

Financial COI Compliance for US Public Health Services Agencies

Information for applicants and grant holders on the US Public Health Service PHS agencies:

A number of US Public Health Service (PHS) agencies, including NIH, have implemented stringent new training and reporting requirements for significant Financial Conflicts of Interest (FCOI) that affect all investigators and co-investigators, their spouses and their dependent children.

To remain eligible for funding, all current grant-holders and new applicants must immediately follow the steps below:

1. Complete and Submit the [UVic Significant Financial Interest Disclosure Form](#)

Investigators holding or applying for PHS funding must submit a Significant Financial Interest (SFI) Disclosure and Consent Form listing his or her known financial interests and those of his/her spouse/partner and/or dependent children.

Please note that the Disclosure Form is set up so that the SFIs of the investigator, spouse/partner, and/or dependent children are all disclosed on a single form.

Please submit the completed forms to Dr. Rachael Scarth avpro@uvic.ca, the Designated Institutional Official for this process, at the time of application for funding.

Please note that you are required to file an updated Disclosure form annually and within 30 days of discovering or acquiring a new SFI.

If any conflicts are identified, the DIO will contact you to determine the course of action according to the regulations.

2. Complete the New Training Requirements

All PHS grant holders and all new applicants must complete an online tutorial on the NIH website, retain a Certificate of Completion and submit a copy to the Designated Institutional Official. The online tutorial takes approximately 45 minutes.

<http://www.grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

Current grant holders must provide certification to ORS that your training was completed on a particular date in order to remain eligible for funding.

This training must be completed prior to engaging in the research, and every four years thereafter.

Please follow the instructions in the video to demonstrate that you have completed this training.

For more information, contact Dr. Rachael Scarth, Designated Institutional Official at avpro@uvic.ca.

Background and Context

In late August 2012, the U.S. Department of Health and Human Services and the Public Health Service PHS implemented new financial conflict of interest (FCOI) regulations. These new rules establish more stringent and prescriptive standards and thresholds for conflict of interest disclosure, assessment and management, new policy and procedure and training requirements, and new requirements for public disclosure of policies and conflicts of interest, all of which must be followed by institutions that apply for or receive research support from PHS agencies, including the National Institutes of Health NIH. The revised US federal requirements are intended to promote objectivity in research funded by the US Public Health Service (PHS) by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS sponsored research will be free from bias resulting from Investigator financial conflicts of interest.

The new requirements affect research funded by the following PHS agencies:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Under the revised US Regulations, one of an investigator's responsibilities is to ensure they avoid activities which place them in a conflict of interest between their official activities and any other interest or obligation.

Major changes to the US Regulations include:

- A more inclusive definition of "Investigator"
- A revised disclosure process at the application stage
- Lower financial disclosure thresholds
- Disclosure of all activities relating to "Institutional Responsibilities"
- A requirement to disclose sponsored travel
- A new conflict-of-interest training requirement

To ensure UVic is compliant with these new reporting and training requirements, the Vice-President, Research is supporting the development of training tools and information on Public Health Service (PHS) funded research.

In December 2012, the Office of Research Services hosted a webinar for faculty receiving PHS funding. Further in-house training opportunities will be made available.

- US Federal Policy and Guidance 42 CFR Part 50: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors

B. Human Subjects Protections Education Programs

Please find the NIH “FAQ” link which has a link to the free tutorial.

http://grants.nih.gov/grants/policy/hs_educ_faq.htm#223

As a public service, the NIH Office of Extramural Research offers a free tutorial on “Protecting Human Research Participants” that institutions may elect to use to meet the human subjects protections education requirement.

NIH site: <http://grants.nih.gov/training/responsibleconduct.htm>

Allegations of Research Misconduct

To report an allegation of research misconduct involving PHS-supported research, please contact Dr. Rachael Scarth, Designated Institutional Official at avpro@uvic.ca.