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Reducing the Regulatory Burden on Federally-Funded Researchers | August 5, 2016

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Over the past several years, the scientific community and policymakers alike have become increasingly concerned about the amount of time and resources scientists must devote to administrative tasks in order to apply for and comply with the terms of federal research grants. In its report, *Optimizing the Nation's Investment in Academic Research*, the National Academies of Sciences, Engineering, and Medicine argues that such regulatory and administrative requirements "are diminishing the effectiveness of the nation's research investment."¹ In fact, a 2012 Federal Demonstration Partnership survey of investigators found that principal investigators of federally-funded research projects spend, on average, 42 percent of their time on associated administrative tasks.² A 2015 study from Vanderbilt University found that the total cost of compliance with research regulations ranged from 11 to 25 percent of total research expenditures and could total as much as \$10 billion across the country.³ As Jeffrey Mervis of *Science* magazine argues, at the intersection of the bureaucracies of universities and the federal government, "it's no great surprise that the government's oversight of campus-based research is larded with requirements that are inefficient, redundant, and simply make no sense."⁴ Lengthy application processes with pre- and post-award requirements, complex accreditation mechanisms, complicated accounting and purchasing regulations, and reporting requirements are just some of the burdensome requirements on federally-funded researchers.

Stakeholders in the federal government and scientific community are seeking a remedy, but finding one has proven difficult.

The following pages discuss some of the major efforts made in recent years to better understand issues of regulatory burden and to begin to develop roadmaps for addressing it. As you will read, there is no shortage of ideas, but given the complexity of the topic and the many players—federal agencies, Congress, research institutions, and researchers themselves—the path to relief is less clear.

Proposals from the Scientific Community

The National Science Board (NSB), the governing board of the National Science Foundation (NSF), and the National Academies of Sciences, Engineering, and Medicine have both released extensive reports in recent years on the administrative workload of federally funded researchers. The reports, NSB's in 2014⁵ and the National Academies' in 2015 and 2016⁶, each recommend multi-faceted approaches to relieving this burden – approaches that would involve the White House, Congress, research funding agencies, and research

¹ http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_055806.pdf

² http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_087667.pdf

³ <http://news.vanderbilt.edu/files/Regulatory-Compliance-Report-Final.pdf>

⁴ <https://www.sciencemag.org/news/2016/06/out-out-red-tape-congress-weighs-bills-reduce-regulatory-burden-academic-science>

⁵ <http://www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf>

⁶ <http://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory>

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institutions. However, neither the National Science Board nor the National Academies have the authority to implement these recommendations, creating more questions than answers in terms of next steps.

The National Academies

Originally published in two parts, the National Academies' *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*, makes recommendations to completely reexamine and recalibrate the federal research enterprise (the full report can be read [here](#)). At the center of the recommendations and proposed regulatory framework is the creation of a Research Policy Board. This board would be created by Congress, along with an Associate Director for the Academic Research Enterprise who would work in the White House Office of Science and Technology Policy (OSTP) and would help develop consistent research policies across the federal government. The board would be responsible for providing an "analytical, anticipatory, and coordinating forum for research policy." According to the report, the research policies created within this new infrastructure should have a shared commitment between research institutions and federal agencies, be harmonized across agencies, have input from the Research Policy Board, and be reviewed periodically.

The authoring committee includes specific suggestions for the Administration, Congress, funding agencies, and research institutions in their comprehensive report. For example, recommendations for the Administration include requiring the Office of Management and Budget (OMB) to conduct a review of research-related policies, task a single agency to oversee a central database of investigator information, and develop a uniform grant format to be used by all research funding agencies. It recommends that research funding agencies limit proposals to the minimum information necessary—such as biographical information, abstracts, research plans, and budgets—as well as streamline and reduce the number of requirements across all agencies. The responsibilities of Congress would include establishing the Research Policy Board through legislation, directing OMB and OSTP to review the federal research funding agencies' information collection processes, and changing requirements for inspectors general to reflect a more comprehensive and effective method of auditing and reporting. Finally, the committee recommends that research institutions assess and streamline their own regulatory processes as well as revise any self-imposed policies that go beyond those necessary to comply with governmental regulations.

While many of the recommendations of the Academies panel address systemic inefficiencies, they also include recommendations for the federal government to help ease the administrative burden on researchers on a smaller scale. These include affirming that research institutions can take advantage of the flexibility in the [Uniform Guidance](#) regarding the documentation of personal expenses, requiring agencies to use a uniform grant format, adjusting the \$10,000 threshold for micro-purchases of supplies and services, and amending OMB's list of purchasable supplies.

Lastly, the Academies report prioritizes updating the Common Rule, the set of regulations outlining protections for human subjects in research. Recommendations include creating a risk-stratifying Common Rule system, allowing multi-site studies to use the same Institutional Review Board (IRB), and requiring harmonization of agency policies on human research protections. It also suggests that the President be authorized to create a free-standing national commission to recommend regulatory approaches for "unresolved questions in human subjects research." The report is critical of the Administration's current

efforts to update the regulations and recommends it start the process over. See [COSSA's recent reporting](#) on the Common Rule for additional details.⁷

The National Science Board

A year before the National Academies released its report, the National Science Board issued a request for information (RFI) to researchers and research institutions to gain insight into the administrative workload issues affecting federally-funded researchers. The responses informed the development of a set of recommendations that provide a comprehensive picture of the administrative workload of federally-funded researchers. Their full report, *Reducing Investigators' Administrative Workload for Federally Funded Research*, was published in March 2014.⁸

The Board recommended a refocusing on science during the grant application process, suggesting that requirements not critical for assessing the merits of the project be delayed until the application has been positively reviewed. Like the National Academies report, the NSB also called for a centralized database of researcher information, broadening “just-in-time” submissions, limiting annual reports to research outcomes rather than including all 40 questions currently required, and simplifying budget requirements prior to peer review.

