TO: Health Sciences Faculty
FROM: Arthur S. Levine, M.D.
DATE: August 21, 2012
SUBJECT: Revised Conflict of Interest Policy and Required Training

By now, you should have received Vice Provost George Klinzing’s August 2012 memorandum on the above topic, advising all University faculty of actions they need to take to comply with new regulatory requirements imposed by the U.S. Public Health Service (PHS). These regulations establish a lower threshold ($5,000) for reporting outside interests of investigators funded by or applying to the PHS; mandate conflict of interest training for all investigators participating in research funded by or proposed to the PHS; and, require public disclosure by the University of reported conflicts.

Compliance with these new regulations will require that, beginning **August 24, 2012:**

1) **Every faculty investigator** must complete the new conflict of interest training module found at: [http://www.coi.pitt.edu/COITraining.htm](http://www.coi.pitt.edu/COITraining.htm). **Choose** the module that applies to you:
   a) The module for *Investigators with PHS support* (or those expecting to apply for PHS support); or,
   b) The module for *Investigators not working on PHS-funded research* or those who have disclosed outside financial interests on their Faculty/Researcher form.

2) **All faculty funded by or applying for funding from a PHS agency** must complete the new Faculty/Researcher Conflict of Interest disclosure form, which reflects the lower reporting thresholds under the PHS regulations. Your current activities should be reported on this form, which can be found at: [http://www.coi.pitt.edu/COIforms.htm](http://www.coi.pitt.edu/COIforms.htm)

Please note that, effective August 24, 2012, the University’s Office of Research will no longer be able to process grant proposals that include faculty who have not completed the above steps.

You may refer to Dr. Klinzing’s attached memorandum (below) or to the website: [http://www.coi.pitt.edu](http://www.coi.pitt.edu) for a more complete description of these changes and your important role in the University’s compliance with them. If you have additional questions, please call Dr. Klinzing’s office at 412-624-0784.

Thank you.
TO: University Faculty

FROM: George E. Klinzing, Vice Provost for Research

DATE: August 2012

SUBJECT: Revised Conflict of Interest Policy and Required Training

In response to increased scrutiny of potential financial conflicts of interest (COI) of investigators receiving funding support from certain federal agencies, the Public Health Service ("PHS")* enacted revised conflict of interest regulations in late 2011. The PHS regulations apply to all institutions receiving any funding from any PHS agency and establish new, lower thresholds for reporting outside interests of investigators, require greater oversight by institutions of such conflicts, and mandate public disclosure of reported conflicts. University investigators who submit grants for funding to any of these agencies may wish to review the summary of the regulatory requirements on the NIH webpage: http://grants.nih.gov/grants/policy/coi/. The University’s Conflict of Interest Committee has modified our existing COI policy to comply with the revised PHS regulations. These revisions are now complete, the revised University policy has passed through the shared governance process, and the Chancellor has signed off on the changes. On August 24, 2012 the revised policy will go into effect.

Revised COI Policy
Policy 11-01-03 Conflict of Interest for Faculty, Scholars, Researchers, Research Staff/Coordinators will be found at the Conflict of Interest website (http://www.coi.pitt.edu) and the Office of Research website (http://www.pitt.edu/~offres/). The policy has two parallel sets of requirements for reporting outside interests: one for investigators who are subject to the PHS regulations and a second for investigators who are not. Investigators who are not subject to the PHS regulations will not see any change in the reporting thresholds for outside interests on their Faculty/Researcher and/or their research protocol applications to regulatory committees (e.g., IRB, IACUC).
New COI Training required for all faculty
As part of the revised PHS regulations, the federal government has mandated conflict of interest training for all investigators on projects funded or proposed for funding by PHS agencies. The University has two COI training modules: one for those investigators who are planning to participate in or are participating in PHS-funded research, and one for others. The former must be completed shortly after August 24, 2012 by all investigators currently participating in PHS-supported research and by other researchers expecting to participate in future PHS-supported research before the University can submit a proposal to any PHS agency. In addition, such investigators on PHS awards will be required to complete updated COI training every three years.

The latter module must be completed by any University investigator who has not completed the module for PHS investigators and has either: 1) submitted a proposal through the Office of Research for funding from a non-PHS source; or 2) has disclosed outside financial interests on his/her Faculty/Researcher form, or has been directed by his/her department chair or dean to complete COI training. All individuals in this group will need to complete the revised module shortly after August 24, 2012 because significant changes have been made to the content of the previous training module. Investigators who are not subject to PHS regulations are required to complete a COI training module on appointment and/or prior to submission of a proposal for external funding. In order to be in compliance with the revised federal regulations, and to be sure that you are taking the correct training module, please go to the Conflict of Interest website at http://www.coi.pitt.edu for guidance on training requirements, beginning August 24, 2012.

• On completion of training you will receive a certificate which can be printed out for your records. This certification is also placed in a database for the Office of Research, the Institutional Review Board (IRB), and the Institutional Committee on the Care and Use of Animals (IACUC) to review the compliance status of the faculty.

Completion of new COI forms for PHS-funded Faculty/Researcher forms
PHS-funded faculty also will have to complete a new Faculty/Researcher COI disclosure form, which reflects the new, lower reporting thresholds under the PHS regulations. For more information about these requirements, please see the new page “For PHS-funded Researchers” on the COI website at http://www.coi.pitt.edu.

*Agencies of the PHS include:

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