

Simplify Research Regulations

If you ask scientists how they spend their working hours, they will inevitably tell you they spend too much time on paperwork and compliance-related activities and not enough on actual science. Surveys show that scientists spend over 40% of their research time on administrative tasks such as writing proposals, filling out accounting forms, or satisfying regulations for complex animal or human subjects studies. We all know, of course, that some regulation is necessary to ensure research is conducted ethically, safely, and with sufficient accountability. But regulations and compliance requirements from multiple agencies are often duplicative, sometimes contradictory, and could be streamlined. This reality is not only frustrating for scientists, who would rather spend their time on research, but an inefficient use of taxpayer funds that could be better spent focusing on discovery and innovation for the betterment of society.

This is not a new complaint. For decades, calls have been renewed every few years to address the growing body of regulations and policies concerning research. Many associations, organizations, and government agencies have released reports with specific recommendations about how to address this problem, including the National Academies back in 2016. But for a range of reasons, few of those recommendations have been implemented and progress has been slow at best. Some changes, such as updated and simplified peer review processes at the National Institutes of Health and the Department of Health and Human Services, have been an improvement,

but many more changes are needed across multiple areas of regulation to fully address the burden on researchers.

The current policy environment favoring deregulation offers a unique opportunity to act swiftly on this long-standing issue. To inform ongoing deregulatory efforts by the administration and the Office of Management and Budget (OMB), the National Academies of Sciences, Engineering, and Medicine recently released a report taking a somewhat novel approach to suggesting how federal policymakers can simplify and harmonize federal research regulations and policies to reduce the regulatory burden. In the hopes of providing policy advice that is more likely to be implemented, rather than offering a list of recommendations, the report's committee presented alternative strategies that policymakers might pursue to reduce the administrative burden in each of seven areas of research regulations: grant proposals and management, research misconduct, financial conflicts of interest, protecting research assets, research involving biological agents, human subjects research, and research using nonhuman animal models. Within each regulatory area, the committee outlined the problems and proposed alternative ways to address them. Each option detailed the pros and cons of the approach so that policymakers can weigh the evidence and decide on a course of action to reduce the administrative burden and hopefully provide some relief for researchers facing an increasingly complex patchwork of regulations and policies.

For example, the committee identified insufficient government oversight of the regulatory environment as

a problem that has created duplicative, complex, and occasionally contradictory regulations and requirements. Previous reports have addressed this by recommending the creation of a research policy board within OMB to vet all proposed regulations from federal agencies. Congress had passed legislation for the creation of a research policy board in 2016 through the 21st Century Cures Act, but it was never created. The new National Academies' report reiterates the benefits of establishing such a board to enable centralized harmonization and allow input from academic institutions in the research compliance process; however, the committee recognized that the board would not have broad authority to ensure agency coordination, and may also take time to implement. Therefore, the committee presents an alternative option with a similar function: Create a permanent position within OMB to coordinate cross-agency requirements that affect federally funded academic research. This would still allow for a central point of coordination, but it would now have the authority of the White House and could be established without congressional action.

out their unique mission, not for streamlining across agencies, and without additional financial resources, agency staff are limited in the time they can spend on harmonization efforts.

One of us (Leshner) spent much of his career working for several of these federal science agencies and has been struggling with the issue of administrative burden for decades. Firsthand experience has shown how difficult change can be when facing different statutory authorities, tolerance for risk, and processes and definitions that are embedded in agency infrastructure. But to finally drive change on this intractable problem, the perspective needs to shift from prioritizing federal agencies to prioritizing good governance and facilitating researchers' ability to do their science.

Since the release of the National Academies report in September of this year, we have been disseminating it to various audiences. There seems to be a warm reception from policymakers, but what has really stood out throughout our events is how exasperated researchers are. They are desperate for some relief and are understandably skeptical that this renewed attention will finally chip away at our excessive regulations. Our hope is that all of us—policymakers,

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Even as a key priority for the administration, this will not be an easy problem to solve. During President Trump's first administration, the White House Office of Science and Technology Policy launched a task force dedicated to reforming research regulations. Although some progress was made on harmonizing new and developing areas of regulation such as research security, it is telling that this issue has become a renewed priority for Trump's second administration, with more urgency than ever, which raises the question of why it's so difficult to address.

As anyone who has worked in government knows, federal agencies prioritize their own practices, cultures, and interpretations over harmonization among themselves. The US system of multiple scientific funding agencies allows for funding of a diverse set of research priorities and deep scientific expertise within federal agencies. But this diffuse structure also allows for proliferation of research requirements, as funding agencies each develop their own unique policies or guidance documents to comply with regulations. This is understandable: Harmonizing and simplifying policies requires change and compromise. Additionally, federal agencies are rewarded for carrying

scientists, administrators, and the groups that represent them—will work together to ensure that this time is different.

The National Academies report ends with an illustrative example of a multidisciplinary researcher in a world where we've addressed administrative burden. She is able to easily submit grant applications to multiple funding agencies, complete a single annual conflict-of-interest disclosure, and seamlessly work with international collaborators because of streamlined vetting and security procedures. This could be a reality if regulations are harmonized and appropriately tiered to the risks they present, and user-friendly technology is adopted. Let's ensure that our nation's scientists are not wasting their time on unnecessary paperwork but rather using it to advance science and innovation that delivers results for the American public.

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