

**National Institutes of Health (NIH) new Financial Conflict of Interest (FCOI)**

The Public Health Service (PHS) has issued “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought” ([42 CFR Part 50 Subpart F](#)) which will go into effect on August 24, 2012. We refer to this as The National Institutes of Health (NIH) Financial Conflicts of Interest (FCOI). Universities receiving sponsored research funding from the NIH are required to comply with these new regulations. All NIH proposals and awards, increments and continuations here at Rensselaer with an award notice start date of August 24, 2012 or later will be subject to these new regulations.

This policy change at PHS is being instituted to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of sponsored research, including grants, cooperative agreements and contracts, will be free from bias resulting from investigator financial conflicts of interest.

The new requirements include mandatory training for any investigator as defined by NIH; a decreased threshold for determining Significant Financial Interests (SFI) – a drop from \$10,000 to \$5,000; and the requirement that an institution receiving NIH funding have a mechanism in place to publicly disclose certain SFI events upon request. SFI’s must be disclosed at each of these five separate points in time:

- When responding to the Annual Conflict of Interest survey.
- When submitting a proposal.
- At the Just in Time (JIT) stage.
- Within 30 days of acquiring/discovering a SFI.
- Annually during the project period at the time of a noncompeting submissions.

There are several components to Rensselaer’s compliance with these new regulations:

- In each NIH or NIH Prime application for funding that is submitted Rensselaer must certify that we:
  - Have in effect an up-to-date written and enforced administrative process to identify and manage FCOI’s related to PHS research projects.
  - Will promote and enforce investigator compliance with the regulation pertaining to the disclosure of SFIs.
  - Will manage FCOI and provide initial and ongoing FCOI reports to PHS/NIH.
  - Will make information available upon request relating to any investigator disclosure of financial interest and the Rensselaer review of and response to such disclosure, whether or not the disclosure resulted in Rensselaer’s determination of an FCOI.
  - Will fully comply with the requirements of this regulation.
- Inform investigators of Rensselaer’s policy on FCOI, the regulations, and their responsibilities.
- Establish required mandatory training, a lower threshold for determining SFI’s, and establish a mechanism for additional reporting of certain SFI events to PHS and awarding NIH unit.
- Review all investigator disclosures, develop mandatory management plans when necessary, provide initial and ongoing reports to NIH provide reports to public upon request, and review management.

Please view the full text of the [NIH Notice](#) and [FAQ](#), along with the [Federal Register Notice](#) for additional information.

Research Administration & Finance have revised our procedures so that we are now compliant with the new NIH FCOI regulations. There are additional steps to be taken at the proposal, just-in-time, award and subaward stages of NIH funding opportunities.

**At time of Proposal submission:**

- The Project Information Form ([PIF](#)) has been revised to include two new sections that must be completed for NIH proposals:
  - Section requesting list of investigators. An investigator, as defined by NIH is “*the PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding*”.
  - Section requesting disclosure of any reportable significant conflict of interest related to the project.
- Subrecipients on NIH proposals will be asked to provide letters of collaboration that contain a statement certifying that the entity is PHS FCOI compliant, or that will be by the time of award, and that its investigators will complete the required training prior to engaging in any PHS funded grant.

**At the time of a Just in Time (JIT):**

- PI and Subrecipients will be required to declare any changes in their conflict of interest status.

**At the time of award:**

- PI's must provide or confirm list of investigators working on the project.
- **MANDATORY FCOI TRAINING FOR ALL INVESTIGATORS.**
  - The FCOI training is now available at the Collaborative Institutional Training Initiative or [CITI](#) website. This site is also used for other required PI compliance training. The FCOI course consists of an introduction, two segments with associated tests, and an optional module on conflicts of commitment, conscience, and institutional COI. The course takes about 1.5 hours to complete. Please contact HR, Research or RAF if you have any questions regarding the use of this site.
  - Notice of satisfactory completion of training must be sent to pre-award grant administrator.
  - This training will be required prior to receipt of any NIH funding with an award Notice Date of 8/24/12 or later. Investigators will be required to retest every four years.
  - **NO NIH AWARD WILL BE ACTIVATED BY RENSSELAER UNTIL ALL INVESTIGATORS ON THE PROJECT HAVE UNDERGONE THE MANDATORY TRAINING.**

**When extending subawards:**

- Sub recipients on NIH Prime awards must have a valid FCOI policy in place. They will be required to certify whether they currently have a PHS FCOI compliant policy in place.
  - If they do not, they will be asked to certify that they will use the awardees policy
  - OR they will be provided with a template for their use in adopting a PHS FCOI compliant policy.
  - Subrecipient investigators must declare any changes in their conflict of interest status.

Please feel free to contact your pre award grant administrator with any questions you might have.