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# Financial Conflict of Interest Regulations: Assessing and Addressing the Impact

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June 4, 2015

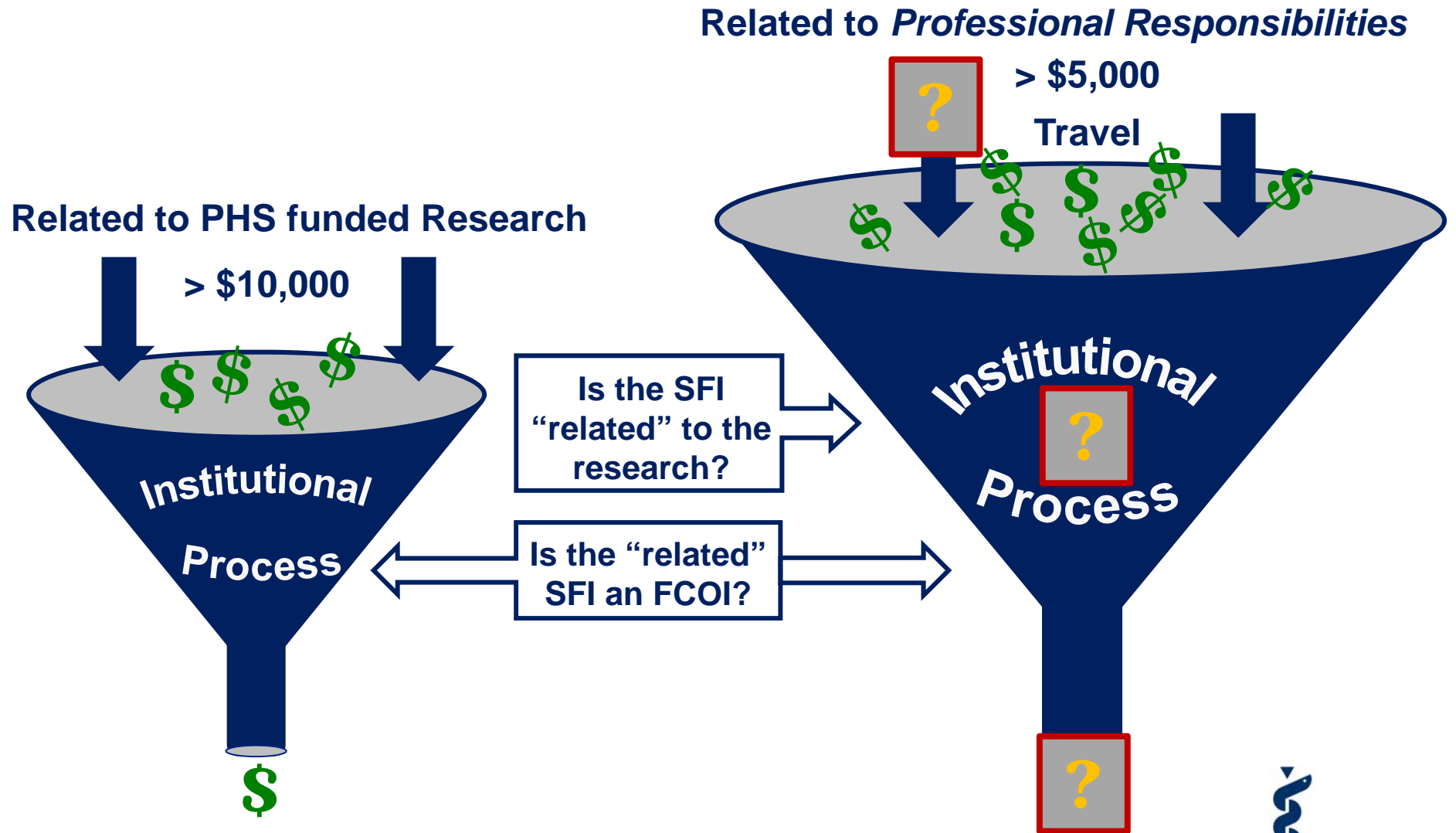


Association of  
American Medical Colleges

# Changing the Rules on Conflicts of Interest (42 CFR Part 50)

- Prior regulations promulgated: 1995
- Advance Notice: May 8, 2009
- Proposed Rule: May 21, 2010
- Final Rule: August 25, 2011
- Compliance Date: August 24, 2012 *or* when the new COI policy was on the institution's website

