Reforming Regulation of Research Universities

Regulatory and reporting requirements have become excessively burdensome. A more balanced approach is needed.

In recent years, research universities and their faculty have seen a steady stream of new federal regulations and reporting requirements imposed on them. These new requirements, in combination with other factors, have exacerbated already significant institutional financial stress and diverted faculty time from research and education.

The oversight of research that uses human subjects or animals, involves select agents, chemicals, or other potentially dangerous substances, or involves export-controlled technologies is necessary and important. Universities and researchers take seriously their responsibilities to comply with requirements and account for their use of federal resources. However, increasing regulatory and reporting requirements are not only costly in monetary terms; they also reduce faculty productivity and result in inefficient use of federal research dollars.

Quantifying the monetary and productivity costs of regulations is often difficult. Whereas the cost of each individual regulation may not appear to be significant, the real problem is the gradual, ever-increasing growth or stacking of regulations.

The fiscal situation of our universities requires a reexamination of regulatory and reporting requirements to ensure a proper balance between accountability and risk management and to ensure that federal and institutional resources, as well as researchers’ time and effort, are being used effectively and efficiently.

The current climate of fiscal austerity has sparked a renewed interest in reforming and streamlining government regulations to eliminate waste and improve productivity. In January, President Obama released Executive Order 13563 (“Improving Regulation and Regulatory Review”), along with two presidential memoranda focused on regulation. These documents require federal agencies to develop plans for regulatory review to ensure that regulations become more effective and less burdensome.

Congress is also interested in regulatory reform. Rep.
Increasing regulatory burdens are occurring during a period of severe financial pressure on universities. State educational appropriations per full-time student in 2010 constant dollars were 21% lower in 2010 than they were two decades earlier and 25% lower than a decade ago. Endowments have yet to recover from the substantial losses incurred in the recent financial crisis. Gifts and donations have declined. Raising tuition is not a realistic option for filling this gap, especially for public universities facing heightened scrutiny from state legislators or bound by state constitutions to minimize tuition rates.

At the same time that other funding sources have become constrained, the cost of performing research has become increasingly expensive for universities, in part because of the expanded costs of federal compliance. Between 1972 and 2009, the proportion of total academic R&D expenditures drawn from institutional funds nearly doubled from 11.6% to 20.4%. At the same time, the proportion funded by federal, state, and local governments decreased from 78.5% to 66%. Because of White House Office of Management and Budget (OMB) rules, universities are restricted in how much they can be reimbursed by the federal government to pay for compliance costs.

Heavy compliance burdens affect not only institutions, but also the morale and productivity of researchers within them. According to an often-cited and illustrative figure from the 2007 Federal Demonstration Partnership (FDP) Faculty Burden Survey, 42% of faculty time relating to the conduct of federally funded research is spent on administrative duties. Some of this additional time is the result of increased activities relating to compliance with federal regulations. In effect, at a time of limited resources, compliance requirements are taking researchers out of the laboratory and reducing their ability to perform the research that leads to the innovations that improve our quality of life.

Numerous research institutions provided us with data indicating that compliance costs have grown during the past decade. Recovery of these costs is determined by rules set by OMB. Most of the research compliance costs are accumulated in a pool of costs classified by OMB as “sponsored projects administration” (SPA), and analysis of SPA can be insightful in measuring the growth of research compliance costs. One private institution in the midwest estimated that its SPA costs increased from $4.2 million in 2002 to $7.3 million in 2008. A prominent medical school in the southeast reported that its compliance and quality assurance costs increased from about $3 million in 2000 to $12.5 million in 2010.

More telling than the increases in SPA and associated research compliance costs are trends showing that these costs have increased more rapidly than the associated direct research expenditures, such as salaries, lab supplies, and research equipment. For example, the medical school mentioned above had a cumulative increase in compliance and quality-assurance costs of more than 300% between 2001 and 2010, whereas sponsored expenditures associated with the direct costs of research increased by only 125% during the same period. A private university in the south told us that its SPA-related costs associated with research increased by nearly 120% between fiscal year 2002 and 2010, whereas its direct research expenditures increased by less than 100%.

It is important to note that this is not a case of adminis-
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trative inefficiency. University-wide administration and departmental and school-specific academic administration rates have fallen over the past decade, due mainly to drastic cuts in state appropriations and a strong emphasis on administrative efficiency and effective management. At the same time, SPA costs, which are closely linked to the cost of research compliance, have increased. The onslaught of research compliance regulation and unfunded mandates has overwhelmed the strong downward pressures of budget cuts and emphasis on administrative efficiency.

