ACADEMIC RESEARCH REGULATORY RELIEF: A REVIEW OF NEW RECOMMENDATIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

September 29, 2016

Serial No. 114–96

Printed for the use of the Committee on Science, Space, and Technology

Available via the World Wide Web: http://science.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

22–565PDF WASHINGTON : 2017

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HON. LAMAR S. SMITH, Texas, *Chair*

FRANK D. LUCAS, Oklahoma
F. JAMES SENSENBRENNER, JR., Wisconsin
DANA ROHRABACHER, California
RANDY NEUGEBAUER, Texas
MICHAEL T. MCCAUL, Texas
MO BROOKS, Alabama
RANDY HULTGREN, Illinois
BILL POSEY, Florida
THOMAS MASSIE, Kentucky
JIM BRIDENSTINE, Oklahoma
RANDY K. WEBER, Texas
JOHN R. MOOLENAAR, Michigan
STEPHEN KNIGHT, California
BRIAN BABIN, Texas
BRUCE WESTERMAN, Arkansas
BARBARA COMSTOCK, Virginia
GARY PALMER, Alabama
BARRY LOUDERMILK, Georgia
RALPH LEE ABRAHAM, Louisiana
DRAIN LAHOOD, Illinois
WARREN DAVIDSON, Ohio
EDDIE BERNICE JOHNSON, Texas
ZOE LOFGREN, California
DANIEL LIPINSKI, Illinois
DONNA F. EDWARDS, Maryland
SUZANNE BONAMICI, Oregon
ERIC SWALWELL, California
ALAN GRAYSON, Florida
AMI BERA, California
ELIZABETH H. ESTY, Connecticut
MARC A. VEASEY, Texas
KATHERINE M. CLARK, Massachusetts
DONALD S. BEYER, JR., Virginia
ED PERLMUTTER, Colorado
PAUL TONKO, New York
MARK TAKANO, California
BILL FOSTER, Illinois

SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

HON. BARBARA COMSTOCK, Virginia, *Chair*

FRANK D. LUCAS, Oklahoma
MICHAEL T. MCCAUL, Texas
RANDY HULTGREN, Illinois
JOHN R. MOOLENAAR, Michigan
BRUCE WESTERMAN, Arkansas
GARY PALMER, Alabama
RALPH LEE ABRAHAM, Louisiana
DARIN LAHOOD, Illinois
LAMAR S. SMITH, Texas
DANIEL LIPINSKI, Illinois
ELIZABETH H. ESTY, Connecticut
KATHERINE M. CLARK, Massachusetts
PAUL TONKO, New York
SUZANNE BONAMICI, Oregon
ERIC SWALWELL, California
EDDIE BERNICE JOHNSON, Texas

CONTENTS

September 29, 2016

Page

Appendix II: Additional Material for the Record

ACADEMIC RESEARCH REGULATORY RELIEF: A REVIEW OF NEW RECOMMENDATIONS

THURSDAY, SEPTEMBER 29, 2016

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Subcommittee met, pursuant to call, at 10:05 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Barbara Comstock [Chairwoman of the Subcommittee] presiding.

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6301
(202) 225–6371
www.science.house.gov

Academic Research Regulatory Relief: A Review of New Recommendations

Thursday, September 29, 2016
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Witnesses

Dr. Larry R. Faulkner, President Emeritus, The University of Texas at Austin

Mr. John Neumann, Director, Natural Resources and Environment Team, Government Accountability Office

Mr. Jim Luther, Associate Vice President for Finance & Compliance Officer, Duke University

Dr. Ángel Cabrera, President, George Mason University

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HEARING CHARTER

Thursday, September 29, 2016

TO: Members, Committee on Science, Space, and Technology

FROM: Majority Staff, Committee on Science, Space, and Technology

SUBJECT: Research and Technology Subcommittee hearing
"Academic Research Regulatory Relief: A Review of New Recommendations"

The Subcommittee on Research and Technology of the Committee on Science, Space, and Technology will hold a hearing titled *Academic Research Regulatory Relief: A Review of New Recommendations* on Thursday, September 29, 2016 at 10:00 a.m. in Room 2318 of the Rayburn House Office Building.

Hearing Purpose:

The purpose of the hearing is to review recent recommendations made by the National Academy of Sciences (NAS)[1] and the U.S. Government Accountability Office (GAO)[2] for streamlining federal regulations on academic scientific research to optimize the nation's investment in research, while ensuring accountability and scientific integrity.

Witness List

- **Dr. Larry R. Faulkner,** President Emeritus, The University of Texas at Austin
- **Mr. John Neumann**, Director, Natural Resources and Environment Team, Government Accountability Office
- **Mr. Jim Luther,** Associate Vice President for Finance & Compliance Officer, Duke University
- **Dr. Ángel Cabrera,** President, George Mason University

Staff Contact

For questions related to the hearing, please contact Jenn Wickre of the Majority Staff at 202-225-6371.

---

[1] National Academies of Sciences, Engineering, and Medicine, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century.* Available at: https://www.nap.edu/catalog/21824/optimizing-the-nations-investment-in-academic-research-a-new-regulatory

[2] U.S. Government Accountability Office, *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements, GAO-16-573.* Available at: http://www.gao.gov/products/GAO-16-573

Chairwoman COMSTOCK. The Committee on Science, Space, and Technology will come to order.

Without objection, the Chair is authorized to declare recesses of the Committee at any time.

Good morning, and welcome to today's hearing titled "Academic Research Regulatory Relief: A Review of New Recommendations." I now recognize myself for five minutes for an opening statement.

How can we cut the red tape to optimize our Nation's investment in scientific research? That is the question we aim to answer in today's hearing.

Since becoming Chair of the Subcommittee on Research and Technology, I have heard concern from many scientists and university leaders that too much time and money is being spent complying with federal rules, regulations and other administrative work, thereby taking away from vital research and education. Surveys have shown that, on average, researchers spend 42 percent of their time meeting administrative requirements.

Last year, I introduced the Research and Development Efficiency Act, a bill to establish a working group under the National Science and Technology Council to review federal regulations and make recommendations on how to streamline and minimize the regulatory burden on research institutions. That bill overwhelmingly passed this Committee on a bipartisan basis and in the House in May of last year. I guess we're still awaiting the Senate as always.

Since that time, work has continued by the National Academy of Sciences and the Government Accountability Office to study and report on solutions for fixing the patchwork of rules and regulations that govern federally funded research. In June, the National Academy of Sciences issued its final report: "Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century." The report includes four major findings and dozens of recommendations for updating and reforming regulations. We are grateful to have Dr. Larry Faulkner here, the chair of the committee that authored the report, who will testify on those recommendations.

Also in June, the Government Accountability Office released a report called "Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements." That report makes three major recommendations, which we'll hear more about from Dr. Neumann, who led the study team.

We are also fortunate to have two university leaders with us today to talk about the impacts of regulations on their institutions and share their expertise. I'm pleased to have Dr. Cabrera here, President of George Mason University, which serves northern—well, serves the whole country but I'm very proud to work with you in our region, and leads not only one of the fastest growing research institutions in the country, but one that happens to be partially in my district, and my daughter's alma mater with her graduate degree also, and actually I'm leaving after the hearing today. I'm going to a Women in Virginia Bioscience that also has George Mason folks there, so thank you for your leadership, Dr. Cabrera.

I look forward to hearing from all of our witnesses about what actions Congress and agencies can take to provide regulatory relief to the research community, ensuring that more of our federal re-

search dollars are spent on scientific breakthroughs and developing a STEM-trained workforce.

[The prepared statement of Chairwoman Comstock follows:]

COMMITTEE ON
SCIENCE, SPACE, & TECHNOLOGY
Lamar Smith, Chairman

For Immediate Release
September 29, 2016

Media Contact: Kristina Baum
(202) 225-6371

Statement of Research and Technology Subcommittee Chairwoman Barbara Comstock (R-Va.)

Academic Research Regulatory Relief: A Review of New Recommendations

Chairwoman Comstock: How can we cut the red tape to optimize our nation's investment in scientific research? That is the question we aim to answer in today's hearing.

Since becoming chair of the Subcommittee on Research and Technology, I have heard concern from many scientists and university leaders that too much time and money is being spent complying with federal rules, regulations and other administrative work, thereby taking away from research and education. Surveys have shown that, on average, researchers spend 42 percent of their time meeting administrative requirements.

Last year, I introduced the Research and Development Efficiency Act, a bill to establish a working group under the National Science and Technology Council to review federal regulations and make recommendations on how to streamline and minimize the regulatory burden on research institutions. That bill overwhelmingly passed this Committee and the House in May of last year.

Since that time, work has continued by the National Academy of Sciences and the Government Accountability Office to study and report on solutions for fixing the patchwork of rules and regulations that govern federally funded research.

In June, the National Academy of Sciences issued its final report: "Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century." The report includes four major findings and dozens of recommendations for updating and reforming regulations. We are grateful to have Dr. Larry Faulkner here, the chair of the committee that authored the report, who will testify on those recommendations.

Also in June, the Government Accountability Office released a report, "Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements."

That report makes three major recommendations, which we'll hear more about from Mr. John Neumann, who led the study team.

