

Investigator Briefing

INTRODUCTION

The eDGE system was created to facilitate UCLA's compliance with the [U.S. Public Health Service regulations on Promoting Objectivity](#) in Research. These are their conflict of interest rules.

Under these rules, the Investigators on an award from [Research Sponsors That Require Compliance with PHS Regulations](#) who will share responsibility for the design, conduct or reporting of the project must disclose all personal (or individual) financial interests that meet the PHS definition.

Investigators must also complete a training session prior to participating in research related to any PHS-funded project. UCLA Policy 926, "PHS Regulations on Objectivity of Research," implements the 2011 PHS regulations. Under this policy, you must disclose financial interests that fall within the reporting categories and meet thresholds that PHS defines as "Significant Financial Interests", to be explained later.

In this briefing module you will learn about basic PHS regulations that relate to your role as an investigator on a PHS sponsored project or a non-PHS sponsored project that has adopted the PHS regulations. During this training session you will be asked a few questions that will enhance your understanding of the PHS regulations. By completing this briefing module you will fulfill the PHS training obligation.

Key Terms:

- **Financial Interest** - anything of monetary value, whether that value can be easily determined or not, that is held by you. Except for travel, financial interests held by your spouse or registered domestic partner, and dependent children must also be included in your disclosure
- **Investigator** - the principal investigator (PI) or project director (PD) and 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

Acronyms:

- **CIRC** - Conflict of Interest Review Committee
- **eDGE** - Electronic Disclosure Gateway
- **FCOI** - Financial Conflict of Interest
- **PHS** - US Public Health Science
- **RPC** - Research Policy and Compliance Office
- **SFI** - Significant Financial Interest

Note: You will find additional PHS, UC, and UCLA resources by clicking on the links throughout this module.

PHS Regulations



SIGNIFICANT FINANCIAL INTEREST (SFI)

Under the PHS definitions, **a financial interest becomes significant when it:**

- Reasonably appears to be related to or is in the same field of expertise as your institutional responsibilities - which include the teaching/education, research, outreach, clinical services, and University and public service performed in the course and scope of your UCLA appointment, and
- Meets any of the following reporting categories and thresholds for both US and foreign entities:
 - Income received from a publicly-traded entity during the 12 months prior to disclosure which, when combined with the value of any equity interest you hold in the entity, exceeds \$5,000;
 - Income received from a non-publicly traded entity (which includes non-profits and some education institutions) during the 12 months prior to disclosure that exceeds \$5,000 OR any amount of equity interest you hold in that entity;
 - Income received from an entity for intellectual property rights and interests during the 12 months prior to disclosure that exceeds \$5,000. This could include royalties for books, or license fees for software or technology you may have invented before you came to UCLA; or,
 - The occurrence of travel paid for or reimbursed on your behalf by a for-profit or non-profit entity, including professional organizations and foreign universities.



Keep in mind that **SFIs do not include:**

- Mutual funds or other investment vehicles such as retirement funds as long as you do not directly control the investment decisions;
- Payments made to you by UC for salary, stipends, royalties, honoraria, reimbursement of expenses or any other remuneration from the University;
- Income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with a US institution of higher education; or,
- Travel paid for or reimbursed by a US federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with a US institution of higher education.



SIGNIFICANT FINANCIAL INTEREST REVIEW

- Your SFI disclosure must be current before UCLA submits any new or renewal applications to PHS on which you plan to participate.
- Staff of the UCLA Office of Research Policy & Compliance will conduct a preliminary review of all disclosed SFIs to determine whether any of them appear to be related to your proposed research - that is, whether the SFI could be affected by the research or whether the SFI is in an entity whose financial interests could be affected by the research. However, review by RPC staff will not begin until Just-in-Time or similar notifications is received from the sponsor.
- If a *FCOI has been previously reported to PHS* under any ongoing awards, your SFI disclosure must be current and review by RPC staff must be completed *before* the annual progress report is submitted.
- For all other ongoing awards, your SFI disclosure must be current and review by RPC staff must be completed prior to the acceptance of additional funds or approval of no-cost time extensions.
- You may be required to complete additional training, your research funding may be withheld, or other UC or sponsor enforcement mechanisms be implemented if you failed to disclose as detailed in [UCLA Policy 926](#) and this training, or because you failed to comply with a plan put in place to manage your FCOI.

SFIs must be disclosed through eDGE **at least annually**, and must also be **updated within 30 days of acquiring or discovering a new SFI**.

Related SFIs will be reviewed a second time, usually by the CIRC. This review is conducted to determine if an SFI that is related to the PHS research constitutes a FCOI; that is, whether the SFI could reasonably appear to directly and significantly affect the design, conduct or reporting of the research.

If a FCOI does exist, the CIRC will develop a plan designed to eliminate, reduce or manage the FCOI. You may be asked to help in developing the plan, and you will be required to review it and confirm its acceptability. RPC staff will then provide all necessary reports to the sponsor, and, as necessary, will respond to public requests for information.

- RPC staff may confer with you to gather more information or clarification, and may collect additional details from other campus units, such as the Technology Development Group if UC IP is being used or further developed in the research.



SUMMARY

As an investigator you will be in compliance with the PHS regulations if you:

- Complete this briefing at least every four years and on other occasions if specifically notified by RPC staff;
- Complete the annual certification in eEDGE: 1) if you have no financial interests that meet the SFI definition, you must go into the system to certify that you have "no significant financial interests" and follow the submission instructions; or 2) if you have previously reported financial interests, you must update your disclosures at least annually by revising those where information has changed or deleting those that are older than 12 months and therefore no longer need to be part of your certification;
- Update your disclosure by reporting any new SFIs within 30 days of acquiring or discovering the interest throughout the period during which you are participating in any PHS- funded project;
- Provide any additional information requested by RPC staff or the CIRC as they review your disclosure;
- If a FCOI management plan is created, acknowledge acceptance of the plan promptly so RPC staff can submit the required report to the research sponsor. This must be done before any pending funding is released or spending can begin; and,
- If a FCOI management plan is in place, abide by its terms and conditions since there are federal sanctions for non-compliance. As UCLA is responsible for monitoring compliance with the plan, please respond promptly to all requests for information.

Helpful Links:

- [Conflict of Interest Review Committee](#)
- [Frequently Asked Questions on the PHS COI Regulations](#)
- [Research Sponsors That Require Compliance with PHS Regulations](#)

