Council on Governmental Relations
Association of American Universities

April 13, 2011

Christina E. McDonald
Acting Associate General Counsel for Regulatory Affairs
Department of Homeland Security
Office of the General Counsel
245 Murray Lane, Mail Stop 0485
Washington DC 20528-0485

SUBJECT: Reducing Regulatory Burden: Retrospective Review Under Executive Order 13563

Dear Ms. McDonald:

The Council on Governmental Relations (COGR) is an association of over 180 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. The Association of American Universities (AAU) is an association of 61 leading public and private U.S. research institutions. AAU focuses on issues important to research intensive universities, such as funding for research, research policy issues, and graduate education.

Our member institutions conduct over $55 billion in research and development activities each year and play a major role in performing basic research on behalf of the federal government. The research institutions represented by COGR and AAU receive support from more than 26 federal agencies through a variety of funding mechanisms, grants, contracts, cooperative agreements, etc. Our associations, therefore, bring a unique perspective to the question of regulatory burdens as we struggle to ensure compliance with each agency's multiple rules, regulations, and guidance.

We are encouraged that President Obama has asked the federal agencies to conduct this retrospective review of existing rules to assess which should be maintained, modified, strengthened or repealed to increase efficiencies and decrease burden. Research institutions seek to find a balance between achieving regulatory compliance and conducting research. We have advocated for a fundamental examination and evaluation of the current relationship between research institutions and the federal government to strengthen and, in some cases, repair the relationship to ensure increased productivity. One of the key aspects of this assessment is regulatory reform.

Recommendations to the National Research Council

As a part of this call for change, COGR and AAU joined with the Association of Public and Land-grant Universities (APLU) to prepare recommendations to the National Research Council's (NRC) ongoing Committee on Research Universities' examination of actions that can be taken by all stakeholders to assure the ability of the American research university to maintain excellence in research and doctoral education. A copy of the joint Association response is attached here for your information.

The recommendations address principles that are articulated in Executive Order (EO) 13563, most notably the need for coordination and harmonization, as appropriate; the burden of cumulative, prescriptive regulations; and the need for a balance between regulation and flexibility in the performance of work under a federal grant or contract. Specifically, the recommendations call for harmonization of regulations and information systems across agencies to eliminate duplication and redundancy; elimination of regulations that do not add value or enhance accountability; and designing regulations that set performance goals rather than simply procedural compliance.

The recommendations address financial reforms as well because of the unique challenges faced by research universities under the severe limitations imposed by a cap on the recovery of our facilities and administrative (F&A) costs when conducting research for federal agencies. This cap results in a situation where every new regulation is an unfunded mandate placed on the university.

Principles for Improving Regulations

The principles that informed our recommendations to the NRC echo the principles for improving regulations outlined in EO 13563 and more fully described in the guidance provided by the Office of Management and Budget to the federal agencies.

We need consistent, harmonized performance-based standards in regulatory programs across the agencies and for all funding mechanisms. The principles of coordination and harmonization across agencies and establishing performance objectives rather than prescriptive compliance requirements were first articulated in EO 12866 and are reiterated in EO 13563. Agencies frequently pledge to harmonize but then do not implement the appropriate common forms, rules, etc. to achieve that goal.

EO 13563 calls for an assessment of the burden and related costs of cumulative regulations on the affected communities. As OMB notes in its guidance, simplification and harmonization are critical components of a regulatory program because "regulated entities might be subject to requirements that, even if individually justified, may have a cumulative effect imposing undue, unduly complex or inconsistent burdens." This is a particular concern for research institutions who engage in research with multiple federal agencies. The stacking of regulations within and across agencies increases the burden without any apparent benefit and in many cases results in increased costs and decreased research productivity. Specifically, agencies are asked to promote coordination and integration among agencies to reduce redundancy, inconsistency or overlapping requirements and begin to address the significant growth in the number of overly burdensome regulatory requirements. No single regulation may meet the threshold of significance required to trigger increased scrutiny under the Paperwork Reduction Act, Regulatory Flexibility Act and/or Administrative Procedures Act, but the cumulative impact of each unique agency regulation significantly increases the overall costs of doing business.

