

**From:** NIH-Alert (NIH/OD)

**Sent:** Monday, August 25, 2008 2:19 PM

**Subject:** Reminder from NIH on Financial Conflict of Interest Requirements

Dear Institutional Official,

I am writing to remind you and your Institution of the importance of the financial conflict of interest (FCOI) requirements applicable to all Institutions that apply for NIH research funding. Proper stewardship of Federal funds includes ensuring objectivity of results by protecting Federally-funded research from compromise by FCOI. It is essential that all NIH-funded Institutions and Investigators are fully aware of their obligations under the FCOI regulation (42 CFR Part 50, Subpart F). To this end, we have developed a Web-based tutorial which reviews the requirements of, and the Institutional and Investigator responsibilities for compliance with, the regulation. The tutorial is designed for use by Institutional officials responsible for managing NIH funded projects and for individuals who are responsible for the design, conduct or reporting of NIH-supported research. I urge you to encourage all NIH-funded investigators at your Institution to take the tutorial (which can be accessed at <http://grants.nih.gov/grants/policy/coi/index.htm>).

As you know, the Public Health Service (PHS) regulation at 42 CFR Part 50, Subpart F is designed to promote objectivity in PHS-funded research by establishing standards to ensure that the design, conduct, and reporting of research funded under PHS grant awards is not biased by any conflicting financial interests of an Investigator (defined under the regulation as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding; for purposes of the regulatory requirement relating to financial interests, the definition includes the Investigator's spouse and dependent children). The regulation places the responsibility for the identification and management of Investigators' FCOI with the Institution, which oversees the Investigator's activities. The NIH, as the grantor agency, has primary responsibility for overseeing institutional compliance with these requirements.

Essential to the compliance process are: (1) Investigators' prompt and full disclosure of financial interests that may be impacted by their NIH-supported research; and (2) sound Institutional management of any conflicting interests, including reporting those interests to the NIH

(specifically, to the appropriate Chief Grants Management Officer of the funding Institute/Center).

At NIH, program staff in the Institute or Center that funds the research, together with staff in the Office of Extramural Research (OER), address FCOI issues. The program staff has an in-depth understanding of the science itself and the risks involved with the particular research project(s), while the OER staff oversees Institutional compliance with the regulation. The protocol we follow when addressing FCOI issues involves a careful review of all relevant information obtained through, among other sources, applications for NIH funding, progress reports and/or other information submitted to the NIH, and FCOI reports received from the recipient institution, as well as a review of any publicly available information. We may then follow-up with the recipient institution to determine the extent of compliance with the regulation and the adequacy of any actions that the Institution has taken to assure that the NIH-supported research is not biased by the financial interests of the Investigator(s).

In all cases, the NIH has the authority to take appropriate action to protect the safety of any research participants and safeguard the integrity of the research. These actions are determined on a case-by-case basis and are dictated by the specific status and circumstances of the project and the risks associated with a failure to manage the financial interests effectively. We are committed to working closely with the recipient institution to resolve issues quickly and comprehensively.

I am confident that by working together we can continue to uphold the highest standards of conduct and support the best biomedical research.

Sincerely yours,

Norka Ruiz Bravo, Ph.D.  
NIH Deputy Director for Extramural Research

For more information on the regulation governing FCOI see the Frequently Asked Questions document on the NIH Web site (<http://grants.nih.gov/grants/policy/coifaq.htm>) or contact [FCOICompliance@mail.nih.gov](mailto:FCOICompliance@mail.nih.gov).