

Conflict of Interest Awards Certification Workflow

Gus Fernandez-Wolff

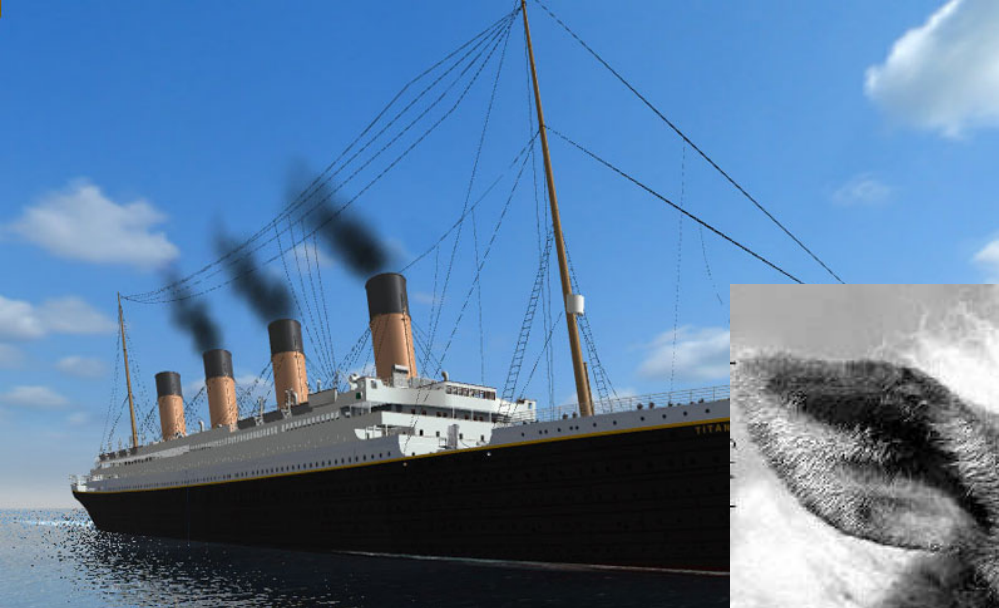
4/20/16



Nuts & Bolts



WELCOM TURIST WE SPIK INGLISH





Conflict of Interest

A conflict of interest is a situation in which financial or other personal considerations have the **potential** to compromise or bias professional judgment and objectivity



The NIH is committed to preserving the public's trust that the **research supported by us is conducted without bias** and with the highest scientific and ethical standards.

We believe that strengthening the existing regulations on **managing financial conflicts of interest is key** to assuring the public that NIH and the institutions we support are taking a rigorous approach to managing the essential relationships between the government, federally-funded research institutions, and the private sector

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 50

45 CFR Part 94

[Docket Number NIH-2010-0001]

RIN 0925-AA53

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule implements changes to the regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors. Since the promulgation of the regulations in 1995, biomedical and behavioral research and the resulting interactions among government, research Institutions, and the private sector have become increasingly complex. This complexity, as well as a need to strengthen accountability, led to changes that expand and add transparency to Investigators' disclosure of Significant Financial Interests (SFIs), enhance regulatory compliance and effective institutional oversight and management of Investigators' financial conflicts of interests, as well as increase the Department of Health and Human Services' (HHS) compliance oversight.

DATES: *Effective Date:* This final rule is effective as of September 26, 2011.

Compliance Date: An Institution applying for or receiving PHS funding

e-mail jm40z@nih.gov, concerning questions about the rulemaking process; and Dr. Sally Rockey, NIH Deputy Director for Extramural Research, concerning substantive questions about the rule, e-mail

FCOICompliance@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1995, the PHS and the Office of the Secretary of HHS published regulations at 42 CFR part 50, subpart F and 45 CFR part 94 (the 1995 regulations), that are designed to promote objectivity in PHS-funded research. The 1995 regulations cover Institutions that apply for or seek PHS funding for research (except for Small Business Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) Phase I applications) and, through implementation of the regulations by these Institutions, to each Investigator participating in the research.

Generally, under the 1995 regulations:

- The Institution¹ is responsible for complying with the regulations, including maintaining a written and enforced FCOI policy; managing, reducing, or eliminating identified conflicts to the PHS Awarding Component. The reports denote the existence of an FCOI and the Institution's assurance that it has been managed, reduced, or eliminated.

