Summary of Changes to PHS Conflict of Interest Requirements

Beginning August 24, 2012, Public Health Services (PHS) revisions to Promoting Objectivity in Research (Conflict of Interest) regulations go into effect. These revisions change the requirements for financial interest disclosure and related proposal and award requirements. The requirements apply to any proposal being submitted to PHS (includes NIH, SAMHSA, IHS, HRSA, FDA, CDC, and AHRQ) and other organizations that have adopted the PHS regulations.

The PHS regulation will affect PHS Principal Investigators (PI), Co-Investigators and anyone designated by the PI as responsible for the design, conduct, or reporting of the research. In addition, subrecipients must certify prior to proposal submission that they have a compliant PHS policy.

Due to the complexity of these changes and related compliance review requirements, faculty and business offices are reminded and strongly advised to submit proposals to GCA at least five (5) days in advance of the sponsor’s proposal submission deadline.

I. Prior to Submitting Proposal, Principal Investigators Must:

1. Identify senior/key personnel (Section V of the TranSum) and any other individuals who are responsible for the design, conduct or reporting of the research and ensure that they comply with the PHS regulations.

2. Complete Yale’s revised, PHS compliant, Financial Interest Disclosure form which is available at: External Interest Disclosure Form Login. Please select “External Interests” in the upper left hand column and click “Update”.
   - Disclosures must include all reportable non-travel significant financial interests (SFI) received/acquired over the past 12 months.
   - All travel (excluding travel paid by the U.S. government and U.S. higher education and their affiliated organizations) paid or reimbursed in whole or in part by a third party, related to Yale responsibilities, for the 30 days prior to the date of disclosure, and occurring on or after August 24, 2012.  [Guidance for administrators on this requirement will be available soon on the GCA website].
   - Disclosures must be updated either annually or within 30 days of acquiring a new SFI and/or completion of reportable travel that was paid for by a third party.
     - Note: Failing to timely disclose financial interests will require a retrospective review by the Conflict of Interest Committee to assess the potential for research bias.

3. Determine if consultants are responsible for the design, conduct or reporting of the research.
   - Note: If the consultant is a colleague, from another institution and is working independently from that institution, s/he may not rely on their home institution’s COI policy for compliance.  In such instances, contact GCA for assistance and guidance.
Summary of Changes to PHS Conflict of Interest Requirements (continued)

4. The Subrecipient’s Authorized Responsible Official **must certify** whether or not the subrecipient institution has a PHS compliant COI policy.
   - If the subrecipient does not have a compliant PHS policy, the subrecipient is expected to develop a policy or may adopt Yale’s model policy and model disclosure statement in order to implement a compliant policy. These documents are available at the [GCA website](http://www.yale.edu/training).
   - If a PHS compliant policy does not exist, as a fallback position to permit proposal submission, the subrecipient’s investigator and other personnel responsible for the design, conduct or reporting of the research may submit a Yale provided financial interest disclosure form to Yale prior to the submission of Yale’s application to the sponsor. Under such circumstances, it is understood that prior to Yale issuing a subaward to the subrecipient, said subrecipient will have already adopted a PHS compliant policy.
   - A **Subrecipient Information and Compliance form** is required to be completed and signed by the subrecipient’s Authorized Responsible Official prior to submission of the proposal to the sponsor.

II. **Upon Notification of Award or When Receiving a Non Competing Continuation (Installment) on or after August 24, 2012** (applies if proposal or progress report was submitted prior to August 24, 2012)

   - All responsible personnel must have on file with the COI Office a completed Yale's revised PHS compliant disclosure form before award setup.
   - A Subrecipient must certify that it has a compliant PHS COI policy by completing the Subrecipient Information and Compliance form before the subaward will be issued.

**PHS & NSF COI Information Sessions**

Register in TMS ([http://www.yale.edu/training](http://www.yale.edu/training)) for course offerings:

- Scroll down to and click on “Grant and Contract Training”
- Click on the “Courses” button under “GCA and GCFA”
- Select one of the PHS COI (Objectivity in Research) Informational Sessions

To assist investigators and department business offices with the application of the PHS regulations to proposals and awards, GCA has created a PHS and NSF COI Resource Repository website: [http://www.yale.edu/grants/FCOI](http://www.yale.edu/grants/FCOI). A **Summary for Investigators** of the PHS COI changes is available at this site. Information is also available on the Conflict of Interest Office’s website: [http://coioffice.yale.edu/information-revised-phs-coi-regulations](http://coioffice.yale.edu/information-revised-phs-coi-regulations).