

**Congress of the United States
House of Representatives**

Committee on Science, Space, and Technology
Subcommittee on Research and Technology
The Honorable Barbara Comstock, Chairwoman

Written Testimony of

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**“Academic Research Regulatory Relief:
A Review of New Recommendations”**

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Introduction

Good Morning Subcommittee Chairwoman Comstock, Ranking Member Lipinski and members of the Subcommittee. My name is Jim Luther. I am the Associate Vice President for Finance and Research Compliance Officer at Duke University. I also serve as the Board Chair for the Council on Governmental Relations (COGR), an association of 190 research universities, affiliated medical centers and research institutes, and co-chair of the Federal Demonstration Partnership’s (FDP) Administrative Cost Working Group.

I would like to start by expressing my gratitude for the work of the [National Academies](#) and [Government Accountability Office](#) (GAO) and for this subcommittee’s interest in identifying opportunities to more effectively regulate research policy. Congress has long supported the U.S. research enterprise, providing [\\$62.9 billion](#) in funding for research in Fiscal Year (FY) 2014 alone. Members of Congress have also expressed concern about the amount of time and funding spent on administrative processes required for federally funded research and the desire to balance the need for oversight and transparency with facilitating research and maximizing the use of federal funds.

The National Academies and GAO reports that are the subject of today’s hearing join previous reports on this topic including the National Academies report [Research Universities and the Future of America](#), the

National Science Board report [*Reducing Investigators' Administrative Workload for Federally Funded Research*](#) and the Federal Demonstration Partnership [*Faculty Workload Surveys*](#). All have come to similar conclusions;

- that the regulation of research continues to steadily increase;
- that there is a lack of standardization of regulations, policies, guidance, systems and forms across agencies; and,
- that federally funded research could be regulated much more efficiently. Unfortunately the regulatory environment remains largely unchanged since the publication of these reports.

The return on investment of federal research dollars in terms of benefit to the United States cannot be argued. At Duke alone, we are advancing the cure for AIDS, making huge strides in cancer detection and cures, and advancing promising research in the area of national defense. Unfortunately, steady growth in federal regulatory requirements is impacting the productivity of the research enterprise. We are continually challenged as to how to cost-effectively ensure compliance with federal regulations while at the same time supporting the fundamental research.

Universities fully recognize the important role that regulations play to protect the taxpayer dollar, the research participant, and broad national interests. Universities are committed to working with federal partners to ensure effective oversight and efficient use of taxpayer funds. This commitment has led to a number of successes, including a thoughtful development and rollout of the Office of Management and Budget (OMB) Uniform Guidance, and we continue to work with OMB to overcome challenges in areas such as procurement and subrecipient monitoring, both of which are targeted for reform in pending legislation.

Successful engagement with federal regulators and sponsors has historically been heavily dependent on relationships with individual agency employees and trust that is established over time. These relationships can be extremely productive, but when the critical staff member departs, so does the productivity of the relationship. It is also frequently the case that the university perspective is not sought and that regulations do not include material changes recommended. This is noted in the Academies report with respect to the Public Health Services Conflict of Interest Regulations. Per the report, "The [Advance Notice of Proposed Rulemaking] ANPRM elicited a flood of critical comments from the research community, though these comments were not reflected in the Notice of Proposed Rulemaking (NPRM) issued a year later, nor in the final rule issued in August 2011..." Per the GAO report, the Department of Health and Human Services (HHS) plans to evaluate the effects of certain provisions of the regulation, but the status of this evaluation is unclear. COGR, the Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU) and the Association of American Medical Colleges (AAMC) have provided [data](#) and [information](#) demonstrating that the costs and negative impacts of the new rule far exceed what HHS anticipated and that minimal benefits have been achieved. The GAO report recommends that HHS "evaluate options for targeting requirements on areas of greatest risk for researcher conflicts, including adjusting the threshold and types of financial interests that need to be disclosed and the timing of disclosures."

Another example of regulations that do not include material changes recommended is the Common Rule. A [COGR-APLU analysis](#) of comments on proposed changes found that [74% of all responses](#) and approximately 96% of responses from patients and members of the research community opposed the

proposed changes to biospecimens on the grounds that they would be detrimental to research and health. This is consistent with [HHS findings](#) that a “strong majority of commenters oppose these proposals” with “opposition across all subgroups.” The Academies report suggests that the proposed revisions to the Common Rule are “marred by omissions, the absence of essential elements, and a lack of clarity,” “could be detrimental to areas of important research,” and should be withdrawn. COGR, its members, and advisory groups such as the HHS Secretary’s Advisory Committee on Human Research Protections have also called for the NPRM to be withdrawn. Yet we understand that HHS is still trying to move forward with a final rule for which many of the proposals remain unchanged from the ANPRM despite overwhelmingly negative comments. The Academies report recommends that a national commission be appointed to examine “the ethical, legal and institutional frameworks for protecting human research subjects” and that the regulations “not be revised until the national commission has issued its report” and stakeholders have had an opportunity to respond.