- Investigators² are responsible for complying with their Institution's written FCOI policy and for disclosing their SFIs³ to the Institution.

¹ "Institution" was defined under 42 CFR part 50, subpart F, as any domestic or foreign, public or private, entity or organization (excluding a Federal agency), and under 45 CFR part 94 as any public or private entity or organization (excluding a

- Maintaining objectivity in research requires a commitment from Institutions and their Investigators to completely disclose, appropriately review, and robustly manage identified conflicts.

- The PHS Awarding Components⁴ are responsible for overseeing institutional compliance with the regulations.

The purpose of the 1995 regulations was to ensure that there is no reasonable expectation that the design, conduct, or reporting of PHS-funded research will be biased by any Investigator FCOI. Since the publication of the 1995 regulations, the pace by which new discoveries are translated from the research bench into effective treatment of patients has accelerated significantly, and the biomedical and behavioral research enterprise in the United States has grown in size and complexity. For example, an analysis of financial support of biomedical research from 1994 to 2004⁵ showed that funding increased from \$37.1 billion in 1994 to \$94.3 billion in 2003. Fifty seven percent of the funding in 2003 came from industry sources. At the same time, relationships between individual academic researchers and industry have also increased from 28% in a 1996 survey⁶ to 52.8% in a survey conducted in 2007.⁷ Researchers frequently work in multidisciplinary teams to develop new strategies and approaches for translating basic research into clinical application, thus hastening discovery and advancing human health. In addition, these newer translational strategies often involve complex collaborations between Investigators and the private sector.

Recent studies from several sources have also highlighted the increasing complexity of the financial relationships



BEFORE



AFTER

PHS

Affiliated Physician Agency for Healthcare Research and Quality

Agency for Toxic Substances and Disease Registry

CDC Centers for Disease Control and Prevention

FDA Food and Drug Administration

HRSA Health Resources and Services Adm.

IHS Indian Health Service

NIH National Institutes of Health

Substance Abuse and Mental Health Services Adm.

Non-PHS Agencies

- Alliance for Lupus Research (ALR)
- Alpha-1 Foundation
- American Asthma Foundation
- **American Cancer Society (ACS)**
- **American Heart Association (AHA)**
- **American Lung Association (ALA)**
- Arthritis Foundation (AF)
- CurePSP
- Juvenile Diabetes Research Foundation (JDRF)
- Lupus Foundation of America (LFA)
- Patient-Centered Outcomes Research Institute (PCORI)
- **Susan G. Komen for the Cure**
- **PCORI. Patient-Centered Outcomes Research Institute.**

DO EMAILS STILL GET DELIVERED



ON THANKSGIVING?

