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Optimizing the Nation's Investment in Academic Research

A New Regulatory Framework for the 21st Century

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Committee on Federal Research Regulations and Reporting Requirements:
A New Framework for the 21st Century

2016

When effective and well coordinated, federal regulation protects the government, universities, investigators, and the public and helps prevent fraud, waste, and abuse.

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However, concerns have been raised repeatedly that federal laws, regulations, rules, policies, guidances, and reporting requirements, while essential to a well-functioning, responsible system of research, have led over time to an environment wherein a significant percentage of an investigator's time and resources are spent complying with regulations, taking valuable time away from research, education, and scholarship.

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As the result of these concerns, Congress called upon the National Academy of Sciences to convene a Committee on Federal Research Regulations and Reporting Requirements and tasked the committee to

“Develop a framework and supporting principles for the Federal regulation of research universities in the 21st century...”

The committee’s operations were funded by the U.S. Department of Education and the National Institutes of Health.

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Although the study was originally planned for 18 months, 3 months after the committee's first meeting in early 2015, Senator Lamar Alexander, Chair, Senate Committee on Health, Education, Labor and Pensions, asked for an expedited report by summer's end, 2015.

Chairman Alexander explained his belief that fall 2015 presented a unique opportunity to reconsider, in a bipartisan manner, the regulatory environment governing federally funded research.

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Part 1: September 2015

- The Research Partnership
- Overarching Findings
- Overarching Conclusions
- Acquisition and Use of Federal Research Grants
- Conduct of Research
- Financial Management of Research Grants
- A New Regulatory Framework

Part 2: June 2016

- Human Subjects Research
- Intellectual Property and Technology Transfer
- Select Agents and Toxins/Dual-Use Research of Concern
- Export Controls
- Operationalizing the New Regulatory Framework

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From stakeholders at every level and perspective, the committee heard how increasing regulations hinder the output of the remarkable research enterprise that arose from the government-academic partnership.

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Universities “stand at the central locus of the new innovation ecosystem...they require special attention in the area of regulatory and policy reform.”

“The Federal Government should identify and achieve regulatory policy reforms, particularly relating to regulatory burdens on research universities.”

Report to the President: Transformation and Opportunity: The Future of the U.S. Research Enterprise
President’s Council of Advisors on Science and Technology (PCAST), 2012

“I am concerned with the amount of time and resources being spent on duplicative and burdensome paperwork and red tape in the conduct of federally funded scientific research.”

Mo Brooks (Congressman, Chairman, Subcommittee on Research and Science Education),
Letter to Gene Dodaro, Comptroller General of the United States, U.S. Government Accountability Office,
requesting that GAO review the current regulatory and reporting requirements (October 3, 2012)

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“The Federal Government’s partnership with America’s colleges and universities through a variety of research grant programs remains strong but perhaps not as efficient and beneficial for American taxpayers as it could be. University management of Federal contracts, grants, and other awards requires several layers of reporting to multiple agencies, and the costs of unnecessary duplication within and across colleges and universities can be substantial. Resources that should be going to education and research are thereby diverted to less productive activities. Some of this duplication and inefficiency results from a lack of clear compliance standards, while in other cases the burdens result from accrued legacy requirements and processes that need to be reviewed and updated. Removal of unnecessary reporting burdens could free universities to further focus their resources on vital research and educational missions; to achieve this objective we need your *[colleges and universities]* help and engagement.”

Howard Shelanski, David Mader, and Anne Rung
“National Dialogue: Driving Efficiency for America’s Colleges & Universities,” The White House
August 14, 2015

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In the course of its study, the committee discovered little rigorous analysis or supporting data precisely quantifying the total burden and cost to investigators and research institutions of complying with federal regulations specific to the conduct of federally funded research but from presentations and other data the committee learned that the burden had increased and was diminishing the nation's investment.

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Overarching Findings from Part 1

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1. Effective regulation is essential to the overall health of the research enterprise, protecting both national investment and the various parties in the partnership.
2. Continuing expansion of the federal regulatory system and its ever-growing requirements are diminishing the effectiveness of the nation's research.
3. Most federal regulations, policies, and guidance, in and of themselves, are efforts to address important issues of accountability and performance, but these well-intended efforts often result in unintended consequences that needlessly encumber the nation's investment in research.
4. Many regulations fail to recognize the significant diversity of academic research.

