CPI Meeting Agenda
August 8, 2012 (11:30 a.m. – 1:15 p.m.)
Rudder Tower, room 601

(11:30 – 11:45) Lunch

(11:45 – 11:55) Call to Order/Opening Remarks: (Moderated by L. Rauchwerger)

15.01.03 – Ms. Kristen L. Worman, Assistant General Counsel, Office of General Counsel, The Texas A&M University System

(12:10 – 12:20) Open Forum Discussion: (Moderated by L. Rauchwerger)

(12:20 – 12:30) Recognition of outgoing Council Members and Members of the 2011-12 Executive Committee; closing remarks – Dr. Lawrence Rauchwerger, 2011-12 CPI Chair

(12:30 – 12:40) Open Forum Discussion / Installation of 2012-13 CPI Officers (Moderated by L. Rauchwerger)

(12:40 – 12:50) Recognition of incoming Council Members (terms beginning September 1, 2012); preparations for 2012-13 CPI Session; request for recommendations for 2012-13 Executive Committee; closed session/planning meeting on September 12, 2012; closing remarks – Dr. Reza Langari, 2012-13 CPI Chair

(12:50 – 1:05) Update on June 27, 2012 speech to Congress – Dr. Jeffrey R. Seemann, Vice President for Research, Texas A&M University, and Chief Research Officer, The Texas A&M University System

(1:05 – 1:15) Open Forum Discussion: (Moderated by L. Rauchwerger)

(1:15) Adjournment
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III. Slides – 2011-12 Outgoing CPI Members and Executive Committee; 2012-13 Incoming CPI Members (pp. 11 – 18)

IV. Presentation Slides – The Role of Research Universities in Securing America’s Future Prosperity: Challenges and Expectations (pp. 19 – 20)

V. Recommendations for Regulatory Relief (pp. 22 – 32)
Included in this issue are updates/information on:

- Summary of July 11, 2012 CPI meeting
- Summary of July 11, 2012 CPI EC meeting with the President, Provost and VPR
- Summary of August 1, 2012 CPI EC meeting with meeting research administration representatives from Texas A&M, AgriLife Research, HSC, TEES and TTI
- Preview of September 12, 2012 Closed Session CPI Meeting
- Memorandum: New Financial Conflict of Interest Requirements in Research
- Limited Submission Proposals: Partnerships for Innovation – Building Innovation Capacity (PFI:BIC); and Science, Technology, Engineering and Mathematics Talent Expansion Program (STEP)
- Increasing Investment in Research - New Formula for the Distribution of Indirect Cost for Sponsored Research Grants and Contracts Awarded to Texas A&M University
- Task Force on Research Data Stewardship at Texas A&M University
- Maestro Off-line for Upgrades from August 9 – August 13, 2012
- Chancellor to Announce New Research Fund
- Registration Open for NCURA TV Workshop for August 23, 2012 – Export Controls

Summary of July 11, 2012 CPI Meeting

At the July 11, 2012 CPI meeting (held in Rudder 601 from 11:30-1:15 p.m.), Dr. James Moore, Carolyn S. and Tommie E. Lohman '59 Professor of Biomedical Engineering and Chair of the System Intellectual Property Constituent Committee (IPCC), provided an overview of proposed changes to TAMUS Policies 17.01 (IP management) and 31.05 (external employment); TAMUS Regulation 31.05.01 (faculty consulting); and the IPCC’s comments on the proposed revisions. Dr. Terry Thomas, Chair of the OSRS PI/Faculty Advisory Committee (PIFAC) will provide an update on PIFAC activities. The agenda, meeting materials, and video are available at http://cpi.tamu.edu/archives/meetingmaterials/2011_12meetings#7.11.12.

Summary of July 11, 2012 CPI EC meeting with the President, Provost and VPR

The CPI EC held its coordination meeting with the President, Provost and VPR on July 11, 2012 from 1:30 – 2:30 p.m. in the President’s Conference Room, 10th floor Rudder Tower. Attendees discussed the following: Texas A&M Center for Innovation; purchase of the Texas Wesleyan School of Law; update on outsourcing; and the proposed merger of Texas A&M University and the Texas A&M Health Science Center.