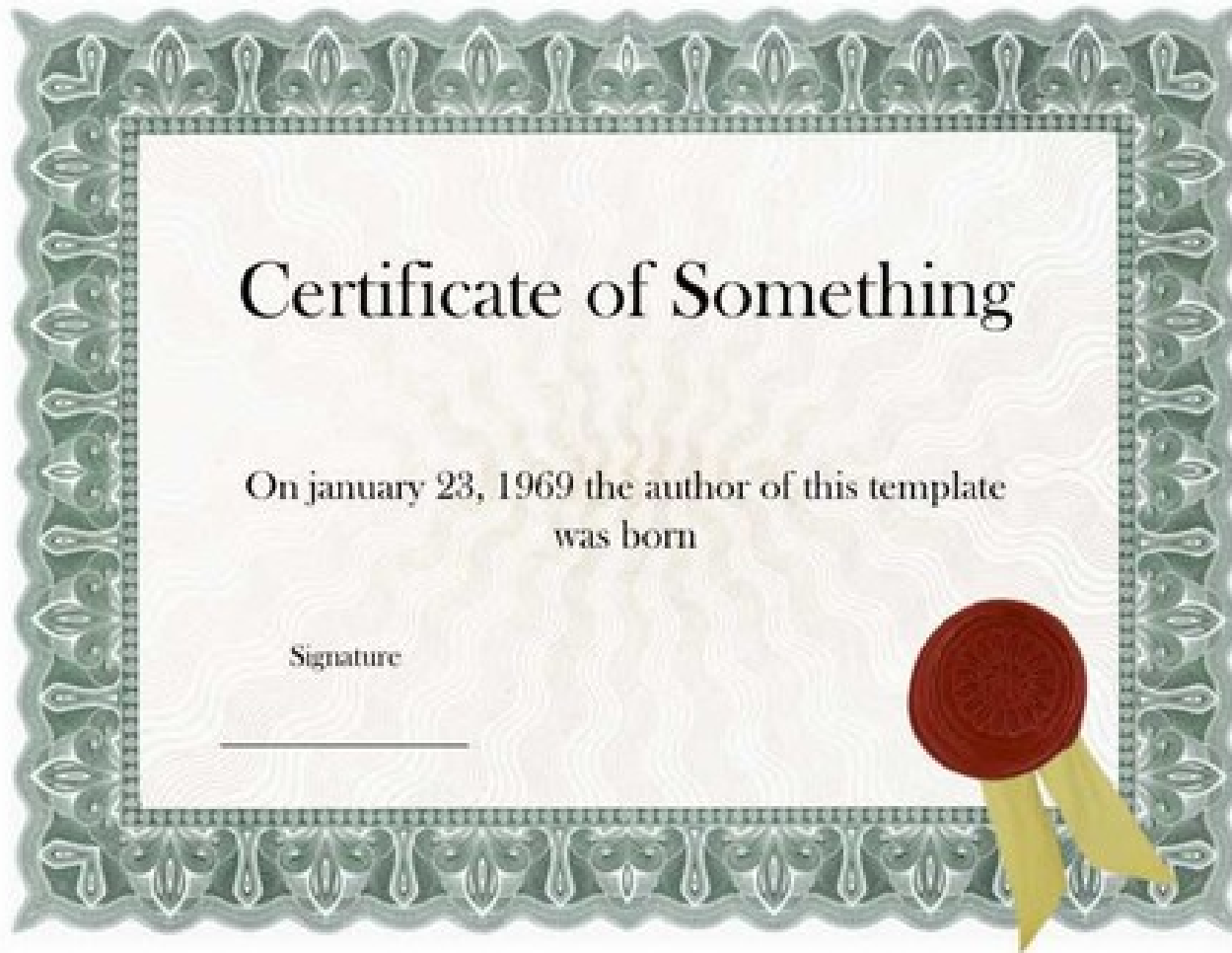
memecenter.com 



CALL OF DUTY

It impacts some people more than others.

memecenter.com 



§ 50.605 Management and reporting of financial conflicts of interest.

Prior to the Institution's expenditure of any funds under a PHS funded research project, the designated official(s) of an Institution shall, consistent with § 50.604(f): **review all Investigator disclosures of significant financial interests**; determine whether any significant financial interests relate to PHS-funded research; **determine whether a financial conflict of interest exists**; and, if so, develop and implement a management

Who is an investigator?