# 2012: Investigators Disclose Significant Financial Interests (SFIs):

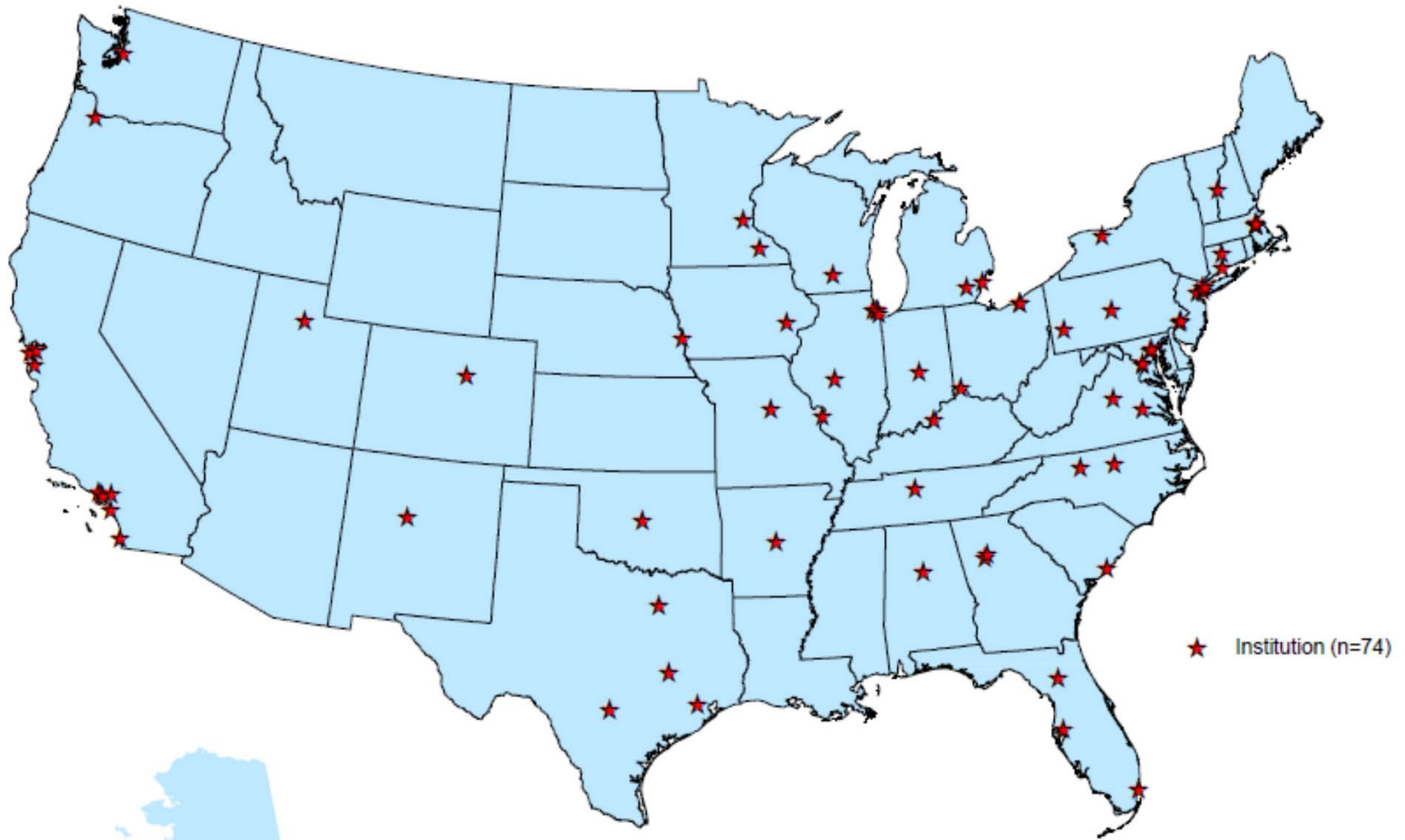


Institutions Report Financial Conflicts of Interest (FCOIs)