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5. When regulations are inconsistent, duplicative, or unclear, universities may place additional requirements on research investigators, thereby diminishing the effectiveness of the national investment in research.
6. Academic research institutions often receive research funding from multiple federal agencies, but approaches to similar shared goals and requirements are not harmonized across these agencies.
7. Some academic research institutions have failed to respond appropriately to investigators' transgressions or failed to use effectively the range of tools available to create an environment that strongly discourages, at both the institutional and the individual level, behaviors in conflict with the standards and norms of the scientific community.

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8. Academic research institutions may be audited by any agency's Inspector General office, many of which have very different approaches that in some cases are incongruent with stated policies of their agency.
9. The relationship between federal research funding agencies and academic research institutions has for the past seven decades been considered a partnership. Yet, there exists no formal entity, mechanism, or process by which senior stakeholders from both partners, dedicated to fostering, sustaining, and strengthening our nation's unique research partnership, can consider the effectiveness of existing research policies and review proposed new policies needed to sustain a maximally dynamic, efficient, and effective research enterprise.

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Overarching Recommendations from Part 1

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RECOMMENDATION ONE

The regulatory regime (comprising laws, regulations, rules, policies, guidances, and requirements) governing federally funded academic research should be critically reexamined and recalibrated.

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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 a newly established Research Policy Board (RPB) should collaborate with research institutions on the development of a policy to hold institutions accountable for such transgressions.

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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. 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.

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RECOMMENDATION FOUR

The committee recommends the creation of a new mechanism, a Research Policy Board, 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.

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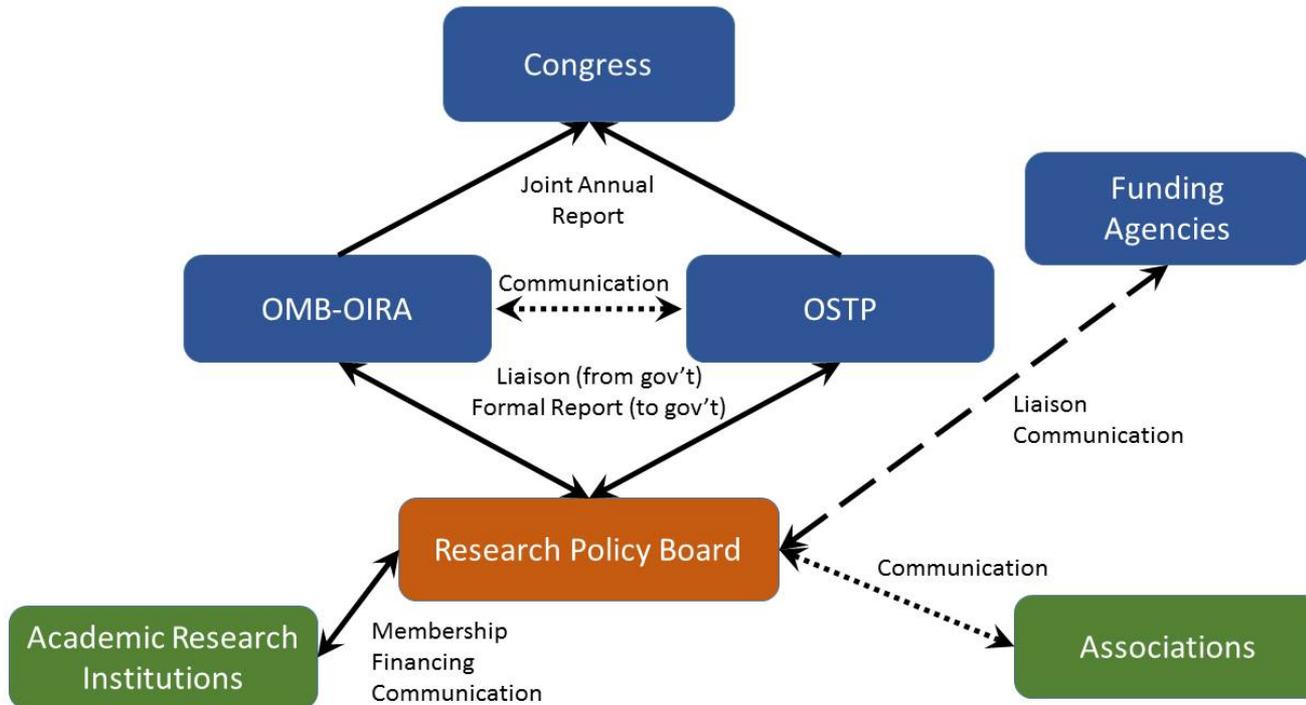
Concept of the Research Policy Board