Summary of August 1, 2012 CPI EC meeting with meeting research administration representatives from Texas A&M, AgriLife Research, HSC, TEES and TTI

The CPI Executive Committee (EC) held its monthly coordination meeting on August 1, 2012 from 11:30-1:15 p.m. Research administration representatives from Texas A&M, AgriLife Research, HSC, TEES and TTI are invited to these coordination meetings. Attendees discussed the following: updates on conflict of interest and
the disclosure process; request for CPI feedback on the Draft Interim Consulting Approval Guidelines; update on the Management Review (MGT Consulting Report) of The Texas A&M University System Offices; plans for the 2012-13 CPI session and proposed selection of new executive committee members; agenda items for the August 8, 2012 CPI EC meeting with the President and VPR; suggestions for the August CPI newsletter; and an overview of the last meeting of the 2011-12 CPI session on August 8, 2012.

Preview of closed session September 12, 2012 CPI Meeting

The first meeting of the 2012-13 CPI session will be held in closed/executive session (elected CPI members only) on September 12, 2012 in Rudder Tower, room 601 from 11:30 – 1:15 p.m. At this meeting the 2012-13 Chair and Council members will discuss strategic plans to address critical issues affecting the research community; mechanisms to more fluidly communicate with the PI community; and opportunities to provide regularly scheduled reports at monthly CPI meetings on behalf of PI constituents. The next open CPI meeting will be held on October 10, 2012 in Rudder Tower, room 601 from 11:30 – 1:15 p.m. Click here to view the full 2012-13 CPI meeting schedule.

Memorandum: New Financial Conflict of Interest Requirements in Research

The Texas A&M University System recently developed and approved a new regulation, 15.01.03, Financial Conflict of Interest in Research, in the wake of new federal regulations from the U.S. Department of Health and Human Services (HHS).

The Office of the Vice President for Research distributed a memorandum to the Texas A&M research community on August 3, 2012, regarding the new financial conflict of interest requirements in research. The full memorandum is available at http://e2.ma/message/71bfd/75yzvd.

Limited Submission Proposals: Partnerships for Innovation – Building Innovation Capacity (PFI:BIC); and Science, Technology, Engineering and Mathematics Talent Expansion Program (STEP)

Information on the Partnerships for Innovation – Building Innovation Capacity (PFI:BIC) limited submission funding opportunity for Texas A&M University is available at http://www.nsf.gov/pubs/2012/nsf12578/nsf12578.htm. The deadline for email of intent is August 9, 2012 at 5:00 p.m. Include names of the PI and Co-PIs, title of internal proposal and a 1-3 sentence description of the project. Send email of intent to limitedsubmissions@tamu.edu.

Information on the Science, Technology, Engineering and Mathematics Talent Expansion Program (STEP) limited submission funding opportunity for Texas A&M University is available at http://www.nsf.gov/pubs/2011/nsf11550/nsf11550.pdf. The deadline for email of intent is August 8, 2012 at 5:00 p.m. Include names of the PI and Co-PIs, title of internal proposal and a 1-3 sentence description of the project. Send email of intent to limitedsubmissions@tamu.edu.

Contact:
Libby Pasciak, libbyp@tamu.edu or 979.845.1811

Increasing Investment in Research - New Formula for the Distribution of Indirect Cost for Sponsored Research Grants and Contracts Awarded to Texas A&M University

To help stimulate the growth of research and scholarship on campus, the formula for the distribution of indirect cost return earned on direct expenditures from sponsored research grants and contracts has been revamped. Details can be found at http://tx.ag/qch4u2.