# **The AAMC COI Metrics Project:**

Measuring the Cost, Effect, and Effectiveness  
of the PHS FCOI Regulations

**74** AAMC member institutions are providing annual aggregate data to AAMC



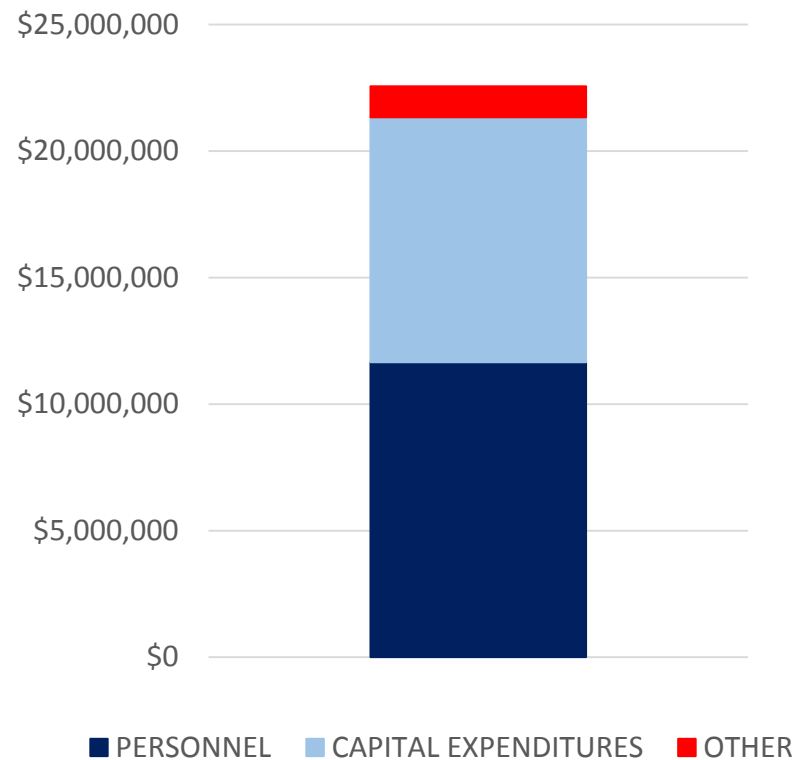
# Information Collected and Analyzed

- Baseline data – one year before implementation of the regulations
- Up to 3 years after implementation
- Data include:
  - One-time investments and ongoing administration costs
  - Significant Financial Interests reviewed and FCOIs reported (including assessment of \$10K - \$5K threshold change and travel reporting)
  - Policy changes
  - Personnel changes
- Benchmarking data to each participating institution
- De-identified data to NIH for retrospective review