We believe before any regulation is implemented, agencies should do a risk assessment to determine whether requirements can be tiered by risk to prevent over-regulation across activities. Whether to prevent fraud, control toxic agents, or ensure the protection of human subjects, agencies should determine the

situations and/or organizations that pose the highest risks for non-compliance. OMB should then design requirements that apply the appropriate level of control to the affected communities.

These principles inform the comments that COGR and AAU offer on new regulations, policies, or guidance.

Recommendations for the Department of Homeland Security (DHS)

Chemical Facilities Anti-Terrorism Standards **(CFATS – 6 CFR Part 27):**

Since 2007, the research community has urged the Department of Homeland Security (DHS) to reconsider the application of CFATS to research laboratories. The current regulations fail to recognize the differences between research laboratories and major chemical manufacturing and production facilities, including how chemicals are used and stored for research purposes. Unlike major chemical manufacturing and production facilities, which store large volumes of toxic substances, research laboratories generally have no such concentrated volumes of these substances. Rather, they distribute the regulated Chemicals of Interest (COI) in very small quantities, among multiple 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.

We believe research laboratories – non-production research laboratories with similar chemical use patterns located at non-commercial, non-profit research organizations and institutes such as colleges and universities – should be regulated differently. These laboratories use chemicals differently than do major chemical manufacturing and production organizations, e.g., in highly distributed environments using very small quantities of a diverse chemical inventory maintained for short periods of time.

DHS should secure these facilities by establishing separate but robust standards, protocols, and procedures for assessing vulnerabilities and improving the security of COI in a research setting. Based on our experience in complying with federal regulations governing health, safety, and security, including those issued by OSHA, CDC, EPA, USDA, and the NRC, we have found that such regulations best achieve their goals when the standards and procedures they establish reflect the nature of our chemical use. Several federal agencies have established separate, and successful, standards for research laboratories. These include separate chemical safety regulations at OSHA and separate hazardous waste management regulations at EPA, both of which are distinct from those applied to industrial production and other facilities.

The Department should take an approach that focuses specifically on at-risk laboratories, not the entire campus. The current CFATS regulations take an inappropriately broad look at our campuses and treat an entire campus as a single entity. Although CFATS allows some flexibility in defining the boundaries of their facilities for the purposes of the initial Top Screen, they are required to develop site security plans or alternative security plans in the aggregate and may not be developed specifically for a lab or unit operation. The security requirements should apply only to the individual laboratories where chemicals of interest exist in quantities greater than the threshold planning quantity.

US Citizenship and Immigration Services Changes to the *I-129 Form*

On April 9, 2010 and again on July 29, 2010, our associations jointly submitted comments to the U.S. Citizenship and Immigration Service (USCIS) concerning the addition of a "Deemed Export Acknowledgement" certification to the I-129 Form. Despite objections from the research community, as well as the broader employer community, USCIS choose to proceed with the implementation of this *Certification Regarding the Release of Controlled Technology or Technical Data to Foreign Persons in the United States* on February 20, 2011. As a result, I-129 petitioners now have to complete a new Part 6 certification for H-1B visas and certain other specialty occupation visa petitions.

This new attestation requirement remains a concern for the research university community for the following reasons:

1. As stated in the 2010 comment letters, USCIS has no regulatory authority or jurisdiction over the enforcement of export control regulations. The Export Administration Act of 1979 (as extended by Presidential Executive Orders under the International Emergency Economic Powers Act) and the Arms Export Control Act grant the U.S. Departments of Commerce and State regulatory authority over export control regulations.

   At the direction of President Obama, the National Economic Council and the National Security Council began a review of the nation's export control policies last year. From our perspective the implementation of the Deemed Export attestation is not only premature, it directly contradicts the goals of the Administration's current export control reform efforts and those announced as a part of the retrospective review of regulations requested in EO 13563.

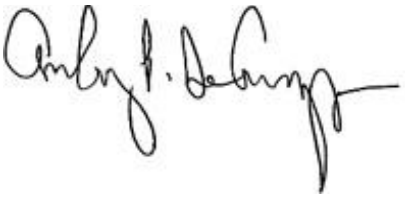
2. As we also stated in our comment letters to USCIS, the new attestation requirement increases university costs, requiring additional personnel time to adequately review the potential activities of all H-1B visa applicants and other specialty visas for individuals who are hosted by colleges and universities.