We are also fortunate to have two university leaders with us today, to talk about the impacts of regulations on their institutions, and share their expertise. Dr. Angel Cabrera, President of George Mason University, leads not only one of the fastest growing research institutions in the country, but one that happens to be partially in my district (and my daughter's alma mater for her master's degree, I might add).

I look forward to hearing from all of our witnesses about what actions Congress and agencies can take to provide regulatory relief to the research community, ensuring that more of our federal research dollars are spent on scientific breakthroughs and developing a STEM-trained workforce.

###

Chairwoman COMSTOCK. I now recognized the Ranking Member, the gentleman from Illinois, Mr. Lipinski, for his opening statement.

Mr. LIPINSKI. Thank you, Chairwoman Comstock, for holding this hearing, and thank Chairwoman Comstock and Chairman Smith for being here this morning and all of the witnesses for being here. As you all know, we finished up our work for a few weeks last night, so I'm glad that we're able to still hold this hearing.

Efforts to streamline and reduce the burden of administrative requirements placed on academic researchers while maintaining a strong system of accountability and scientific integrity are not new. The Federal Demonstration Partnership (FDP) began 30 years ago, and the Council on Governmental Relations, which represents and supports universities in complying with federal regulations, dates back to the post-WW II era.

However, as research budgets have flattened or declined and our best and brightest young researchers increasingly look elsewhere, the topic of reducing the administrative burden on federal research has taken on new urgency. The FDP reported that academic researchers spend 42 percent of their time on activities other than academic research, including administrative burden. That number has since been challenged, but I think we all agree with the basic premise of this hearing and all of the related reports: too much valuable time of our researchers is wasted on excessive compliance with excessive regulations. Issues like subrecipient monitoring, micropurchase threshold, biosketches, open access policies, and time and effort reporting adds up to a lot of time for researchers. I understand this from my own experiences as a college professor, through discussions with former colleagues, and from talking to researchers and research university administrators as I have served as Chair and then the Ranking Member of this subcommittee for the past eight years.

The Uniform Guidance issued by the Office of Management and Budget in December 2013 made several steps in the right direction. For example, it provided flexibility for universities to examine alternatives to traditional time and effort reporting on grants including using payroll systems to verify work performed. Inspectors General, who opposed this change, still have full authority to conduct audits of those systems to ensure accountability for federal funds. Unfortunately, the Uniform Guidance also included changes that increased administrative burden without obviously increasing accountability, such as the reduction of the micropurchase threshold for competitive bids.

Two years ago, we held a hearing to review the findings and recommendations from the National Science Board about reducing the administrative burden on academic research.

Today we are reviewing two more recent reports, one from the National Academies and the other from the GAO. In response to these reports, and working closely with the stakeholder community, I developed bipartisan legislation, H.R. 5583, to implement some of the key recommendations to Congress. This bill, the University Regulation Streamlining and Harmonization Act, would address issues around researcher biosketches, the micropurchase threshold, and other regulations on academic research.

However, the most important part of the legislation is the creation of a Research Policy Board at OMB. The board would allow members of the research community to meet with agency and OMB officials to suggest ways to streamline rules across agencies. This board would not be able to overrule or delay any actions taken by OMB, but rather would serve to give the research community a seat at the table to help advise against overly onerous research regulations both now and in the future.

This bill has received strong support from the research community, including endorsements from the Association of American Universities and the Council on Governmental Relations among others. While the clock is ticking on this Congress, I hope we will be able to implement at least some of these proposals, if not this entire bill, before the end of the year. Either way, I hope that OMB, OSTP, and federal research agencies will continue to work on the issues identified in these reports and in my legislation.

These hearings on administrative burden, along with the legislative efforts offered by myself and Chairwoman Comstock, should demonstrate clearly to the research community and agency officials alike that this Committee is engaged on this issue and will continue to provide oversight and fix problems as they are identified.

With that, I want to thank today's witnesses for your contributions to these efforts and for your testimony. I look forward to a fruitful discussion, and I yield back.

[The prepared statement of Mr. Lipinski follows:]

OPENING STATEMENT
Ranking Member Dan Lipinski (D-IL)
Subcommittee on Research and Technology

House Committee on Science, Space, and Technology
Subcommittee on Research and Technology
"Academic Research Regulatory Relief: A Review of New Recommendations"
September 29, 2016

Thank you Chairwoman Comstock for holding this hearing, and thank you to all of the witnesses for being here this morning.

Efforts to streamline and reduce the burden of administrative requirements placed on academic researchers – while maintaining a strong system of accountability and scientific integrity – are not new. The Federal Demonstration Partnership (FDP) began 30 years ago, and the Council on Governmental Relations, which represents and supports universities in complying with federal regulations, dates back to the post-WWII era.

However, as research budgets have flattened or declined and our best and brightest young researchers increasingly look elsewhere, the topic of reducing the administrative burden on federal research has taken on new urgency. The FDP reported that academic researchers spend 42 percent of their time on activities other than academic research, including administrative burden. That number has since been challenged, but I think we all agree with the basic premise of this hearing and all of the related reports – too much valuable time of our researchers is wasted on excessive compliance with excessive regulations. Issues like subrecipient monitoring, micropurchase threshold, biosketches, open access policies, and time and effort reporting adds up to a lot of time for researchers. I understand this from my own experiences as a college professor, through discussions with former colleagues, and from talking to researchers and research university administrators as I have served as chair and then the ranking member of this subcommittee for the past 8 years.

The Uniform Guidance issued by the Office of Management and Budget in December 2013 made several steps in the right direction. For example, it provided flexibility for universities to examine alternatives to traditional time and effort reporting on grants including using payroll systems to verify work performed. Inspectors general, who opposed this change, still have full authority to conduct audits of those systems to ensure accountability for federal funds. Unfortunately, the Uniform Guidance also included changes that increased administrative burden without obviously increasing accountability, such as the reduction of the micro-purchase threshold for competitive bids.

Two years ago we held a hearing to review the findings and recommendations from the National Science Board about reducing the administrative burden on academic research. Today we are reviewing two more recent reports, one from the National Academies and the other from the GAO. In response to these reports, and working closely with the stakeholder community, I developed bipartisan legislation, H.R. 5583, to implement some of the key recommendations to Congress.

H.R. 5583, the University Regulation Streamlining and Harmonization Act, would address issues around researcher biosketches, the micro-purchase threshold, and other regulations on academic research. However, the most important part of the legislation is the creation of a research policy board at OMB. The board would allow members of the research community to meet with agency and OMB officials to suggest ways to streamline rules across agencies. This board would not be able to overrule or delay any

actions taken by OMB, but rather would serve to give the research community a seat at the table to help advise against overly onerous research regulations both now and in the future.

This bill has received strong support from the research community, including endorsements from the Association of American Universities and the Council on Governmental Relations among others. While the clock is ticking on this Congress, I hope we will be able to implement at least some of these proposals – if not this entire bill – before the end of the year. Either way, I hope that OMB, OSTP, and federal research agencies will continue to work on the issues identified in these reports and in my legislation.

These hearings on administrative burden, along with the legislative efforts offered by myself and Chairwoman Comstock, should demonstrate clearly to the research community and agency officials alike that this committee is engaged on this issue and will continue to provide oversight and fix problems as they are identified.

With that, I want to thank today's witnesses for your contributions to these efforts and for your testimony. I look forward to a fruitful discussion, and I yield back.

Chairwoman COMSTOCK. Thank you, and I now recognize Chairman Smith, who is with us here this morning, for his statement, and he will also be introducing our first witness from Texas.

Chairman SMITH. Thank you, Madam Chairwoman.

Let me say on behalf of the witnesses and even on behalf of the American people, I want to thank you and the Ranking Member, Mr. Lipinski, for making a huge effort to be here this morning. Not everybody may realize that because we finished votes last night, and we will not be convening again as a Congress until after the November election, we knew a lot of people were going to be leaving town this morning and I thought we were going to have to cancel this hearing, as important as it was, and the fact that the Chairwoman and the Ranking Member said that they would stay and be here enabled us to go forward and have this hearing.

Now, I do want to point out that the Chairwoman has already passed what we could call a regulatory relief bill, and deserves congratulations for that, and there's more to come. Mr. Lipinski has a bill that we're working on, and I do have to question his motive for being here because he knows that by being here we're going to be more favorably disposed towards his legislation. But I do appreciate both his efforts to bring some sanity to the regulatory process and what the Chairwoman has done too.

The Committee has held many hearings on the regulatory overreach of agencies during this Administration. Americans from small business owners to scientists in the lab want to be free from overly burdensome regulations, not tied up in more red tape.

For several years, the research community has expressed concern that time spent on administrative and reporting requirements for federal research seriously cuts into lab time. This negatively affects the science conducted under those grants.

The Federal Government spends about $30 billion a year on research and development at our Nation's colleges and universities. Over time, a patchwork of federal laws, regulations, rules, policies, and reporting requirements have developed to manage this research.

A survey of universities found that up to 25 percent of grant funding was spent on research-related regulatory compliance—25 percent. We must ensure accountability and scientific integrity when spending taxpayer dollars on research. However, there are opportunities for Congress and agencies to streamline regulations to optimize the Nation's investment in research.