# Results: Institutional Investment to Implement and Administer the Rule

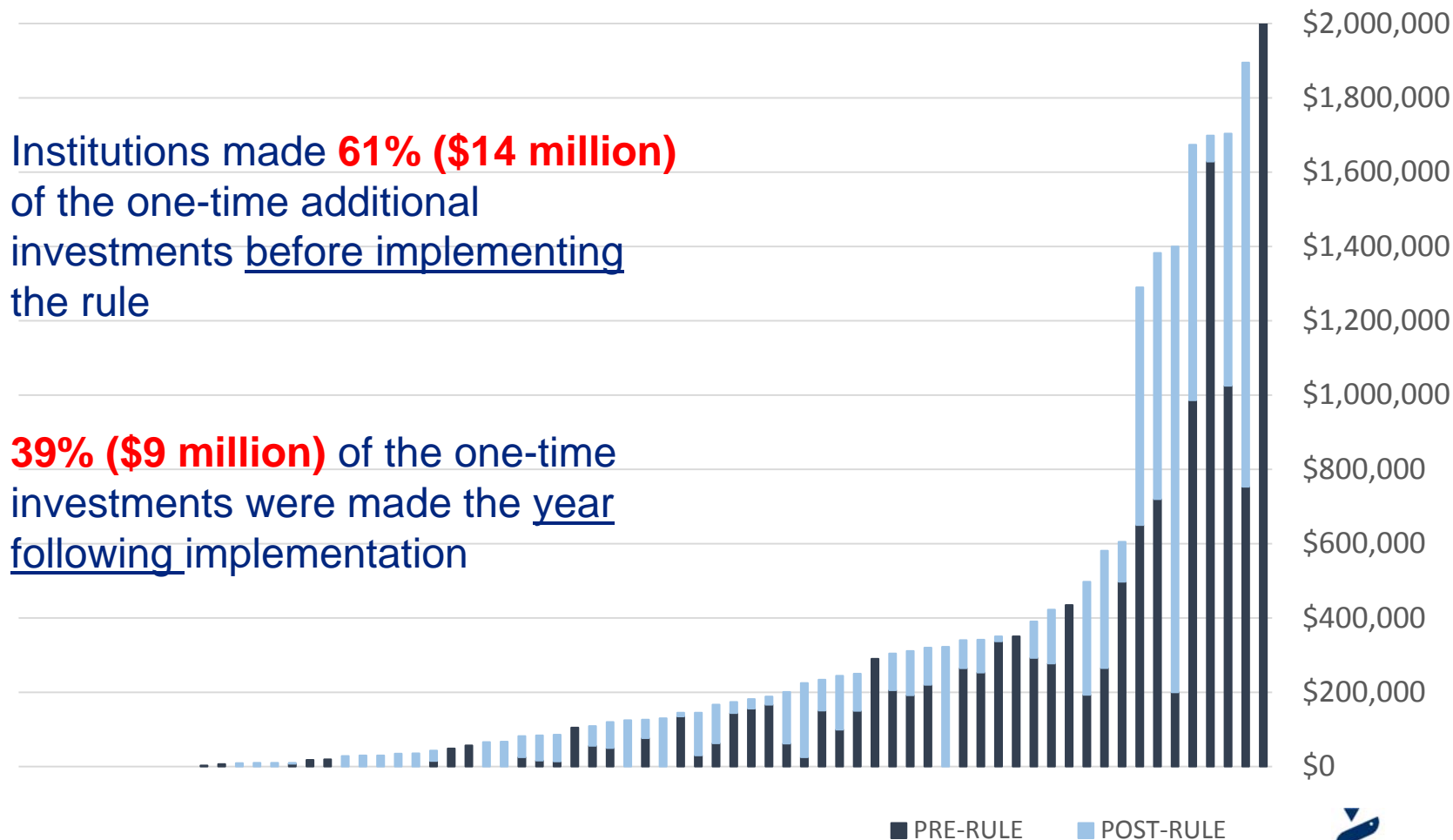
71 institutions spent  
**\$23 million in one-time costs**  
to implement the rule

