



Measuring the Cost and Outcomes of the NIH Regulations on Financial Conflicts of Interest in Public Health Service Funded Research:

The AAMC Conflict of Interest Metrics Project

Background

On August 25, 2011, the U.S. Department of Health and Human Services published the final rule on financial conflicts of interest related to the conduct of research funded by the Public Health Service.¹ The revised regulations had a substantial impact on the costs and personnel at medical schools and teaching hospitals conducting federally funded research.

The AAMC measured the rule's impact, costs, and effectiveness using annual aggregate data about institutions conflicts of interest programs and review processes, disclosures made by investigators to institutions, and FCOIs identified and reported to the National Institutes of Health (NIH) or other funding entities. The goal of the project was to provide benchmarking information to institutions and aggregate, de-identified data to the NIH to promote agency-level review of the individual and institutional burden of the rule as implemented.

Methods

The AAMC member institutions were invited to participate in the Conflict of Interest (COI) Metrics Project through a series of emails, electronic announcements, information provided on the AAMC website,² and discussions of the project between the project kickoff in March 2012 and the first data collection activity.

A total of 74 institutions registered for the COI Metrics Project and provided qualitative and quantitative data to the AAMC. Registration was confirmed by an institutional official identified by the participating institution, and each participating institution identified a primary and secondary contact who were responsible for data collection and survey submission to the AAMC.

The data collection involved three surveys which covered the year before the August 24, 2012 implementation date for the revised Public Health Service rules on financial conflicts of interest in federally funded research and the first two years after implementation. For each survey, institutions were asked to provide aggregate data for a designated twelve-month period. No survey questions asked institutions to identify individuals, so no data or identifying information about individual researchers or staff were transmitted to AAMC. The first survey was distributed in November 2012 and covered twelve months immediately prior to the implementation deadline or the twelve months prior to an institution fully implementing the requirements of the revised regulations, whichever was earlier. Prior to administration of the second and third surveys, participating institutions were asked to identify two consecutive twelve month periods after August 24, 2012 for which they would be collecting and submitting data to the AAMC. This designated "Data Collection Period" was chosen by each institution to represent a complete cycle of the

¹ Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, 76 Fed. Reg. 53265, August 25, 2011.

² AAMC COI Metrics Project: <https://www.aamc.org/what-we-do/mission-areas/medical-research/conflicts-of-interest/metrics-project>.

institution's financial interest disclosure and review process, as determined by that institution's policy and procedures. Based on the start and end date of the identified Data Collection Period, each participating institution was assigned to one of four groups and given a specific survey start and end date.

The survey development process involved AAMC staff, input from external stakeholders including representatives from institutions involved in the AAMC Forum on Conflict of Interest in Academe, conversations with key individuals at the National Institutes of Health (NIH) involved in the implementation of the revised regulations, and consultation with the COI Metrics Project External Advisory Group, which consisted of three subject matter experts from AAMC member institutions.

To initiate each of the three data collection surveys, each participating institution's primary contact received an email with an institution-specific survey link, accompanied by a survey instruction guide, definitions of terms, and frequently asked questions document to assist in answering the survey questions. Help text and definitions for key terms were also embedded within the survey instrument itself to provide additional information about a specific question or when applicable, a reminder of respondents' previous survey results. Respondents were given six weeks from their designated start date to complete each survey. The data were collected and stored using the Verint survey tool, a web-based system.

As surveys were received, respondents were supplied with an electronic copy of their survey responses for review and verification. The research team developed codes to represent conceptual categories found in the open-ended survey responses. Each code was assigned example text from the survey and rules for use to ensure appropriate and consistent application of the codes. All survey responses were evaluated by AAMC staff and designated consultants to ensure internal consistency or identify necessary follow up clarification questions to participating institutions. Each institution's surveys were compared to identify any potential inconsistencies or confusion about the data request, especially in the cases where the primary contact changed during the project due to staff turnover.

Limitations

The COI Metrics Project relies on data provided and verified by each participating institution, but not independently verified by AAMC. How each question was approached may have varied across institutions as a result of respondent interpretation. To minimize the impact of these variations, detailed instructions for each survey as well as embedded help text and definitions were provided to each participating institution. Comment boxes were included throughout the survey in order to allow respondents to clarify answers or limitations on collecting the requested data.

