

# **New report examines regulation of federally funded research**

September 22 2015

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Continuing expansion of federal research regulations and requirements is diminishing the effectiveness of the U.S. scientific enterprise and lowering the return on the federal investment in research by directing investigators' time away from research and toward administrative matters, says a new congressionally mandated report from the National Academies of Sciences, Engineering, and Medicine. The report identifies specific actions Congress, the White House, federal agencies, and research institutions should take to reduce the regulatory burden.

Steps should also be taken to strengthen the nation's government-university research partnership, which is currently under stress, the report says. It urges Congress to create a public-private Research Policy Board to support this partnership and cooperative efforts to streamline research policies going forward. The report also calls upon universities to demand the highest standards in institutional and individual behavior, noting that some institutions have failed to respond appropriately to researchers' transgressions.

"Federal regulations and reporting requirements, which began as a way to exercise responsible oversight, have increased dramatically in recent decades and are now unduly encumbering the very research enterprise they were intended to facilitate," said Larry Faulkner, chair of the committee that conducted the study and wrote the report, and president emeritus of the University of Texas, Austin. "A significant amount of investigators' time is now spent complying with regulations, taking valuable time from research, teaching, and scholarship."

Academic institutions and individual investigators often receive research funding from multiple federal agencies, but approaches to similar 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, often leading universities to implement overly prescriptive procedures in an effort to avoid penalties, thereby adding to the administrative burden.

"Research institutions have an obligation to be proper stewards of federal funds. Effective and efficient regulations are necessary to protect participants in research and to ensure the credibility of scientific investigations," said Harriet Rabb, vice chair of the committee and general counsel of The Rockefeller University. The report finds, however, that inefficient, duplicative, and over-scaled regulation needlessly encumbers the nation's investment in research, inevitably resulting in a less ambitious national research agenda.

## **New Framework for Research Regulation Needed**

A new framework is needed to approach regulation in a holistic, rather than piecemeal, way to ensure that regulatory requirements are harmonized across funding agencies and create a more effective and efficient partnership between funding agencies and [research institutions](#), the report says.

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 report says. The board should be a government-enabled, private-sector entity that will foster 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.

Strengthening the research partnership also requires that universities demand the highest standards in institutional and individual behavior, foster a culture of integrity, and mete out appropriate sanctions when behavior deviates from ethical and professional norms, the report emphasizes. The Research Policy Board should collaborate with research institutions to develop a policy that holds universities accountable, sanctioning institutions that fail to enforce standards.

The report also recommends a number of specific actions - a sample of which are listed below - that are intended 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 conflict-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.

The White House Office of Management and Budget should:

- require that research funding agencies use a uniform format for research 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 minimum 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 investigator to carry out that research. Any supplementary information - IRB approval, conflict-of-interest disclosures, detailed budgets, etc.—should be provided "just in time," after the research proposal is deemed likely to be funded; and
- reduce and streamline reporting, assurances, and verifications. Agencies should also develop a central repository to house assurances.

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 burden; and
- revise self-imposed burdensome institutional policies that go

beyond those necessary and sufficient to comply with federal, state, and local requirements.

The release of the report completes the first phase of the committee's study, which was expedited at the request of Congress. The committee will now continue its assessment and issue a spring 2016 addendum report addressing additional items in its charge and other regulations, such as export controls and dual-use [research](#) of concern, that it has been unable to address in the first phase.

**More information:** [www.nap.edu/catalog/21803/opti ... rch-a-new-regulatory](http://www.nap.edu/catalog/21803/opti...rch-a-new-regulatory)

Provided by National Academy of Sciences

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