



## NIH Continues FCOI Compliance and Oversight Activities in Grantee Community



The term “financial conflict of interest” (FCOI) garners much attention in the medical research community. Since 1995, NIH-supported grantee institutions have been required to comply with the FCOI regulations (42 CFR Part 50 Subpart F) as they pertain to NIH grants.

The NIH recently announced a pilot compliance program to assess institutional compliance with the regulatory requirements of FCOI in research pertaining to NIH grants and cooperative agreements. A number of institutions will be selected for review by requesting a copy of their FCOI policy and related information.

The compliance program is a follow up to the NIH targeted site reviews that took place in 2006 as part of NIH’s oversight responsibilities. The NIH Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, OER, conducted targeted site reviews of 18 NIH-supported institutions to determine if grantee institutions were fully and correctly implementing the FCOI regulation and if reporting requirements are being met. These 18 institutions represented approximately \$4 billion in fiscal year 2005 research grant awards, or about 25 percent of the NIH budget allocated for research grants that year. Observations from the targeted site reviews are posted on the OER Web site.

As with the targeted site reviews, if areas of noncompliance are noted as a result of the current compliance program, institutions will be expected to formally address and resolve the issues with the NIH Division of Grants Compliance and Oversight.

The results of the pilot program will be shared with the NIH research community as part of its continuing educational efforts to improve and enhance compliance with FCOI requirements. The continuation of this program will be based on an assessment of this pilot.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-010.html>