There are some commonsense recommendations to reduce governmental hurdles for our scientists. For example, when a researcher applies for a grant at the National Science Foundation, they should be able to use the same biographical information and format they use when applying for a grant at the Department of Energy or other agencies. If a researcher has a grant from the National Oceanic and Atmospheric Administration and NASA, the format for research progress reporting to both agencies should be the same.

Confusing, costly, and burdensome regulations take time and money away from research. They also make it more difficult for young, new innovators to apply and compete for federal funding.

We should not lose out on developing new breakthrough ideas or new talent because of bureaucratic hurdles.

So I commend Chairwoman Comstock for holding this hearing and for her previous work on tackling regulatory relief. I look forward to working with you and our colleagues on both sides of the aisle towards developing some legislative solutions, and I mentioned Mr. Lipinski's bill a minute ago. We must continue to ensure that our Nation's research investments are efficient and effective.

Thank you, and I'll yield back.

[The prepared statement of Chairman Smith follows:]

COMMITTEE ON
SCIENCE, SPACE, & TECHNOLOGY
Lamar Smith, Chairman

For Immediate Release
September 29, 2016

Media Contact: Kristina Baum
(202) 225-6371

Statement of Chairman Lamar Smith (R-Texas)

Academic Research Regulatory Relief: A Review of New Recommendations

Chairman Smith: Thank you Madam Chair. And thanks to our expert witnesses for being here today.

This Committee has held many hearings on the regulatory overreach of agencies during this administration. Americans – from small business owners to scientists in the lab – want to be free from overly burdensome regulations, not tied up in more red tape.

For several years, the research community has expressed concern that time spent on administrative and reporting requirements for federal research seriously cuts into lab time. This negatively affects the science conducted under those grants.

The federal government spends about $30 billion a year on research and development at our nation's colleges and universities. Over time, a patchwork of federal laws, regulations, rules, policies and reporting requirements have developed to manage this research. A survey of universities found that up to 25 percent of grant funding was spent on research-related regulatory compliance.

We must ensure accountability and scientific integrity when spending taxpayer dollars on research. However, there are opportunities for Congress and agencies to streamline regulations to optimize the nation's investment in research.

There are some common sense recommendations to reduce governmental hurdles for our scientists. For example, when a researcher applies for a grant at the National Science Foundation, they should be able to use the same biographical information and format they use when applying for a grant at the Department of Energy or other agencies.

If a researcher has a grant from the National Oceanic and Atmospheric Administration and NASA, the format for research progress reporting to both agencies should be the same.

Confusing, costly and burdensome regulations take time and money away from research. They also make it more difficult for young, new innovators to apply and compete for federal funding.

We should not lose out on developing new breakthrough ideas or new talent because of bureaucratic hurdles.

I commend Chairwoman Comstock for holding this hearing and for her previous work on tackling regulatory relief. I look forward to working with you and our colleagues on both sides of the aisle towards developing some legislative solutions.

We must continue to ensure that our nation's research investments are efficient and effective.

###

Chairwoman COMSTOCK. I now recognize the Chairman to introduce Dr. Faulkner.

Chairman SMITH. Thank you, Madam Chairwoman.

It should be obvious why I'd like to, or asked to introduce our first witness today because he is Dr. Larry Faulkner, President Emeritus of the University of Texas at Austin.

I might interject here that at one point I represented all of the University of Texas at Austin and now only represent a part of it. I do have in my district the administration building, and I also have all the sororities and fraternities, and I haven't yet figured out why that was given to me, but nevertheless, that's how it stands and I'm pleased to represent at least part of——

Chairwoman COMSTOCK. I have two sister-in-laws from those sororities.

Chairman SMITH. I mentioned that Dr. Faulkner had been President of the University of Texas at Austin. Most recently Dr. Faulkner chaired the National Academies Committee on Federal Regulation of Research, which carried out a comprehensive review and made numerous specific recommendations for improving regulations, regulatory procedures, and regulatory apparatus. As President of the University of Texas at Austin, he oversaw a seven-year capital campaign that raised over $1.6 billion, appointed and supported the work of the Commission of 125, a citizens' group that provided guidance on the future of the university and its relationship to the public. Dr. Faulkner received a B.S. degree from Southern Methodist University and was awarded a Ph.D. in chemistry from the University of Texas at Austin. We welcome you, Dr. Faulkner. It's nice to have you back, and I'll yield back.

Dr. FAULKNER. Thank you, Mr. Chairman. It's a pleasure to see you. I had the pleasure of being in your district at one time.

Chairwoman COMSTOCK. I'm sorry. I have to introduce the other witnesses now, then we'll go through, so sorry for the mix-up there.

Chairman SMITH. I liked what he was saying about having lived in my district, but we'll——

Chairwoman COMSTOCK. Okay. Our second witness today is Mr. John Neumann, Director, Natural Resources and Environment Team at the Government Accountability Office. Mr. Neumann currently leads efforts in the science and technology area including the management and oversight of federal research and development programs, protection of intellectual property, and federal efforts to support innovation. He received his B.A. in political science cum laude from the State University of New York at Stony Brook and holds an MBA from American University as well as a J.D. from Georgetown University.

Our third witness today is Mr. Jim Luther, Associate Vice President for Finance and Compliance Officer at Duke University. Mr. Luther's responsibilities include oversight of the post-award areas for the university and School of Medicine, management of fixed and movable assets, negotiation of Duke's indirect cost and fringe benefit rates, and all aspects of Duke's research cost and compliance program. Over the past several years, he has instituted a research cost and compliance program that includes mandatory training for faculty and administrators, a comprehensive compliance certification program, and a compliance monitoring program. Mr. Luther

earned his B.S. in engineering from the U.S. Naval Academy and an M.A. from Duke University.

Our final witness today is Dr. Ángel Cabrera, President of George Mason University. Prior to joining George Mason in 2012, he served as President of the Thunderbird School of Global Management in Arizona and is Dean of the I.E. Business School in Madrid. Dr. Cabrera has been recognized by the World Economic Forum as a Young Global Leader, by the Aspen Institute as a Henry Crown Fellow, by Business Week as a Star of Europe, and by the Financial Times as one of the world's best business deans. Dr. Cabrera earned his Ph.D. and M.S. from the Georgia Institute of Technology and his B.S. and M.S. in computer and electrical engineering from the Polytechnic University of Madrid.

I now recognize Dr. Faulkner for five minutes to present his testimony.

TESTIMONY OF DR. LARRY R. FAULKNER,
PRESIDENT EMERITUS,
THE UNIVERSITY OF TEXAS AT AUSTIN

Dr. FAULKNER. Good morning, Chairwoman Comstock and Ranking Member Lipinski, Chairman Smith. I thank you for your invitation to testify on a congressionally mandated study conducted by a committee of the National Academies.

The general message is that the continuing expansion of federal regulation is decreasing the return on the federal investment in research by diverting investigators' time and other resources away from research toward administration and compliance.

The committee has seven overarching findings: first, that effective regulation is essential to the overall health of the research enterprise; second, that most federal regulations, policies and guidance represent efforts to address important issues but often have unintended consequences needlessly encumbering the Nation's research; third, in recent decades, the amount of regulation has grown dramatically; fourth, this continuing expansion of the regulatory system diminishes the effectiveness of the Nation's investment in research; fifth, universities receive research funding from multiple agencies but approaches to similar tasks and goals such as the submission of grant proposals are not harmonized across agencies; six, that regulations sometimes have resulted when universities did not respond appropriately to investigators' transgressions; and seventh, the relationship between research universities and institutions and federal funders has long been considered a partnership yet there is no formal mechanism by which senior stakeholders from both partners can review existing or proposed policies.

Based on these findings, the committee offered four overarching recommendations: first, that the regulatory regime for federal research be reexamined and recalibrated. We recommend that Congress, OMB, federal agencies and research institutions take steps to improve efficiency. We provide many detailed possibilities.

Second, research institutions should take action to reinvigorate the research partnership and to re-instill trust.

Third, the responsibilities of the Inspector General should be rebalanced so that consideration is given both to uncovering waste,

fraud, and abuse and to advising on economy, efficiency, and effectiveness.

Fourth, the government-university research partnership should be made more functional through changes in the regulatory framework.

For the remainder of my remarks I will focus on human subjects research and the proposed new regulatory framework. Midway through the committee's work, the DHHS issued a Notice of Proposed Rule Making on the Federal Policy for the Protection of Human Subjects. Over 2,000 comments were submitted in response. Most commentators brought up deficiencies and indicated that if the rule were implemented as written, it would create serious obstacles for research. From testimony and much other evidence, the committee concluded that the proposed rule is marred by omissions, an absence of essential elements, and a lack of clarity. Given that a national review has not taken place in almost forty years of human subjects research, that related research has grown tremendously, and that the complexity of the issues has greatly increased, the committee recommends that Congress authorize and the President appoint an independent, national commission to examine and to recommend updates to the ethical, legal, and institutional framework governing human subjects research.

Finally, the committee is calling upon the executive branch to withdraw the NPRM, giving the proposed commission full scope to meet its charge.