Compounding the issue of engagement is a significant increase in federal research regulations over the last two decades as demonstrated by the [COGR List of Regulatory Changes Since 1991](#) (attached) and figure 2-3 of the National Academies report, which suggests a rate of 5.8 new or substantially changed regulations annually. This month alone a new regulation on Clinical Trials results reporting; a National Institutes of Health (NIH) policy on Clinical Trials reporting; an NIH Good Clinical Practice training requirement; and the National Archives and Records Administration Controlled Unclassified Information Final Rule were issued. In June NIH issued its *Policy on the Use of a Single Institutional Review Board for Multi-Site Studies* and in May the Department of Labor issued its new salary rule. These new regulations and policies will cost each university anywhere from several hundred thousand to several million dollars and result in a significant increase in administrative and faculty workload. Many associated costs will not be reimbursed as administrative costs long ago exceeded the 26% threshold. At Duke we are approximately \$25 million over the threshold annually. This is not administrative bloat as we have significant budgetary controls that are carefully operationalized to limit administrative growth with an objective of maximizing programmatic spending. It is due to the increasing number of regulations and policies and the scope of the regulations, and it is not sustainable.

Regarding other major recommendations included in the National Academies report, COGR and AAU have strongly endorsed H.R. 5583, the [University Regulatory Streamlining and Harmonization Act of 2016](#) and [S. 2742 the Promoting Biomedical Research and Public Health For Patients Act](#). Both would create the Research Policy Board that is a centerpiece of the Academies recommendations, and the former, the appointment of an Associate Administrator for the Academic Research Enterprise for unified oversight as detailed in H.R. 5583.

H.R. 5583 proposes that the Research Policy Board be composed of federal and university officials charged with reviewing existing and proposed regulations with the goal of reducing regulatory burden. No mechanism currently exists to serve this function with respect to the research enterprise at large, but there are many examples of non-federal entities serving in a related capacity. The Cost Accounting Standards Board is a statutorily-established board that includes three federal members, a member from industry and a member from the accounting profession. Per the OMB website “The Board has the exclusive authority to make, promulgate and amend cost accounting standards and interpretations...”; the Health and Human Services Secretary’s Advisory Committee on Human Research Protections which includes non-federal members and ex-officio members representing federal agencies and serves an

advisory role to the HHS Secretary; the Patient Centered Outcomes Research Institute's Board of Governors which includes the NIH and Agency for Healthcare Research and Quality (AHRQ) directors as well as 17 non-federal members representing a range of stakeholders; and the National Science Board, whose members are drawn from universities and industry, which establishes the policies of the National Science Foundation. The National Academies report also highlights the Financial Accounting Standards Board under the Securities and Exchange Commission; the Advisory Committee on Intergovernmental Relations; panels under the Small Business Regulatory Enforcement Act; the Base Realignment and Closure Commission; and the Public Company Accounting Oversight Board.

Critical discussions with the research community coupled with congressional and GAO oversight would support mutual, inter-dependent accountability and increase the likelihood of achieving thoughtful and effective policy outcomes. This partnership is critical because universities' share of funding for research now constitutes 23.5% of total academic R&D. According to a [report](#) by the National Science Foundation's National Center for Science and Engineering Statistics, university funding for research and development rose 5.3% to \$15.8 billion in FY 2014 and has been the fastest-growing source for the past 5 years. As partner's in the federal research enterprise with extensive knowledge of the laws and regulations governing research and their implications for research and investigators, university administrators and associations are well-suited to the task of facilitating the efficient use of federal funds in research through participation in a Research Policy Board. It is critical to note that universities recognize the role that regulations play in our federal funding environment; we support clear, thoughtful, accountable and effective regulations that protect the taxpayer dollar and maximize results that lead to new discoveries and cures. But critical to the regulatory environment is thoughtful consideration for the direct as well as the unintended consequences related to new and expanded regulations.

