

Finally the Final Rule:

HHS Issues Long-Awaited Final Rule Revising Public Health Service Conflict Of Interest Requirements

On August 23, 2011, the U.S. Department of Health and Human Services (“HHS”) issued a final rule amending the Public Health Service (“PHS”) regulations on the *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors* (42 C.F.R. Part 50). The rule, which regulates the disclosure of financial conflicts of interests by research institutions and investigators that seek or receive PHS funding, was initially adopted in 1995. The final rule reflects HHS’ efforts to strengthen transparency and oversight in the face of increasing numbers of, and complexity in, financial relationships between biomedical researchers and industry.

To access Ropes & Gray’s annotation of the chart prepared by HHS that compares the final rule to the 1995 regulations, please [click here](#). The key revisions in the final rule are:

- Modifying the scope of reportable significant financial interests, including limiting the sources of income excluded from the definition of significant financial interests (*e.g.*, certain income previously excluded when received from any public or nonprofit entity will now be excluded only if received from specified categories of public and nonprofit entities);
- Lowering the minimum threshold at which investigators must disclose significant financial interests to research institutions *from* \$10,000 for any financial interest *to* any equity interest in non-publicly traded entities and \$5,000 for any other financial interest;
- Requiring investigators to disclose to their research institutions all significant financial interests related to the investigators’ institutional responsibilities (*rather than* only those significant financial interests related to the PHS-funded research) and focusing on the twelve months preceding the disclosure (*rather than* the twelve months following disclosure);
- Clarifying and increasing institutions’ responsibilities with respect to identifying significant financial interests related to PHS-funded research; managing financial conflicts of interest, particularly when such interests were not timely identified; and ensuring subrecipient compliance;
- Requiring institutions to provide a financial conflict of interest report to PHS containing the details of any investigators’ financial conflict of interest (*rather than* just reporting the existence of a conflict of interest) *as well as* details of the institution’s plan for managing the conflicts of interest prior to the expenditure of funds in a PHS-funded research project;
- Mandating public accessibility (*via* a publicly accessible web site or, in certain cases, written response to any requestor within five business days of a request) of institutions’ financial conflict of interest policies and certain information concerning any financial conflict of interest held by key personnel whose significant financial interests are related to the PHS-funded research; and
- Requiring investigators to complete training prior to engaging in research related to any PHS-funded grant or contract and at least every four years thereafter.

Institutions may find that the final rule increases significantly the pressure on the adequacy of their policies; the effectiveness of their internal reporting systems; and the terms of their conflict management plans. Institutions were, however, spared the need to address institutional conflicts of interest in the near future as part of the final rule. HHS did *not* expand the rule to apply to *institutional* conflicts of interest. The agency instead promised “to consider the issue . . . together with the biomedical research community,” suggesting that no new proposal is on the immediate horizon.

An institution must comply with the new requirements:

- “No later than August 24, 2012; and
- Immediately upon making its institutional Financial Conflict of Interest (FCOI) policy publicly accessible.”

The new requirements apply to each grant or cooperative agreement with a notice of award issue date after the compliance date (including noncompeting continuations). Institutions may choose instead to apply the new requirements simultaneously to all active PHS awards after the compliance date.

The final rule is available [here](#) along with HHS guidance. The final rule was also published in the Federal Register on August 25, 2011.

If you have any questions about the final rule, please contact the Ropes & Gray attorney who normally advises you.