Precisely answering the seemingly simple question “How much does it cost universities to comply with any particular regulation?” is difficult. The cost of compliance frequently results from the time that faculty, staff, and administrators spend in fulfilling compliance and reporting responsibilities. This results in both monetary costs and the diversion of faculty time away from research and teaching, reducing productivity.

Productivity declines are a challenge to measure, with the 2007 FDP survey providing perhaps the best data. With regard to monetary costs, estimates of compliance for the same regulation or research area may range widely among different universities. This is not unexpected; the range reflects variability among universities in the size and nature of their research endeavors, as well as the differing degree to which institutional research engages in areas requiring compliance. For example, one university may conduct more human subjects studies, whereas another has more researchers working with hazardous materials or select agents.

Universities account for compliance costs in different ways. Compliance burdens are spread across many offices and units at an institution, and in many cases compliance costs are difficult to separate from other associated research operating costs. Finally, new compliance requirements, even when they seem small, can strain university systems. For instance, new regulations on export controls have added considerable burden to the usually one or two employees who deal with such matters, in some cases requiring the hiring of additional personnel. Proposed new National Institutes of Health (NIH) guidelines on conflict of interest are yet another example that will probably increase the workload.

A framework for evaluation and solutions
Although the ever-growing array of research regulations affecting universities can seem bewildering, solutions for problematic regulations fit within a relatively small number of categories:
- Eliminate outright or exempt universities from the regulation
- Harmonize the regulation across agencies to avoid duplication and redundancy
- Tier the regulation to levels of risk rather than assuming that one size fits all
- Refocus the regulation on performance-based goals rather than on process
- Adjust the regulation to better fit the academic research environment.

Table 1 is a matrix that associates examples of regulations with the solutions defined above. In most cases, regulatory relief does not mean simply eliminating a regulation. Solutions tend to fall within several categories (for example, harmonization and tiering to risk) rather than only one, and should be pursued carefully to ensure that they make sense and are not counterproductive. Below we discuss specific examples from the table in more detail:

Effort reporting. Effort reports show the percentage of total effort that individuals contribute to university activities. Faculty commit to devote a certain fraction of their work time to specific projects funded by the federal government, and must regularly certify that they are devoting this amount of time to those activities.

Effort reporting has been widely criticized for imposing significant cost without adding value. For example, according to FDP, “…effort reporting is based on effort which is difficult to measure, provides limited internal control value, is expensive, lacks timeliness, does not focus specifically on supporting direct charges, and is confusing when all forms of remuneration are considered.”
Effort reporting can be eliminated without any detriment to the accountability or oversight of the research enterprise for five reasons. First, it is redundant. Requirements that faculty provide regular progress reports to funding agencies serve the same function as effort reporting, but do so more effectively because they better align with incentives for faculty performance such as research accomplishments, success on subsequent grant proposals, and ultimately promotion and tenure. Second, it is unnecessary. Faculty rarely spend less time than they initially commit to federally funded research. Indeed, as acknowledged by the OMB A-21 Clarification Memo of January 2001, faculty routinely spend more time than they committed to. Third, it lacks precision. It is incompatible with an academic research environment in which researchers do not work on billable hours and researcher responsibilities such as student supervision often cannot realistically be billed reliably to a single project. Fourth, it is expensive and wasteful of government funds. The federal government must spend money in the auditing of effort reports and associated administrative processes. Finally, effort reporting is responsible for adding considerably to universities’ administrative costs and taking faculty away from research. Virtually every institution that responded to our request for information identified effort reporting as an area that has had significant cost and productivity implications.

The costs are significant. For example, one public university in the Midwest told us that nine employees spend about one quarter of their time each year monitoring certifications, at an estimated annual cost of $117,000. For many schools, effort reporting also requires the development or purchase and the continuing maintenance of specialized software systems. A public university in the midwest reported that the cost of the necessary software was more than $500,000, exclusive of implementation and training costs. Several universities reported that they spent in the range of $500,000 to $1 million annually on effort reporting.

