

## ***UNC Policy Manual 300.2.2 - Summary of Revisions***

The U.S. Public Health Service (PHS) issued a final rule August 23, 2011 changing the requirements for the disclosure and reporting of financial interests of faculty researchers and institutions that apply for or receive funding from the Public Health Service, including the National Institutes of Health (NIH). UNC institutions and PHS-funded researchers must be in compliance with the final rule by August 24, 2012.

The UNC System received over \$1.2B in external funding in FY 2011 with approximately 41% awarded by PHS/NIH. UNC-CH receives ~60% of its external funds from the PHS/NIH and all UNC campuses except NCSSM and UNCSA have received some PHS/NIH funding.

The changes in PHS/NIH regulations were prompted by the growing complexity of interaction among federal agencies, research institutions and the private sector in the research enterprise and highly publicized events over the last several years involving medical school/clinical faculty and their financial interests in pharmaceutical firms that either sponsor their research or whose drugs they are testing. The primary interest of PHS/NIH is to achieve greater transparency, greater assurance that research results are not biased and greater accountability from institutions and investigators.

A working group comprised of research compliance/conflict of interest officers, university attorneys and technology transfer officers reviewed the current BOG policy against the revised federal regulations and crafted the revised BOG policy. Stakeholders at the campus level including Chief Research Officers, Provosts, University Attorneys, Technology Transfer Officers and others then vetted the revised policy at the campus level. The revised policy, regulations and guidelines are the result of this multi-stage review process.

The Board of Governor's Policy on Conflict of Interest and Conflict of Commitment has been substantially revised to be compliant with the revised federal regulations and has been edited throughout for presentation and clarity of intent and understanding by institutional officials and faculty. Following are some new aspects of the revised BOG policy:

- I. Financial interests and conflicts of interest are reviewed in the context of the Covered Employee's University Employment Responsibilities;
- II. Constituent Institutions are directed to develop implementing policies and procedures that clarify permissible and impermissible conduct, include processes to manage or mitigate conflicts of interest, provide for training on the Conflict of Interest Policy and comply with prevailing federal regulations; and
- III. The revised policy cites an August 24, 2012 implementation date. This is the required date of compliance and will give Constituent Institutions time to further develop implementing policies and procedures, train Covered Employees on the Conflict of Interest policy, and develop mechanisms to meet the requirements of the PHS/NIH final rule.

### **Specific Revisions to UNC Policy Manual 300.2.2**

Reordered the policy sections as follows: I-Definitions, II-Conflicts of Interest and III-Conflicts of Commitment

Edited the definition of Conflict of Interest to provide for the review of financial interests in terms of the Covered Employee's University Employment Responsibilities

Added a definition of Financial Interest

Edited the definition of University Employment Responsibilities for clarity

Added a definition of Covered Employee

Edited the definition of Inappropriate Use or Exploitation of University Resources for clarity

Expanded Section II-Conflicts of Interest to address the responsibilities of Constituent Institutions to develop implementing policies and procedures and text on "Avoiding Conflicts of Interest" moved to this section

Edited Section III Conflict of Commitment to include reference to External Professional Activities for Pay and for clarity