Average ~\$318,000  
Median ~\$126,000

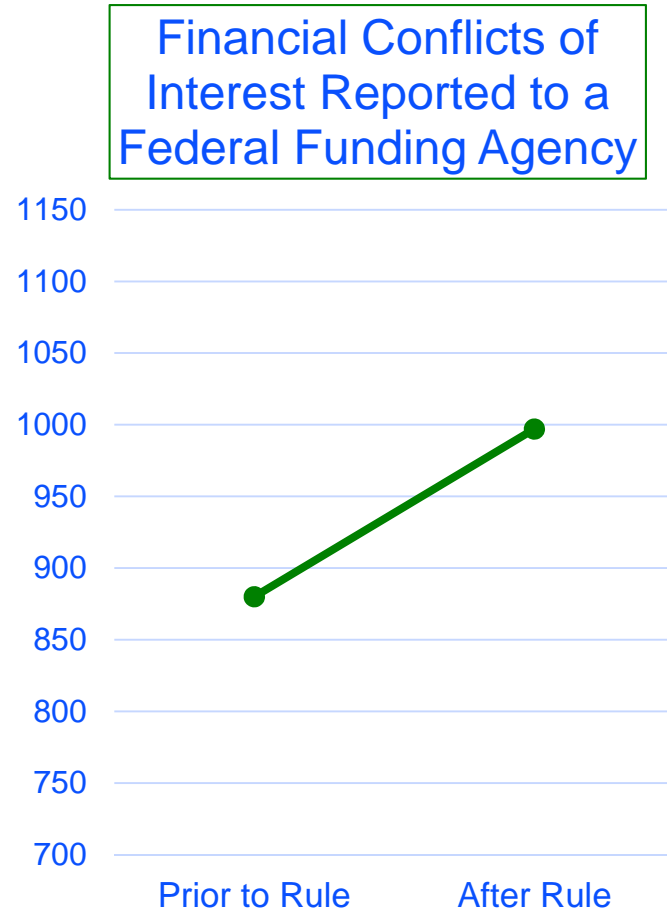
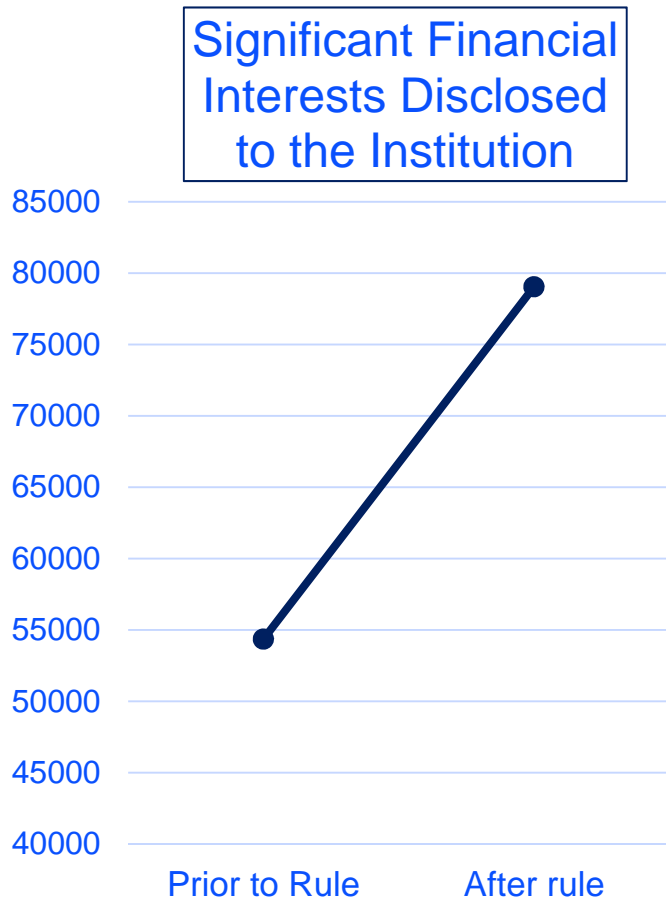




