Measuring and Addressing Regulatory Burden

Committee on Federal Regulations and Reporting Requirements

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- Identifying the Problem: Unlikely Sources of Regulatory Burden
- Measuring Effect and Effectiveness: A Model for Evidence Based Regulation
- Responding to a Call for Action: Convening Stakeholders Develop Systems that Decrease Burden
Sources of Regulatory Burden

- Lack of harmonization leads to overlapping regulatory schemes
- Unequal balance of cap on recovery of administrative costs with exponential increase in regulatory requirements
- “Knee jerk” regulatory responses
- No provisions for re-evaluating or recalibrating regulations
- Institutional misinterpretation or over-interpretation
Sources of Regulatory Burden

Unexpected and Unpredictable:

- Legislation written as regulation
  - Physician Payments Sunshine Act

- Ambiguous guidance
  - OHRP’s Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care

- Legislative regulatory interpretation

  “Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations… For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.” P.L. 113-240, signed 12-18-2014
2011 PHS FCOI Regulations

Investigator Responsibilities

- Remuneration?
- Is it an SFI?
- Appear to be related to Institutional Responsibilities?

Institutional Responsibilities

- Appear to be affected by the research?
- In entities whose interests appear to be affected?
- Is the SFI a Financial Conflict of Interest?
- Report details of COI to funder
- Report SFI to Institution
- Management Plan
- Mitigation Plan
- Training
- Disclose COI on public website or respond to requests

☆ = Changes from 1995
PHS FCOI Regulations: Impact on Institutions and Faculty

“We had to revise our policies and processes to assure compliance with the regulations. We continue to review our administrative processes, which takes time away from other projects that could be more helpful to our faculty.”

“The new regulations have added to the feeling that the scientific enterprise has become a bureaucratic endeavor which has a negative impact on faculty morale.”

“There has been a significant increase in work load for existing staff and there are no funds to support additional staff.”

“Researchers regularly complain about the PHS requirements but, to our knowledge, none have decided to forego a relationship with industry specifically to avoid the PHS reporting.”
AAMC Conflict of Interest (COI) Metrics Project: Measuring the Cost, Effect, and Effectiveness of the PHS FCOI Regulations

• 74 AAMC member institutions provide aggregate data to AAMC
  • Baseline – year before implementation
  • 3 years after implementation
• Data include
  - One-time and ongoing administration costs
  - Financial Interests reviewed and FCOIs reported (including assessment of $10K - $5K threshold change)
  - Resources needed
• Benchmarking data provided to institutions, de-identified data provided to NIH for retrospective review

71 institutions spent $22.6 million to implement the rule
Capital Expenditures $9.7M
Personnel Costs $11.6M
Other costs $1.2M

1.9 to 2.7 Full time equivalent (FTE) employees per institution to administer the requirements

www.aamc.org/metricsproject
Disclosure and Reporting Obligations Are Not Limited to PHS Or to Regulations

PHS Rule on Financial Conflicts of Interest in Federally Funded Research; Institutional COI Policy

ICMJE Requirements

Journal Submissions

Presentations at Meetings, Educational Events

Organization Rules

Home Institution

ACCME Standards

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A Single Repository Could Maintain Individual Financial Interests for All Disclosure Purposes
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