PHS Financial Disclosure (FCOI Forms Instructions)

The Public Health Service (PHS) requires disclosure of significant financial interests by investigators who participate in PHS-funded research either directly or via subaward. This form is also required with grant applications submitted to non-federal sponsors that have adopted the PHS FCOI policy as their own. The American Cancer Society, American Heart Association, Alliance for Lupus Research, Arthritis Foundation, and Susan G. Komen for the Cure have also adopted the PHS requirements.

The Office of Sponsored Programs has developed a three-stage process to implement the disclosure, review and reporting requirements of the revised PHS financial disclosure regulations, which are effective August 24, 2012.

This new process, with new PHS financial disclosure forms, has been designed to reduce and simplify the administrative burden associated with financial disclosure and review at the initial proposal submission stage for new and competing continuation/renewal proposals. More detailed financial information will not be collected unless and until a proposal is likely to be funded, generally when a Just-in-Time (JIT) or similar request is received. This will allow the COI Committee to concentrate its efforts on review associated only with projects that are likely to be funded and reduce the administrative burden on both investigators and COI Committee staff at the time a new or competing continuation/renewal proposal is submitted.

The requirement in the 2011 PHS regulations for annual disclosure, however, means that SFI must be re-disclosed on or before the due date of the progress report/non-competing continuation proposal. While this does represent an additional burden, the revised disclosure process should still minimize that for most investigators.

**New or Competing Continuation/Renewal Proposals**

**Step 1**

At the time a proposal is submitted, whether TUC will be the prime awardee or the subawardee to another entity, any individual on the proposed project who has been named by the TUC Principal Investigator as an investigator (as defined by the regulations) is required to complete and sign the PHS Financial Disclosure (Form 1), which contains four questions pertinent to the requirement for disclosure of Significant Financial Interests (SFI). This form must accompany the proposal when it is submitted to the Office of Sponsored Programs. **A proposal will not be considered complete and cannot be submitted to the funding agency by the Office of Sponsored Programs unless required financial disclosures are in place.**

Unless a proposal is likely to be funded, this is the extent of the financial disclosure requirement for most investigators.
Step 2

If and when a proposal receives a JIT request or some other indication from the funding agency that indicates it is likely to be funded and when the PHS Financial Disclosure (Form 1) has “yes” responses, only those investigators with “yes” responses will be contacted by the Conflict of Interest (COI) Coordinator (OSP) to request completion and submission of the PHS Financial Disclosure (Form 2). The PHS Financial Disclosure (Form 2) contains a set of questions, the answers to which will be used by the campus Designated Official (in consultation with the Principal Investigator, investigator and others, as necessary) to determine whether or not a disclosed SFI is related to the research project to be funded.

NOTE: At this time the Principal Investigator should make sure that he/she and all other investigators participating in the project complete the required PHS-compliant training.

Only those investigators for whom relatedness has been established will move to Step 3.

Step 3

- Any investigator who is notified by the COI Coordinator that s/he has a related SFI will complete a PHS Financial Disclosure (Form 3), which contains a set of questions developed to determine the extent to which the identified SFI may directly and significantly affect the design, conduct or reporting of the PHS-funded research project.

- The COI Committee will review the PHS Financial Disclosure (Forms 1 - 3) in conjunction with the proposal and any other information, which may have been provided or requested, to decide whether the related SFI constitutes a financial conflict of interest (FCOI) under the regulations. If it is determined that an FCOI exists, then the COI Committee will develop an appropriate management plan with the purpose of providing reasonable expectation that the FCOI of the investigator(s) will not bias the research results of the PHS-funded research. That management plan requires the signed concurrence of the investigator(s) with the FCOI. The COI Coordinator will then report required details of the FCOI to the NIH (or the prime awardee if TUC is a subrecipient.) FCOI’s must be reported to NIH prior to the expenditure of funds. PIs and investigators must plan for sufficient processing and review time, as review by the COI Committee will take time.

A Special Note about Subrecipients:

Each subrecipient must complete a TUC Subrecipient Commitment Form (dated 9/2012 or later), which has questions pertinent to the new PHS financial disclosure regulations to determine if a subrecipient has a PHS-compliant policy in place. If the subrecipient has completed and signed a previous version of the TUC Subrecipient Commitment Form (earlier than 9/2012), then each subrecipient must complete a TUC Subrecipient Commitment Form: FCOI Addendum, so that the new information is provided.

In most cases, a subrecipient will be an educational institution or non-profit entity, which will have a PHS-compliant policy in place as of August 24, 2012. However, in those rare instances where this is not the case the subrecipient must agree to rely on the TUC policy, including submission of the TUC financial
disclosure forms and adherence to the procedures and processes put in place by the campus for review, management and reporting of financial conflicts of interest.

For those subrecipients *without* a PHS-compliant policy: Each investigator of the subrecipient must complete the TUC **PHS Financial Disclosure (Form 5)** before TUC submits its proposal to PHS. A proposal will not be considered complete and cannot be submitted by the Office of Sponsored Programs unless PHS Financial Disclosure (Form 5) has been submitted by all investigators of the subrecipient. If the proposal is selected for funding, then Steps 2 and 3 (as described above) will apply equally to disclosures from subrecipient investigators.

Those subrecipients *with* a PHS-compliant policy will be expected to rely on that subrecipients policy and report FCOIs to TUC in accordance with the PHS requirements; they will not have the option of relying on the TUC policy.