- A private-sector entity formally linked to and overseen by OSTP and OMB, with a governance structure to be determined.
- Funded by mandatory assessments on research institutions.
- Organized and financially able to undertake relevant projects on a current-need or anticipated-need basis.
- Able to work flexibly with relevant associations.

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Schematic Representation of Relationships in a New Regulatory Framework



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Operationalizing the RBP

1. Consider, in an anticipatory fashion, issues, policies, concerns, and regulations that affect the multiple agencies that support or regulate federally funded research;
2. Consider, in an anticipatory fashion, new and emerging fields of research that may necessitate policy changes or new regulations;
3. Evaluate and assess the effects of existing, new, or proposed policies, regulations, and guidance documents; and
4. Collect and evaluate data for the development of metrics that provide a quantitative assessment of the cost and benefit of specific regulations.

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Associate Director, Academic Research Enterprise, OSTP

- Helps coordinate federal research policy and regulatory process.
- Routinely integrates and organizes input in a broadly representative fashion among
 - federal research agencies,
 - the Research Policy Board,
 - other representatives of institutions of higher education and their associations.
- Focused on the operational health of the research partnership.

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Part 2

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Part 2

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Human Subjects Research

The committee recommends that Congress authorize, and the President appoint, an independent, free-standing national commission that would exist outside of the structure of federal departments and agencies, would have a direct line-item appropriation, appoint its own staff, and set its own agenda.

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Human Subjects Research

Commission should have two broad charges:

1. Recommend to the President and Congress ethically sound regulatory approaches for unresolved questions in human subjects research; and
2. Recommend to the President and Congress revisions in the legal and institutional structures for regulating research with human subjects.

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Human Subjects Research

To avoid pre-empting the proposed commission's work, the committee recommends that:

- The executive branch withdraw the NPRM on the Federal Policy for the Protection of Human Subjects.
- The regulatory structure governing human subjects research not be revised until the national commission has issued its report and stakeholders have an opportunity to consider and respond to the commission's recommendations.

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Intellectual Property & Technology Transfer

The committee recommends that:

1. Congress transfer responsibility for the operation of the invention report system to the Department of Commerce and allocate resources for upgrading the system
2. Commerce, in consultation with the RPB, develop a uniform set of requirements
3. Congress authorize Commerce to require that the invention data reporting obligations are aligned across the federal funding agencies.

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Select Agents and Toxins

The committee recommends that :

1. The President assign responsibility for regulating microbes and toxins on Select Agents and Toxins List (SATL) to a single agency;
2. The Federal Select Agent Program develop and promulgate a reasonable inventory management system that takes account of the living, self-replicating nature of biological agents; and
3. The regulations governing select agents and toxins be amended to:
 - a. Allow researchers to more readily access relevant select agents in times of public health emergencies;
 - b. Increase the number of lower-virulence strains of select biological agents available to researchers; and
 - c. Make more transparent the process by which materials are added to or removed from the SATL

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Export Controls

The committee recommends:

1. That Congress and the Administration support a robust continuation and renewal of the Export Control Reform Initiative;
2. That the Reform Initiative seek university input at all stages of the process; and
3. That the Reform Initiative work closely with universities and other stakeholders to address the deemed export provisions.

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Concluding Remark

Congress, the President, and the agencies have an opportunity for a course correction that can yield significantly greater value to the public from the nation's investment in research. We hope our recommendations will guide that effort.

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