3. There is no clear justification for these additional costs and burdens. Government representatives have cited a series of reports on export controls by the U.S. Government Accountability Office (GAO) as a major factor in establishing this new certification. The most recent of these reports (GAO-11-354) in February updates a 2002 report on deemed exports and reiterates that DHS immigration data should be used to identify foreign nationals who could be subject to deemed export licensing regulations. However, the apparent rationale for this recommendation is a simplistic comparison of the number of specialty occupation visas issued to foreign nationals from 13 countries of concern with the number of deemed export licenses issued to foreign nationals from these countries over a recent five-year time period. This comparison yielded a relatively small percentage (0.3 percent) of deemed export licenses compared to the number of specialty occupation visas. While the report acknowledges that there is no requirement that a foreign national who holds a specialty occupation visa also be covered by a deemed export license, GAO apparently believes that this low percentage implies some degree of risk that has not been properly assessed.

In fact, our universities receive a large number of H-1B and other specialty occupation visitors in science and engineering fields for whom deemed export licenses are not required because they are covered by various exclusions or exemptions from license requirements, such as those engaged in fundamental research or educational activities. The GAO report contains no discussion of the reasons why deemed export licenses may not be required, even though the authors of the report participated in several meetings with university representatives to discuss these issues. According to the report, Commerce concluded that the proportion of deemed exports is about the right order of magnitude since it is roughly the same as the proportion of deemed export licenses to licenses for actual physical exports. The report asserts that Commerce provided no rationale for why this ratio should be relevant. However, we note that GAO also fails to provide any rationale for why GAO considers its comparison to be more meaningful. In our view the GAO findings provide a dubious basis and unsubstantiated for policymaking in this area.

While the university community disagrees with this new deemed export attestation requirement and questions its rationale and value, we are equally concerned with the manner in which it is being implemented. In the last few months, we have received disturbing reports from our member institutions concerning the implementation of this new requirement. While this attestation only applies to H-1B and certain H-1B1, L-1, and O-1A visa petitioners, we understand that the Department of State's Consular Affairs Officers may, in some cases, be requiring that petitioners for J-1 student visas prove that they are not required to have a Deemed Export license. Our information is that in some instances, J-1 visa applicants are being required to show that they have paid the fee for the license. The research community is very concerned about this issue and strongly encourages DHS and USCIS to provide the appropriate information and training to State Department officials, and specifically its consular affairs officers, concerning the implementation of this new requirement.

We appreciate DHS providing this opportunity for public participation and hope to have additional opportunities for participation as the agency constructs its initial list of regulations to be reviewed under EO 13563.



Anthony P. DeCrappeo
President
Council on Governmental Relations

Robert M. Berdahl
Presdient
Association of American Universities

Attachment (1)

cc: Cass Sunstein, Office of Management and Budget

AAU *Association of American Universities*
APLU *Association of Public and Land-grant Universities*
COGR *Council on Governmental Relations*

Regulatory and Financial Reform of Federal Research Policy
Recommendations to the NRC Committee on Research Universities
January 21, 2011

Introduction

At the request of the National Research Council (NRC) Committee on Research Universities, the Council on Governmental Relations (COGR), the Association of American Universities (AAU), and the Association of Public and Land-grant Universities (APLU) have assembled a set of ten recommendations for regulatory reform that would improve research universities' ability to carry out their missions without requiring a significant financial investment by the Federal government.

We firmly believe that compliance and regulatory oversight are essential to the conduct of federally-supported research. Rationalizing the Federal regulatory infrastructure is essential to the health of the university-government research partnership and to the efficient and productive use of federal research funding. Research universities strongly support the objectives of accountability, transparency, and implementation of important policy and regulatory requirements. However, the current regulatory climate has become dysfunctional – regulations do not align closely with true risk, and new regulatory mandates are unfunded due to the 26-percent cap on reimbursement of administrative costs. It is a growing fiscal challenge for universities to manage unfunded mandates as institutional budgets are being reduced, administrative cost reimbursements are being suppressed, and cost-sharing requirements are increasing.

