

Memorandum

To: GW SPH Faculty and Staff

From: Kimberly Horn, Associate Dean of Research

Date: 10/8/12 REVISIONS 11/3/15, 4/7/16

Re: Frequently asked questions on the federal policy on filing Financial Interest Disclosure Forms for PHS research

1. What is the difference between the Financial Conflict of Interest (FCOI) form filed by GW faculty in Lyterati and the Public Health Service (PHS) requirement? The PHS requirement relates to the disclosure of Significant Financial Interest (SFI), regardless of whether or not an investigator and key personnel perceive it to be related to the proposal at hand. It is reported on the PHS FCOI Disclosure Form. The PHS FCOI Disclosure Form must be filed in addition to the FCOI process in Lyterati, not in lieu of.

2. Who is required to report SFI on the PHS FCOI Disclosure Forms and how are the forms filed? Per federal policy, as of August 24, 2012 investigators submitting a proposal (for a grant or contract) under the PHS umbrella must file the PHS FCOI Disclosure Form also called the “supplemental form.”

Find the form at <http://research.gwu.edu/financial-disclosure-form-phs>, along with other general information about the federal disclosure requirements. *Upon completion of the form, investigators must submit the form via email to OVPR, rescomp@gwu.edu.* No grant or contract under the PHS umbrella can be submitted without these forms on file in OVPR. Moreover, no PHS award can be set up without these forms in place at GW, even if the application was submitted prior to August 24, 2012. *Investigators are not required to email nor should they be asked by others to email or copy these forms to any other individuals.* See Table 1 below for a summary of the required disclosures. Note that most disclosures are unlikely to be considered financial conflicts of interest.

3. Who qualifies as an investigator? According to PHS, the definition of an investigator is as follows: *“...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...and may include consultants and collaborators.”* This definition may be independent of an investigator’s employment at GW. Final determination about investigator status will be made on a proposal-by-proposal basis following routine proposal review by the SPH Office of Research Excellence. Generally, consultants on most of the SPH proposals are not considered “investigators”, but the SPH Associate Dean of Research will review all consultants and collaborator roles for final determination. Sub-awardees will also be reviewed as potential investigators. Investigators (either as consultants or sub awardees) from other institutions who provide official documentation that their institutions have a Financial Conflict of Interest/Disclosure process in place will not need to submit a disclosure form to GW. However, if external investigators’ agencies or institutions do not have this process in place, they must file the forms with GW according to SPH

and GW procedures. Please contact the Associate Dean of Research if there are any issues or concerns among international collaborations related to the GW disclosure form.

Are students or research assistants and associates included on research proposals required to file PHS FCOI Disclosure Forms? Students and research staff are unlikely to serve as investigators or key personnel on PHS research. An exception may apply to doctoral students submitting as a PI on a federal application to support their dissertation research. Final determination will be made by SPH Associate Dean of Research upon routine proposal review.

5. Who has to complete the required FCOI training? All investigators and key personnel who have or may plan to apply for funding from PHS must complete the training, which is provided via CITI. Investigators should complete the training a.s.a.p. Importantly, no award can be issued without completed training. See CITI FCOI Training. In accordance with the current federal policy, training must be renewed every four years. Upon completion of training, investigators will receive an email from CITI certifying that training is complete. Please maintain the email confirmation in your files.

6. How often must investigators update disclosure forms? Investigators are responsible for updating PHS FCOI Disclosure Forms promptly whenever circumstances change. *Submit updated disclosure forms to rescomp@gwu.edu*. Disclosures should be reported within 30 days of initiation of the relevant activity or change in financial interest. Proposals will be submitted as long as all GW investigators have filed a PHS FCOI Disclosure Form. NOTE: The faculty and staff disclosure form in Lyterati is not the same as the PHS FCOI Disclosure Form.

In order for the Dean's Office to ensure a complete and up-to-date review of conflicts of interests and financial disclosures prior to the initial award set up or for continuations, a new SPH policy requires that Principal Investigators and Key Personnel update their FCOI Disclosure Forms at least annually, or whenever circumstances change. This update should coincide with annual reviews, typically occurring from mid-April through May. As such, please provide a new PHS FCOI Disclosure Form to rescomp@gwu.edu during this time period every year, beginning with 2016. This will eliminate the need for email updates to OVPR.