Let me turn last to the proposed new regulatory framework. The goal is to provide a mechanism that can forestall duplicative and incongruous regulations, streamline and harmonize existing regulations, and provide a means to eliminate ineffective regulations. We believe that the only clear path to strengthening the U.S. research enterprise and preparing it for continued leadership is through the establishment of a new research policy board, which would act as the primary analytical, anticipatory and coordinating forum on regulatory policy, bringing together high-level stakeholders from the research community and from federal funding agencies. We further recommend that a new position of associate director for the academic research enterprise be established in the White House OSTP. This officer would perform an essential role by focusing on the operational health of the research partnership.

For nearly 70 years, that partnership has yielded tremendous benefits for the American people, improving their economic wellbeing, health, and security. It behooves all of us to take steps to ensure that it continues to flourish.

Thank you for this opportunity.

[The prepared statement of Dr. Faulkner follows:]

OPTIMIZING THE NATION'S INVESTMENT IN ACADEMIC RESEARCH

A NEW REGULATORY FRAMEWORK FOR THE 21ST CENTURY

Statement of

Larry R. Faulkner, Ph.D.
President Emeritus
The University of Texas at Austin
and
Chair, Committee on Federal Research Regulations and Reporting Requirements
A New Framework for Research Universities in the 21st Century
Committee on Science, Technology, and Law
Board on Higher Education and Workforce
Policy and Global Affairs
The National Academies of Sciences, Engineering, and Medicine

before the

Subcommittee on Research and Technology
Committee on Science, Space, and Technology
U.S. House of Representatives

September 29, 2016

Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century

The National Academy of Sciences, Engineering, and Medicine

Good Morning Chairwoman Comstock and Ranking Member Lipinski. Thank you for your invitation to provide testimony about a congressionally mandated study conducted by the National Academies of Sciences, Engineering, and Medicine with the sponsorship of the U.S. Department of Education and the National Institutes of Health. I was privileged to chair the committee that issued our report, entitled *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century.*

Shortly after beginning the study, Congress asked that we expedite an initial report and so unlike most Academies reports, our report was issued in two parts: Part 1 issued in September 2015 and Part 2 issued as the final report in June 2016. In my remarks today, I will focus on the committee's overarching findings and recommendations. Copies of the full report have been provided to staff.

The overarching message of our report is that the continuing expansion of federal regulations and requirements is diminishing the effectiveness of the US research enterprise and decreasing the return on the federal investment in basic and applied research by diverting investigators' time and institutional resources away from research and toward administrative and compliance matters. The committee believes there is a need for a new framework to ensure that regulatory requirements are justified, proportional to the problems being addressed, and harmonized across federal agencies, so as to create a more effective and efficient research partnership. This new framework, which I will describe later in my remarks in greater detail, is embodied in our recommendations calling for the establishment of a Research Policy Board, a new associate director for the academic research enterprise at the White House Office of Science and Technology Policy (OSTP), and a set of guiding principles to govern and strengthen the government-research institution partnership.

In the course of our study, the committee reviewed and analyzed previous reports and studies. We also heard presentations from representatives of federal research funding agencies, inspectors general, university administrators and researchers, and independent organizations engaged in advancing scientific research and promoting the health of the nation's research enterprise.

While our ability to report a precise measure the cumulative effect of regulations was constrained by lack of data, we illustrate instances where the cumulative effect of inconsistent and overlapping regulations leads to a reduction in the time spent on research. From stakeholders at every level and perspective, we heard how, over the past several decades, increasing federal regulations hinder the output of the remarkable research enterprise that arose from the government-academic partnership.

Having said this, let me be very clear that the committee believes that effective regulation is essential to the overall health of the research enterprise. Our concern is that the current regulatory scheme is harming the very system it was supposed to protect. We are worried that, if this regulatory trend continues, we will cause significant damage to a system of education, mentorship, and discovery that is renowned internationally, consistently attracts the best talent from around the world, and serves as a model for other nations seeking to advance science and engineering in pursuit of economic and social progress and prosperity. In effect, we may jeopardize our nation's leadership in science, technology, and the social and behavioral sciences, all of which contribute to our security, health, education, and well-being.

The committee identified several overarching findings:

1. Effective regulation is essential to the overall health of the research enterprise. It protects both our nation's investment and various parties in the research partnership – research participants, investigators, universities, and agencies.

2. Most federal regulations, policies, and guidance are efforts to address important issues related to scientific integrity, the stewardship of federal funds, and the well-being of people and animals involved in research. But these well-intended efforts often result in unintended consequences that needlessly encumber the nation's research enterprise.

3. In recent decades, the amount of regulation has grown dramatically. Since 1991 the federal government has instituted 90 new regulatory changes with which universities must comply. The last decade in particular has seen striking growth in regulation: In the 1990s, the federal government promulgated approximately 1.5 new or substantially changed federal regulations and policies per year that directly affected the conduct and management of research under Federal grants and contracts. During the years 2003-2012, this number increased to 5.8 per year.

4. This continuing expansion of the federal regulatory system and its requirements diminish the effectiveness of the nation's investment in research. These growing requirements are directing investigators' time away from research and education and toward administrative tasks that are inconsistent, duplicative, or unclear. Regulations also add financial cost to the research enterprise, particularly as they accumulate over time.

5. Universities frequently receive research funding from multiple federal agencies, but approaches to similar tasks and goals – such as the submission of grant proposals and accounting for potential conflicts of interest – are not harmonized across funding agencies. Because of this, investigators and administrative staff spend unnecessary time and resources complying with different sets of rules and regulations. When requirements are duplicative, inconsistent, or unclear, universities themselves may place additional requirements on research investigators, adding to the burden.

6. At times regulations have resulted when universities did not respond appropriately to investigators' transgressions, or failed to create an environment that strongly discourages behaviors in conflict with scientific standards and norms. It is, however, also important to note that regulations have also been triggered by egregious transgressions that are found to be isolated events.

7. In recent decades, stresses in the federal-academic partnership have diminished the effectiveness of the nation's investment in academic research.

8. The relationship between research institutions and federal funders of research has long been considered a partnership. There is, however, no formal entity, mechanism, or process by which senior stakeholders from both partners can consider the effectiveness of existing research policies and review proposed new policies to sustain a dynamic and effective research enterprise.

With these findings in mind, the committee offered four overarching recommendations with specific actions provided to implement these recommendations.

1. First is that the regulatory regime governing federally funded research should be critically reexamined and recalibrated. We recommend that Congress, the White House Office of Management and Budget, federal agencies, and research institutions take a number of specific steps to improve the efficiency of rules and regulations.

   For example, we urge the federal government to develop a uniform approach and format for grant proposals, conflicts of interest policy, and research with animals. We also urge institutions to review internal policies developed to comply with federal regulations, so as to determine whether such policies have themselves contributed to administrative burden. Additional recommendations – many of which can be acted upon immediately -- are detailed in our report.

2. Our second overarching recommendation concerns actions research institutions should take to reinvigorate the government-university research partnership and to re-instill trust. Research institutions must demand the highest standards in institutional and individual behavior. They must foster a culture of integrity among academic leaders, faculty, students, staff and administrators. And they must mete out appropriate sanctions where behavior deviates from ethical and professional norms. Universities that fail to enforce these norms should themselves face sanctions.

3. Our third overarching recommendation concerns the responsibilities of Inspectors General. Research institutions are subject to frequent federal audits as part of their acceptance of federal research funds. There is a growing concern, however, that there is a lack of shared understanding with regard to expectations concerning compliance with financial policies and procedures. When agencies, Inspectors General, and research institutions have shared understandings and interpretations

of the rules and regulations governing financial expenditures, there are fewer disagreements about the expenditure of federal funds. Without a shared understanding, an environment is created with competing assertions and findings. Consequently, we recommend that the responsibilities of the Inspectors General be rebalanced so that appropriate consideration is given both to uncovering waste, fraud, and abuse and to advising on economy, efficiency, and effectiveness.

4. Our final overarching recommendation is aimed at strengthening and renewing the government-university research partnership. We recommend that Congress create a new entity, a Research Policy Board, which would serve as the primary policy forum for discussions related to the regulation of federally funded research institutions. The board will bring together high-level stakeholders from the academic research community and from federal funding agencies to foster more-effective conception, development, and harmonization of research policies going forward.

For the remainder of my remarks I would like to focus attention on two specific areas: 1) human subjects research and 2) the new framework.

At about the same time that the committee issued Part 1 of its report, the Department of Health and Human Services issued a Notice of Proposed Rule Making (the "NPRM") on the Federal Policy for the Protection of Human Subjects. The fundamental premise shared by all is the protection of human participants in research. Central to the goals of human subjects regulations are the principles of respect for persons, beneficence, and justice. These principles, articulated almost forty years ago in the Belmont Report, have served the nation well as it sought to protect human participants in research while advancing the biomedical and socio-behavioral research enterprise. However, since these principles were first articulated, the research enterprise has grown enormously and has witnessed profound changes in knowledge, technologies, methodologies, and capabilities, as well as in the potential implications of research findings for individual participants and for society. These changes in research contexts and capabilities have raised urgent questions about the proper application and balancing of the Belmont principles.