Chemical Facilities Anti-Terrorism Standards (CFATS). The Department of Homeland Security (DHS) Appropriations Act of 2007 granted DHS the authority to regulate chemical facilities that present “high levels of security risk.” Under this authority, DHS promulgated CFATS. Since 2007, the research community has urged DHS to reconsider the manner in which CFATS is applied to research laboratories located at universities.

The current regulations fail to recognize the differences between university research laboratories and major chemical manufacturing and production facilities, including how chemicals are used and stored for research purposes. Chemical plants often store large volumes of toxic substances; universities generally do not. Rather, they distribute regulated “chemicals of interest” in very small quantities, among laboratories in multiple buildings and generally in more than one geographic location. Given this distributed environment, research organizations present a low risk for serious toxic releases through theft, sabotage, or attack.

Nonproduction research laboratories with similar chemical use patterns located at noncommercial, nonprofit research organizations such as colleges and universities should be regulated differently. DHS should establish separate but robust standards, protocols, and procedures for assessing vulnerabilities and improving the security of chemicals of interest in a research setting. Several other federal agencies have established separate and successful standards for research laboratories; these standards include separate chemical safety regulations at the Occupational Safety and Health Administration and separate hazardous waste management regulations at the Environmental Protection Agency, both of which are distinct from those applied to industrial production and other facilities.

The current CFATS regulations take an inappropriately broad look at campuses, treating an entire campus as a single entity. Although CFATS allows some flexibility in defining the boundaries of facilities, site security plans or alternative security plans must be developed in the aggregate and may not be developed specifically for a lab or unit operation. DHS should take an approach in which the security requirements apply only to individual laboratories where chemicals of interest exist in quantities greater than the threshold planning quantity.

U.S. Citizenship and Immigration Services changes to Form I-129. In early 2011, the U.S. Citizenship and Immigration Service (USCIS) added a question about export control licenses to its Form I-129, which employers must complete when petitioning for a foreign worker to come to the United States temporarily to perform services. As a result, I-129 petitioners now have to complete a new certification for H-1B visas and certain other specialty occupation visa petitions. This new requirement puts substantial burdens on universities with questionable benefit for national security.

The value and purpose of Form I-129 remain unclear, especially considering that USCIS has no responsibility for export control enforcement or compliance and that other security checks are already incorporated into the existing visa process. Under the Visa Mantis program, for example, the State Department provides extra screening of visa applicants who are seeking to study or work in certain fields that are deemed to have national security implications. The change
### TABLE 1

A framework for remedies for some regulatory burdens faced by research institutions

<table>
<thead>
<tr>
<th>Exempt universities or eliminate</th>
<th>Harmonize/avoid duplication and redundancy</th>
<th>Tier to risk</th>
<th>Focus on performance, not process</th>
<th>Better synch with university R&amp;D</th>
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<tr>
<td>Human subjects</td>
<td>Harmonize human subjects protections between the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA). Eliminate Health Insurance Portability and Accountability Act (HIPAA) from research, or harmonize HIPAA regulations with OHRP regulations.</td>
<td>Tier human subjects research for exemption from Institutional Review Board review (e.g., social science research vs. clinical trials).</td>
<td>Consult on whether the Animal Enterprise Terrorism Act provides sufficient protection for animal researchers.</td>
<td>For purposes of enforcement of deemed export control laws, require that individuals have knowledge or intent that controlled information will be exported or transmitted without proper authorization.</td>
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<td>Animal research</td>
<td>Harmonize International Traffic in Arms Regulation, Export Administration Regulations, and Office of Foreign Assets Control controls.</td>
<td>Tier export control lists to risk, removing much of what is currently on these lists or reclassify to lower their control levels.</td>
<td></td>
<td>Federal Funding Accountability and Transparency Act (FFATA): Raise subreporting threshold from $25,000 to the simplified acquisition threshold, use OMB definition of “subcontract” (which eliminates procurements), and only report first tier. FFATA: Make reporting annual or eliminate more onerous requirements for universities.</td>
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<td>Effort reporting</td>
<td>Eliminate effort reporting.</td>
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<td>Financial reporting</td>
<td>Expanded Form 1099 Reporting Requirements will create an additional burden on financial reporting.</td>
<td>Sub-recipient monitoring: Modify requirement so that grantees would no longer be required to monitor sub-recipients who regularly receive Federal awards.</td>
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<td>Conflict of interest/ research integrity</td>
<td>Eliminate negative patent reports, which require form completion even when there are no intellectual property concerns.</td>
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<td>Direct Office of Science and Technology Policy to convene agencies to develop a conflict of interest policy like the Misconduct in Science Policy, which articulates general goals and objectives.</td>
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<td>Select toxins and agents</td>
<td></td>
<td>Develop a tiered list and associated requirements, as has been documented by the American Society of Microbiology.</td>
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<td>Hazardous materials</td>
<td>CFATS: Wherever possible, create an exception for research laboratories.</td>
<td>CFATS: Tier chemicals of interest to risk when exemption isn’t possible.</td>
<td></td>
<td>Examine and consider university facilities as different from large chemical facilities: Design alternative approaches in light of these differences.</td>
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Mechanisms should be developed to allow universities to be exempted from certain regulatory and reporting requirements, when appropriate, and if not exempted, to more easily be reimbursed for their associated costs.