**MY ADVICE IS TO INVEST IN
TENNIS BALLS**

THEY HAVE A HIGH RATE OF RETURN

Key Personnel

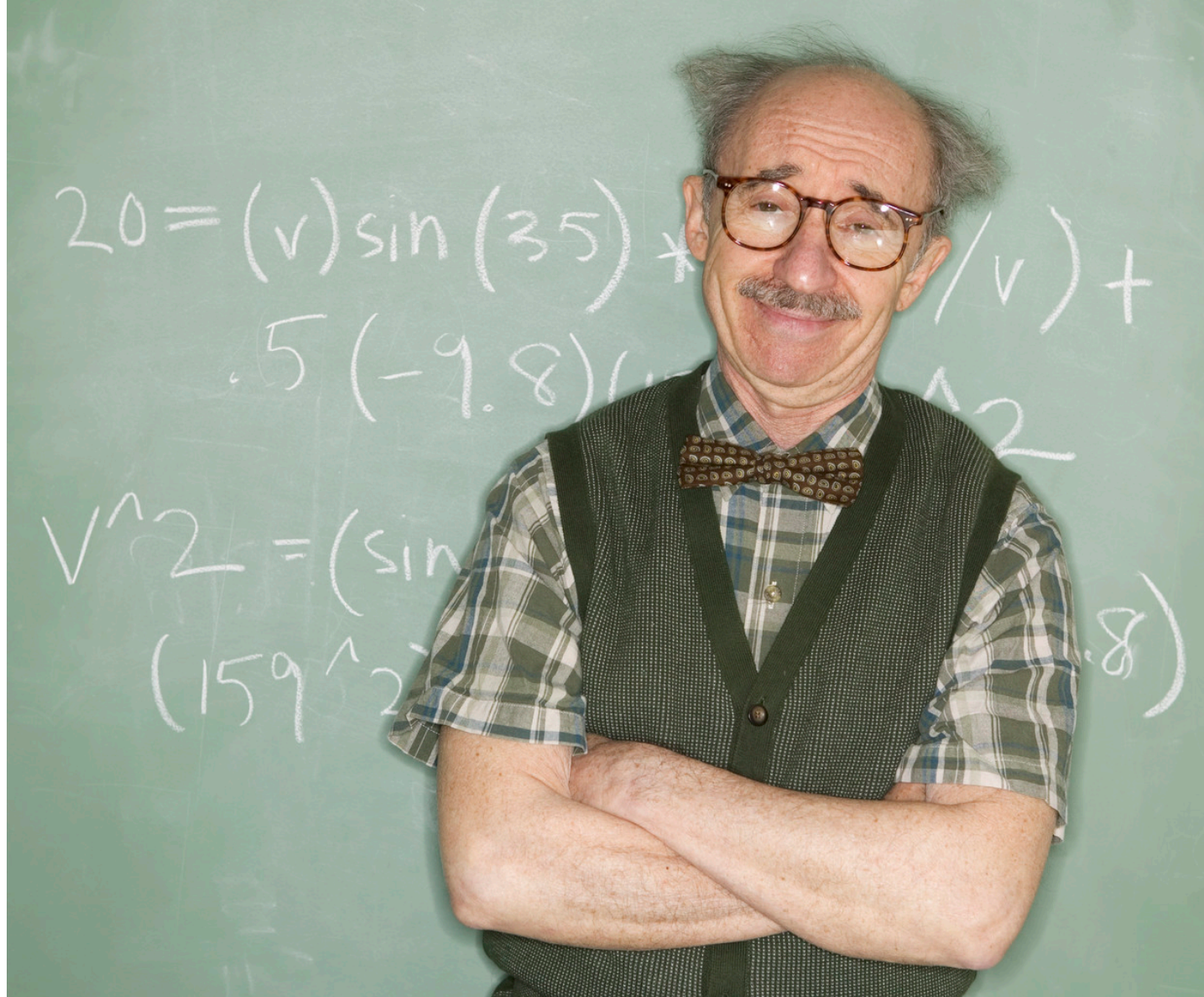


Principal Investigator

Co-Investigator

Consultants

Whoever is listed as Key
Personnel



Budget Justification

BUDGET

responsible

in charge

design

conducting

analyzing

oversight

supervise

Certificate of Financial Disclosure Training



2016



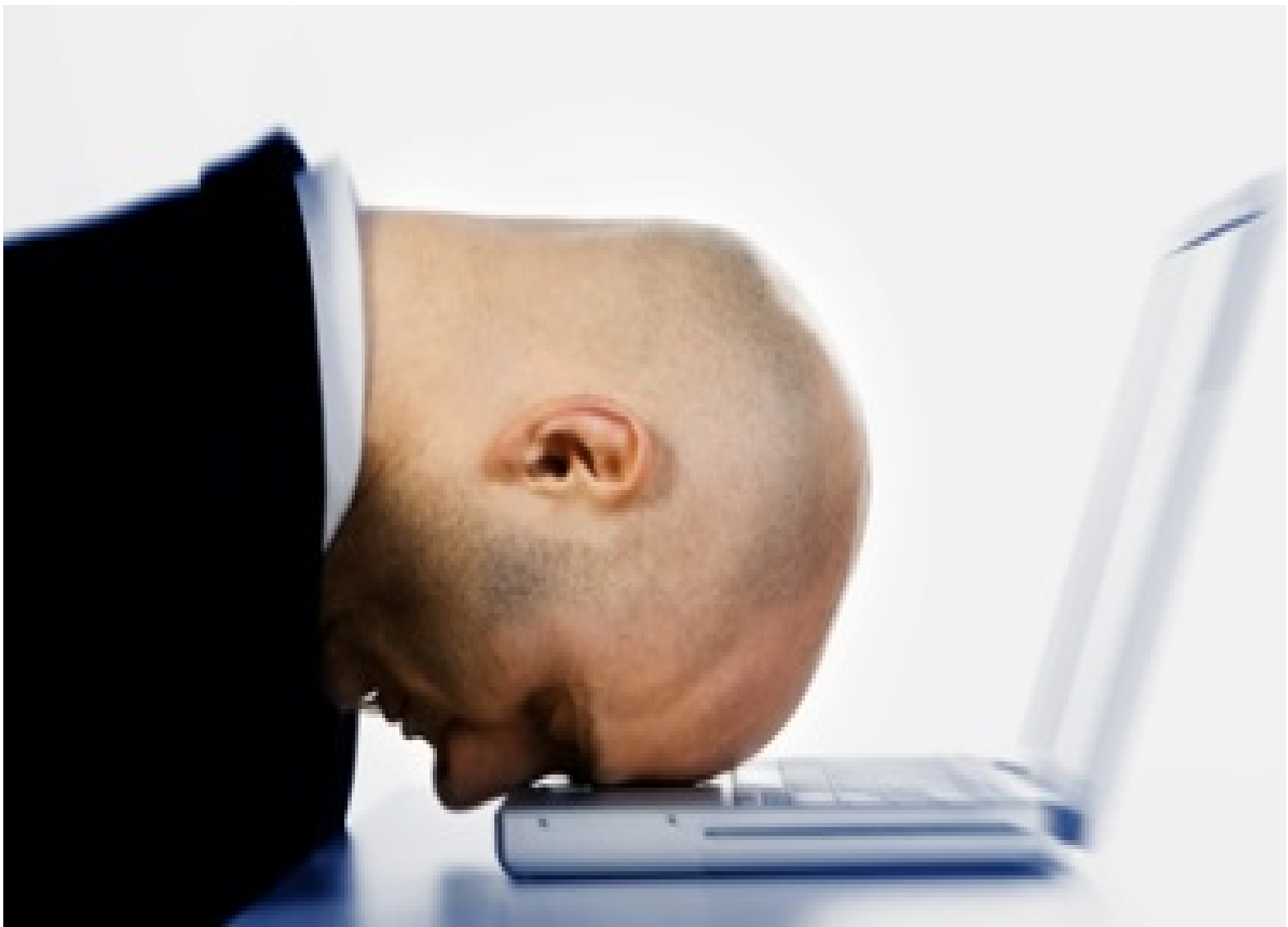
Disclosure = Training

Grants Listing

UConn Health Employees







There's going to be about a

A yellow school bus is shown from a rear-three-quarter view, completely stuck in a massive, deep snowdrift. The snow is piled high against the sides and back of the bus, reaching up to its windows. The bus's rear window has a "SCHOOL BUS" sign. The sky above is dark and cloudy, suggesting a storm or late evening. The overall scene conveys a sense of being trapped and delayed.

2 Hours delay



60



Where's my worm!





Grants Listing

Non-UConn Health Employees

(whether paid or unpaid)

(Sub award)



Sub Awardee

- Has a PHS-Compliant FCOI Policy
- Subcontract indicates that Institution's Policy is being followed
- No further action taken by COI office

Grants Listing

Non-UConn Health Employees

(whether paid or unpaid)

(Sub award)



Sub awardee

- Doesn't have a PHS-compliant FCOI
- Sub awardee chooses to follow UConn Health Policy

COI Office

COI staff work with SPS to ask PI to complete ***FCOI Certification Form***

(identify role of each contributor on the project, specifically whether “Independently Responsible” for key areas)

Identify all contributors named on the above project (except for Subawards). Indicate each person's role on the project, and mark any area in which they will be independently responsible. This form will be directed to Research Compliance Services (RCS) for review and verification of mandatory FCOI training and financial disclosure.

