In 2011, the Department of Health and Human Services (DHHS) revised its regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought or received (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). As of August 24, 2012, all Institutions applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with these regulatory requirements.

Because of the scope of changes needed to meet the new federal policy requirements, it is important for the Winthrop research community to become aware of these changes before the August 24, 2012 implementation date. A revised FCOI policy is being prepared and an addendum will be prepared specifically for PHS funded research.

New Regulatory Requirements that Require Your Attention
While much of our practice in managing financial conflicts of interest will not change, there are several new elements in the federal policy that require your attention, and individuals applying for and receiving NIH research grants (including all key personnel included on a grant application or awarded project) will now be required to complete an FCOI disclosure form.

Changes You Should Know About and who is effected
“Investigator” now refers to any 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, including persons who are grantees, contractors, consortium participants, collaborators, or consultants. This includes investigators on Cooperative Group Projects such as CALBGB, SWOG, COG and GOG. The definition of “Investigator” includes all KEY Personnel on a PHS funded study.

1. “Significant Financial Interest (SFI)” is now defined as:
   a. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:
      i. For a publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.
         For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
      ii. For a non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
      iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests
   b. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator), related to their institutional responsibilities. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
   c. Investigators must complete NIH Approved initial training and retraining every 4 years:

2. All SFI related to institutional responsibilities must be disclosed.
   a. This includes all research, instruction and extension / outreach activities

3. Investigator must disclose SFI as follows:
   a. No later than at the time of application for NIH-funded research
   b. Within 30 days of discovering or acquiring (e.g., through purchase, marriage or inheritance) a new SFI
   c. At least annually.

4. The nature and monetary value of any SFI determined to constitute a financial conflict of interest will be posted on a publicly accessible web site and/or provided to requestors within 5 business days.