to Form I-129 is therefore redundant and unnecessary. Most research conducted by foreign nationals at U.S. research universities is fundamental research, which is excluded from export control requirements. Whether technology is subject to Export Administration Regulations is irrelevant if a foreign national is performing fundamental research. Because of this exclusion, there will probably be very few instances in which export control licenses will be required for foreign nationals employed at research universities on H-1B visas. However, universities must do significant additional review for I-129 submissions to confirm that this is indeed the case.

The inclusion of the “Deemed Export Acknowledgment” makes filling out Form I-129 and the H1-B application process much more complicated for visa petitioners and university employers. At research universities, international affairs and human resources offices typically complete and file the form for potential visa employees. However, to respond correctly to such a narrow question concerning exports licenses, other university officials from the office of sponsored programs and technology licensing, campus compliance officers, and sponsoring faculty must become involved in the petition to hire temporary employees. This has dramatically increased the time it takes university staff to complete Form I-129.

It is also unrealistic in a research environment to expect that export-control issues and technologies connected to a particular line of research in which a researcher is involved will remain static from the time Form I-129 is completed. Universities cannot predict where scientific inquiry will go, and many technologies involved in conducting research may change during the course of the research project as findings and discoveries progress. It is thus easy for universities to inadvertently respond to this question in a way that could eventually turn out to be inaccurate.

Other Examples. Several other examples of redundant and unnecessary research regulations exist. For example, many collaborative research projects involving investigators at different institutions require that subawards be made to other partnering institutions. In these instances, the prime award recipient is also required to “monitor” the business practices and internal controls at the subrecipient institution. Although there may be value to monitoring subrecipients that are not established recipients of federal funding, to monitor and report on other research universities that regularly receive federal awards is a wasteful exercise and should be eliminated.

Other examples involve tiering regulations to risk. In human subjects research, minimal-risk studies, such as many in the social sciences, should not require the same level of review as clinical trials. Similarly, not all research involving pathogens or biological toxins that pose potential risks to public health and safety pose the same level of risk. The requirements associated with the regulation of this “select agents” research should be tiered to risk, as documented by the American Society of Microbiology.

And finally, newly proposed conflict of interest guidelines from NIH that require public posting of faculty-industry relationships, even when potential conflicts are being effectively managed, will create public confusion and unnecessary work and have a potential chilling effect on university-industry interactions. The full impact of these regulatory changes should be carefully evaluated before they are implemented.

Steps toward reform

The specific regulations in Table 1 and discussed here are just a small sample of the regulatory issues facing research universities. Beyond the matrix we have laid out for addressing such issues, several other actions would help universities and the federal government work better together to reduce regulatory burden while still ensuring safety and accountability.

First, we need to improve understanding of the costs of regulation. As we have already discussed, quantifying the costs and burdens of regulations is difficult. The NRC and the Department of Education should conduct the study on regulation in higher education called for by Section 1106 of the Higher Education Opportunities Act (H. R. 4137), to
describe by agency the number of federal regulations and reporting requirements affecting institutions of higher education; the estimated time required and costs to institutions of higher education (disaggregated by types of institutions) to comply with these regulations; and recommendations for consolidating, streamlining, and eliminating redundant and burdensome federal regulations and reporting requirements affecting institutions of higher education.