List of UCH Contributors									
		FOR PI USE					FOR RCS USE		
		PI indicates here whether the contributor is <u>independently responsible</u> for any of the following. *If the person is <u>not</u> independently responsible for any of these functions, mark "X" under "NOT independently responsible for any of these".					Enter date of completion	Yes or No	
Names of UCH contributors (Do NOT list names on any Subawards)	Role on Project (e.g., Principal Investigator, Co-Investigator, Other Key Study Personnel, etc.)	Project design	Project conduct /implementation	Required reporting of the research	Publications or Presentations	NOT independently responsible for any of these*	FCOI Training	Disclosure Form	*Any SFIs?
	PI								

(insert additional rows, if needed)

List of External (non-UCH) Contributors										
		FOR PI USE					FOR RCS USE			
		PI indicates here whether the contributor is <u>independently responsible</u> for any of the following. *If the person is <u>not</u> independently responsible for any of these functions, mark "X" under "NOT independently responsible for any of these".					Enter date of completion	Yes or No		
Names of External (non-UCH) contributors (Do NOT list names on any Subawards, unless the Subawardee institution opted to follow UCH FCOI policy)	Institution	Role on Project (e.g., Collaborator, Consultant, etc.)	Project design	Project conduct /implementation	Required reporting of the research	Publications or Presentations	NOT independently responsible for any of these*	FCOI Training	Disclosure Form	*Any SFIs?

(insert additional rows, if needed)

PI Signature

As Principal Investigator named on the above project, I certify that all contributors currently named on the project (except for

[illegible]

Project Conduct / implementation

Required reporting of the research

Publications or Presentations

COI Office

- COI staff work with SPS and PI to contact all External KSPs (and any other External people meeting definition of Investigator) to complete ***External Investigator Disclosure Form***
- and provide evidence of FCOI training, if training is not incorporated into the form

External Investigator (Non-UConn Health) Disclosure Form

Section I and II may be completed by OVPR staff. Section III may be completed by the PI. Section IV and V MUST be completed by the External Investigator.

I. External Investigator's Information

Name: _____

Institution: _____

Role on Project: _____

II. UConn Health Project Information

UConn Health Principal Investigator: _____

Project Title: _____

Funding entity: _____

III. FCOI Training

Has the External Investigator
named in Section I completed
training in conflicts of interest?

☐ Yes → Enter date of COI training: _____

Provide evidence of training (e.g., copy of certificate).

☐ No*

*PHS requires each Investigator to complete training regarding conflict of interest *prior to engaging in research* related to any PHS-funded grant. Prior to engaging in this research, the External Investigator should complete the NIH Office of Extramural Research Financial Conflict of Interest tutorial (available at: <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>). Or, the External Investigator may contact UConn Health Conflict of Interest Staff (gfernandez@uchc.edu) to discuss alternative training options.

IV. Disclosure of Significant Financial Interests (SFIs) (To be Completed by the External Investigator)

1. **REMUNERATION:** Have you, your spouse or dependent children received **remuneration** either directly or indirectly through a third party during the past 12 months or anticipated for the next 12 months related to the drugs, devices, products, or technologies being tested in this study, the sponsor of this study, and/or the companies or entities whose drug, device, product, or technology are being tested in this research study? *Remuneration means honoraria, payment for consulting, speaking, advisory board participation, paid authorships, stock or equity distributions, travel reimbursement, etc. Remuneration does not include salary or support from grants and contracts.*

☐ No remuneration has been received or is anticipated.

☐ Yes → Remuneration was received or is anticipated that when aggregated was/will be: ☐ Less than \$5,000

☐ \$5,000-\$9,999

☐ \$10,000-\$19,999

☐ \$20,000-\$39,999

☐ \$40,000-\$59,999

☐ \$60,000-\$79,999

☐ \$80,000-\$99,999

☐ \$100,000-\$149,999

☐ \$150,000 or greater



Provide evidence of FCOI training

Grants Listing

Non-UConn Health Employees
(whether paid or unpaid)

(non- sub award)



Same Scenario

- PI complete ***FCOI Certification Form.***
- PI ask them to complete ***External Investigator Disclosure Form.***
- Proof of COI training.

UConn – Storrs employees



Grants Listing

UConn-Storrs Employees

(whether paid or unpaid)

(Sub awardees)

No further action taken by COI office

(subcontract indicates Storrs' PHS
policy is being followed)



Grants Listing

UConn-Storrs Employees

(whether paid or unpaid)

(Subward)



- COI staff contacts Storrs COI staff
- for confirmation of the Storrs contributor's compliance with disclosure and training
- and to ascertain whether any SFIs were disclosed.

Acknowledgments

Kristen Tremblay

SPS Staff

In alphabetical order

Barbara,
Jen,
Pam,
Paul,
Tracy,
Wendy
and Zofia