At Duke, we have a senior leadership committee (RACI – Research Administration Continuous Improvement) that includes financial, administration, human resources, and faculty leadership whose sole focus is to evaluate and deploy solutions to better support our faculty and extend the effectiveness of research funding in a compliant manner. Further, we are evaluating a university version of a Research Policy Board that would review the burden impact of current "policy;" prioritize the development of new policy; harmonize existing policy across schools and offices; anticipate implications of proposed rules; and be an institutionalized venue for departments to raise concerns about burden and impact on faculty.

Similarly, COGR has developed a checklist that is already in use by some institutions to gauge whether each institution is adding layers of requirements in complying with federal regulations. All of this leads to conscious and deliberate decision-making focused on value, reducing burden and safeguarding sponsor funds. As a compliance officer and administrator at Duke, my job is to safeguard sponsor's funds, reduce administrative burden and then step aside and let the faculty focus on their work, but there is only so much that research universities can do. The bulk of the administrative burden results from federal regulations and policies.

With respect to other recommendations, both the Academies and GAO reports address the issues of procurement thresholds, subrecipient monitoring and conflict-of-interest. As the GAO report notes, "Despite efforts to allow universities more flexibility, as previously discussed, several administrative requirements—in particular, OMB requirements related to purchases (i.e., the micropurchase threshold)

and subrecipients and NIH requirements related to financial conflicts of interest—limit universities' flexibility and require them to allocate administrative resources toward oversight of lower-risk purchases, subrecipients, and financial interests." COGR supports the Academies recommendation to raise the micropurchase threshold and the legislation that would implement the recommendations, H.R. 5583. Currently there is no micropurchase threshold for procurement. OMB may propose changes to the Uniform Guidance in the next few weeks that would remove the threshold imposed by the 2014 Guidance. COGR also strongly supports the recommendation that OMB amend the Uniform Guidance to clarify that subrecipient monitoring requirements apply to institutions of higher education only to the extent necessary for prudent project and performance monitoring, and the language in H.R. 5583. COGR institutions also agree that OMB should amend the Uniform Guidance to establish a mandatory, consistent 120-day timetable for the submission of financial reports, and recommend that this be extended to all reports, financial, technical, property and others, required by the terms and conditions of the federal award. This would enhance institutional accuracy and compliance with close-out requirements without compromising federal efforts to ensure timely closeout of programs. The current requirement varies by sponsor and type of report requiring that the entire lifecycle of grant closeout be hyper-managed by administrators and faculty and requiring the development of processes to individually manage each deadline.

COGR and Duke University support the language in H.R. 5583 that would "examine the procedures of Federal science agencies regarding requirements for providing public access to the results of federally funded research and identify methods for reducing the burdens of compliance on funded researchers, university research administrators, publishers, and others impacted by agency public access policies." COGR member universities also fully agree with the Academies recommendations specific to Inspectors General. Identifying the full cost of audits and only posting findings following audit resolution would bring about necessary transparency. COGR also supports greater use of just-in-time submission of supplementary materials and harmonization of federal requirements as recommended in the Academies and GAO reports.

With respect to export controls and select agents, COGR agrees overall that export reform activities should continue. A revised Export Administration Regulations (EAR) definition confirmed institutions' understanding of fundamental research and National Security Decision Directive (NSDD) 189. COGR supports an International Traffic in Arms Regulations (ITAR) definition that further affirms NSDD 189 and is consistent with the EAR. Specific to select agents, COGR supports the Academies recommendations that the responsibility for regulating select agents and toxins be assigned to a single agency; that the Federal Select Agent Program develop an inventory management system that takes into account the self-replicating nature of biological agents; and that the regulations be amended to increase researcher access during public health emergencies, increase the number of low-virulence strains available to researchers, and make the process by which materials are added and removed from the list more transparent. This may require amendment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. COGR also fully supports the recommendation to develop a uniform set of requirements for reporting of invention data applicable to all agencies and strongly urges that any such uniform requirements be streamlined to minimize burdens placed on universities while preserving the core principles of the Bayh-Dole Act.

In summary, COGR and universities like Duke support the findings and recommendations of the Academies and GAO reports and the legislation that would implement them. We can't rely on a handful of strategic relationships to safeguard and ensure the effectiveness of the Nation's \$63 billion investment in research. And, as stated so appropriately in Chairwoman Comstock's *Research and Development Efficiency Act*, administrative burden is "eroding funds available to carry out basic scientific research." With your support, and the opportunity for reasonable university input into the policy development and implementation process, we can achieve thoughtful and effective regulations that protect the taxpayer's dollar and maximize results.

Thank you for your time and interest in these important issues.