# One-Time Investments Made Before and After the Implementation Deadline

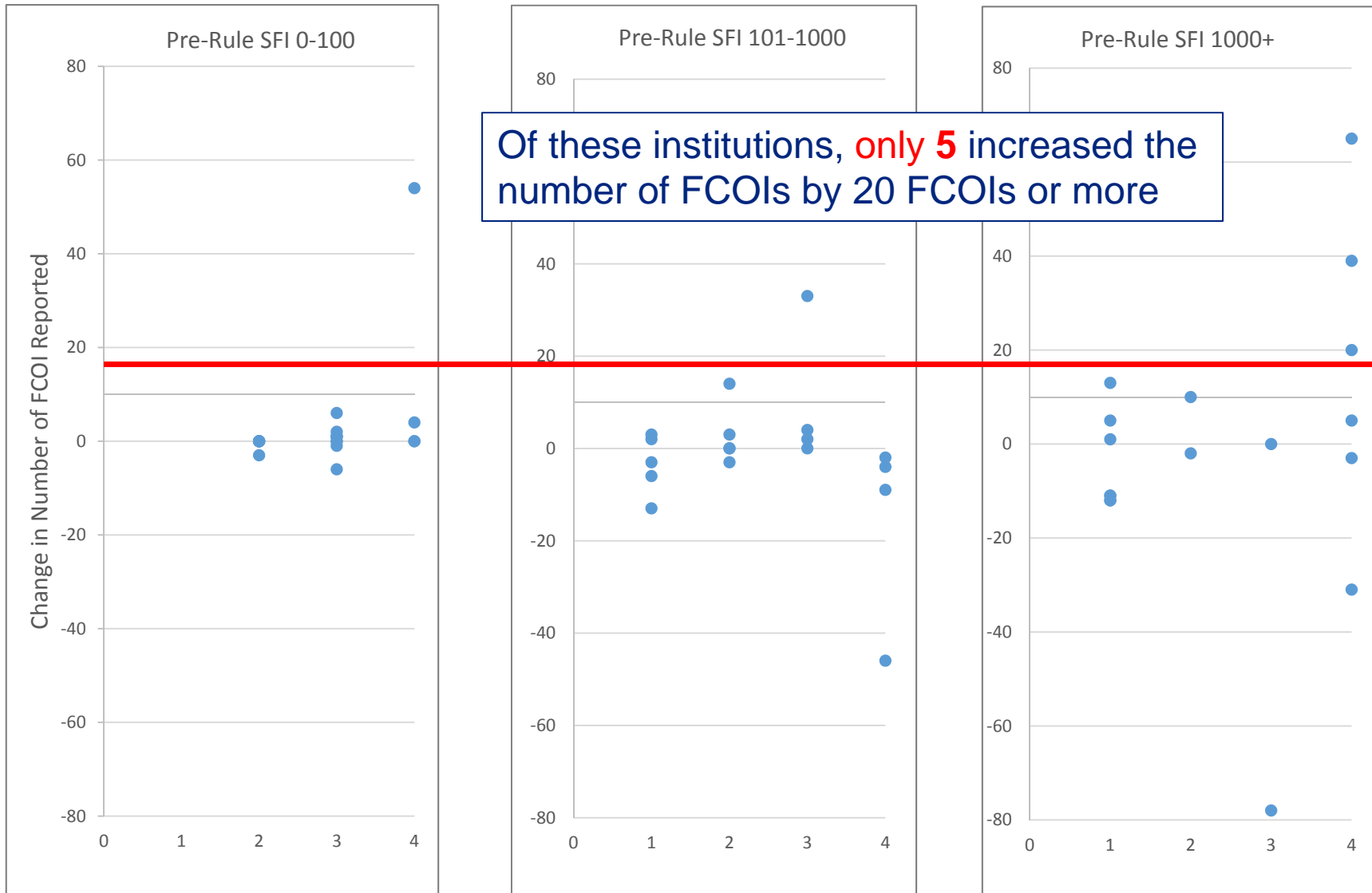


# Change in the Number of SFIs Disclosed and FCOIs Reported



Disclosed SFIs found to be FCOIs **decreased from 4.8 to 1.4%** after implementation of the regulations

# Change in the Number of FCOIs Reported as a Function of the Change in Disclosed SFIs



# Administering the COI Program

In 2012, 61 institutions estimated that it would cost on average \$289,016 annually

In 2013 those institutions reported spending \$329,078

Personnel administering the program increased from **1.9 to 2.7 FTE employees**



# Additional Data and Next Steps

Survey includes policy and COI office structure questions

Benchmarking reports to participating institutions

Aggregate, unidentifiable data to NIH

Second annual survey is ongoing

Future analysis will include retrospective reviews, public accessibility, FCOIs

# Addressing the Burden of Disclosure

2009

**Institute of Medicine Report: Conflict of Interest in Medical Research, Education, and Practice**

2010

IOM Multi-Stakeholder Event  
[Sunshine Act]

2011

IOM-Convened Working Group  
[PHS FCOI Regulations]

2012

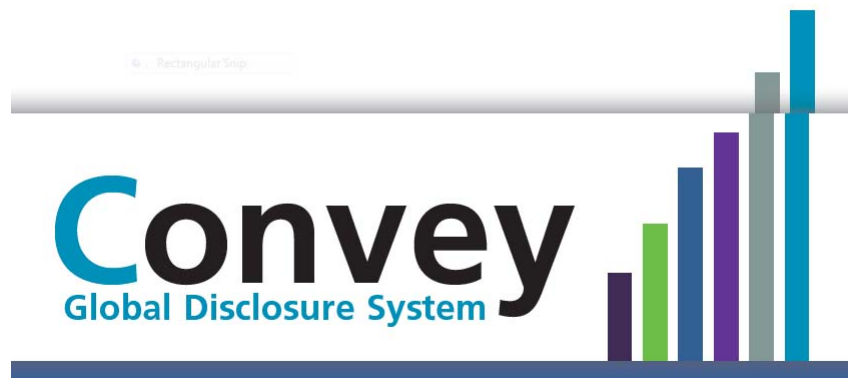
Discussion Paper and JAMA Editorial

2013

IOM Implementation Committee

# From IOM Recommendation to Prototype

- Secure, user-controlled
- Draws from single source of financial interests
- Interoperable with COI management systems – based on data standards
- Intuitive and easy to use for both individuals and subscribing organizations
- Provides relevant disclosure information based on organization criteria and user assessment





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# Questions and Discussion

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