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OPTIMIZING THE NATION'S INVESTMENT IN ACADEMIC RESEARCH

A New Regulatory Framework for the 21st Century

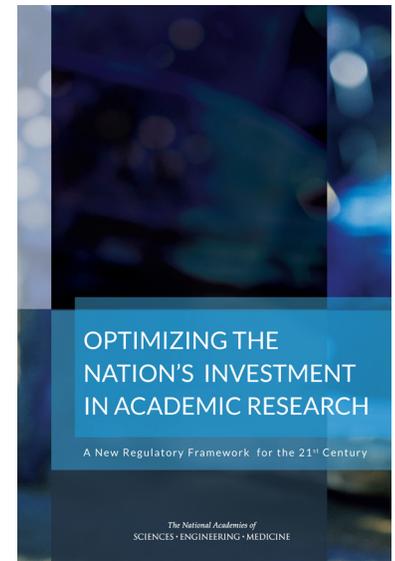
A unique partnership between the U.S. government and research universities has existed for nearly 70 years. Research institutions, with the investment of federal funds, have helped to create an educated citizenry and made fundamental discoveries that have enhanced the lives of Americans and others around the world.

This partnership is now under stress. Concerns have been raised repeatedly that federal regulations and reporting requirements, while essential to a well-functioning, responsible system of research, have increased over time to the point where time spent complying with regulations is taking away from time that could be spent on research. In light of these concerns, Congress asked the National Academies of Sciences, Engineering, and Medicine to investigate this issue and to recommend a new framework for regulating research in the 21st century.

Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century concludes that the continuing expansion of federal research regulations and requirements diminishes the effectiveness of the U.S. scientific enterprise and lowers the return on the federal investment in research by directing investigators' time away from research and toward administrative matters. The report identifies specific steps Congress, the White House, federal agencies, and research institutions should take to reduce the regulatory burden. It also suggests actions that should be taken to strengthen the nation's government-university research partnership and calls for the creation of a public-private Research Policy Board as a mechanism that allows research institutions to: 1) participate in the development of new regulations and the harmonization of existing regulations; 2) review the effectiveness and efficiency of existing regulations; and 3) suggest modifications to existing regulations that minimize burden while maintaining and enhancing their effectiveness.

THE GROWTH OF REGULATION

Research institutions have an obligation to be proper stewards of federal funds, and effective and efficient regulations are necessary to protect participants in research and to ensure the credibility of scientific investigations. Although regulation and oversight are



“This report has specific steps Congress and the administration can take to fix this problem,” Sen. Lamar Alexander of Tennessee, chairman of the Health, Education, Labor, and Pensions Committee, said in a brief written response to the report, **“and we intend to include many of the recommendations in legislation.”** *The Chronicle of Higher Education*

essential elements of the research enterprise, the regulation of research institutions has increased dramatically in recent decades. Data from the Council on Governmental Relations indicates that over 90 regulatory changes that affect research institutions have been instituted since 1990. While during the 1990s new or substantially changed regulations were promulgated at a rate of 1.5 per year, that rate increased to 5.8 per year during the decade 2003 to 2012. This regulatory growth is unduly encumbering the research enterprise.

Academic institutions and individual investigators often receive research funding from multiple federal agencies. Unfortunately, approaches to similar shared requirements—such as grant proposals, disclosure of financial conflict of interest, and animal care—are not harmonized across agencies. Regulations, reporting requirements, and congressional mandates frequently overlap, resulting in duplication of effort, multiple reporting of the same information in different formats, and multiple submissions of information on different schedules. Conflicting guidance on compliance requirements has created uncertainty and confusion and often leads universities to implement overly prescriptive procedures in an effort to avoid penalties, thereby adding to administrative burden.

The significant amount of investigators' time now spent complying with regulations takes time away from research, teaching, and scholarship. Inefficient, duplicative, and over-scaled regulation needlessly encumbers the nation's investment in research. This inevitably results in a less ambitious national research agenda.

A NEW FRAMEWORK FOR REGULATION OF RESEARCH

A new framework is needed that approaches regulation in a holistic, rather than piecemeal, way to ensure that regulatory requirements are harmonized across funding agencies and creates, in the process, a more effective and efficient partnership between funding agencies and research institutions.

Recommendation One: The regulatory regime (laws, regulations, rules, policies, guidances, and requirements) governing federally funded academic research should be critically reexamined and recalibrated. A number of specific actions—a sample of which are listed below—should be taken to improve the efficiency of federal regulation and to reduce duplication.

Congress should:

- work with OMB to conduct a review of agency research grant proposal documents for the purpose of developing a uniform format to be used by all funding agencies;
- work with OSTP and research institutions to develop a single financial conflicts of interest policy to be used by all research funding agencies;
- task a single agency with overseeing and unifying efforts to develop a central database of investigators and their professional output;
- direct agencies to align and harmonize their regulations and definitions concerning the protection of human subjects; and
- instruct OSTP to convene representatives from federal agencies that fund animal research and from the research community to assess and report back to Congress on the feasibility and usefulness of a unified federal approach to policies and regulations pertaining to the care and use of research animals.

Congress and the Administration should:

- create an independent, free-standing national commission to examine and update as necessary the ethical, legal, and institutional frameworks governing human subjects research;
- to ensure that the proposed national commission can address the full range of unanswered questions regarding the protection of human subjects in federally funded research, the executive branch should withdraw the September 2015 Notice of Proposed Rulemaking on the Federal Policy for the Protection of Human Subjects; and
- support robust continuation and renewal of the Export Control Reform Initiative.

The White House Office of Management and Budget should:

- require that research funding agencies use a uniform format for progress reporting; and
- amend the new Uniform Guidance to improve the efficiency and consistency of procurement standards, financial reporting, and cost accounting.

Federal agencies should:

- limit research proposals to the minimal information necessary to permit peer evaluation of the merit of the scientific questions being asked, the feasibility of answering those questions, and the ability of the researcher to carry out that research. Any supplementary information—such as IRB approval, conflict-of-interest disclosures, and detailed budgets—should be provided “just in time,” after the research proposal is deemed likely to be funded;
- reduce and streamline reporting, assurances, and verifications;
- develop a central repository to house assurances.
- develop a uniform set of requirements regarding the frequency and type of data to be submitted to federal agencies regarding invention reporting, ensuring that these do not exceed what is required by the Bayh-Dole Act; and
- the Federal Select Agent Program should develop and promulgate a reasonable inventory management system for biological select agents and toxins that takes account of the living, self-replicating nature of biological agents.

Universities should:

- conduct a review of institutional policies developed to comply with federal regulations of research to determine whether the institution itself has created excessive or unnecessary self-imposed burdens; and
- revise self-imposed burdensome institutional policies that go beyond those necessary and sufficient to comply with federal, state, and local requirements.

Recommendation Two: To advance the government-academic research partnership, research institutions must demand the highest standards in institutional and individual behavior. This can only be achieved if universities foster a culture of integrity among academic leaders, faculty, post-doctoral trainees, students, and staff, and institutional administrators, and mete out appropriate sanctions in instances where behavior deviates from the ethical and professional norms of the institution and of the academic research community. Universities that deviate from or fail to enforce the norms of behavior should be sanctioned. The committee recommends that the Research Policy Board described in Recommendation Four collaborate with research institutions to develop a policy that holds institutions accountable for such transgressions.

Recommendation Three: Inspectors General responsibilities should be rebalanced so that appropriate consideration is given both to uncovering waste, fraud, and abuse and to advising on economy, efficiency, and effectiveness. Research institutions are subject to frequent federal audits as part of their acceptance of federal research funds. There is a growing concern about a lack of understanding among federal agencies, Inspectors General, and research institutions regarding what constitutes compliance with financial policies and procedures. Concerns have also been raised about the extent to which Inspectors General, agencies, and research institutions partner in the proactive promotion of economy, efficiency, and effectiveness in the administration of federal grants. The relationship between Inspectors General and research institutions should be based on a shared commitment to advancing the nation’s interest through a dynamic and productive research enterprise.

Recommendation Four: The committee recommends the creation of a new mechanism, to include an active public-private forum and a designated official within government, to foster a more effective conception, development, and harmonization of research policies. Congress should create a Research Policy Board to serve as a public-private forum for discussions related to regulation of federally funded research programs. The board should be a government-enabled, private-sector entity that will foster a more effective conception, development, and synchronization of research policies. The board should be formally connected to government through a new associate director position at the White House Office of Science and Technology Policy and through the Office of Information and Regulatory Affairs at the White House Office of Management and Budget.

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For More Information . . . This Report Highlights was prepared by the Committee on Science, Technology, and Law based on the report *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*. The study was sponsored by the U.S. Department of Education and the National Institutes of Health of the U.S. Department of Health and Human Services. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the authoring committee and do not necessarily reflect those of the sponsor. Copies of the report are available from the National Academies Press, (800) 624-6242; <http://www.nap.edu>.

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