When the NPRM was released in September 2015, it received tremendous attention. Over 2000 comments were submitted to HHS in response. Most commentators expressed concerns about deficiencies in the proposed rule and maintained that if the rule were implemented as written, it would pose significant obstacles to the conduct of research. Having heard from various experts, and having considered analyses of the comments on the NPRM, the committee found that the proposed rule is marred by omissions, an absence of essential elements, and a lack of clarity. In addition, important questions about the overall impact and long-term costs of the proposed regulatory changes were left unresolved. Given that a national review of human subjects research has not taken place in almost forty years, that the biomedical and socio-behavioral research enterprise has grown tremendously during that time, and that the complexity of the issues related to human subjects research has greatly proliferated, the committee recommends that Congress authorize and the President appoint an independent, free-standing national commission on human subjects research.

Congress should charge the commission with examining and updating as necessary the ethical, legal, and institutional framework governing human subjects research with the goal of making recommendations to Congress and the President on ethically sound regulatory approaches to unresolved questions in human subjects research and on needed revisions to the legal and institutional structures governing the regulation of human subjects research.

Finally, and critically importantly, concurrent with this recommendation, the committee is calling upon the executive branch now to withdraw the NPRM, giving the proposed commission full scope to meet its Congressional charge.

Now to the new framework. Let me state clearly that the goal of this new framework is not to increase bureaucracy, but to provide a mechanism that will forestall the creation of duplicative and incongruous regulations, streamline and harmonize existing regulations, and provide a means to eliminate outdated or ineffective regulations.

We recommend that Congress create a new entity, a Research Policy Board, which would serve as the primary policy forum for discussions related to the regulation of federally funded research institutions. The board will bring together high-level stakeholders from the academic research community and from federal funding agencies to foster more-effective conception, development, and harmonization of research policies going forward.

Concurrent with the RPB we recommend that a new position – an Associate Director for the Academic Research Enterprise – be established in the White House office of Science and Technology Policy. This Associate Director would serve as a liaison between the Research Policy Board, funding agencies, Congress, and research institutions. In partnership with OMB's Office of Information and Regulatory Affairs, the director would facilitate concrete and meaningful reduction of institutional regulatory burden. Together, the director and Administrator of OIRA should report annually to Congress on regulatory issues and actions affecting the research partnership.

We believe that the only clear path to strengthening the US research enterprise and preparing it for continued leadership in the 21st century is through the establishment of the proposed Research Policy Board that will act as an analytical, anticipatory, and coordinating forum on research regulatory policy. Further, we believe the proposed associate director for the academic research enterprise will perform an essential role by focusing on the health of the federal-academic research partnership and by facilitating meaningful discussion between research institutions and the federal government, Congress, and inspectors general.

For nearly 70 years, the partnership between research universities and the government has yielded tremendous benefits for the American people, improving their economic well-being, health, and security. It behooves all of us to take steps to ensure that this partnership continues to flourish. The committee's recommendations are intended to strengthen that partnership and to maximize the returns on the nation's investment in research.

We believe our report offers Congress and the Administration a more responsive and efficient regulatory structure that optimizes the nation's investment in academic research while better serving the interests of government, universities, investigators, and the public.

Thank you for this opportunity to testify. I would be happy to take any questions you might have.

LARRY R. FAULKNER

Larry R. Faulkner is President Emeritus of The University of Texas at Austin and a retired President of Houston Endowment, a private philanthropy established by Jesse H. and Mary Gibbs Jones. Over four decades, Dr. Faulkner served on the chemistry faculties of Harvard University, the University of Illinois, and the University of Texas. At Illinois, he was also department head, dean, and provost. From 1998 into 2006, he served the University of Texas as its 27th president, after which he led Houston Endowment for six years. He is a member of the American Academy of Arts and Sciences and chaired both the National Mathematics Advisory Panel (2006-2008) and the recent National Academies Committee on Federal Regulation of Research (2015-2016). He now serves on the boards of Exxon Mobil Corporation, Southern Methodist University, Discovery Green Conservancy, Houston Grand Opera, the Philosophical Society of Texas, Al Akhawayn University in Ifrane, and Covenant Presbyterian Foundation. He was previously on the boards of Temple-Inland, Sandia National Laboratories, Internet2, the Lyndon Baines Johnson Foundation, and Reasoning Mind.

Archival information, including speech texts, is available at http://faulknerchem.com .

Chairwoman COMSTOCK. Thank you.
Mr. Neumann.

TESTIMONY OF MR. JOHN NEUMANN, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT TEAM, GOVERNMENT ACCOUNTABILITY OFFICE

Mr. NEUMANN. Chairwoman Comstock, Ranking Member Lipinski, and Chairman Smith, I appreciate the opportunity to be here today to discuss the findings from our recent report on administrative requirements on federal research grants to universities.

As you know, the federal government provides billions of dollars each year to colleges and universities for research, over $27 billion in fiscal year 2015 alone. To oversee the use of these findings, Congress and federal agencies have established a variety of administrative requirements. However, the research community has raised concerns about the administrative workload and costs for researchers and universities to comply with these requirements.

Today, I would like to briefly highlight the three key findings from our report. First, we looked at selected administrative requirements to understand why they're put in place and found that they fell into two general buckets: OMB's Uniform Guidance for grants and agency-specific guidance. OMB's guidance generally focuses on protecting against fraud, waste, and abuse of funds. For example, it requires competition and documentation of purchases made with grant funds. Agency-specific guidance generally focuses on the quality and effectiveness of research. For example, NIH-funded researchers are required to disclose financial conflicts of interest to promote objectivity in the research they conduct with federal funds.

Our second key finding was that there are certain common factors that add to the workload and cost for universities to comply with these requirements. Specifically, we found that agencies vary in how they implement the same requirements causing universities to develop multiple processes to comply. We also found that funding agencies require detailed documentation as part of the grant application process, even though the likelihood of getting funded is relatively low. And some requirements have become more prescriptive such as recent changes to the Uniform Guidance that will require universities to use competitive procurement methods when purchasing any goods or services costing $3,500 or more, which universities told us will result in added workload and costs. Examples of the workload and costs universities have include purchasing and updating electronic grant management systems, hiring and training administrative staff, and then the time spent by the researchers themselves.

Our third key finding was that while OMB and the funding agencies have made continuing efforts to reduce universities' administrative workload and costs, these reductions have been limited, and we found opportunities for further improvements in a number of areas. For example, we found that agencies have not standardized certain administrative requirements across agencies such as unnecessary variations that remain in the format and content of biographical sketches as well as in budget forms and budget justifications. We also found that several funding agencies have not fully

considered opportunities to streamline pre-award requirements. For example, NSF has been piling efforts to postpone certain requirements such as detailed budgets until after the grant has been awarded but other agencies in our view have not conducted agency-wide reviews for similar opportunities to postpone requirements.

Lastly, we found several areas where funding agencies could consider providing universities with more flexibility including the OMB requirements on competing purchases and NIH conflict-of-interest rules.

Based on these findings, we made four recommendations to OMB and the agencies in our review—the Department of Energy, NASA, NIH and NSF—to identify and pursue further opportunities to streamline administrative requirements on research grants to universities. The agencies generally agreed to take steps to implement our recommendations.

Chairwoman Comstock, Ranking Member Lipinski and Chairman Smith, this concludes my prepared remarks. I'm happy to respond to any questions that you may have.

[The prepared statement of Mr. Neumann follows:]

United States Government Accountability Office

GAO

Testimony before the Subcommittee on Research and Technology, Committee on Science, Space, and Technology, House of Representatives

For Release on Delivery
Expected at 10:00 a.m. ET
Thursday, September 29, 2016

FEDERAL RESEARCH GRANTS

Opportunities Remain for Agencies to Streamline Administrative Requirements

Statement of John Neumann, Director, Natural Resources and Environment

GAO-16-890T

Chairwoman Comstock, Ranking Member Lipinski, and Members of the Subcommittee:

I am pleased to be here today to discuss administrative requirements on federal research grants to universities, as well as federal agency efforts and opportunities to streamline such requirements. According to National Science Foundation (NSF) data, the federal government funds the majority of research performed by colleges and universities, obligating over $27 billion for such research in fiscal year 2015.[1] To allow for oversight, Congress and federal agencies have established a variety of administrative requirements for the use of these funds.[2] Some requirements were established or strengthened in response to cases of researchers improperly spending funds or because of concerns about research integrity. Others were established to meet broader policy objectives, such as increasing access to research data and results.

During the last two decades, organizations that have studied these requirements have raised concerns about the administrative workload and costs for researchers and universities to comply with the requirements and their effects on the efficient conduct of research. In addition, several executive orders and a presidential memorandum have called for streamlining regulations and guidance to reduce grantees' administrative workload and costs. For instance, Executive Order 13563 of January 18, 2011 called for greater coordination across agencies to simplify and harmonize rules, and for agencies to consider regulatory approaches that reduce burdens and maintain flexibility. In December 2013, the Office of Management and Budget (OMB) consolidated its grants management circulars into a single document—the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance)—to streamline its guidance and

[1]National Science Foundation, National Center for Science and Engineering Statistics, *Higher Education Research and Development Survey, Fiscal Year 2014* (November 2015) and *Survey of Federal Funds for Research and Development, Fiscal Years 2014–16* (April 2016). NSF data include funds for basic research, applied research, and development. For purposes of this testimony, we generally refer to these funds as research funding. NSF's data for fiscal year 2015 are preliminary.