While institutions were asked specifically to provide information about one-time investments made to come into compliance with the revised regulations, it cannot be demonstrated definitively that each change in disclosures received, number of individuals disclosing, institutional costs, or employees involved in the conflict of interest process was solely the result of the revised regulations. In the case where an intervening event (e.g., an institutional merger or change in policy) provided an explanation of an observed change that was clearly independent of the revised regulations, data from that institution was removed from the analysis of the relevant questions. These occurrences are identified in the report.

Another limitation was the lack of software or processes at institutions to document and report certain variables from the start of the project, particularly the number of disclosures and financial conflicts of interests, resulting in a significantly reduced sample size for certain analyses. The number of institutions able to supply data for any given analysis is explicitly listed throughout the report.

Due to the heterogeneity in institutional characteristics (including annual PHS funding, institutional components included in the survey, and number of investigators reporting disclosures), the survey responses were influenced by these differences and varied accordingly. Whenever possible the data were analyzed at the level of the individual institution as well as in aggregate to understand and minimize the contribution of any outliers to the overall analysis.

Key Results

One Time Investment Costs (72 institutions*)

Participating institutions made significant financial investments to implement the regulations in the first year after implementation of the regulations. The one-time cost to fully implement the regulations across 72 institutions was close to \$23 million. Most institutions hired new personnel, including IT staff to implement electronic disclosure systems. Other expenditures included software licensing fees, facility expenses, office equipment, faculty training and development fees.

Total Expenditures	\$22,907,744
Personnel Expenditures	\$11,652,031
Capital Expenditures	\$10,033,421
Other Expenditures	\$1,222,292
Overall Average Expenditures	\$318,163
Average Expenditures <i>Public Institutions</i>	\$217,844
Average Expenditures <i>Private Institutions</i>	\$458,609
Median Expenditures	\$128,203

*Not every participating institution could report on all requested metrics, primarily as a result of the variation and limitations on the software processes used in the review and processing of financial interest information.

Ongoing Annual Administration Costs (63 institutions)

Participating institutions incurred ongoing costs to implement the regulations on top of one-time costs, including personnel costs (e.g., employee salary, benefits) electronic disclosure software customization, and costs associated with ongoing maintenance for electronic systems.

One Year Before Implementation	\$329,669
One Year After Implementation	\$315,392

Average Number of Full Time Equivalent (FTE) Employees (70 institutions)

One year after the regulations were implemented, personnel administering COI-related activities increased on average from 1.9 to 2.7 FTE employees. Most of these personnel changes took place shortly after implementation to meet the increased demands of the new disclosure requirements. Many participating institutions continued to hire FTE employees two years after implementation of the regulations. Several institutions commented that hiring personnel was necessary but presented significant difficulties due to the scarcity of financial resources. To alleviate budget constraints, many institutions moved personnel from other departments to take on COI-related responsibilities.

One Year Before Implementation	1.89
One Year After Implementation	2.67
Two Years After Implementation	2.75

Significant Financial Interests (SFIs) Disclosed (53 institutions)

One of the most significant changes in the 2011 regulations was the lower monetary threshold for which financial interests are disclosed by investigators to the institution (\$10,000 to \$5,000), requiring institutions to collect SFIs with aggregated values exceeding \$5,000. Most institutions saw a substantial increase in the number of SFIs disclosed by investigators in the first year after implementation of the regulations.

One Year Before Implementation	53,095 SFIs
One Year After Implementation	63,752 SFIs
Two Years After Implementation	61,811 SFIs

Financial Conflicts of Interests Reported (FCOI) (65 institutions)

