

## HHS Finalizes New Financial Conflicts of Interest Regulations

September 1, 2011

The U.S. Department of Health and Human Services recently published its final rule governing financial conflicts of interest involving investigators conducting Public Health Service (PHS)-supported research. Although similar to the financial conflict of interest regulations promulgated in 1995 that it amends, the 2011 FCOI Regulation contains several modifications that will have a meaningful impact on the conflict of interest compliance programs at grantee organizations.

On August 25, 2011, the U.S. Department of Health and Human Services (HHS) published its final rule governing financial conflicts of interest involving investigators conducting Public Health Service (PHS)-supported research (the 2011 FCOI Regulation), "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors." 76 *Fed. Reg.* 53,256 (Aug. 25, 2011) (to be codified at 42 C.F.R. pts. 50 & 94). Although there are significant similarities between the 2011 FCOI Regulation and the financial conflict of interest regulations promulgated in 1995 (the 1995 FCOI Regulation) that it amends, the 2011 FCOI Regulation contains several modifications that will have a meaningful impact on the conflict of interest compliance programs at grantee organizations. These changes constitute the first major revision to the 1995 FCOI Regulation, and are the result of more than two years' work since the Advance Notice of Proposed Rulemaking was announced by National Institutes of Health (NIH) on May 8, 2009.

The 2011 FCOI Regulation was promulgated in response to both congressional mandate and concerns prompted by several widely reported instances of allegedly mismanaged financial interests held by clinical researchers. The 2011 FCOI Regulation maintains the 1995 FCOI Regulation's focus on financial conflicts of interest involving investigators relating to federally funded research, as well as the reliance on financial thresholds to establish the parameters for the interests that must be disclosed by an investigator, but it does not address other sources of conflicts of interest, such as non-financial conflicts of interest (sometimes referred to as "associational" conflicts of interest) or institutional conflicts of interest (those posed by interests held directly by the institution), both of which have been the subject of considerable trade association and media attention. The 2011 FCOI Regulation sets forth more robust standards of institutional responsibility for the identification and management of conflicts of interest, for example, by requiring that institutions establish published policies and procedures for the assessment and management of disclosed financial conflicts of interests to grantee organizations.

Summarized below are a few key provisions of the 2011 FCOI Regulation.

- **Amended definition of "Investigator" covers who must disclose**—"Investigator" is now more broadly defined as the Project Director/Principal Investigator, as well as any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
- **New definitions of "Key Personnel" and "Senior/Key Personnel" for whom disclosed information must be made publicly available**—"Key Personnel" and "Senior/Key Personnel" are each a subset of the broader term "Investigator." For individuals that fit within either category, a grantee organization must provide access on a publicly available website to certain information pertaining to their disclosed financial conflicts of interest.
- **Lower monetary threshold for mandated disclosures**—the disclosure threshold has been lowered and varies depending on whether the Investigator received remuneration from a publicly traded entity (remuneration or equity value, when aggregated, exceeds \$5,000) or a non-publicly traded entity (either remuneration exceeding \$5,000 or any equity interest), measured retroactively for the 12 months preceding the disclosure.
- **Broader mandated disclosures captured in the revised definition of "Significant Financial Interest" (SFI)**—the revised definition requires Investigators to disclose all SFIs that reasonably appear to be related to an Investigator's "institutional responsibilities," as so defined by the institution. Institutional responsibilities is a new concept that expands the scope of required disclosures beyond those directly related to the research study itself.
- **Fewer excluded interests from definition of SFI**—the 2011 FCOI Regulation now captures within the definition of SFI several interests that were previously excluded. For example, salaries, royalties and other remuneration are now excepted only if the Investigator is employed or otherwise appointed by the institution. Income from seminars, lectures and teaching engagements, or from service on advisory committees or review panels, is excluded only if they are sponsored by or are for a federal, state or local government agency, an institution of higher education (or research institute that is affiliated with an institution of higher education), an academic teaching hospital or medical center.
- **Mandatory disclosure of policies and certain SFIs on a publicly available website**—the 2011 FCOI Regulation requires that conflicts of interest policies, as well as any SFI determined to be a "financial conflict of interest" or "FCOI" (defined as an SFI that could directly and significantly affect the design, conduct or reporting of PHS-funded research), must be made available on a publicly accessible website maintained by the grantee organization.
- **Implications for institutions with more stringent policies**—if an institution's policy on financial conflicts of interest includes standards that are more stringent than the 2011 FCOI Regulation, the institution must

adhere to its internal policy and provide reports regarding identified interests in accordance with its own standards.

Grantee organizations should continue to comply with the 1995 FCOI Regulation until the earlier to occur of either the date they have revised and publicly published their financial conflicts of interest policies compliant with the 2011 FCOI Regulation, or August 24, 2012, the latter being the date all grantee organizations must be in full compliance with the 2011 FCOI Regulation.

Future McDermott publications will provide more detailed commentary regarding the 2011 FCOI Regulation, and its implications on recipients of federal research funding.

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