[2]Some provisions governing these funds appear in statutes or regulations, and others appear in agency guidance documents. For purposes of this testimony, we refer to all of these provisions as "requirements."

reduce the administrative burden on nonfederal entities, as well as to strengthen oversight of federal funds to reduce risk of waste, fraud, and abuse.[3] Nevertheless, universities and stakeholder organizations continue to cite increasing administrative workload and costs for complying with requirements.

My statement today summarizes our June 2016 report on administrative requirements on federal research grants,[4] which examined (1) selected research grant requirements, (2) the factors that contribute to universities' administrative workload and costs for complying with these requirements, and (3) efforts OMB and research funding agencies have made to reduce the administrative workload and costs for complying with these requirements, and the results of these efforts. For our report, we selected and examined administrative requirements in nine categories that multiple universities and university stakeholder organizations had cited as contributing to universities' administrative workload and costs, had been the subject of recent streamlining efforts or other changes, or had been part of the findings of recent reports by agency inspectors general.[5] We reviewed guidance, regulations, and other documentation of the requirements and interviewed officials at OMB and four research funding agencies—the Department of Energy (DOE), National Aeronautics and Space Administration (NASA), National Institutes of Health (NIH), and NSF—which together provided about 83 percent of federal funding for research at universities and colleges in fiscal year 2015. We reviewed documentation from and interviewed administrative staff and researchers at six public and private universities that vary in the amount of research funding they receive and in other characteristics. We also interviewed representatives of several university stakeholder organizations. The results of our reviews of selected requirements, agencies, universities, and stakeholder organizations cannot be generalized to those not included in our review. More detailed information on our scope and methodology can be found in our June 2016 report. We conducted the

[3]The Uniform Guidance is implemented through individual federal agency regulations that were to take effect no later than December 26, 2014.

[4]GAO, *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements*, GAO-16-573 (Washington, D.C.: June 22, 2016).

[5]For example, these include requirements related to research project budgets, research personnel, and oversight of subrecipients.

work on which this statement is based in accordance with generally accepted government auditing standards.

Summary

Selected administrative requirements in OMB's government-wide grant guidance generally focus on protecting against waste, fraud, and abuse of funds; in contrast, the requirements in agency-specific guidance generally focus on promoting the quality and effectiveness of federally funded research. Selected universities and stakeholder organizations identified the following common factors that add to their administrative workload and costs for complying with the requirements: (1) variation in funding agencies' implementation of requirements, (2) development of grant proposal documentation at a stage when details of a research project remain uncertain, and (3) recent policy reforms that resulted in certain requirements becoming more prescriptive. OMB and funding agencies' streamlining efforts resulted in some reductions to universities' administrative workload and costs for complying with selected requirements, but these reductions were limited.

Selected Requirements Govern the Proper Use of Grant Funds and Research Quality and Effectiveness

Selected administrative requirements in the Uniform Guidance, OMB's government-wide grant guidance, generally focus on protecting against waste, fraud, and abuse of funds, as we found in our June 2016 report. These include requirements related to competition and documentation of purchases, documentation of personnel expenses, and preparation and management of project budgets. For example, funding agencies implement Uniform Guidance requirements for budget preparation and management by designing agency-specific forms and processes to review applicants' requests for funding and grantees' use of funding. These requirements allow for identification of questionable requests for funding in applications and unallowable post-award charges to grants.

In contrast, selected administrative requirements in agency-specific guidance generally focus on promoting the quality and effectiveness of federally funded research. Specifically, funding agencies have established administrative requirements to promote the selection and development of qualified researchers, protect against bias in the conduct of research, and improve access to research data and results. For example, since 1995, NIH-funded researchers have been subject to Department of Health and Human Services (HHS) financial conflict of interest regulations designed to promote objectivity. NASA and NSF have also implemented financial conflict of interest requirements to help protect

against bias in the conduct of research, and DOE was in the process of establishing such requirements as of June 2016.

Selected Universities Identified Common Factors That Add to Their Workload and Costs for Complying with Selected Administrative Requirements

In our June 2016 report, we found that selected universities and stakeholder organizations identified common factors that add to their administrative workload and costs for complying with selected requirements. First, at all six universities, officials told us that variation in funding agencies' implementation of certain administrative requirements contributes to workload and costs because, for example, universities have to design and implement multiple processes and may need to invest in electronic systems to comply with agencies' requirements. Officials we interviewed cited variation in three categories of requirements in particular: developing and submitting biographical sketches describing researchers' professional accomplishments; identifying, reporting, and managing financial conflicts of interest; and preparing and managing project budgets. For example, agency implementation of budget preparation and management requirements differs in several ways, including the forms and level of detail required in proposed budgets and the systems for grantee financial reporting.

A second factor, according to university officials we interviewed, is the workload and costs of developing grant proposal documentation. To help select proposals for funding, funding agencies require researchers to prepare detailed documentation—including proposed project budgets, data management plans, and in some cases information on conflicts of interest—as part of the application process. Given recent proposal funding rates, the likelihood of an agency selecting a proposal for funding is relatively low. For example, in fiscal year 2015, NIH awarded funding to 18 percent of applicants, and NSF awarded funding to 24 percent of applicants—rates similar to those of other years. As a result, for most proposals, universities' investments of time and resources do not result in research funding. Furthermore, researchers and administrative staff we interviewed said that during the pre-award stage, there can be a relatively high level of uncertainty about specific details of a research project, including budget details about potential vendors or travel costs and details about expected research data and results. They said that complying with requirements to prepare and submit documents at a stage when these details remain uncertain is not an efficient use of time.

Finally, recent OMB and HHS policy reforms resulted in changes to selected requirements that, according to university officials, made them more prescriptive and added to administrative workload and costs.

Specifically, the Uniform Guidance includes revised requirements for competition and documentation of purchases that are more prescriptive than those in OMB's prior circular that applied to universities.[6] In addition, in 2011, HHS revised regulations governing financial conflicts of interest—which apply to research funded by NIH—to address concerns about the objectivity of the research HHS funds. These revisions included more prescriptive requirements for, among other things, the types of financial interests researchers must disclose. Officials at universities in our review stated that the more prescriptive requirements add to universities' workload and costs in several ways. For example, officials at all six universities told us that they expect the new purchasing competition and documentation requirements—particularly the lower threshold at which price or rate quotations must be obtained from multiple vendors—will result in added costs for updating their electronic purchasing systems.[7] More specifically, officials at five of the universities in our review told us that, prior to the Uniform Guidance, their thresholds for obtaining multiple quotations had been higher than the threshold in the Uniform Guidance, and that they will now need to obtain multiple quotations for more transactions than before.

[6]Stakeholder organizations raised concerns to OMB about increased administrative workload and costs resulting from its revised purchasing requirements, and OMB delayed implementation of the new requirements for 2 full fiscal years after the effective date of the Uniform Guidance. The revised purchasing requirements will become effective for universities sometime in 2017, depending on universities' fiscal calendars.

[7]The Uniform Guidance establishes five methods for purchasing goods or services. One of these methods, procurement by micropurchases, applies to purchases under $3,500 and does not require soliciting competitive quotations if the grantee considers the price to be reasonable. The Uniform Guidance defines the micropurchase threshold as the threshold set by the Federal Acquisition Regulation at 48 C.F.R. Subpart 2.1 (Definitions). When the Uniform Guidance was issued, the threshold was $3,000 except as otherwise discussed in Subpart 2.1 of that regulation, but it is periodically adjusted for inflation. See 2 C.F.R. § 200.67. At the time of our June 2016 report, the threshold was $3,500. Purchases that exceed this threshold trigger additional requirements for providing full and open competition, such as obtaining price or rate quotations from an adequate number of qualified sources.

OMB and Funding Agencies Have Made Continuing Efforts to Reduce Universities' Administrative Workload and Costs, with Limited Results

OMB and the four research funding agencies in our June 2016 report have made continuing efforts to reduce universities' administrative workload and costs for complying with selected requirements. These efforts include (1) standardizing requirements across agencies, (2) streamlining pre-award requirements, and (3) in some cases allowing universities more flexibility to assess and manage risks for some requirements. In each of these areas, OMB and agency efforts resulted in some reductions to administrative workload and costs, but these reductions were limited. We made recommendations in our June 2016 report that agencies make further improvements in each area. DOE, NASA, and NIH generally concurred, and OMB and NSF did not comment on the recommendations.

Standardizing Administrative Requirements

In accordance with federal goals for standardization, OMB led several efforts to standardize selected requirements, primarily those related to budget preparation and management. For example, OMB's Uniform Guidance established standard requirements for financial management of federal awards and generally requires the use of OMB-approved government-wide standard forms for reporting financial and performance information. Funding agencies made similar efforts to standardize requirements through the Office of Science and Technology Policy's (OSTP) Research Business Models working group (RBM)—an interagency group that consists of officials from DOE, NASA, NIH, NSF, and other federal research funding agencies. RBM's charter calls for it to examine opportunities and develop options to unify agency research grants administration practices and to assess and report periodically on the status, efficiency, and performance of the federal-academic research partnership. However, neither OMB nor funding agency efforts to standardize requirements fully addressed the variations in requirements, thereby limiting the potential reductions in universities' administrative workload and costs. For example, the Uniform Guidance does not prohibit agencies from varying in how they implement aspects of budget preparation and management requirements, such as the forms and level of detail required in proposed budgets, agency systems for financial reporting, or the budget revisions agencies allow grantees to make without obtaining prior approval. Similarly, RBM's efforts to standardize research terms and conditions allow for agency-specific exceptions. Also, RBM's efforts have primarily focused on post-award requirements, and it has not initiated a process to standardize pre-award requirements.