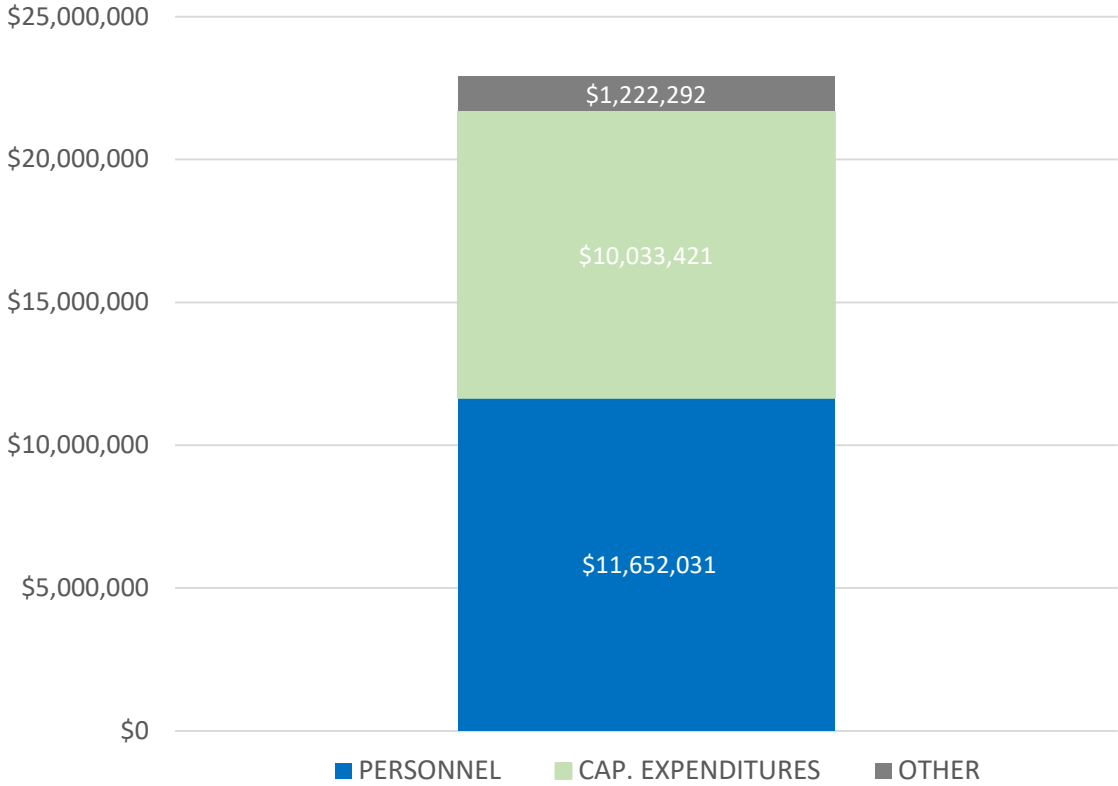
For many institutions the SFI review and FOCI determination process was the most burdensome given the disproportionate increase in time spent reviewing SFIs without identification of any new FCOIs as the regulations intended. For the institutions that provided complete data on both the number of SFIs disclosed and FCOIs reported, the percentage of SFIs found to be FCOIS decreased from 4.5% to 1.6% in the year after implementation of the regulations and decreased further to 1.3% in the second year after implementation.

One Year Before Implementation	846 FCOIs
One Year After Implementation	1003 FCOIs
Two Years After Implementation	712 FCOIs

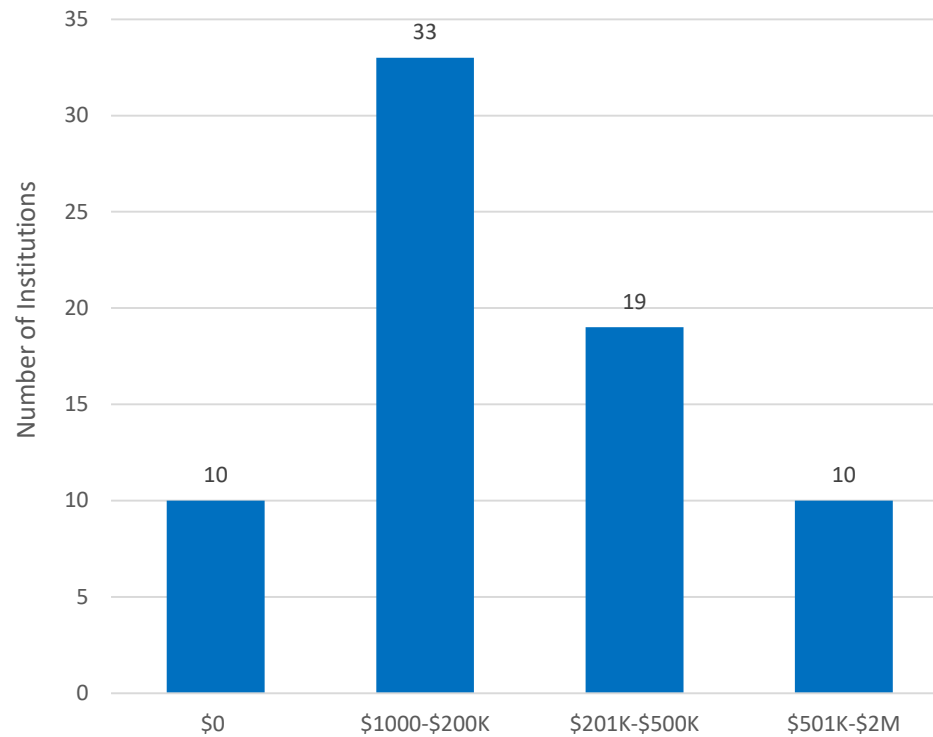
Additional institution-level data is presented in the following graphs.

For questions, contact Heather Pierce, Senior Director and Regulatory Counsel (hpierce@aamc.org). Additional information about the Metrics Project can be found on our Conflicts of Interest and Transparency Initiatives webpage (www.aamc.org/coi).

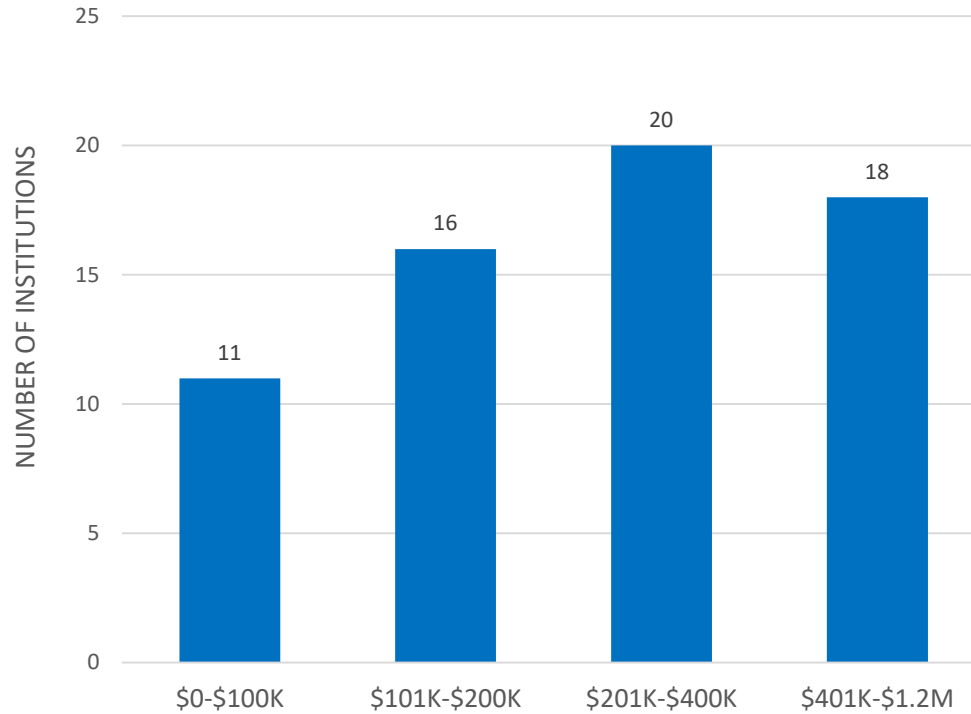
One-Time Investment Costs for Implementation of PHS COI Rule



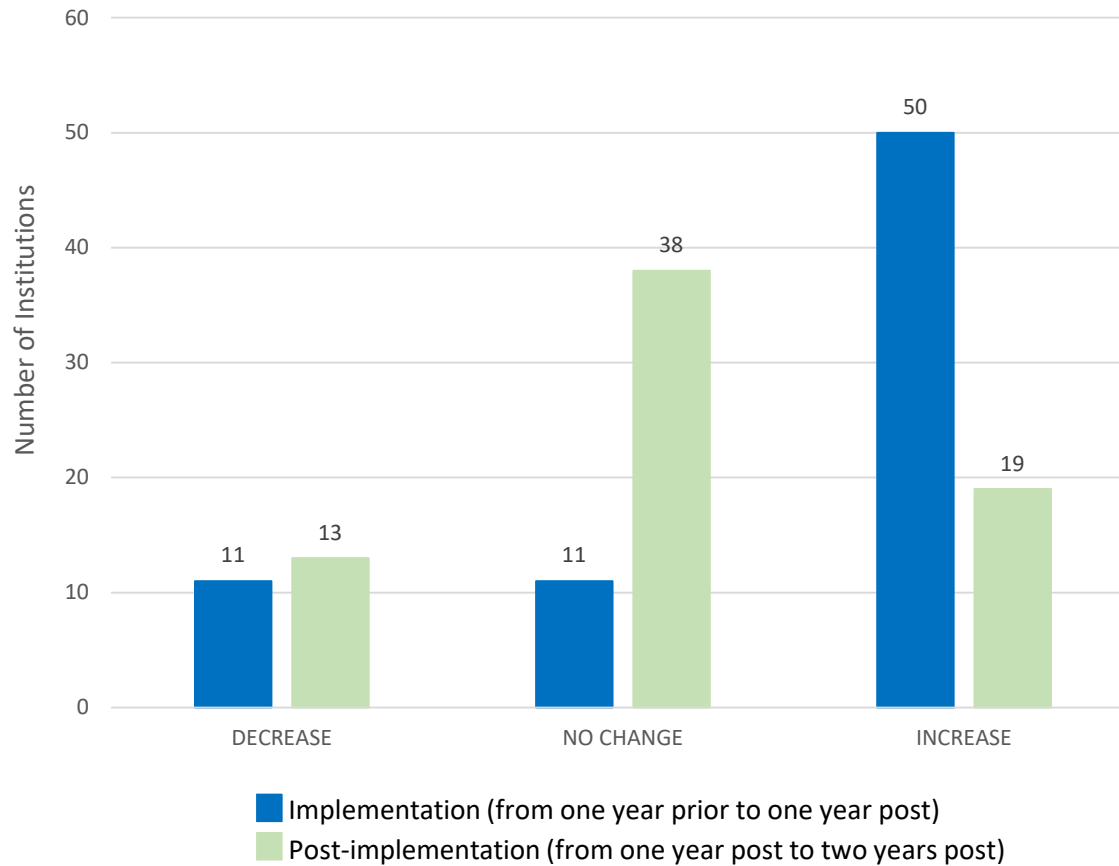
One-Time Investment Costs for Implementation of the PHS COI Rule



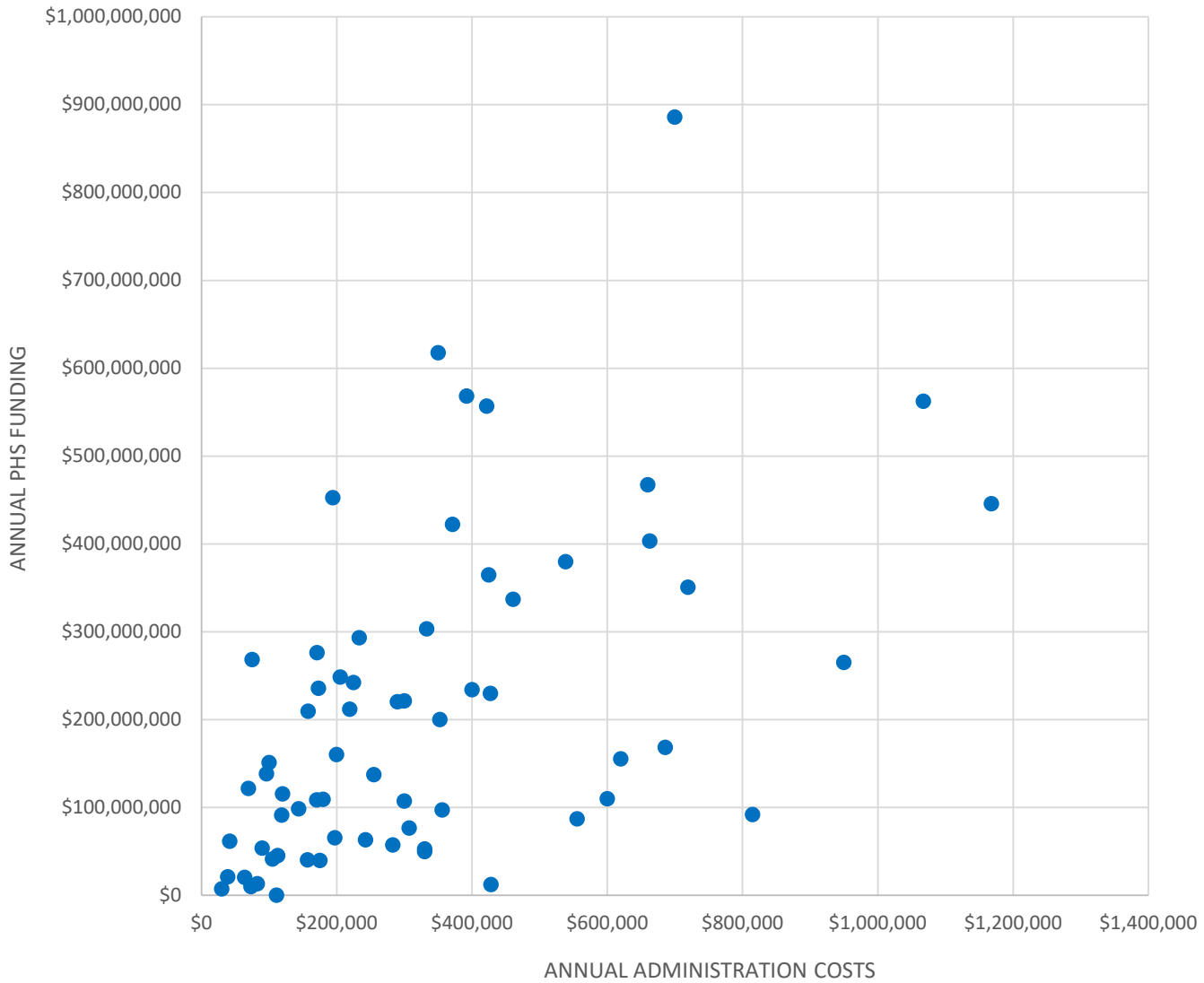
Ongoing Annual Administration Costs One Year After Implementation of PHS COI Rule



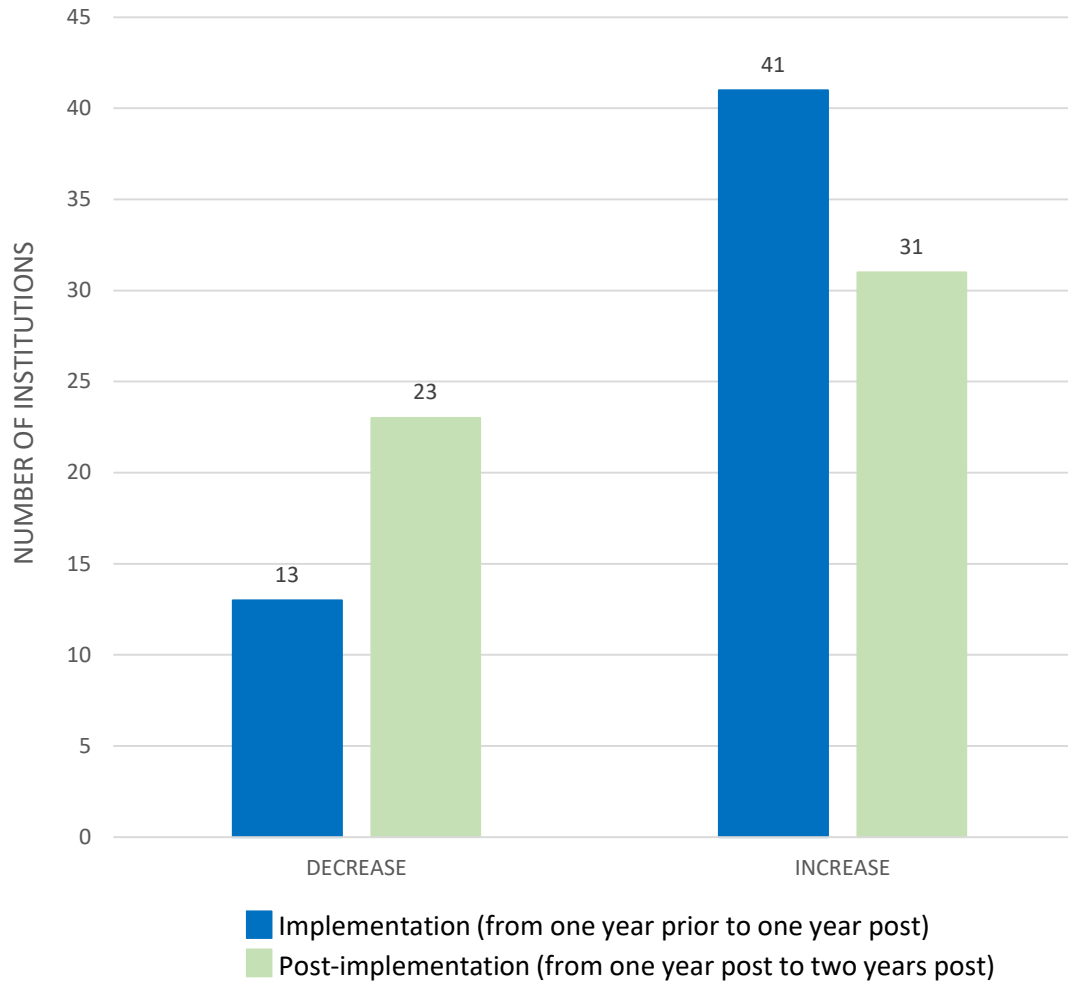
Change in the Number of FTE Employees Administering the COI Program



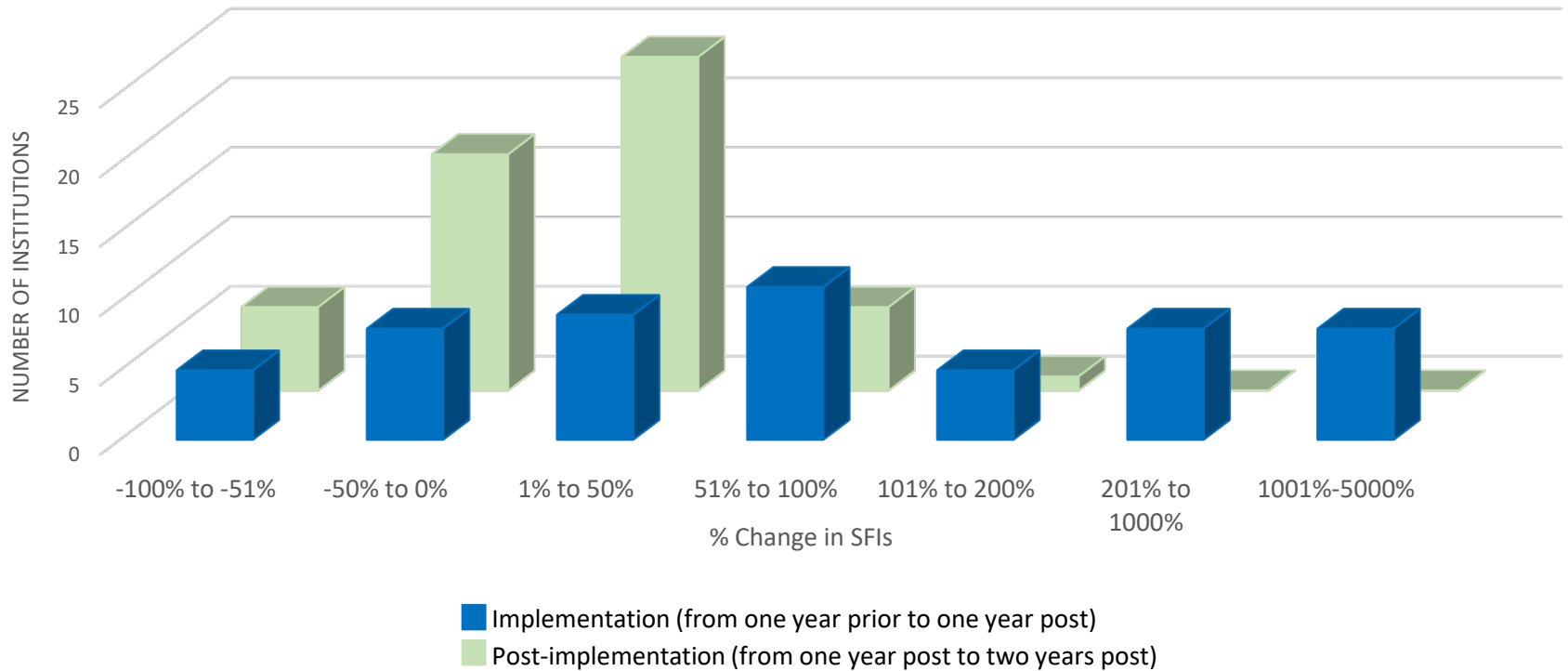
PHS Funding vs. COI Program Administration Costs (One Year After Implementation)



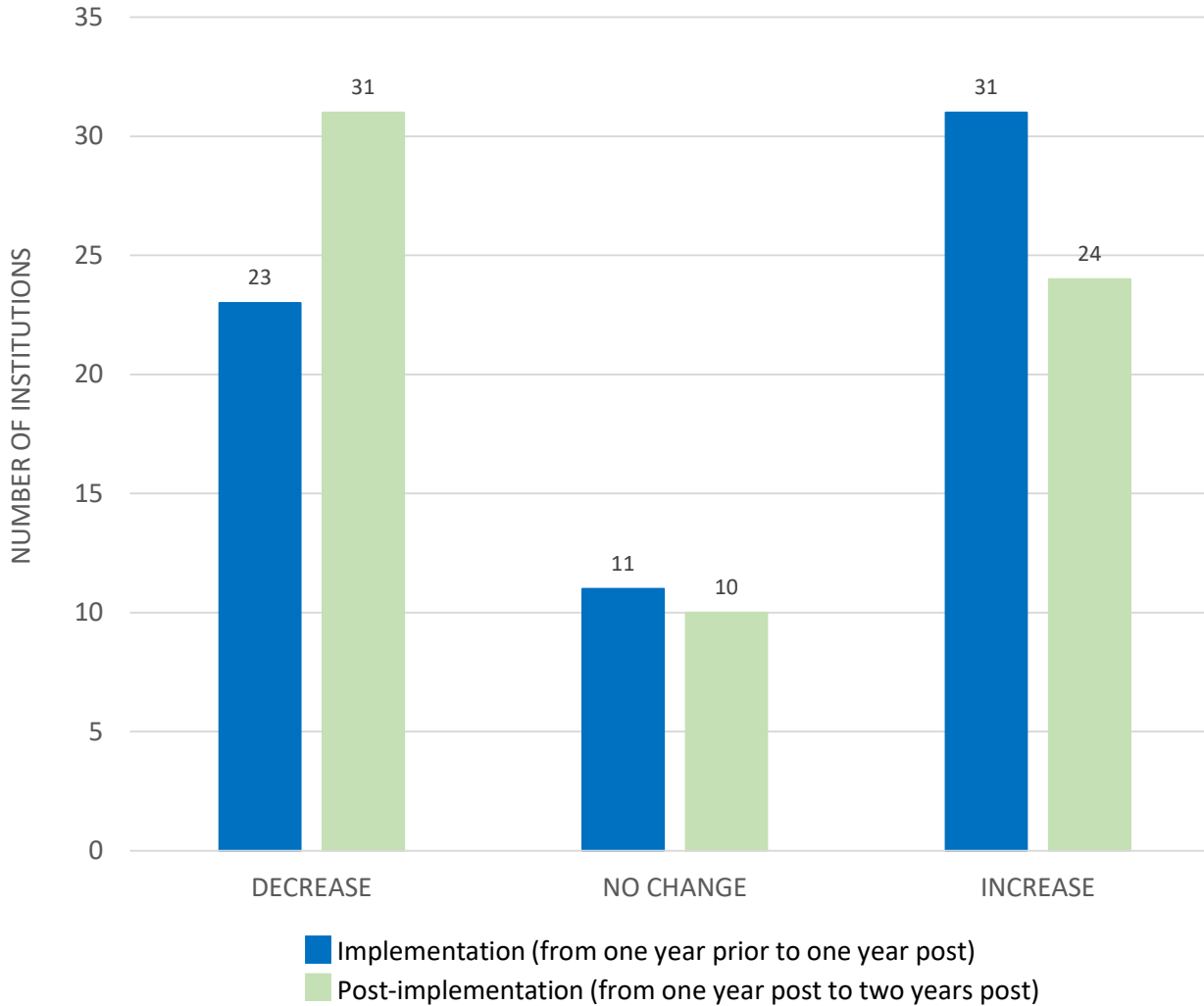
Change in the Number of Significant Financial Interests Disclosed to Institutions



Percent Change in the Number of Significant Financial Interests Disclosed to Institutions



Change in the Number of Financial Conflicts of Interest Reported to a PHS Funding Agency



Change in the Number of Financial Conflicts of Interest Reported to a PHS Funding Agency

