Measuring the Cost and Outcomes of the New Rule on Financial Conflicts of Interest in PHS-Funded Research

AN AAMC DATA COLLECTION PROJECT

On August 25, 2011, the U.S. Department of Health and Human Services published the final rule on financial conflicts of interest (FCOIs) related to the conduct of research funded by the Public Health Service (PHS), entitled “Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought.” The regulations significantly expanded the previous rules that were in place since 1995, lowering the threshold for financial interests that must be disclosed to institutions, shifting the burden of determining whether a financial interest is related to federally funded research from the investigator to the institution, and requiring that information about identified FCOIs be publicly accessible.

The Association of American Medical Colleges (AAMC) is committed to working with AAMC member medical schools and teaching hospitals to implement this new rule, and has initiated the AAMC COI Metrics Project to measure the new rule’s impact, costs and effectiveness. The goal of the project is to provide benchmarking data and tools to institutions and aggregate, de-identified data to the National Institutes of Health (NIH) to promote agency-level review of the individual and institutional burden of the rule as implemented. We are hopeful that the information collected through the COI Metrics Project can assist the agency in assessing whether the rule is accomplishing the goals of the regulation and can improve the process on a national level. AAMC will periodically consult with key individuals at the NIH to ensure that the data AAMC collects can be used in NIH’s review of the effect and effectiveness of the rule. The COI Metrics Project is not an NIH-funded activity.

This project, which was initially announced on March 31, 2012 at the AAMC Forum on Conflict of Interest in Academe (FOCI Academe) meeting in Atlanta, is a three year project. Project registration began after August 24, 2012, which was the date that an institution applying for or receiving PHS funding from a grant, cooperative agreement, or contract covered by this rule had to be in full compliance with the regulation. Institutions participating in this program are providing AAMC with aggregate data on an annual basis for three years post-implementation. Participating institutions will also provide certain baseline and historic data related to their conflict of interest programs and review processes. No individual data about investigators will be collected.

For more information about the AAMC COI Metrics Project, including registration information, FAQs, and first results from the Background and Historical Data Survey, please visit www.aamc.org/metricsproject. Questions may be sent to COIMetrics@aamc.org.