According to OMB staff and funding agency officials, several factors can limit agencies' ability to standardize administrative requirements on

research grants. For example, funding agencies must comply with differing statutory or other requirements, which can result in differences in their requirements for grantees. There are also differences in the types of research or recipients that agencies fund that can limit their ability to standardize requirements. Nevertheless, agencies have opportunities to standardize requirements to a greater extent than they have already done. In particular, they have flexibility in how they implement aspects of selected requirements that are not subject to statutory or other requirements or to agency-specific differences in types of research or recipients. According to some funding agency officials we interviewed, aspects of requirements for which agencies have such flexibility include the format and content of biographical sketches, the budget forms and content of budget justifications that agencies require in applications, and the types of budget revisions agencies allow grantees to make without obtaining prior approval. Officials at NSF, NIH, and OSTP who co-chair RBM told us that the group is well suited to pursue further standardization efforts and to report on them. Such efforts could help agencies reduce universities' administrative workload and costs and improve their oversight of funding and support of research quality. Accordingly, in our June 2016 report, we recommended that DOE, NASA, HHS, and NSF coordinate through RBM to identify additional areas where they can standardize requirements, and to report on these efforts. DOE, NASA, and HHS generally agreed with this recommendation and said they would continue to build on RBM's previous efforts, and NSF did not formally comment on the recommendation.

Streamlining Pre-Award Requirements

DOE, NASA, NIH, and NSF have made efforts to streamline administrative requirements associated with proposal preparation by allowing applicants to postpone their submission of certain documentation until after a preliminary decision about an their likelihood of obtaining funding. Under these efforts, applicants are required to provide only a limited set of application materials—often referred to as a preliminary proposal—for initial evaluation before possible submission of a full proposal. Preliminary proposals are intended, in part, to reduce applicants' administrative workload and costs when applicants' chances of success are very small. Such efforts are in line with RBM's charter, which calls for agencies to identify approaches to streamline administration practices for research grants. The funding agencies in our review use a range of preliminary proposal processes, which can allow applicants to postpone submitting documentation related to budget preparation, biographical sketches, and developing plans to manage and share research data and to mentor researchers. According to university

officials, stakeholder organizations, and information from the four funding agencies in our review, efforts to defer certain pre-award requirements generally have led to reductions in universities' administrative workload and costs. For example, one NSF division evaluated its preliminary proposal pilot in 2014 and reported that the pilot led to reduced applicant workload by lessening the number of proposal pages researchers needed to write and simplifying the documents university administrative offices required, since preliminary proposals do not include budgets.

Preliminary proposals may not be effective in reducing administrative workload and costs for certain solicitations or grant programs, such as specialized grants for which a small number of scientists are likely to apply, according to agency officials. Nevertheless, agencies have not extended pre-award streamlining efforts to all grant solicitations for which they could be used to reduce workload and costs. In certain instances, agencies still require documentation they may not need to effectively evaluate initial proposals. For instance, NIH does not generally allow applicants to defer submitting documentation for proposed budgets, biographical sketches, or other requirements that other agencies have determined are not necessary for preliminary proposals. In addition, pre-award streamlining efforts at DOE, NASA, and NSF are limited to certain offices or certain programs within the agencies, in some cases because the efforts are still in pilot phases.

We found in our June 2016 report that NSF had taken steps to expand its use of preliminary proposals and that opportunities remain for other agencies to do so as well. Specifically, in 2015, NSF senior leadership directed officials from NSF's directorates to review and identify options to reduce researchers' administrative workload and costs, including by expanding use of preliminary proposals and focusing application reviews on a minimum set of elements needed to meet NSF's merit review criteria.[8] As a result of the directive, three NSF directorates expanded

[8]NSF took these steps partly in response to the National Science Board's 2014 recommendations to reduce administrative workload by expanding the use of preliminary proposals or just-in-time submissions. See National Science Board, *Reducing Investigators' Administrative Workload for Federally Funded Research*, NSB-14-18 (Mar. 10, 2014). The National Science Board establishes the policies of NSF within the policy framework set forth by the President and Congress and serves as an independent policy advisory body to the President and Congress on science and engineering research and education issues.

their use of preliminary proposals, for instance, by allowing applicants to postpone submitting detailed budgets until proposals are recommended for award. DOE, NASA, and NIH have not conducted similar agency-wide reviews to identify opportunities for expanded use of preliminary proposals or just-in-time submissions.[9] As a result, we recommended that these three agencies conduct agency-wide reviews of possible actions, such as further use of preliminary proposals, to postpone pre-award requirements until after a preliminary decision about an applicant's likelihood of funding. Such reviews may help ensure that agencies do not miss opportunities to reduce unnecessary pre-award administrative workload and costs for applicants that do not receive awards. DOE, HHS, and NASA generally concurred with this recommendation.

Allowing Universities More Flexibility

OMB and funding agencies have made efforts, in accordance with federal goals, to reduce administrative workload and costs by allowing universities more flexibility to assess and manage risks related to certain administrative requirements. One of OMB's stated objectives for its reforms in the Uniform Guidance was "focusing on performance over compliance for accountability," for instance, by allowing recipients of federal awards the flexibility to devote more effort to achieving programmatic objectives rather than to complying with complex requirements. Efforts by OMB and the funding agencies in our review to allow universities more flexibility to assess and manage risks related to administrative requirements—particularly requirements for budget preparation and management and documenting personnel expenses—have led to reductions in administrative workload and costs, according to officials from the four funding agencies and six universities in our review. For example, in the Uniform Guidance, OMB modified requirements for documenting personnel expenses to focus on establishing standards for recipients' internal controls over salary and wage expenses, without prescribing procedures grantees must use to meet the standards. Officials from the two universities in our review that piloted streamlined

[9]In commenting on a draft of our June 2016 report, HHS stated that in 2014, NIH commissioned an evaluation to recommend ways to further optimize the process of reviewing, awarding, and managing grants and to maximize the time researchers can devote to research. The resulting report also found that the use of preliminary proposals could be expanded and included a recommendation that NIH pilot test preliminary proposals. NIH, Scientific Management Review Board, *Report on Streamlining the NIH Grant Review, Award, and Management Process* (July 2015).

methods for documenting salary and wage charges to federal awards said these pilots resulted in over an 80-percent reduction in the number of forms that principal investigators needed to review and corresponding reductions in time needed to develop and process these forms, as well as reductions in the time and costs of training staff.

In contrast, several administrative requirements—including OMB requirements related to purchases 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 and financial interests. First, in developing the Uniform Guidance, OMB based the micro-purchase threshold—above which grantees must generally obtain price or rate quotations, competitive bids, or competitive proposals—on the threshold for competition of purchases made under federal contracts. Officials from all six universities in our review said that for relatively small purchases that exceed the threshold, the administrative workload and costs associated with competition may outweigh the savings gained. Second, under the 2011 revised HHS regulations governing NIH's conflict of interest requirements, researchers must disclose to their institution a range of financial interests held by them, their spouses, and their dependent children. University and stakeholder organization officials we interviewed generally agreed that the additional financial interests that must be disclosed and reviewed under the revised requirements—particularly reimbursed or sponsored travel costs, which officials said are common among academic researchers—rarely result in identification of actual conflicts that could bias their research.

Both OMB and HHS plan to evaluate their revised guidance and regulation, respectively. Since issuing these rules, OMB and HHS, as well as stakeholder organizations, have begun collecting information on the effects of the rules that the agencies can use in their evaluations. For example, OMB directed agencies to report, beginning in January 2015, information on their implementation of the Uniform Guidance, including metrics on the overall impact on burden and waste, fraud, and abuse.[10] The additional information could allow OMB and HHS to more fully

[10]Office of Management and Budget, *Metrics for Uniform Guidance (2 C.F.R. 200)*, OMB Memorandum M-14-17 (Washington, D.C.: Sept. 30, 2014).

consider the requirements' effects on universities' administrative workload and costs and balance such considerations against the requirements' added protections for accountability and research integrity. Accordingly, we recommended that HHS, as part of the planned evaluation of its regulation governing financial conflicts of interest in NIH-funded research, 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. HHS concurred and stated in its comments on our draft report that it plans to measure the effectiveness of the financial conflict of interest requirements and identify areas that may create administrative burden. Similarly, we recommended that OMB, as part of its planned evaluation of the Uniform Guidance, evaluate options for targeting requirements for research grants to universities. OMB did not formally state whether it concurred with this recommendation, but OMB staff told us that they agree that opportunities remain for streamlining administrative requirements.

Chairwoman Comstock, Ranking Member Lipinski, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff members have any questions concerning this testimony, please contact me at (202) 512-3841 or neumannj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Other individuals who made key contributions to this testimony include Joseph Cook, Assistant Director, and Miles Ingram.