Task Force on Research Data Stewardship at Texas A&M University

Council of Principal Investigators | August 2012 Newsletter
Dr. Jeffrey R. Seemann, Vice President for Research at Texas A&M University, has established a task force on research data stewardship at Texas A&M University. The charge of the task force includes:

- Identify, evaluate, and recommend changes to existing and/or available Texas A&M researcher services and administrative support; recommend ways to maximize existing resources to minimize impacts on an already constrained budget;
- Review policies and best practices at other peer research institutions, evaluate them for appropriateness at Texas A&M, and make recommendations accordingly.
- Define and make recommendations on University-wide roles and responsibilities for research data stewardship.
- Review current University rules on research data management and make recommendations for revising rules, implementing new rules, and/or instituting standard administrative procedures that may be needed.
- Review current procedures for tracking research data for the purpose of meeting commitments to research sponsors regarding retention, access, and other requirements on contracts and grants.

Ms. Carol J. Cantrell, Senior Associate Vice President for Research Administration, Division of Research, will serve as chair of this committee. CPI members serving on the task force include Dr. Lawrence Rauchwerger, Dr. Terry Thomas, and Ms. Sandy Tucker.

**Maestro Off-line for Upgrades from August 9 – August 13, 2012**

Maestro will be taken off line from 6:00 p.m. August 9 through 8:00 a.m. August 13 to allow for upgrades to the system. This will not affect the ability of your project administrator or proposal administrator to assist you with your projects or proposals.

Please contact your Proposal Administrator if you have any questions (see ). If all goes well, we should have the Maestro system back Monday morning.

**Chancellor to Announce New Research Fund**

http://www.texastribune.org/texas-education/higher-education/m-system-chancellor-announce-new-research-fund/

**Registration Open for NCURA TV Workshop for August 23, 2012 – Export Controls**

The Texas A&M University Division of Research will host a training workshop by the National Council of University Research Administrators (NCURA), Export Controls and Other Security Concerns, on Thursday, August 23, 2012, from 10:30 a.m. to 2:30 p.m., in 101A General Services Complex.

TAMUS Moderators will include: Lesa Feldhousen, Director of Conflict of Interest Management and Contract Liaison, Division of Research - TAMU; and Bradley Krugel, Research Compliance Coordinator, Office of Research Compliance & Biosafety, TAMU. The Workshop Guide will be made available at a later date.

Please register at http://vpr.tamu.edu/resources/researchadmin/resources/training/ncurareregistration by Monday, August 20, at 11 AM. To view by teleconference, contact TTVN at 979-862-2240 or ttvn-schedule@tamu.edu and use TTVN confirmation number #183069. Only Texas A&M System members may participate.

Contact:
Janet Killion, jkillion@tamu.edu
Welcome to the August 8, 2012 CPI meeting

Today’s agenda includes the following items:

• Financial Conflict of Interest in Research: 2012 Changes in Federal Law & System Regulation 15.01.03

• Recognition of Outgoing Officers, Executive Committee and Council Members; remarks by 2011-12 CPI Chair

• Introduction of Incoming CPI Members; remarks by 2012-13 CPI Chair

• Update on Dr. Jeffrey R. Seemann’s speech to Congress
Financial Conflict of Interest

2012 Changes in Federal Law
& System Regulation 15.01.03

Kristen Worman
Assistant General Counsel
kworman@tamus.edu
(979) 458-6124

Conflict of Interest: Why now?

Fracking researcher has ties to industry

The Texas A&M University System
Changes in Federal Law

- US Dep't of HHS adopted amendments to federal conflict of interest regulations:
  - PIs required to disclose Significant Financial Interests (SFIs) related to institutional responsibilities;
  - Institutional review to determine if FCOI exists;
  - Mandatory Training; and
  - Reporting and Management of FCOIs.

