

OPTIMIZING THE NATION'S INVESTMENT IN ACADEMIC RESEARCH
A NEW REGULATORY FRAMEWORK FOR THE 21ST CENTURY

Statement of

Larry R. Faulkner, Ph.D.
President Emeritus
The University of Texas at Austin
and
Chair, Committee on Federal Research Regulations and Reporting Requirements
A New Framework for Research Universities in the 21st Century
Committee on Science, Technology, and Law
Board on Higher Education and Workforce
Policy and Global Affairs
The National Academies of Sciences, Engineering, and Medicine

before the

Subcommittee on Research and Technology
Committee on Science, Space, and Technology
U.S. House of Representatives

September 29, 2016

**Optimizing the Nation's Investment in Academic Research: A New
Regulatory Framework for the 21st Century
The National Academy of Sciences, Engineering, and Medicine**

Good Morning Chairwoman Comstock and Ranking Member Lipinski. Thank you for your invitation to provide testimony about a congressionally mandated study conducted by the National Academies of Sciences, Engineering, and Medicine with the sponsorship of the U.S. Department of Education and the National Institutes of Health. I was privileged to chair the committee that issued our report, entitled *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*.

Shortly after beginning the study, Congress asked that we expedite an initial report and so unlike most Academies reports, our report was issued in two parts: Part 1 issued in September 2015 and Part 2 issued as the final report in June 2016. In my remarks today, I will focus on the committee's overarching findings and recommendations. Copies of the full report have been provided to staff.

The overarching message of our report is that the continuing expansion of federal regulations and requirements is diminishing the effectiveness of the US research enterprise and decreasing the return on the federal investment in basic and applied research by diverting investigators' time and institutional resources away from research and toward administrative and compliance matters. The committee believes there is a need for a new framework to ensure that regulatory requirements are justified, proportional to the problems being addressed, and harmonized across federal agencies, so as to create a more effective and efficient research partnership. This new framework, which I will describe later in my remarks in greater detail, is embodied in our recommendations calling for the establishment of a Research Policy Board, a new associate director for the academic research enterprise at the White House Office of Science and Technology Policy (OSTP), and a set of guiding principles to govern and strengthen the government-research institution partnership.

In the course of our study, the committee reviewed and analyzed previous reports and studies. We also heard presentations from representatives of federal research funding agencies, inspectors general, university administrators and researchers, and independent organizations engaged in advancing scientific research and promoting the health of the nation's research enterprise.

While our ability to report a precise measure the cumulative effect of regulations was constrained by lack of data, we illustrate instances where the cumulative effect of inconsistent and overlapping regulations leads to a reduction in the time spent on research. From stakeholders at every level and perspective, we heard how, over the past several decades, increasing federal regulations hinder the output of the remarkable research enterprise that arose from the government-academic partnership.

Having said this, let me be very clear that the committee believes that effective regulation is essential to the overall health of the research enterprise. Our concern is that the current regulatory scheme is harming the very system it was supposed to protect. We are worried that, if this regulatory trend continues, we will cause significant damage to a system of education, mentorship, and discovery that is renowned internationally, consistently attracts the best talent from around the world, and serves as a model for other nations seeking to advance science and engineering in pursuit of economic and social progress and prosperity. In effect, we may jeopardize our nation's leadership in science, technology, and the social and behavioral sciences, all of which contribute to our security, health, education, and well-being.

The committee identified several overarching findings:

1. Effective regulation is essential to the overall health of the research enterprise. It protects both our nation's investment and various parties in the research partnership – research participants, investigators, universities, and agencies.
2. Most federal regulations, policies, and guidance are efforts to address important issues related to scientific integrity, the stewardship of federal funds, and the well-being of people and animals involved in research. But these well-intended efforts often result in unintended consequences that needlessly encumber the nation's research enterprise.
3. In recent decades, the amount of regulation has grown dramatically. Since 1991 the federal government has instituted 90 new regulatory changes with which universities must comply. The last decade in particular has seen striking growth in regulation: In the 1990s, the federal government promulgated approximately 1.5 new or substantially changed federal regulations and policies per year that directly affected the conduct and management of research under Federal grants and contracts. During the years 2003-2012, this number increased to 5.8 per year.
4. This continuing expansion of the federal regulatory system and its requirements diminish the effectiveness of the nation's investment in research. These growing requirements are directing investigators' time away from research and education and toward administrative tasks that are inconsistent, duplicative, or unclear. Regulations also add financial cost to the research enterprise, particularly as they accumulate over time.
5. Universities frequently receive research funding from multiple federal agencies, but approaches to similar tasks and goals – such as the submission of grant proposals and accounting for potential conflicts of interest – are not harmonized across funding agencies. Because of this, investigators and administrative staff spend unnecessary time and resources complying with different sets of rules and regulations. When requirements are duplicative, inconsistent, or unclear, universities themselves may place additional requirements on research investigators, adding to the burden.

6. At times regulations have resulted when universities did not respond appropriately to investigators' transgressions, or failed to create an environment that strongly discourages behaviors in conflict with scientific standards and norms. It is, however, also important to note that regulations have also been triggered by egregious transgressions that are found to be isolated events.
7. In recent decades, stresses in the federal-academic partnership have diminished the effectiveness of the nation's investment in academic research.
8. The relationship between research institutions and federal funders of research has long been considered a partnership. There is, however, no formal entity, mechanism, or process by which senior stakeholders from both partners can consider the effectiveness of existing research policies and review proposed new policies to sustain a dynamic and effective research enterprise.

With these findings in mind, the committee offered four overarching recommendations with specific actions provided to implement these recommendations.

1. First is that the regulatory regime governing federally funded research should be critically reexamined and recalibrated. We recommend that Congress, the White House Office of Management and Budget, federal agencies, and research institutions take a number of specific steps to improve the efficiency of rules and regulations.

For example, we urge the federal government to develop a uniform approach and format for grant proposals, conflicts of interest policy, and research with animals. We also urge institutions to review internal policies developed to comply with federal regulations, so as to determine whether such policies have themselves contributed to administrative burden. Additional recommendations – many of which can be acted upon immediately -- are detailed in our report.

2. Our second overarching recommendation concerns actions research institutions should take to reinvigorate the government-university research partnership and to re-instill trust. Research institutions must demand the highest standards in institutional and individual behavior. They must foster a culture of integrity among academic leaders, faculty, students, staff and administrators. And they must mete out appropriate sanctions where behavior deviates from ethical and professional norms. Universities that fail to enforce these norms should themselves face sanctions.
3. Our third overarching recommendation concerns the responsibilities of Inspectors General. Research institutions are subject to frequent federal audits as part of their acceptance of federal research funds. There is a growing concern, however, that there is a lack of shared understanding with regard to expectations concerning compliance with financial policies and procedures. When agencies, Inspectors General, and research institutions have shared understandings and interpretations

of the rules and regulations governing financial expenditures, there are fewer disagreements about the expenditure of federal funds. Without a shared understanding, an environment is created with competing assertions and findings. Consequently, we recommend that the responsibilities of the Inspectors General be rebalanced so that appropriate consideration is given both to uncovering waste, fraud, and abuse and to advising on economy, efficiency, and effectiveness.

4. Our final overarching recommendation is aimed at strengthening and renewing the government-university research partnership. We recommend that Congress create a new entity, a Research Policy Board, which would serve as the primary policy forum for discussions related to the regulation of federally funded research institutions. The board will bring together high-level stakeholders from the academic research community and from federal funding agencies to foster more-effective conception, development, and harmonization of research policies going forward.

For the remainder of my remarks I would like to focus attention on two specific areas: 1) human subjects research and 2) the new framework.

At about the same time that the committee issued Part 1 of its report, the Department of Health and Human Services issued a Notice of Proposed Rule Making (the “NPRM”) on the Federal Policy for the Protection of Human Subjects. The fundamental premise shared by all is the protection of human participants in research. Central to the goals of human subjects regulations are the principles of respect for persons, beneficence, and justice. These principles, articulated almost forty years ago in the Belmont Report, have served the nation well as it sought to protect human participants in research while advancing the biomedical and socio-behavioral research enterprise. However, since these principles were first articulated, the research enterprise has grown enormously and has witnessed profound changes in knowledge, technologies, methodologies, and capabilities, as well as in the potential implications of research findings for individual participants and for society. These changes in research contexts and capabilities have raised urgent questions about the proper application and balancing of the Belmont principles.

When the NPRM was released in September 2015, it received tremendous attention. Over 2000 comments were submitted to HHS in response. Most commentators expressed concerns about deficiencies in the proposed rule and maintained that if the rule were implemented as written, it would pose significant obstacles to the conduct of research. Having heard from various experts, and having considered analyses of the comments on the NPRM, the committee found that the proposed rule is marred by omissions, an absence of essential elements, and a lack of clarity. In addition, important questions about the overall impact and long-term costs of the proposed regulatory changes were left unresolved. Given that a national review of human subjects research has not taken place in almost forty years, that the biomedical and socio-behavioral research enterprise has grown tremendously during that time, and that the complexity of the issues related to human subjects research has greatly proliferated, the committee recommends that Congress authorize and the President appoint an independent, free-standing national commission on human subjects research.

Congress should charge the commission with examining and updating as necessary the ethical, legal, and institutional framework governing human subjects research with the goal of making recommendations to Congress and the President on ethically sound regulatory approaches to unresolved questions in human subjects research and on needed revisions to the legal and institutional structures governing the regulation of human subjects research.

Finally, and critically importantly, concurrent with this recommendation, the committee is calling upon the executive branch now to withdraw the NPRM, giving the proposed commission full scope to meet its Congressional charge.

Now to the new framework. Let me state clearly that the goal of this new framework is not to increase bureaucracy, but to provide a mechanism that will forestall the creation of duplicative and incongruous regulations, streamline and harmonize existing regulations, and provide a means to eliminate outdated or ineffective regulations.

We recommend that Congress create a new entity, a Research Policy Board, which would serve as the primary policy forum for discussions related to the regulation of federally funded research institutions. The board will bring together high-level stakeholders from the academic research community and from federal funding agencies to foster more-effective conception, development, and harmonization of research policies going forward.

Concurrent with the RPB we recommend that a new position – an Associate Director for the Academic Research Enterprise – be established in the White House office of Science and Technology Policy. This Associate Director would serve as a liaison between the Research Policy Board, funding agencies, Congress, and research institutions. In partnership with OMB's Office of Information and Regulatory Affairs, the director would facilitate concrete and meaningful reduction of institutional regulatory burden. Together, the director and Administrator of OIRA should report annually to Congress on regulatory issues and actions affecting the research partnership.

We believe that the only clear path to strengthening the US research enterprise and preparing it for continued leadership in the 21st century is through the establishment of the proposed Research Policy Board that will act as an analytical, anticipatory, and coordinating forum on research regulatory policy. Further, we believe the proposed associate director for the academic research enterprise will perform an essential role by focusing on the health of the federal-academic research partnership and by facilitating meaningful discussion between research institutions and the federal government, Congress, and inspectors general.

For nearly 70 years, the partnership between research universities and the government has yielded tremendous benefits for the American people, improving their economic well-being, health, and security. It behooves all of us to take steps to ensure that this partnership continues to flourish. The committee's recommendations are intended to strengthen that partnership and to maximize the returns on the nation's investment in research.

We believe our report offers Congress and the Administration a more responsive and efficient regulatory structure that optimizes the nation's investment in academic research while better serving the interests of government, universities, investigators, and the public.

Thank you for this opportunity to testify. I would be happy to take any questions you might have.