Implementation of the recommendations made by COGR, AAU, and APLU should allow research universities to enhance their productivity and reduce compliance costs. Minimizing administrative and compliance costs ultimately will provide a cost benefit to the Federal government and to university administrators, faculty, and students by freeing up resources and time to directly support educational and research efforts.

Over the past few months, our organizations have submitted other materials to the committee that discuss the growth of regulatory compliance and reporting requirements on research universities and the need for those costs to be reimbursed appropriately by the Federal government in ways that will maximize faculty research productivity. Specifically, our associations have either individually or collectively recommended that:

- *OMB fully enforce existing cost-reimbursement rules and prohibit federal agencies from practices and/or policies inconsistent with Federal cost principles.*
- *OMB ensure that rate setting practices by government negotiators are consistent and fair across all institutions.*
- *Researchers be allowed to charge some level of administrative and compliance support directly to their Federal grants and contracts.*
- *The current 26 percent cap on the administrative cost reimbursement rate be adjusted to account for increasing Federal compliance costs.*

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Recommendations

In addition to the prior recommendations we have made concerning steps that can be taken to ensure that the Federal government and other research sponsors equitably share in the costs of research, we also recommend significant regulatory reform. Quantifying the burdens associated with specific regulations is difficult, though we provide anecdotal information in Appendix A. The larger issue is the accretion of regulatory burdens and the increase in overall compliance costs over time.

While we are able to identify several regulations for outright elimination, it is often difficult to isolate or object to one regulation or category of requirements. Instead, it is the proliferation of those requirements and their uneven and unsynchronized implementation across many Federal agencies that create a compliance miasma. In this environment, universities are often forced to institute one agency's compliance requirements across an entire campus, even where they don't make sense, and to sift through each agency's specific rules and develop different compliance mechanisms all aimed at the same ultimate purpose.

COGR, AAU, and APLU make the following ten recommendations which are not necessarily in order of priority:[1]

1) *Harmonize regulations and information systems between agencies and statutes where reasonable and eliminate unnecessary duplication and redundancy*. University research is funded by 25 different Federal agencies, each with a unique approach to regulatory implementation. While regulations concerning areas like human subject protections, animal welfare, export controls, select agents, responsible conduct of research, and financial conflicts of interest all serve important public policy goals, unique interpretations and implementations across agencies are difficult to manage, create inefficiencies, and increase costs. Additional challenges occur when rules applicable to grants (established by OMB) are inconsistent with rules applicable to contracts (established under the Federal Acquisition Regulations Councils).

2) *Eliminate regulations which do not add value or enhance accountability.* At least two requirements, Effort Reporting and Cost Accounting Standards, neither add value nor enhance accountability. As characterized by the Federal Demonstration Project, 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."[2] Cost Accounting Standards require institutions to disclose in writing accounting policies that are already documented in other institutional systems. Both of these regulations could be eliminated without any detriment to the accountability or oversight of the research enterprise. As other valueless regulations are indentified, there should be a formal process in which each can be reviewed and made eligible for elimination.

3) *Provide targeted exemptions for research universities similar to protections provided for small entities under the Regulatory Flexibility Act (RFA).* The RFA requires agencies to prepare and

[1] More specific suggestions relating to some of these recommendations are contained in Appendix B.
[2] Federal Demonstration Project, "Payroll Certifications: A Proposed Alternative to Effort Reporting." January 3, 2011, p.3. (see: http://sites.nationalacademies.org/PGA/fdp/PGA_055834)

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 could be amended to include organizations engaged in conducting Federally sponsored research. For example, the Chemical Facilities and Anti-Terrorism Standards (CFATS) capture universities in the same class with chemical manufacturers and industrial agricultural corporations, requiring identical policy and procedure implementation and reporting. In a similar vein, the cumbersome export controls promulgated by the Departments of State and Commerce, even while currently undergoing much needed revision, fail to recognize the fundamental difference between the physical export of very sensitive technologies to a foreign country and the legitimate sharing of information at U.S. universities between U.S. researchers and foreign nationals.