In addition, OMB and the Office of Science and Technology Policy should jointly co-chair an interagency working group that regularly reviews regulations affecting research universities. This group could be organized as a new subcommittee of the National Science and Technology Council Committee on Science, or as part of the existing Research Business Models Subcommittee. Through an application process, research universities or university associations could submit proposals to fix or eliminate rules that add no value or promote inefficiency and excessive regulatory burden. Such a group would also be able to closely examine regulation costs.

Government flexibility and responsiveness must be increased. New or enhanced relationships and pathways of communication between universities and the government will help improve efforts to reduce regulatory burdens. The administration’s EO 13563 provides an impetus for establishing these pathways. We should designate a high-level official within OMB’s Office of Regulatory Affairs to serve as a federal ombudsman. This official would be responsible for addressing university regulatory concerns and seeking ways to increase efficiency and minimize regulatory burdens. The ombudsman would assist in harmonizing and streamlining federal regulations and would also have responsibility for reviewing specific simplification requests. The ombudsman should be OMB’s co-chair on the interagency working group recommended above.

Protocols should be established to address statutorily mandated regulatory concerns. When new laws are passed by Congress to achieve important public policy goals, unintended regulatory burden can be an unfortunate byproduct. When requirements create unintended regulatory burdens for universities, a fast-track approach to amending the law would be a useful tool that could help to minimize burdensome regulations.

Mechanisms should be developed to allow universities to be exempted from certain regulatory and reporting requirements, when appropriate, and if not exempted, to more easily be reimbursed for their associated costs. There are three ways in which this can be done.

First, research universities should be given exemptions similar to those provided to small entities under the Regulatory Flexibility Act (RFA). The RFA requires agencies to prepare and publish a regulatory flexibility analysis describing the impact of a proposed rule on small entities. In addition, agencies are encouraged to facilitate participation of the affected entities by holding conferences and public hearings on the proposed rule. The RFA encourages tiering of government regulations or the identification of “significant alternatives” designed to make proposed rules less burdensome. The law should be amended to include organizations engaged in conducting federally sponsored research and education activities.

Second, coverage provided under the Unfunded Mandates Reform Act (UMRA) should be extended to research universities. It is often not a single regulation that creates compliance challenges, but the stacking of regulations over time. Agencies rarely reevaluate, eliminate, or redesign regulatory schemes to reduce the burden of compliance. The UMRA requires Congress and agencies to give special consideration to the costs and regulatory impact of new regulations on state and local governments, as well as on tribal entities. Extending coverage to public and private universities would result in research funding agencies being more responsive to the cost burdens of new requirements.

Third, institutions should be allowed to better account for new regulatory costs and to charge these costs to federal awards. The Paperwork Reduction Act requires that all proposed regulations be analyzed for the paperwork that they require and that paperwork be reduced to a minimum. Regulations creating new paperwork requirements must be cleared by OMB. Unfortunately, agency projections of paperwork burden are often underestimated and do not recognize how new reporting requirements will be paid for. The American Recovery and Reinvestment Act reporting requirements and the recently proposed NIH reporting requirements related to financial conflicts of interest are two notable examples. In cases in which new requirements are not effectively controlled to minimize the imposition of additional and sometimes substantial new costs, institutions should be allowed to establish a cost reimbursement mechanism in which the incremental costs can be recovered as a direct charge to the federal award.

Finally, cost sharing policies that are appropriate for the research community and that differentiate universities from for-profit entities should be developed. Although a cost sharing commitment between government agencies and industry partners may be appropriate, requiring the same commitment from university partners ignores universities’ educational and public service roles and their nonprofit status.
The President’s Council of Advisors on Science and Technology, in a 2010 report on energy R&D, recommended that universities be exempted from cost sharing requirements. The National Science Foundation (NSF) recently implemented a new policy that prohibits voluntary cost sharing on NSF programs, while also reaffirming its policy that mandatory cost sharing be required only in exceptional situations where it is necessary for long-term program success. Congress and other research funding agencies should follow NSF’s lead and prohibit cost sharing policies that inappropriately impose additional costs on universities.

To better address regulatory issues at research universities, we need new and more timely and flexible mechanisms for universities and associations to work with federal officials. We have proposed a set of recommendations that would begin to establish these mechanisms. Only by working together can research universities and the federal government reach the shared goal of reducing undue regulatory requirements while maintaining safety and accountability. A more balanced regulatory load would help ease financial burdens on universities and improve the morale and productivity of the researchers whose discoveries and innovations will drive our nation’s economy in this century.

**Recommended reading**


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