The general findings and recommendations of the two reports are nearly identical. Both the NSB and the National Academies call for a review of human and animal subjects research regulations, broad harmonization of regulatory requirements across agencies, and streamlining grant proposal and post-award requirements. Like the National Academies, the NSB report emphasizes the importance of increasing university efficiency and ensuring that universities are accountable for their internal policies that add to the administrative burden on scientists. The NSB also suggests that universities communicate the origin of compliance to researchers and review IRB and institutional animal care and use committee (IACUC) staffing and organization.

The most notable difference between the two reports is the idea of creating a Research Policy Board, or equivalent, to oversee the academic research enterprise; the NSB report does not tackle the issues of agency coordination.

Legislative Proposals in the 114th Congress

If the job of the scientific community writ large is to take stock of the challenge associated with administrative burden and come to some consensus on feasible, actionable ways to address it, then the role of Congress is to legislate the necessary authority to put the wheels in motion.

During the 114th Congress, lawmakers have introduced a variety of legislative proposals to address the toll federal research regulations take on investigators. Democrats and Republicans alike have introduced legislation, many sharing common themes and motivations—administrative burden stifles science and wastes money. However, the mechanisms the various bills would use to relieve scientists of this burden vary.

⁷ <http://www.cossa.org/2016/07/12/academies-report-recommends-abandoning-proposed-changes-to-the-common-rule/>

⁸ <http://www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf>

This Congress is not significantly different than previous Congresses in attempting to address the issue, as summarized in [this article](#) from *Science*, published in 2014.

In June of this year, two bills were introduced specific to this topic. The *American Innovation and Competitiveness Act* (AICA) ([S. 3084](#)) is bipartisan legislation that serves as the Senate's version of the reauthorization of the *America COMPETES Act* and dedicates an entire title to the issue (the House version, H.R. 1806, passed the House in the spring of 2015 and includes a smaller section on research regulations). The Senate proposal would establish an interagency working group to reduce the administrative burdens on federally funded researchers, create a uniform grant format and a centralized researcher database, and repeal a number of agency-specific reports. Additionally, the legislation would update procurement processes and direct OSTP to revise its attendance policies for scientific and technical conferences and workshops. The COSSA summary of AICA can be read [here](#).

The second related bill introduced this June, the *University Regulation Streamlining and Harmonization Act of 2016* ([H.R. 5583](#)), was introduced with bipartisan support by Representative Daniel Lipinski (D-IL), Ranking Member of the Research and Technology Subcommittee of the House Committee on Science, Space, and Technology. Mirroring the first part of the National Academies report, this legislation would create a Research Policy Board to coordinate research regulatory policy. Additionally, it would establish the position of Associate Administrator for the Academic Research Enterprise to serve as co-chair of the board while also serving as a liaison between the Office of Information and Regulatory Affairs (OIRA) and OSTP. The COSSA summary of H.R. 5583 can be read [here](#).

An important distinction between these bills is their approach to oversight in the federal research enterprise. While both bills propose oversight boards, the Research Policy Board in H.R. 5583 would be designated as an advisory committee under the Federal Advisory Committee Act (FACA), while the interagency working group in S. 3084 would not. This designation would provide a level of formality to the Research Policy Board while also requiring it to be objective and transparent with the public. Another notable difference is that H.R. 5583 does not include a review of attendance policies for conferences and workshops, which is an issue of concern to professional scientific societies. A side-by-side comparison of the two bills can be read [here](#).

While S. 3084 and H.R. 5583 are the most recently introduced bills addressing administrative burden on researchers, there have been many other attempts to address this issue in the 114th Congress. Some legislators propose addressing burdensome regulations one agency at a time, evident in the proposals of Senator Lamar Alexander (R-TN) ([S. 2742](#)) and Representative Joe Barton (R-TX) ([H.R. 2420](#)) that specifically address the regulatory requirements of the National Institutes of Health (NIH). Others, such as the House COMPETES bill ([H.R. 1806](#)), sponsored by Representative Lamar Smith (R-TX) and a bill from Representative Barbara Comstock (R-VA) ([H.R. 1119](#)), propose multi-agency approaches.

There are certainly similarities among the many bills that have been introduced in recent years, but a consensus has not yet emerged. Federal agencies and research institutions can take some steps to reduce burden around the edges, but an overhaul of the federal regulatory system will at least in part require new authority granted through legislation.

While many of these pieces of legislation represent bipartisan efforts and compromise, the current political climate and laser-like focus on avoiding a government shutdown for the remainder of the 114th Congress will likely not allow time for further consideration of these bills. This issue will be among the many that will need to wait for the next Congress, leaving the question of how to alleviate the effects of administrative burden on researchers unresolved for at least a little while longer.