4) *Ensure that regulations are meeting their goals in terms of performance, rather than simply in terms of process*. Research universities support the objectives of implementing important policy and regulatory requirements – research institutions take their stewardship responsibilities seriously. However, when implementation of regulation is premised on overly prescriptive measures issued by agencies, and subject to audit by Federal and local auditors, institutional management of regulation becomes grossly complex and expensive. "Performance-based regulatory compliance" focuses on regulatory outcomes (e.g., research animals are treated in a humane manner) rather than intermediate measurements (e.g., all holding areas must meet specific dimensions). A regulatory approach that is based on performance-based standards offer universities greater flexibility to achieve regulatory goals and results in a more rational and cost-effective regulatory infrastructure.

5) *Extend coverage provided under the Unfunded Mandates Reform Act (UMRA) to research universities and allow institutions to better account for new regulatory costs, and to charge these costs to Federal awards.* 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 Environmental Protection Agency's development of Subpart K of the hazardous waste regulations is a notable exception). 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 universities would result in agencies being more responsive to the cost burdens of new requirements.

   Additionally, the Paperwork Reduction Act (PRA) 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 the paperwork burden are often underestimated and do not recognize how new reporting requirements will be paid for. (American Recovery and Reinvestment Act reporting requirements and the recently proposed NIH reporting requirements related to financial conflicts of interest are two notable examples.) Suggestions by federal officials that indirect cost reimbursements will pay for new regulatory costs fail to recognize that the 26 percent administrative cap precludes additional recovery of these costs. In situations when new

requirements are not effectively controlled to minimize cost burden, 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.

6) *Simplify sub-recipient monitoring requirements*. Sub-recipient monitoring requirements continue to expand under both regulatory and statutory mandates. While there may be value to monitoring sub-recipients that are not established recipients of Federal funding, to monitor sub-recipients (e.g., other research universities) that regularly receive Federal awards is a wasteful exercise and should be eliminated. A monitoring requirement that would apply only to those sub-recipients that are not Federal awardees would be a logical improvement.

7) *Reinforce the original intent of the Single Audit Act*. Research universities spend significant money on an annual basis to complete their A-133 audit as required under the Single Audit Act. Results of the A-133 audit provide assurance to Federal agencies that an institution's internal controls, oversight, and compliance infrastructure are adequate to manage Federal funds. While agencies should conduct program expenditure audits in those situations deemed necessary, many agency audits and reviews are duplicative of the audit work completed in the A-133 audit. All agency audits and reviews should be subject to pre-approval by the Federal Ombudsman (see Recommendation #10) to determine which aspects of a proposed audit or review are duplicative of the A-133 audit. Those aspects of the proposed audit or review that are duplicative should be eliminated from the scope of the audit.

8) *Prohibit voluntary committed cost sharing across the Federal government and create a mandatory cost sharing exemption for research universities.* Based on a 2009 recommendation by the National Science Board (NSB), the National Science Foundation (NSF) has implemented a new policy that prohibits voluntary cost sharing on all NSF programs. The NSF policy should be implemented by all agencies that fund research since such cost sharing inappropriately imposes additional costs on universities and frequently is not truly voluntary.

   The 2009 NSB recommendation encourages mandatory cost sharing requirements only for a small subset of NSF programs – specifically, programs where it has been determined that an institutional commitment is critical to long-term program success, as well as programs built on partnerships with industry and state and local governments. Programs sponsored by other agencies should be subject to similar scrutiny before mandatory cost sharing can be imposed. For example, the Department of Energy has a long history of requiring a mandatory cost share commitment with its industry partners. While this may be an appropriate expectation of for-profit industry enterprises, to require the same commitment from university partners ignores both the public policy role and the non-profit status of research universities. Exempting research universities from mandatory cost sharing requirements would be an important step forward.

9) *Establish protocols 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 by-product. When statutorily-mandated 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.

