity of the sponsor/organizer;
 - c. the trip destination; and the duration of the trip.
- L. **“Institutional Responsibilities”** means a Covered Individual’s professional responsibilities on behalf of the University including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels.