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AAMC Conflicts of Interest Metrics Project

Measuring the Impact of the Public Health Service Regulations on Conflicts of Interest

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Association of
American Medical Colleges

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Executive Summary

Background

On Aug. 25, 2011, the U.S. Department of Health and Human Services (HHS) issued regulations revising an existing rule related to the identification and management of potential financial conflicts of interest (FCOIs) in federally funded research. The revised rule retained the overall structure of the regulations but made notable changes to the scope of relationships that must be disclosed by researchers to the institutions receiving federal grants, including lowering the monetary-disclosure threshold and adding new institutional reporting requirements for identified FCOIs.[1]

In 2012, the AAMC (Association of American Medical Colleges) initiated the Conflict of Interest (COI) Metrics Project to evaluate the cost and impact of the regulatory changes on participating institutions. Data were captured from institutions from the year before the Aug. 24, 2012, compliance deadline and for two years after that date. The 74 participating institutions varied in size, geographic location, public and private status, and amount of annual Public Health Service (PHS) funding. Institutions provided aggregate data about their COI programs and review processes, including the cost to implement and carry out the regulatory requirements and the number of FCOIs identified and reported to the National Institutes of Health (NIH) and other PHS funding entities as a result of changing the disclosure threshold for finding an FCOI to $5,000.

In 2020, the AAMC conducted a follow-up to the COI Metrics Project, a limited survey of institutions to better understand the ongoing effect of the regulations in 2019. In this phase of the project, the AAMC engaged 65 institutions, 24 of which had participated in the original project. Institutions provided information about the total number of FCOIs reported to a PHS funding entity in 2019, including how often these FCOIs had a value between the pre-2012 regulatory threshold of $10,000 and the revised threshold of $5,000. The analysis in 2020 concerned both reports of newly identified FCOIs and reports of modifications made to institutional management plans for previously identified FCOIs.

Methods

AAMC-member institutions were invited to participate in the COI Metrics Project through a series of email announcements and information on the COI Metrics Project website.[2] Registration was confirmed by an institutional representative, and each participating institution identified at least one primary contact who would be responsible for data collection and survey submission.

The project relied on data provided by each institution through surveys. The initial project involved three surveys covering the year before the Aug. 24, 2012, implementation date for the revised regulations and the first two years after that date. In 2020, participants completed one survey that collected information about 2019 only. No surveys asked institutions to identify individuals, and no identifying information about individual researchers or staff was transmitted to the AAMC.

The way each question was answered could vary across institutions because respondents interpreted questions differently. To minimize the impact of these variations, survey instructions and definitions were provided to each institution, and comment boxes were included throughout the survey to allow respondents to clarify answers or limitations on collecting the requested data. In cases where an intervening event such as an institutional merger or a change in policy provided an explanation of an observed change that was clearly independent of the revised regulations, data from that institution were removed from the analysis of the relevant questions, and this was indicated in the report. In some circumstances, institutions lacked software to document and report certain variables from the start of the project, particularly related to the number of disclosures of significant financial interests in the first two years after implementation. This resulted in fewer institutions providing data for certain analyses, and the number of institutions able to supply data is indicated throughout the report.

The heterogeneity of institutional characteristics such as annual PHS funding amount and number of investigators reporting disclosures influenced survey responses, which varied accordingly. Whenever possible, the data were analyzed at the level of the individual institution as well as in aggregate so that the contribution of any outliers to the overall analysis could be identified and minimized.

AAMC staff and designated external experts evaluated survey responses to ensure internal consistency in how responses were reported to the AAMC and to identify follow-up questions to clarify certain responses. Each institution's responses were compared over time to identify any potential inconsistencies or confusion about the data requested, especially in cases where the primary or secondary contact may have changed during the data collection.

Selected Key Findings

- **Implementation Costs:** The one-time cost to implement the regulations in the year after implementation was $22,907,744 across 72 institutions.
- **Ongoing Costs:** The ongoing annual administration costs were $329,669 in the year before implementation of the regulations and $315,392 one year after implementation across 63 institutions.
- **Full-Time-Equivalent (FTE) Employees:** FTE employees in roles relevant to FCOI collection (or similar) increased, on average, from 1.9 to 2.7 FTEs in the year after implementation.
- **Significant Financial Interests (SFIs) Disclosed by Investigators:** The number of SFIs disclosed to institutions was 53,095 in the year before implementation and 63,752 in the year after across 53 institutions. SFIs remained constant in the two years after implementation.
- **Reported FCOIs:** The percentage of SFIs found to be FCOIs decreased from an average of 4.5% before implementation to 1.6% in the year after implementation and to 1.3% two years after implementation. In 2019, 701 FCOIs were newly identified and reported to a PHS funding agency.

- **Travel-Related Disclosures:** Of the total number of FCOIs reported to a PHS funding agency in 2019 (701), only one institution reported any FCOIs based solely on travel.
- **Retrospective Reviews for Bias:** In 2019, 20 institutions conducted between one and 35 retrospective reviews, for a total of 89 retrospective reviews. No institution reported a finding of bias.

Conclusions

The results from the COI Metrics Project suggest that overall, the small increase in the number of FCOIs reported to federal funding agencies following the regulatory revisions does not justify the substantial administrative and financial burden institutions incurred in implementing and administering the requirements. The results also highlight the ongoing concerns about the increase in regulatory burden and the need for federal agencies to harmonize COI regulations and policies to reduce workload and costs. The 2020 limited review of the impact of the regulations indicates that the additional burden has remained well after institutions fully implemented the rule's requirements.

The COI Metrics Project provided insight into the national impact of the rules on institutions subject to the revised regulations and demonstrated how objective, rigorous, and systematic evaluation can be used in the prospective and retrospective assessment of federal regulations, policies, and government activities. The increase in regulatory burden across the biomedical research enterprise was further underscored in reports from the National Academies of Sciences, Engineering, and Medicine (NASEM) and the Government Accountability Office (GAO).[3] Both identified a need for federal agencies to harmonize regulations, reduce workload and costs, and consider evidence-based regulatory approaches.

NASEM found "little rigorous analysis or supporting data precisely quantifying the total burden and cost to investigators and research institutions of complying with federal regulations specific to the conduct of federally funded research" and highlighted the difficulty of finding data about the costs associated with diverting time and resources from the conduct of research. NASEM also outlined specific actions Congress should take to address regulatory burden. Building on these recommendations, Section 2034 (Reducing Administrative Burden for Research) in the 21st Century Cures Act of 2016 ("Cures") aims to harmonize regulations and policies across funding agencies to minimize burden and directs HHS to review all regulations and policies related to the disclosure of FCOIs and implement measures to reduce burden on researchers.[4]

The NASEM and GAO reports cite the COI Metrics Project as an example of how data can be used to quantify the impact and burden of research regulations on institutions and, as part of HHS's planned evaluation of the regulations, "[t]o better target requirements on areas of greatest risk, while maintaining accountability over grant funds."[5] The aggregated, de-identified results of the COI Metrics Project were provided to the NIH to assist with its retrospective review of the regulations and to the White House Office of Science and Technology Policy (OSTP) to help with its current assessment of the impact of various agencies' COI regulations and policies on the research environment.[6]

The data from the COI Metrics Project have also been used by participating institutions, and other AAMC-member institutions, to facilitate internal review of institutional policies and processes and justify the request for additional personnel and electronic COI disclosure systems. For example, one institution commented that their leadership was "apprised of how much time and resources have gone into implementing a regulation that[,] at least at [the] institution, has little bang for the buck." Other examples of how the COI Metrics Project data have been used include:

- Tracking the effort and time faculty and staff spend reviewing investigator disclosures.
- Identifying how to streamline or revise institutional policies and processes.
- Identifying institutional budget and personnel priorities.
- Garnering support from institutional leadership for the purchase of a new COI disclosure system or justifying updates to an existing system.
- Informing institutional COI and compliance reviews using the metrics from the COI Metrics Project surveys.

AAMC COI Metrics Project: Impact of the Regulations One Year Before Implementation and Two Years After

One-Time Costs to Implement the Regulations: One Year After Implementation (72 Institutions Provided Data)

In addition to the changes participating institutions made to their COI policies and processes, they made one-time financial investments to implement the regulations. These included hiring additional staff to review financial disclosures, conduct investigator training, and implement and administer electronic-disclosure and COI-review systems. Other expenditures included initial software licensing fees, facility expenses, and faculty training and development fees.

For the 72 institutions that reported data, the total expenditure to implement the regulations was close to $23 million. The mean expenditure was $318,163, with public institutions averaging $217,844 and private institutions averaging $458,609 in one-time costs. Figure 1 presents data on the one-time cost to fully implement the regulations between the date the regulations were issued and the first year after the regulations were implemented.

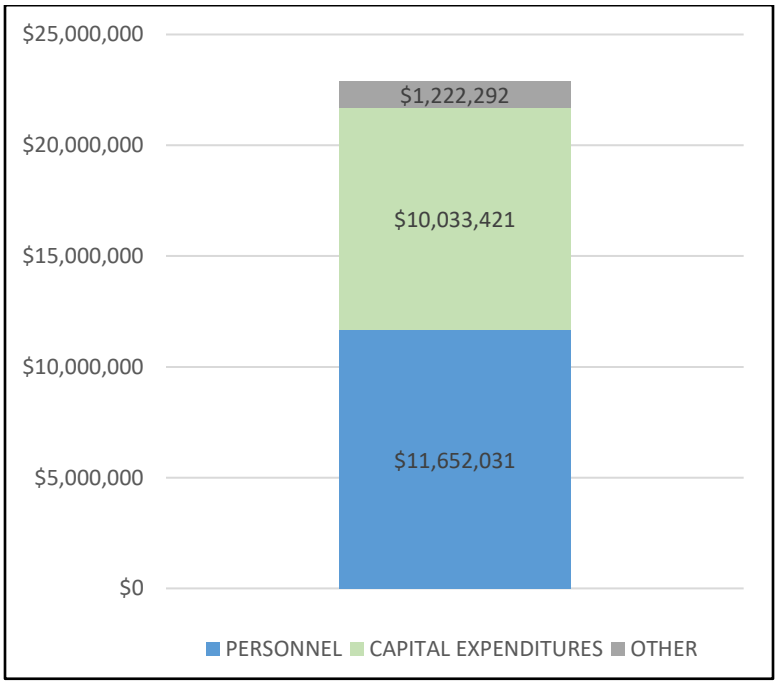

Figure 1. One-time investment costs to implement the regulations by cost category one year after the implementation deadline for 72 institutions (total = $22,907,744).

Figure 2 displays the one-time investment cost by the number of institutions that reported the following spending amounts: $0, $1,000-$200,000, $201,000-500,000, and $501,000-$2,000,000.

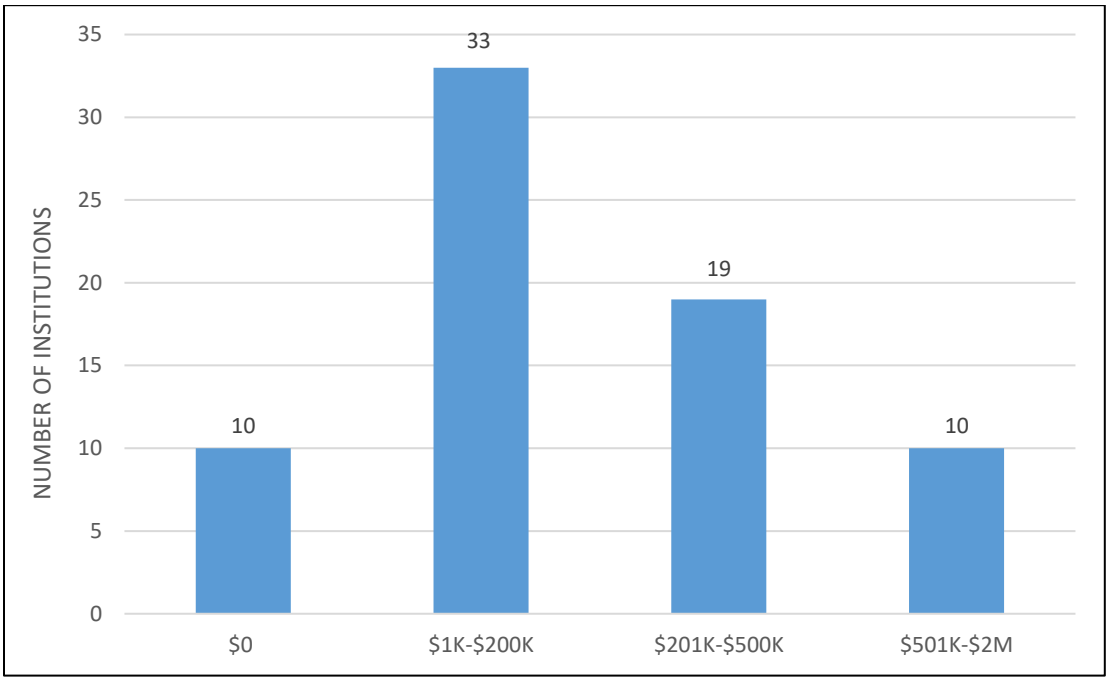

Figure 2. One-time investment costs to implement the regulations by cost amount for 72 institutions.

Ongoing Annual Costs to Implement the Regulations (63 Institutions Provided Data)

Institutions also incurred ongoing administration costs to implement the regulations on top of the one-time implementation costs (Figure 3). This included personnel costs in addition to the continued costs of maintaining electronic disclosure systems.

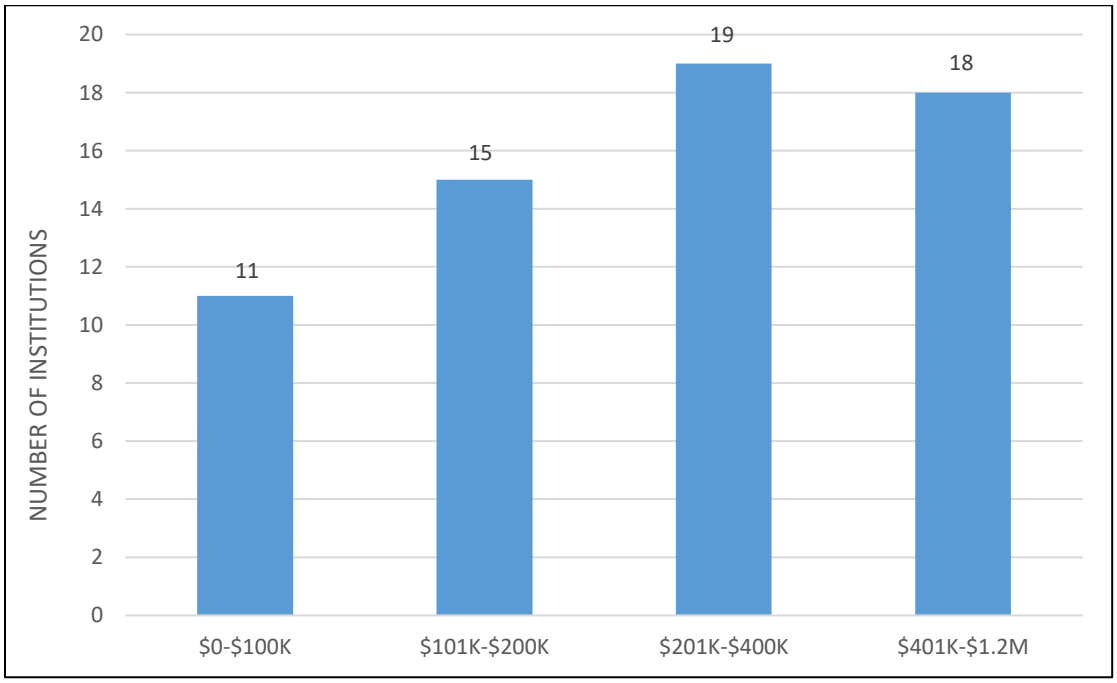

Figure 3. Ongoing annual administration costs by spending amount one year after implementation for 63 institutions.

To alleviate administrative burden, many institutions reported making changes to disclosure systems and related processes for collecting financial interest information, such as:

- Discontinuing the use of paper disclosures and launching an online disclosure model for investigator COI trainings.
- Integrating trainings directly into the electronic disclosure form.
- Combining the institution's electronic disclosure system with the grants management system.
- Moving from a "project-specific" disclosure system to an "annual-only" system to minimize the burden on investigators and staff who spend a significant amount of time tracking project-related disclosures.
- Connecting the institution's electronic disclosure system to the Institutional Review Board system to streamline interactions and improve identification of potential conflicts of interest.
- Implementing electronic reminders for faculty and staff to update disclosures and access online trainings.
- Implementing an electronic system that has "smart forms," developed to increase accuracy by tailoring the researcher's "online dashboard" using specific COI information. The system also interfaces with the institution's award and proposal platform.

- Incorporating a faculty communication mechanism into the disclosure system and, to save time and paper, electronic signature and approval for conflict-management plans.
- Developing a post-award monitoring process using payroll reports to ensure investigators are added to the PHS-funded project during the lifecycle of the award.
- Developing a disclosure form and output report to facilitate COI reviews. This provides an overall view of the disclosure content, helping minimize the time associated with reviewing COI information.

Average Number of Full-Time-Equivalent Employees One Year After Implementation (70 Institutions Provided Data)

To meet the increased demands of the COI-disclosure requirements, many institutions hired new personnel shortly after the implementation deadline. One year after implementation, the number of FTE employees administering COI-related activities at 70 institutions increased, on average, from 1.9 to 2.7 FTEs.

Many institutions reported that hiring personnel was necessary to meet the demands of the COI program but presented significant difficulties due to the scarcity of financial resources. This often resulted in having to make difficult decisions such as whether to purchase an electronic disclosure system or hire additional FTE employees to implement the regulations and administer COI activities. Notably, in an attempt to alleviate budget constraints, several institutions moved personnel from other departments to take on COI-related responsibilities, which often required COI training and personnel support to conduct those trainings.

Due to the increased workload, several institutions reported a significant decrease in faculty morale. One institution commented, "[The regulations] have had a negative impact on the morale of faculty and staff. They report feeling like they have been treated as if they have done something wrong. They also feel overwhelmed by using the electronic reporting system [and] often complain about the regulatory burden in general."

Significant Financial Interests Disclosed to Institutions One Year Before and After Implementation (53 Institutions Provided Data)

One of the most significant changes in the regulations was lowering the monetary disclosure threshold for investigators to disclose financial interests to their institutions from $10,000 to $5,000. This meant that investigators were required to disclose to their institutions any SFIs with a value of $5,000 or greater. Most institutions saw a substantial increase in the number of SFIs disclosed by investigators in the first year after implementation of the regulations, with 53,095 reported across 53 institutions one year before implementation and 63,752 in the year after implementation. SFIs remained relatively constant two years after implementation, at 61,811. As a result of the increase in the number of disclosed SFIs, institutions had to increase resources to assist with the review of those SFIs for potential conflicts of interest.

Figure 4 shows that most institutions saw an increase in the number of SFIs disclosed by investigators in the years after the regulations were implemented.

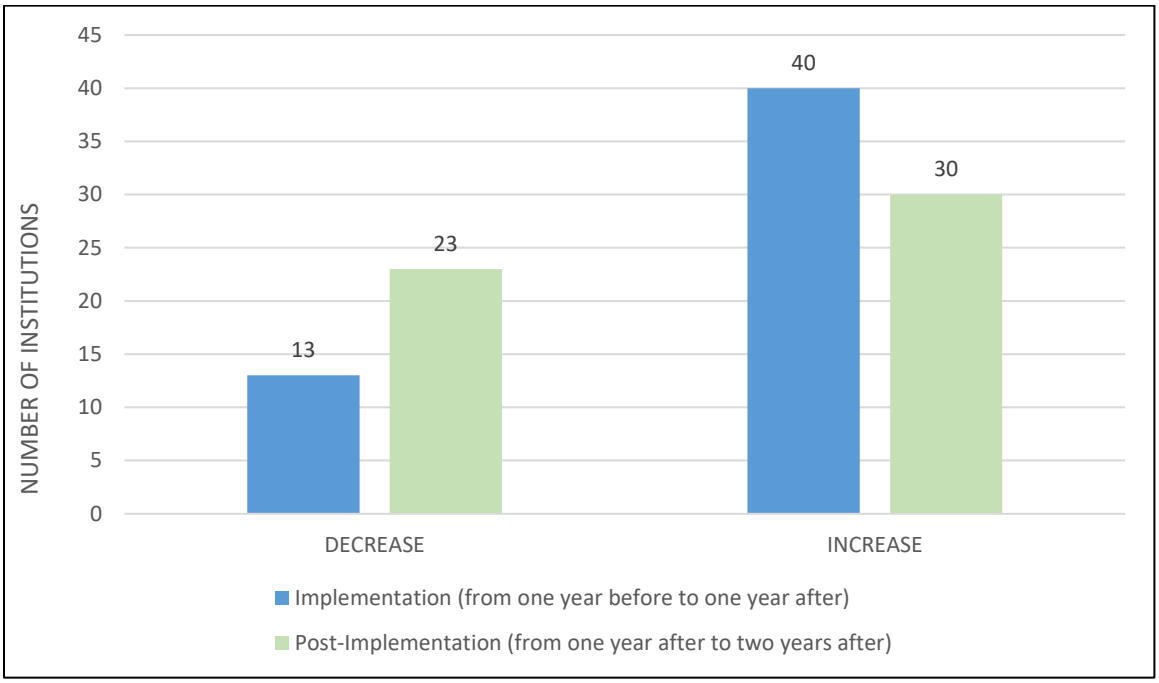

Figure 4. Change in the number of significant financial interests disclosed to institutions for 53 institutions.

Financial Conflicts of Interests Identified and Reported to a PHS Funding Agency (53 Institutions Provided Data)

For many institutions, the SFI review and FCOI determination process was the most burdensome aspect of the requirements, given the disproportionate increase in time spent reviewing SFIs without identifying a commensurate number of new FCOIs. Several institutions expressed concern that no evidence supporting this revision of the regulations was presented in the preamble to the revised regulations — namely, whether financial interests with values between $5,000 and $10,000 had been shown to compromise safety in research with humans or research integrity. Many institutions noted the significant resources needed to comply with this aspect of the regulations. One institution noted it had "devoted many more institutional resources to COI compliance but [had not] identified many new issues or conflicts."

For the institutions that provided complete data on both SFIs and FCOIs, the percentage of SFIs found to be FCOIs decreased from an average of 4.5% before the revisions to the regulations to 1.6% in the year after implementation and 1.3% in the two years after the regulations went into effect.

AAMC COI Metrics Project Addendum: Impact of the Regulations in 2019

Financial Conflicts of Interest Identified and Reported to a PHS Funding Agency in 2019

In 2019, 701 newly identified FCOIs were reported to a PHS funding agency by 53 participating institutions (10 institutions did not report any FCOIs) (Table 1). Institutions that reported any FCOIs in 2019 reported between 1 and 87, and less than 5% of the 701 FCOIs reported had a value of $5,000-$9,999. No institution reported more than four FCOIs in this value range.

Table 1. Newly Identified Financial Conflicts of Interest (FCOIs) Reported to a PHS Funding Agency in 2019 by 63 Institutions That Provided Data

Reported Value of FCOIs	Number of FCOIs	Percentage of total FCOIs reported	Number of institutions reporting at least one FCOI of this value	Percentage of institutions reporting at least one FCOI of this value
$0-$4,999*	99	14%	15	24%
$5,000-$9,999	32	5%	21	33%
≥$10,000	228	33%	37	59%
Could not be determined**	342	49%	38	60%
All FCOIs reported	701	100%	53	84%

*Under the PHS regulations, significant financial interests (SFIs) are interests with a value of $5,000 or greater, but a change to the regulations was a provision that held institutions responsible for requirements in institutional policies that were more stringent than the regulations. Therefore, an institution that had in place a disclosure threshold of $0 would be required to report any financial interests determined to be FCOIs under the policy, even if the underlying SFI that is the basis of the FCOI was less than $5,000.

**An FCOI report represents the totality of one individual investigator's relationship with a single entity (that is, the financial interests combined). This report may include distinct financial components such as equity and consulting. FCOI reports that included more than one financial component were included in the category representing the total value reported. When the reported FCOIs are categorized as having a value that could not be determined, this is primarily because the investigator holds equity in a nonpublicly traded company.

Institutions provided additional details about whether or how management plans for FCOIs with a value between $5,000 and $9,999 differed from other management plans put in place at those institutions. Most institutions indicated they followed a standard management-plan template each time an FCOI was identified, regardless of the value of the interest, and then added elements for specific risks such as research involving human subjects or financial interests with a higher value. For example, one institution reported that for the 11 FCOIs identified, it used templates that included standard disclosure terms for all identified FCOIs regardless of value. Another institution included the requirement that the level of compensation be reduced to $25,000 or less moving forward if the SFI exceeded $25,000.

Institutions' management strategies ranged from requiring the disclosure of FCOIs (e.g., to research subjects, in publications, or in presentations) to replacing an investigator on the research project. Other components incorporated into their management plans during the decision-making process included:

- Incorporating "special terms" related to the extent of the relationship (e.g., removing the researcher from the project and/or restricting the role of the investigator in research involving human subjects).
- Restricting data management and statistical analysis to staff who are not researchers and incorporating independent data-monitoring standards such as the review by an independent researcher.
- Disclosing the company name in the informed consent form if the reported FCOI is related to consulting and the company is also the sponsor of the research.
- Disclosing and conducting independent oversight of nonpublic equity interests and intellectual property.

Reports Sent to a PHS Agency in 2019 Detailing Changes Made to Management Plans for Previously Identified Financial Conflicts of Interest (FCOIs) (62 Institutions Provided Data)

In 2019, nine institutions sent a total of 25 FCOI reports to PHS agencies about changes to management plans for FCOIs that had been reported to PHS agencies before 2019, as shown in Table 2.

Table 2. Reports Sent to a PHS Agency in 2019 Detailing Changes Made to Management Plans for 62 Institutions

Reported Value of Updated FCOIs	Number of FCOIs
$0-$4,999	5
$5,000-$9,999	1
≥$10,000	14
Could not be determined	5

Travel Disclosures (63 Institutions Provided Data)

Under the revised regulations, institutions are now required to collect and review investigators' sponsored or reimbursed travel as SFIs that may be FCOIs. Institutions identified this requirement as one of the most burdensome aspects of the revised requirements throughout the COI Metrics Project, particularly due to the increased volume of SFIs and record-keeping requirements and few identified FCOIs. Of the total number of FCOIs reported to a PHS funding agency in 2019 (701 FCOIs), *only one* participating institution reported any FCOIs (four) based solely on travel disclosures.

Further highlighting this burden, one institution commented that "[a] significant number of our investigators disclose travel that is for investigator meetings and is usually less than $2,000. It is exceedingly rare that the travel they disclose is considered a related financial interest." Another institution noted that "37% of financial interests disclosed are travel expenses […] and represent more disclosures than any other category income. Though these disclosures require additional record keeping for faculty, they have so far resulted in the detection of no financial conflicts of interest not apparent from other conventional disclosures."

Relationships With a Not-for-Profit Entity (62 Institutions Provided Data)

In a change from the previous requirements, the revised regulations required disclosure of remuneration from not-for-profit entities. Of the 701 FCOIs reported to a PHS funding agency in 2019, *five institutions* reported a total of 15 FCOIs based solely on a relationship with a not-for-profit entity.

Retrospective Reviews for Bias (65 Institutions Provided Data)

Under the current regulations, if an FCOI is not identified or managed in a timely manner, institutions are required to complete a retrospective review of the investigator's activities and research to determine whether the research or a portion of the research was biased (42 CFR §50.605(a)(3)(ii)). Participating institutions were asked to provide information about the number of retrospective reviews conducted in 2019 and how many of those reviews resulted in a reportable finding of bias.

Of the 65 institutions that provided data, 20 conducted between one and 35 retrospective reviews, for a total of 89 retrospective reviews. Notably, *no institution* that conducted a retrospective review reported a finding of bias. Consistent with earlier findings by the AAMC,[7] institutions participating in the 2020 survey continued to express strong concerns about the significant burden associated with the retrospective-review process and indicated that in some cases, the reviews were comparable to a research-misconduct review in terms of time and resource expenditures.

Institutional Perspectives on a Federalwide FCOI Policy

Benefits of a Federalwide FCOI Policy

In November 2019, the White House Office of Science and Technology Policy solicited public feedback on how to better coordinate administrative research requirements, including the potential development of a streamlined, harmonized federalwide FCOI policy.[8] The AAMC responded to that request for information (RFI) after consulting with its member institutions.[9] In 2020, participating institutions were asked to respond to the question in that RFI about whether there should be a single federalwide FCOI policy and what the benefits and challenges of implementing such a policy would be.

All institutions that responded to this question on the AAMC survey favored a single federalwide FCOI policy. Most institutions commented that a uniform policy would allow for consistent definitions (e.g., clarification of COI language), disclosure thresholds, and record-keeping requirements. Some noted that a consistent policy would streamline the process for all federally sponsored research projects. For example, one institution commented that it has "two standard processes for the Public Health Service [regulations] and National Science Foundation [COI policy] and […] conducts case by case analysis for any other COI language from the other federal agencies, which can come from multiple sources […] with very different and often vague requirements."

Potential Challenges Related to a Federalwide FCOI Policy

Although there was consensus among institutions in support of a streamlined policy, several noted potential challenges:

- Requirements may become overly burdensome in the attempt to address the concerns and needs of various agencies.
- Achieving harmonization may be difficult, which could impede successful harmonization (e.g., difficulty facilitating agreement among all federal agencies).
- The number of reports submitted by institutions to sponsoring agencies may increase.
- Requirements may be overly burdensome, including increased burden related to the need to update electronic disclosure systems.

Suggestions for Implementing a Federalwide FCOI Policy

Many institutions offered specific recommendations and suggestions about the implementation of a federalwide FCOI policy, emphasizing the need for robust stakeholder engagement not only at the development stage but throughout the implementation process. Some noted that key stakeholders should include medical journals, professional societies, and international collaborations. Other suggestions included:

- Examine existing agreements and arrangements across U.S. institutions before implementation.

- Align the definition of COI and SFI across federal agencies.
- Eliminate the retrospective-review requirement given the limited findings of bias. It was noted that the elimination of this requirement would save considerable time "without compromising any of the intended goals or outcomes of the [PHS] regulation."
- Eliminate the investigator travel-disclosure requirement.
- Move the monetary disclosure threshold from $5,000 to $10,000 to mirror the National Science Foundation (NSF) COI policy.
- Consolidate the eRA Commons system so there could be a single repository for FCOI reporting to all federal agencies. This would allow reporting of FCOIs to be consistent across institutions.
- Use existing COI policies or regulations as models. Some institutions expressed a preference for using the NSF COI policy as a model, while others suggested the PHS regulations serve as a better framework. A few institutions stated either model would be advantageous, given that most have already instituted policies and procedures based on both NSF and PHS requirements. As one institution noted, "[s]tarting with either the NSF or PHS model would allow institutions to apply the already existing requirements with greater ease than implementing an entirely new policy."
- Restrict federal agencies from developing agency-specific COI requirements in addition to the federalwide COI policy.
- Recognize the need for additional training and for the institutional infrastructure to support the training.

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For more information about this project and reducing regulatory burden, see:

- Conflicts of Interest Metrics Project, aamc.org/metricsproject.
- Conflicts of Interest and Transparency Initiatives, aamc.org/coi.
- Implementing the Final Rule on Financial Conflicts of Interest in Public Health Service Funded Research, aamc.org/media/41336/download.
- Forum on Conflict of Interest in Academe (FOCI Academe), aamc.org/professional-development/affinity-groups/foci.
- Reducing Regulatory Burden, aamc.org/what-we-do/mission-areas/medical-research/regulatory-burden.