10) *Designate a high level official within OMB's Office of Regulatory Affairs (OIRA) to serve as a Federal Ombudsman, responsible for addressing university regulatory concerns and for seeking ways to increase regulatory efficiency.* This individual should be empowered with broad responsibilities to manage and minimize regulatory burdens applicable to research universities and institutions. The Ombudsman would assist in harmonizing and streamlining Federal regulations, and would also have responsibility for reviewing specific "simplification requests." Under the auspices of the National Science and Technology Council (NSTC), the Ombudsman – along with a designated representative from OSTP – should lead an interagency group charged with regularly reviewing regulations affecting research universities. This interagency group could be organized as a new subcommittee of the National Science and Technology Council (NSTC) 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 either add no value or promote inefficiency and excessive regulatory burden.

Conclusion

Implementation of these ten recommendations would help rationalize the regulatory environment in which research universities and institutions currently operate. COGR, AAU, and APLU are prepared to assist the National Research Council Committee on Research Universities in any manner that is appropriate to advance these ten recommendations.

Appendix A

Costs of Research Compliance

COGR, AAU, and APLU jointly requested information on compliance burdens and costs from our institutions, and present some of that information in this Appendix. It is important to note that there are caveats associated with this information and usually, it is difficult to answer the seemingly simple question, "How much does it cost universities to comply with any particular regulation?" with a precise number.

The cost of compliance frequently results from the time that faculty, staff, and administrators spend fulfilling compliance responsibilities. This results in both monetary costs and diversion of faculty time away from research and teaching, resulting in declines in productivity. Different universities account for this in different ways. Compliance burdens are spread throughout many different areas, and in some cases costs of compliance are difficult to split out from other associated costs of research.

Productivity declines are very difficult to measure. However, the Federal Demonstration Project has conducted a study that demonstrates that 42 percent of faculty time relating to the conduct of Federally funded research is now being spent on administrative duties, compared to only 18 percent two decades ago.[3] Some of this additional time is the result of increased activities relating to compliance with federal regulations.

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 instance, one university may conduct more Human Subjects studies, while another has more faculty researchers working with hazardous materials or select agents).

Our institutions agree, however, that overall compliance is a significant cost. For example, the Environmental Health & Safety office at one private university in the West reported that they spend approximately 70 percent of its total general fund budget in support of research safety and compliance in research.

COGR's compilation of Federal regulatory changes since 1991 shows the number of new and revised regulations with which universities must comply.[4] Our member institutions agree that compliance burdens have increased concomitantly during this time. One public university in the Northeast noted that the costs of managing its Sponsored Project Administration cost pool increased from $3.5 million in FY 2005 to nearly $6 million in FY 2010. Another, a private institution in the Midwest, estimated that its costs had increased from $4.2 million in 2002 to $7.3 million in 2008. A prominent medical school in the Southeast saw its compliance and quality assurance costs increase from approximately $3 million in 2000 to $12.5 million in 2010.

[3] See: http://sites.nationalacademies.org/PGA/fdp/index.htm.
[4] Council on Governmental Relations, "Federal Regulatory Changes Since 1991," (see: http://www.cogr.edu/viewDoc.cfm?DocID=151793.

Perhaps more telling than the numbers themselves is a comparison of the rate of increase in compliance costs to other cost increases. For that same prominent Southeastern medical school, compliance and quality assurance costs exhibited a cumulative growth rate of more than 300 percent between 2001 and 2010, while sponsored expenditures increased by only 125 percent during that same time. An urban public university in the West reported that its Sponsored Project Administration costs allocated to the administrative component of its F&A rate increased 86 percent from 2001 to 2009, while its direct expenditures increased only 53 percent during the same time period. A private university in the South told us that its research-related administrative costs increased by nearly 120 percent between FY 2002 and FY 2010, whereas its direct expenditures had increased by less than 100 percent. No data that we received ran contrary to these trends.

Some specific compliance areas have relatively large costs associated with them. For example, virtually every institution that responded to our request for information identified effort reporting as an area that has had significant cost and productivity implications. Effort reporting requires significant faculty and staff time, which was difficult for many universities to quantify.

Effort reporting also requires administrative time. One public university in the Midwest told us that nine separate full-time employees (FTEs) spend approximately one quarter of their time each year monitoring certifications, at a total estimated cost per year of $117,000. Another public university, this one in the West, estimated its annual central administrative cost was $320,000, with an additional department administrative staff and faculty cost of $241,000.