System Regulation 15.01.03

- Chancellor approved revisions to System Regulation 15.01.03:
  - Mirrors changes to federal law;
  - Applies to ALL research;
  - PIs disclose SFIs related to institutional responsibilities;
  - Member COI Official reviews disclosures;
  - Mandatory Training; and
  - Reporting and Management of FCOIs.
Useful Internet Links

- System Regulation 15.01.03
  [http://policies.tamus.edu/15-01-03.pdf](http://policies.tamus.edu/15-01-03.pdf)

- SFI Disclosure Form & Instructions
Texas A&M University COI Official

Lesa Feldhousen, Director
TAMU, Office of the Vice President for Research

coi@tamu.edu
(979) 862-7986

Questions?
Recognition of 2011-12 Outgoing CPI Members (College/Unit)

Presented by Dr. Lawrence Rauchwerger, 2011-12 CPI Chair
# 2011-12 Outgoing CPI Members (College/Unit)

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2011-12 CPI Officers (Chair, Chair-Elect, Past Chair) and Executive Committee Members & Activities

Presented by Dr. Lawrence Rauchwerger, 2011-12 CPI Chair

2011-12 CPI Officers (College/Unit)

Lawrence Rauchwerger, Chair (Engineering)
Reza Langari, Chair Elect (Engineering)
Terry Thomas, Past Chair (Science)
2011-12 Executive Committee – includes Officers (College/Unit)

Nancy Amato (Engineering)
Paul Hardin (Science)
Mary Meagher (Liberal Arts)
Niall Slowey (Geosciences)
Vernon Tesh (HSC-College of Medicine)
Heather Wilkinson (Agriculture & Life Sciences)
Jane Welsh (Veterinary Medicine & Biomedical Sciences)

Introduction of 2012-13 CPI Chair

Presented by Dr. Lawrence Rauchwerger, 2011-12 CPI Chair
2012-13 CPI Members Re-Elected to 2\textsuperscript{nd} Term (effective September 1, 2012)

Presented by Dr. Reza Langari, 2012-13 CPI Chair

2012-13 CPI Members Re-Elected to 2\textsuperscript{nd} Term (College/Unit)

Clinton Allred  
(Agriculture & Life Sciences)

Jean-Luc Guermond  
(Science)

Wolfgang Bangerth  
(Science)

Emil Straube  
(Science)

Mary Bryk  
(Agriculture & Life Sciences)

Terry Thomas  
(Science)
2012-13 Incoming CPI Members
(effective September 1, 2012)

Presented by Dr. Reza Langari, 2012-13 CPI Chair

2012-13 Incoming CPI Members
(College/Unit)

Evan Anderson
(Mays Business School)

Joe Arosh
(Veterinary Medicine & Biomedical Sciences)

Joseph Awika
(Agriculture & Life Sciences)

Jaime Grunlan
(Engineering)

Jeffrey Liew
(Education & Human Development)

Leyuan Liu
(HSC-IBT)

Weston Porter
(Veterinary Medicine & Biomedical Sciences)

Joseph Sturino
(Agriculture & Life Sciences)

Susanne Talcott
(Agriculture & Life Sciences)
Cont. - 2012-13 Incoming CPI Members (College/Unit)

Shuping Zhang
(Veterinary Medicine & Biomedical Sciences)

2012-13 CPI Officers (effective September 1, 2012) and remarks about 2012-13 CPI Session

Presented by Dr. Reza Langari, 2012-13 CPI Chair
2012-13 CPI Officers (College/Unit)

**Reza Langari, Chair**  
(Engineering)

**Niall Slowey, Chair Elect**  
(Oceanography)

**Lawrence Rauchwerger, Past Chair**  
(Engineering)
The Role of Research Universities in Securing America’s Future Prosperity: Challenges and Expectations

Hearing
Subcommittee on Research Science and Education
U.S. House of Representatives
June 27, 2012

Key Points at Hearing

• *Research universities* must take bold steps to prioritize investments and break down barriers to focus on grand research challenges.
• *Federal agencies* must continue, if not increase, support for research priorities.
• *Research universities* must take greater action to ensure that we utilize resources even more efficiently and transparently than we already do.
• *Federal agencies* and regulators must in turn act to reduce or eliminate unnecessary and overly burdensome regulatory and reporting obligations.
Texas A&M Activities Since

- Chairman Brooks requested that we focus on regulatory reform.
- Subcommittee staff met with Texas A&M after the hearing, asking us to take the lead.
- Worked with A&M’s D.C. Federal Relations office and AAU, APLU, and COGR (Council on Government Relations) to develop response to request for regulations that congress should consider “amending or repealing.”
- Texas A&M is playing a leadership role in seeing this through and receiving high-level recognition as an important Tier 1 player.
Thank you for attending today’s meeting.