**Non-Competing Continuation Proposals/Progress Reports, No Cost Time Extensions, Requests for Supplements That Also Extend the Period of Performance**

The regulations now require that **annual financial disclosure** of SFI be made by all investigators, including those of any subrecipient who is relying on TUC’s PHS-compliant policy. The three-stage process to be followed is described below:

**Step 1**

On or before the due date of a Progress Report/Non-Competing Continuation Proposal, at the time a no-cost extension is requested or a supplement that extends the period of performance of the award is requested a **PHS Financial Disclosure (Form 1)** must be completed by all investigators and provided to the Office of Sponsored Programs. Any investigators with a “yes” response to any of the questions on Form 1 must complete and submit **PHS Financial Disclosure (Form 2)** at this time, as well. These disclosure documents will serve as the required annual disclosure for investigators who have disclosed previously and the initial disclosure for any new investigators being added to the project.

**Step 2**

The campus Designated Official (in consultation with the Principal Investigator and others, as necessary) will determine whether or not a disclosed SFI is related to the continuation research project to be funded.

**NOTE:** At this time the Principal Investigator should make sure that he/she and all other investigators participating in the project complete the required **PHS-compliant training**.

**Step 3**

- Any investigator with a related SFI will be notified by the COI Coordinator and requested to complete a **PHS Financial Disclosure (Form 3)**, which contains a set of questions developed to determine the extent to which the related SFI may *directly and significantly* affect the design, conduct or reporting of the continuing PHS-funded research project.
• The COI Committee will review the PHS Financial Disclosure (Form 3) in conjunction with the proposal, the PHS Financial Disclosure (Forms 1 and 2) and any other information, which may have been provided or requested, to decide whether the related SFI constitutes a financial conflict of interest (FCOI). If it is determined that an FCOI exists, then the COI Committee will develop the appropriate management plan for the conflicted investigator, and the COI Coordinator will report to the NIH (or the prime awardee if TUC is a subrecipient), as required by the regulations.

No Cost Time Extensions, Requests for Supplements that Also Extend the Period of Performance

• Financial disclosure is also required at the time a no-cost extension is requested or whenever a supplement is requested, which would also extend the period of performance of the project. The procedure for disclosure by all investigators should follow that for progress reports/non-competing continuation proposals.

NOTE: the Office of Sponsored Programs will not release an award until all investigator financial disclosures have been received, reviewed and approved and the PI has certified (PHS FCOI Policy PI Certification Form) that all investigators on the project have completed the PHS-compliant training.

• Overview of PHS Financial Disclosure Procedures - Flowchart
• Briefing Sheet - PHS Requirement to Disclose Significant Financial Interest

Forms

• PHS Financial Disclosure (Form 1)
• PHS Financial Disclosure (Form 2)
• PHS Financial Disclosure (Form 3)
• PHS Financial Disclosure (Form 4)
• PHS Financial Disclosure (Form 5)
• PHS FCOI Policy: PI Certification

Training

All Investigators are required to take PHS-compliant training prior to engaging in PHS-funded research for new awards or no later than the due date of the next subsequent progress report/non-competing continuation proposal for ongoing projects, whether receiving remuneration or not, and at least every four years while engaging in PHS-funded research. Training is also required immediately if an Investigator
is new to the institution, if the TUC policies change in a way that affects Investigator requirements or if TUC finds that an Investigator is noncompliant with any policy or management plan. This training requirement applies equally for those funding agencies that have adopted the PHS regulations. The institution must be able to verify that training has been completed. The training requirement must be met as follows:

- Touro University California Conflict of Interest Training for Researchers (COIR) is available for TUC researchers through CITI. Note that TUC extramurally funded researchers (PHS and non-PHS funded) must complete this COIR training (whether or not they have also completed other PHS-specific training) to satisfy Touro mandated COI training.

  Go to CITIProgram.org, register as a new member or login, select the “add a course or update my learner group” for Touro University California link from the main menu and select “yes” for Conflict of Interest.

  Go through the training modules to complete the course.

  After you have completed the training, you will receive a certification. Keep this for your records.

- PHS researchers should complete the training and take an additional stand-alone COI-PHS course if they meet certain conditions, i.e., a Notice of Award or continuation dated on or after August 24, 2012.

  Go to CITIProgram.org, register as a new member or login, select the “add a course or update my learner group” for Touro University California link from the main menu and select “yes” for Conflict of Interest.

  Go through the training modules to complete the course.

  After you have completed the training, you will receive a certification. Keep this for your records and submit a copy to TUC OSP.

- Only those investigators (those of subrecipients who are relying on the TUC PHS-compliant policy) must complete the COI-PHS training course at CITI by affiliating themselves with Touro University California during registration.

  Go through the training modules to complete the course.

  After you have completed the training, print and sign the certification form provided. Keep this for your records and submit to OSP.

- In addition, all Investigators should complete the on-line training provided by NIH.
TUC Policy

- Disclosure of Financial Interests and Management of Conflicts of Interest, Public Health Service Research Awards

TUC Information

- PHS Financial Disclosure: Policy Guidance
- Conflict of Interest (COI) Message for PHS/NIH-funded Investigators
- Important Proposal Information Regarding PHS COI Regulations and Subcontracts

PHS Policy

- National Institutes of Health Financial Conflict of Interest
- U.S. Department of Health and Human Services (HHS) “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought” (42 C.F.R., Part 50, Subpart F)