For many schools, effort reporting also required the development or purchase, and the continuing maintenance of, specialized software systems. A public university in the Midwest reported that the last estimate to purchase necessary software from an external vendor was over $500,000, exclusive of all the implementation and training costs devoted to it. A public university in the West estimated the cost of its system at $435,000 annually. System implementation for a private university in the South cost $443,000.

One private university in the Midwest estimated that on its campus there are over 6,000 effort reports completed three times per year, resulting in more than 18,000 effort reports processed per year overall. Estimating that 60-90 minutes were spent on each effort report – including issuing instructions, completion by faculty and staff, administrative review, tracking, and storing – yields a conservative estimate of 20,000 hours per year spent on this process. Several universities reported that overall they spent in the range of $500,000 to nearly $1 million annually on effort reporting alone.

Other cost categories may seem small when considered individually but, as we have emphasized in this paper, it is the accretionary nature of regulations that make them so burdensome. In addition, even an increase in regulatory cost that is very small compared to a university's budget can be disproportionately burdensome if it overwhelms a university's existing infrastructure.

Universities have sometimes taken an especially conservative approach to Federal regulatory compliance, in part to ensure they avoid the hefty penalties that would be levied if an IG-ordered audit found them in noncompliance. This conservatism has also added to increased costs, with some universities even failing to take advantage of regulatory exceptions for fear of regulatory non-compliance.

The Federal government needs to help universities ensure they are complying with regulations in the most efficient way possible. It also needs to assist universities in helping assess the costs associated with regulation. Finally, working with universities, a serious attempt should be made by the Federal government to better account for, track, and reduce regulatory costs.

Appendix B

Specific Suggestions for Easing Compliance Burdens on Research Universities

This table lists remedies for some examples of regulatory burdens faced by our institutions. This is by no means a comprehensive list. Columns in the table represent types of suggested remedies for regulatory issues. Rows in the table represent categories of regulation. Note that most categories require a mix of regulatory remedies.

	Exempt universities or eliminate	Harmonize/avoid duplication and redundancy	Tier to risk	Focus on performance, not process	Better synch with university R&D
Human subjects		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.	Tier human subjects research for exemption from IRB review (e.g., social science research vs. clinical trials).		
Animal research			Consult on whether the Animal Enterprise Terrorism Act (AETA) provides sufficient protection for animal researchers.		

	Exempt universities or eliminate	Harmonize/avoid duplication and redundancy	Tier to risk	Focus on performance, not process	Better synch with university R&D
Export Controls	Eliminate new regulations requiring deemed export certification for certain visa applications (I-129 form).	Harmonize ITAR, EAR, and OFAC controls.	Tier export control lists to risk, removing much of what is currently on these lists or reclassify to lower their control levels.		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.
Effort Reporting	Eliminate effort reporting.				
Financial Reporting	Expanded Form 1099 Reporting Requirements will create an additional burden on financial reporting.		Sub-recipient monitoring: modify requirement so that grantees would no longer be required to monitor sub-recipients who regularly receive Federal awards.		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. Change timing of Quarterly Cash Transaction Report – revised timing has put a strain on reporting resources, and it's not clear how the government benefits from getting the data two weeks earlier. The old 45 day timing has been around for at least 20 years.

	Exempt universities or eliminate	Harmonize/avoid duplication and redundancy	Tier to risk	Focus on performance, not process	Better synch with university R&D
Conflict of Interest/Research Integrity	Eliminate negative patent reports, which require form completion even when there are no intellectual property concerns.			Direct OSTP to convene agencies to develop a conflict of interest policy like the Misconduct in Science Policy, which articulates general goals and objectives.	
Select Toxins and Agents			Develop a tiered list and associated requirements, as has been documented by the American Society of Microbiology.		
Hazardous Materials	CFATS: wherever possible, create an exception for research laboratories.		CFATS: tier chemicals of interest to risk when exemption isn't possible.		Examine and consider university facilities as different from large chemical facilities: design alternative approaches in light of these differences.