The next CPI meeting, the first of the 2012-13 session, will be a closed executive session (elected CPI Members only) planning meeting on September 12, 2012 in Rudder 601.

*Activities and staff assistance for the CPI is provided through equal annual funding support by the Texas A&M University Division of Research, AgriLife Research, Texas A&M Health Science Center, Texas Engineering Experiment Station, and the Texas Transportation Institute.
Recommendations for Regulatory Relief

Texas A&M University, along with our colleagues at Association of American Universities (AAU), Association of Public and Land Grant Universities (APLU), and Council on Governmental Relations (COGR) support the objectives of accountability, transparency, and safety that generally motivate the creation of regulatory requirements. However, as the research performed at our institutions has become more complex, there has been a growth of requirements which are overly burdensome, redundant, ineffective, and/or inappropriately applied to universities. As a result, the costs of doing research have gone up and universities have had to do more with less. These overreaching regulatory requirements have further strained already-lean resources. A report prepared for the U.S. Commission on the Future of Higher Education states that, “there may already be more federal regulation of higher education than in most other industries.” An oft-cited statistic from the 2007 Federal Demonstration Partnership Faculty Burden Survey found that “42 percent of time spent on a research award is time spent on doing administration activities associated with the research award”, not on active research (http://sites.nationalacademies.org/PGA/fdp/index.htm). Thus, reducing regulatory burden can have a substantial, immediate impact by maximizing federal investments more directly into research priorities and allowing researchers’ time to be optimally utilized.

We believe the following recommendations for regulatory reform will have a high impact on the efficiency with which the university community can perform the cutting edge research that is so important to our nation’s economic future and security. These reforms are a subset of those mentioned in the National Academies’ report “Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Nation’s Prosperity and Security” (http://www.nap.edu/catalog.php?record_id=13396, see Box 5-7.1) and represent what we believe to be the “low hanging fruit” to produce impactful benefits. More detailed information on these and other recommended regulatory reform is given in the attached article (outlined specifically in Table 1 page 61).

1. **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 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, roundtables, and public hearing on the proposed rule. The RFA encourages tiering of government regulations or the identification of “significant alternatives” designed to make proposed rules less burdensome. As a result of the RFA, in FY 2009 federal agencies created less burdensome regulations resulting in the added benefit of saving small businesses some $7 billion in regulatory costs (http://archive.sba.gov/advo/laws/flex/09regflx.pdf). This
law could be amended to included organizations engaged in conducting federally sponsored research.

2. **Extend coverage provided in 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. The UMRA requires Congress and agencies to give special consideration of the costs and regulatory impact of new regulations on state and local governments, as well as on tribal entities. This Act was also intended to strengthen the partnership and communications between the federal government and these entities ([http://www.gsa.gov/portal/content/245277](http://www.gsa.gov/portal/content/245277)). Extending coverage to universities would result in agencies being more responsive to the cost burdens of new requirements.

Additionally, the Paperwork Reduction Act (PRA) was designed to minimize the paperwork burden for entities and maximize the public benefit resulting from the collection and requirement of information by or for the federal government ([http://www.archives.gov/federal-register/laws/paperwork-reduction/3501.html](http://www.archives.gov/federal-register/laws/paperwork-reduction/3501.html)). This Act also strives to strengthen the partnership between the federal government and the state, local, and tribal entities and 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 the Office of Management and Budget (OMB). Unfortunately, agency projections of the paperwork burden are often underestimated and do not recognize the methods by which new reporting requirements will be paid. Although for some entities indirect cost reimbursement could pay for new regulatory costs, the 26 percent administrative cap placed on universities precludes additional recovery of these costs.