If during a FCOI review by the Dean's Office or by the SPH's Conflict of Interest Committee it is discovered that a PHS FCOI Disclosure Form on file is greater than one year, an updated form will be requested.

Awards cannot be set up until all up-to-date disclosure forms are on file in OVPR and have been reviewed by the Associate Dean of Research or the Dean's designee to determine that there is no conflict of interest.

7. What happens to the completed forms? The only SPH staff with access to the form is the Associate Dean for Research or designee. Department chairs will not have access to the forms, but will be notified if a conflict emerges. Following receipt of the PHS FCOI Disclosure Form in OVPR, a designated individual uploads the forms to a secure GW Docs folder. *The PHS FCOI Disclosure Forms will not be reviewed until there is an award*. If the SPH leadership determines a conflict of interest, a management plan will be enacted (as is the School's current procedure). The Dean or designee will develop a management plan and the plan will be reviewed with the investigator and Chair.

8. What happens if an investigator's form is not filed prior to proposal submission? It is important to underscore that investigators are responsible for sending the PHS FCOI Disclosure

Form to rescomp@gwu.edu. If a researcher is included in a proposal and has not filed the necessary disclosure, the proposal will not be signed by the SPH Dean's Office, nor will it be submitted to the sponsor by OVPR. Also, awards cannot be set up until up-to-date forms are on file.

9. NIH FCOI FAQ's

Table 1: Disclosure Requirements: How the Revised Federal Regulations Affect Disclosure Reporting

Category	On and after August 24, 2012
Significant Financial Interests (SFI) threshold	De minimis threshold of \$5,000 for disclosure generally applies to payments for services and equity interests. Includes any equity interest in non-publicly traded entities.
Which SFIs need to be disclosed (once the threshold is met)	All SFI related to the Investigator's institutional responsibilities.
Types of SFI excluded	Excludes 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.
Consulting for industry	If you participate in Public Health Service ¹ funded research, all travel expenses ² associated with outside activities paid for you or reimbursed to you by industry must now also be disclosed. Travel expenses include transportation, hotel accommodations, and meals.
Consulting for non-profit organizations	All payments for consulting for non-profit entities, AND travel expenses ² associated with outside activities paid for you or reimbursed to you by a non-profit must now also be disclosed.
Teaching, lecturing or giving a seminar	All payments/honoraria AND travel expenses ² for speaking at for-profit AND non-profit sponsored programs paid for you or reimbursed to you must now be disclosed. *This does NOT include income or travel expenses received from U.S. state, federal or local government agencies (e.g., NIH, IOM, CDC, state health departments), teaching hospitals, medical centers, or institutes of higher education and their related research institutes. Examples of non-profit entities that DO require disclosure are the American Heart Association and the Gates Foundation. Foreign government activities DO require disclosure.
Service on boards of directors, scientific advisory boards, advisory committees, study sections or review panels	All payments for serving on such boards or panels AND travel expenses ² for meetings paid for you or reimbursed to you by for-profit AND non-profit entities must now be disclosed. Exclusions and inclusions to this requirement are the same as those listed above (*).
Interests of spouse and dependent children in for-profit entities	Required if these interests could be related to your institutional responsibilities (e.g., research, teaching, clinical practice).

Income received from publishing, editing or authoring	Disclosure now required for any income paid directly to you for these activities.
Service as founder, officer or manager of a company, as well as ownership of equity in that company	Required for for-profit AND non-profit entities.

Notes about Table 1: This table is based on the PHS 2011 Final Rule, and is not an all-inclusive list of required disclosures.

Note that these requirements apply only to associations you have with organizations outside of GW that are not processed through the university or sponsored projects (i.e., OVPR).

¹**Public Health Service (PHS) Funded Research:** This includes research funded by the Public Health Service and its agencies, which include: National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Toxic Substances and Disease Registry (ATSDR).

Acknowledgments: This table was adapted from a document prepared by the Johns Hopkins Bloomberg School of Public Health, August 17, 2012 and [NOT-OD-11-109](#).