Medical research conducted at institutions across the United States fuels economic prosperity, fosters innovation, and contributes to public health. At the same time, research institutions must comply with federal regulations and policies. While federal oversight of medical research is essential for a regulatory system that ensures objectivity, integrity, and accountability, the unintended cumulative effect of federal regulations places significant stress on institutions and individual researchers. Without careful review and the ability to revisit ineffective or outdated requirements, federal regulations and reporting requirements will increase and can impede research productivity without necessarily enhancing oversight.

Background

The member medical schools and teaching hospitals of the AAMC conduct more than half of all extramural research funded by the National Institutes of Health (NIH). Although there are limited data quantifying the regulatory burden on investigators and research institutions to comply with federal regulations, several surveys and reports indicate that compliance and administrative requirements are putting significant strain on the research community.

A 1999 NIH report, NIH Initiative to Reduce Regulatory Burden (Mahoney 1999), assessed the impact of five specific areas of regulation (financial conflict of interest, research integrity, human subjects protections, animal care and use, hazardous waste disposal) and recognized that addressing regulatory burden and developing related solutions require robust collaboration among leadership at federal agencies, research institutions, and the research community.

In 2012, the Federal Demonstration Partnership survey found that investigators of federally funded research spent, on average, 42 percent of their research time performing administrative tasks—which included ensuring compliance with federal regulations—instead of conducting research.

That same year, the National Science Board (NSB) convened a Task Force on Administrative Burdens, which engaged federal agencies, the academic community, and other key stakeholders. The final report, Reducing Investigators' Administrative Workload for Federally Funded Research, acknowledged that although regulatory requirements are critical, "excess regulations, differing agency requirements, and requirements and delays resulting from institutional concerns about liability … slow the pace of research without improving scientific or regulatory outcomes” (National Science Board 2014, 19).

Congress has also recognized the urgent need to address regulatory burden. At the request of Congress, the National Academies convened an 18-member Committee on Federal Research Regulations and Reporting Requirements. In September 2015, this committee issued the expedited report, Optimizing the Nation’s Investment in Academic Research: A New Regulatory Framework for the 21st Century Part 1. The report covers specific regulations and reporting requirements that are important to the research community and that need the immediate action of Congress and the Administration. The report concluded that the continued expansion of federal research regulations is diminishing the effectiveness of the nation’s research investment by diverting investigators’ time away from research and instead toward administrative and compliance duties. It also noted the insufficient research and data quantifying the burden and cost to investigators and research institutions, citing the AAMC Conflict of Interest Metrics Project as an existing, effective mechanism to quantify regulatory burden.
The Conflict of Interest Metrics Project measured the cost and effectiveness of the NIH 2011 revised regulations on financial conflicts of interest. It found that the total new investment by 71 institutions to fully implement the regulations was nearly $23 million, with ongoing average annual costs of approximately $330,000 per institution. At the same time, while institutions reported reviewing a dramatically increased number of significant financial interests, there was not a proportional increase in the number of reported financial conflicts of interest. These findings call into question whether the revised regulation accomplished its intended goals in a manner that appropriately balanced the benefits and burdens of the requirements.

A January 18, 2011, Executive Order (E.O. 13563) emphasized the importance of reducing regulatory burden and costs by requiring a government-wide retrospective review of current regulations. In 2011, the Department of Health and Human Services anticipated that it would save $4 billion over the course of five years and would remove burdensome reporting requirements imposed on hospitals and health care providers. A July 2016 Government Accountability Office (GAO) report on federal research grant requirements and their administrative workload and costs noted that research funding agencies have tried to reduce administrative burden but recommended that five agencies, including NIH and the National Science Foundation (NSF), identify additional areas where regulatory requirements can be “standardized, postponed, or made more flexible, while maintaining oversight of federal funds.” The GAO report also cited the work of the AAMC Conflict of Interest Metrics Project.

AAMC Policy Recommendations

- The AAMC strongly supports initiatives to reduce, streamline, and harmonize regulations.
- The AAMC recommends a prospective evidenced-based review of specific regulations before they are finalized, to ensure that the burden imposed by the regulation is justified.
- The AAMC supports the National Academies’ recommendations to implement a framework to assess regulatory burden across federal agencies and to reduce that burden through a decrease in redundant, overlapping, or unnecessary requirements.

Related Issue

- Research with Human Subjects

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Web Resources

AAMC Conflicts of Interest Metrics Project
www.aamc.org/initiatives/research/coi/metricsproject

AAMC Information on Well-Being in Academic Medicine
www.aamc.org/initiatives/462280/wellbeingacademicmedicine.html

Optimizing the Nation’s Investment in Academic Research: A New Regulatory Framework for the 21st Century
www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory

References