Thus, ever-increasing regulation, coupled with no ability to recover the costs of these additional regulations above the current administrative cap, causes university administrations to buckle under the responsibilities of accepting federal funds. Indeed most universities’ indirect costs are, on average, significantly greater than the present reimbursement allowed under the 26 percent cap, due largely to federal regulatory requirements. 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. If recovery of the increased costs is not an option, then reduction of the burden by collecting and reviewing thoughtful feedback as to the impact of new regulations could prove to be very helpful to the research universities.
3. **Designate a high level official within OMB’s Office of Regulatory Affairs (OIRA) to serve as Federal Ombudsman, responsible for addressing university regulatory concerns for seeking ways to increase regulatory efficiency.** This official 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 request.” Under the auspices of the National Science and Technology Council (NSTC), the Ombudsman, along with a designated representative from the White House Office of Science and Technology Policy (OSTP), should lead an interagency group charged with regularly reviewing regulations affecting research universities. This interagency group could be organized as a new subcommittee or as part of the exiting Research Business Models Subcommittee. Through an application process, research universities or university associations could submit proposal to “fix” or eliminate rules that either add no value or promote inefficiency and excessive regulatory burden. The Ombudsman could be a critical point of contact to ensure frequent and effective contact between the federal government and the research university community.

4. **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. Efforts to provide such an approach would assist with the ongoing partnership with the federal government for continuous improvement. Additionally, proposed new legislation could be provided to the Ombudsman (discussed above in recommendation 3) to assist in determining and developing financial impact statements with and on behalf of the research universities.
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.
Darrell Issa (R-CA), the chairman of the House Committee on Oversight and Government Reform, sent a letter to nearly 200 companies, trade associations, and other organizations, requesting information on existing and proposed regulations that have negatively affected job growth, and soliciting suggestions on reforming regulations and the rule-making process. The committee received nearly 2,000 pages of responses.

University deservethe attention Higher education has largely been absent from recent governmental discussions of regulatory reform, despite evidence contained in a report prepared for the U.S. Commission on the Future of Higher Education that “there may already be more federal regulation of higher education than in most other industries.” As documented by Catholic University of America’s Office of General Counsel, more than 200 federal statutes affect higher education, and the list keeps growing. Sen. Lamar Alexander (R-TN) recognized this when he asked the National Research Council’s (NRC’s) Committee on Research Universities, at their November 2010 meeting, to identify ways to improve the health of U.S. research universities that would not cost the federal government money, pointing specifically at the problem of overregulation.

In addition to research, regulatory issues extend into universities’ educational activities. For example, the Government Accountability Office said in a 2010 report that the Department of Education underestimated the burdens placed on universities associated with mandatory reporting for the Integrated Postsecondary Education System. A 2010 survey of financial aid administrators by the National Association of Student Financial Aid Administrators found that 85% of respondents at institutions with enrollments of more than 1,000 identified greater regulatory compliance workloads as a major cause of current resource shortages.

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 economic 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%. No data that we received ran contrary to these trends.

It is important to note that this is not a case of adminis-
Heavy compliance burdens affect not only institutions, but also the morale and productivity of researchers within them.

trative inefficiency. University-wide administration and department 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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<tbody>
<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).</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>Eliminate Health Insurance Portability and Accountability Act (HIPAA) from research, or harmonize HIPAA regulations with OHRP regulations.</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>Federal Funding Accountability and Transparency Act (FFATA): Make reporting annual or eliminate more onerous requirements for universities.</td>
</tr>
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<td>Export controls</td>
<td>Eliminate new regulations requiring deemed export certification for certain visa applications (I-129 form).</td>
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<td>Effort reporting</td>
<td>Eliminate effort 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>
<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>
<td>Change timing of Quarterly Cash Transaction Report.</td>
</tr>
<tr>
<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>
<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>
<td>Change timing of Quarterly Cash Transaction Report.</td>
</tr>
<tr>
<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>
<td>Change timing of Quarterly Cash Transaction Report.</td>
</tr>
<tr>
<td>Select toxins and agents</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>
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<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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<td>Hazardous materials</td>
<td>CFATS: Wherever possible, create an exception for research laboratories.</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 export 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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