

## HHS Proposes New Rules Regarding PHS-Funded Research and Financial Conflicts of Interest

On May 21, 2010, the Department of Health and Human Services (HHS) published proposed revisions to the rules regarding the identification and management of financial conflicts of interest that apply to institutions that seek or receive Public Health Service (PHS) funding for research. With this [notice](#), the Department intends to revise the regulatory framework governing investigator conflicts of interest, which has been in place since 1995, to respond to the scope and complexity of biomedical research and changes in financial relationships between research institutions and industry sponsors of research. The proposed rule addresses some, but not all, of the issues raised by the Department's May 9, 2009 solicitation of public comments regarding the revision of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought" and 45 CFR Part 94, "Responsible Prospective Contractors." Public comments on the proposed rule will be accepted until July 20, 2010.

The proposed revisions contain a number of noteworthy changes to the current regulations, including the following:

- **Broadened applicability of the regulations.** The Department proposes to eliminate the current exception for Small Business Innovative Research and Small Business Technology Transfer Phase I applications, and to clarify that the regulations continue to apply once any PHS-funded research begins.
- **Expanded definition of Significant Financial Interest (SFI).** The proposed regulations reduce the monetary threshold that triggers a reporting requirement from \$10,000 to \$5,000. This change reflects internal policies that some institutions have already implemented, and other institutions have gone further, reducing to zero the monetary thresholds for interests that must be reported to institutions. In this revised definition, the exclusions have also been narrowed. For example, income from seminars, lectures, or teaching engagements is excluded if the event is sponsored by a federal, state, or local government agency or an institution of higher education, but such income from events sponsored by any other non-profit entity or a for-profit entity would not be excluded.
- **Increased Disclosure Requirements for Investigators.** Under the proposed regulations, disclosures investigators must make would include significant financial interests related to the investigator's "institutional responsibilities," not just the proposed research project. In addition, the proposed rules provide specific timeframes and situations in which investigators must update their initial disclosures.
- **Increased Responsibilities for Institutions.** The proposed regulations shift the burden from the investigator to the institution to determine whether an investigator's SFI (1) is related to PHS-funded research and (2) constitutes a financial conflict of interest (FCOI). Some institutions have already adopted this change. Further, the proposed regulations require institutions to maintain records relating to all investigator disclosures of financial interests and the institution's review of and response to such disclosures, regardless of whether or not the disclosure resulted in the institution's determination of a FCOI. The recordkeeping required for this purpose will be significant.

- **Increased Institutional Certification and Reporting.** The proposed regulations require institutions to submit certifications that include assurances regarding the existence and enforcement of written processes they have in place related to the identification and management of FCOIs, and their agreement to comply with reporting and cooperation requirements of the regulations. Additionally, prior to expenditure of funds, institutions will be required to provide the PHS-awarding entity a report regarding any identified FCOIs, which must include specific information about the nature, value, and description of the FCOI. This reporting requirement is significantly expanded from the current regulations, which only require disclosure that a conflict of interest was identified and managed, reduced, or eliminated. Among other issues, some FCOIs will be difficult to value when the research, and funding for the research, is in its early stages.
- **Website Disclosure.** The proposed regulations would require that prior to expenditure of any funds under PHS-funded research, the Institution make available on a publicly accessible website details related to any SFI that the institution decides is a FCOI.

Notably absent from the proposed revisions is regulation of institutional conflicts of interest. HHS considered, but did not ultimately include in the proposed regulations, a requirement for institutions to adopt a policy on institutional conflicts of interest. Such a requirement is still under consideration for inclusion in the proposed regulations, and the inclusion of such a requirement is likely to be influenced by public comment.

The commentary accompanying the proposed regulations discusses the potential burden that the additional administrative requirements required by the proposed revisions would impose on institutions. HHS had considered potential alternatives to some of the administrative procedures, but concluded that other options were either insufficient as to disclosure and transparency, or further increased the burden of compliance.

It is important to note that the cost of implementing the proposed requirements is an allowable cost eligible for reimbursement as a Facilities and Administrative cost on PHS-supported grants, cooperative agreements, and contracts. This reimbursement should help offset at least some of the cost burdens of implementation for institutions as well as to investigators. Such cost reimbursement should aid institutions, including small businesses, in addressing the administrative burden that these required procedures will impose.

The actual burden that compliance with the proposed regulations will create for institutions will vary based on the size of the institution as well as the extent to which a particular institution has already implemented institutional changes similar to the requirements of the proposed regulations. As noted, some leading research institutions already require investigators to report all financial interests, regardless of value, and some institutions are currently posting FCOI information on publicly accessible websites.

For more information regarding the proposed revisions and their impact on your reporting and compliance programs, please contact the Ropes & Gray attorney who usually advises you.