Biography

John Neumann is a Director in GAO's Natural Resources and Environment Team, with over 25 years of experience leading performance audits of federal programs. He currently leads efforts in the science and technology area, including the management and oversight of federal research and development programs, protection of intellectual property, and federal efforts to support innovation. Mr. Neumann received his B.A. in Political Science cum laude from the State University of New York at Stony Brook, and holds an M.B.A from American University, as well as a J.D. from Georgetown University.

Chairwoman COMSTOCK. Great.
I now recognize Mr. Luther for five minutes.

TESTIMONY OF MR. JIM LUTHER,
ASSOCIATE VICE PRESIDENT
FOR FINANCE & COMPLIANCE OFFICER,
DUKE UNIVERSITY

Mr. LUTHER. Good morning, Subcommittee Chairwoman Comstock, Ranking Member Lipinski, and Chairman Smith. I'll be addressing my comments both from a Duke University perspective but also I serve as the Board Chair for the Council on Governmental Relations, which is an associate of 190 research universities, medical centers, and institutes, and I also co-chair the Federal Demonstration Partnerships Administrative Cost Working Group.

I'd like to start by expressing my gratitude for the Subcommittee's interest in identifying opportunities to more effectively regulate research. Congress has long supported the research enterprise, providing almost $63 billion in research funding for fiscal year 2014 alone. Congress has also expressed concern about the amount of time and funding spent on administrative processes required for federally funded research.

The reports discussed today join several previous reports on this topic. All have come to similar conclusions, number one, that the regulation of research continues to steadily increase; number two, that there is a lack of standardization across agencies; and number three, that federally funded research could be regulated much more efficiently.

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 Uniform Guidance, and we continue to work with OMB to overcome challenges related to procurement and sub-recipient monitoring. Successful engagement has historically been heavily dependent on relationships with individual agency employees. These relationships can be extremely productive, but when the critical staff member departs, so does the productivity of the relationship.

It also frequently is the case that the university perspective is not sought and that regulations do not include material changes recommended. An example is the Common Rule. A COGR–APLU analysis of comments on the proposed changes found that 74 percent of all responses and approximately 96 percent of responses from patients and members of the research community opposed proposed changes to the biospecimens on the grounds that they would be detrimental to research and health. The Academies report suggests that the proposed revisions are marred by omissions, the absence of essential elements, and lack of clarity, and "could be detrimental to areas of important research." The Academies report, the HHS Secretary's Advisory Committee on Human Research Protections, and others have called for the proposed rule to be withdrawn, yet we understand that HHS is still trying to move forward with this final rule.

Compounding the issue of engagement is a significant increase in federal regulations, 5.8 new or substantially changed regulations annually, according to the Academies report. In the last four months alone, three regulations, two significant policies, and a training requirement were issued. These new regulations and policies will cost each university anywhere from several hundred thousand to several million dollars and result in significant increase in administrative and faculty workload. Many associated costs will not be reimbursed as administrative costs long ago exceeded the 26 percent threshold. At Duke, we are approximately $25 million over this threshold annually, largely caused by the proliferation of new regulations.

Regarding other major recommendations including in the National Academies report, COGR and the Association of American Universities have strongly endorsed H.R. 5583, the University Regulatory Streamlining and Harmonization Act of 2016, and S. 2742, Promoting Biomedical Research and Public Health for Patients Act. Both would create the Research Policy Board that is the centerpiece of the Academies recommendation and the former, the appointment of an Administrator for the Academic Research Enterprise for Unified Oversight.

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 research enterprise at large or through many examples of non-federal entities serving in a related capacity. Critical discussions with the research community coupled with Congressional and GAO oversight would support mutual 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 almost 24 percent of total academic R&D.

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 the Research and Development Efficiency Act, administrative burden is "eroding funds available to carry out basic scientific research." With your support, we can achieve thoughtful, effective regulations that protect the taxpayers' dollars and maximize results.

Thank you for your time and interest, and I look forward to answering any questions you may have.

[The prepared statement of Mr. Luther follows:]

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

Mr. James D. Luther
Associate Vice President of Finance
Duke University

"Academic Research Regulatory Relief: A Review of New Recommendations"

September 29, 2016

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.

Bio – Jim Luther
Duke University
(September 2016)

Jim Luther is the Associate VP Finance, Research Costing Compliance and Federal Reimbursement & Compliance Officer. Jim's responsibilities include oversight of the post-award areas for the University and School of Medicine, management of fixed and moveable assets, negotiation of Duke's indirect cost and fringe benefit rates, and all aspects of Duke's research costing compliance program. He came to Duke in 1990 and has served in many capacities, including Assistant Director of the University Budget Office, Assistant Controller of Reimbursement Accounting, and Project System Team Lead for the SAP General Ledger implementation. Over the past several years he has instituted a Research Costing Compliance program that includes mandatory training for faculty and administrators, a comprehensive compliance certification program, and a compliance monitoring program.

He is active nationally and is currently the Chair of the Board of the Council on Governmental Relations (COGR) in Washington DC and the co-chair of the Finance Policy Workgroup with federal representatives for the Federal Demonstration Partnership (sponsored by the National Academies of Science). Before joining Duke, Luther served as a Captain in the U.S. Marine Corps. Luther earned his B.S. in Engineering from the United States Naval Academy and an M.A. from Duke University.

Chairwoman COMSTOCK. Thank you.
I now recognize Dr. Cabrera for five minutes.

TESTIMONY OF DR. ÁNGEL CABRERA, PRESIDENT, GEORGE MASON UNIVERSITY

Dr. CABRERA. Thank you so much, Chairwoman Comstock and Ranking Member Lipinski. Thank you, Chairman Smith, for delaying that departure and holding this very important hearing.

I bring to you the views and feedback from dozens of researchers at George Mason University. Just to set it in context, we are the largest public university in Virginia, and we are the newest and youngest member of that Carnegie tier I group of highest research universities in the country. We conduct research in areas from cybersecurity and computational sciences to proteomics, economics, criminology, psychology and many other areas, and we, like all of our peers in the group of research universities, are a great example of how that research translates not only into new cures and solutions but also into new organizations and enterprises that are driving innovation in our region and in our Nation.

Now, Chairwoman Comstock, you and some of your staff have toured our Institute of Biomedical Innovation, and we really appreciate that visit. You were able to talk with some of those conducting the research and see firsthand how research advances education, leads to jobs and to improved lives, and you saw a glimpse of that wonderful research that happens in our institution and in many others. I would be remiss, Mr. Lipinski, if I did not extend the opportunity for you and your staff to visit at your convenience and to show you what we do.

Now, it doesn't escape you that to do our work as a public university, we rely on state investments and appropriations. We rely also on private contributions and research grants, and very importantly, we depend on student tuition. As the investment from state has declined, the pressure on student tuition is creating real issues of access. The issues of regulatory efficiency and the costs that they generate at the end of the day impact students and impact the social issues around access to higher education.

Now, let me provide some specifics on the areas that the GAO report highlighted. Many of our researchers do receive awards from more than one agency. This means that they have to spend an inordinate amount of time identifying and responding to different requirements regarding proposal submissions, conflict-of-interest purchasing, subrecipient monitoring, reporting and closeout. This problem is compounded by the fact that the success rate of awards in many agencies is getting lower while the time and cost of applying is getting higher. This paradox is discouraging faculty, many of whom balance teaching, mentoring, and research loads from pursuing more research opportunities.

In terms of export controls, the Academies report correctly points out that universities including Mason continue to be concerned about efforts by the State Department to modify the definition of fundamental research in ITAR. If the result is a restricted definition of fundamental research, that may cause real problems in terms of driving innovation and bringing about the resources from

around the world that sometimes are necessary to drive that innovation.

We have a great example of innovation in regulation with effort reporting. In 2011, Mason was the first of four pilot schools to participate in a payroll certification pilot under the auspices of the Federal Demonstration Partnership, and effort reporting is often cited as one of the most burdensome administrative requirements for researchers. Effort incurred across multiple activities is difficult to measure and track, and administration is very inefficient and costly.

With payroll certification, we aim to improve the efficiency and at the same time not diminish the accountability. The result of that pilot at Mason was a reduction in 85 percent in the reports produced without any negative and adverse impact in the supervision in accountability. That's a great example of how we can have smarter processes that really reduce the cost.

Finally, the Academies report calls for Congress to create a Research Policy Board, and there are many other recommendations that we endorse and support. To some extent, Madam Chair, your bill 1119, which passed the House, and your bill, Ranking Member Lipinski, implement what the National Academies is recommending, and we are grateful to both of you. Your bills will allow for broader discussion of that monster that lurks behind every rule, the law of unintended consequences. By providing a pause button or the ability to raise a red flag and means for redress and revisiting existing rules, you have done a tremendous service to the research enterprise and the Nation's future innovation.

Thank you so much.

[The prepared statement of Dr. Cabrera follows:]

WRITTEN STATEMENT

BY

DR. ÁNGEL CABRERA

PRESIDENT

GEORGE MASON UNIVERSITY

FOR

HEARING

ACADEMIC RESEARCH REGULATORY RELIEF: A REVIEW OF NEW RECOMMENDATIONS

THE SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

REPRESENTATIVE BARBARA COMSTOCK, CHAIRWOMAN

10:00 A.M., THURSDAY, SEPTEMBER 29, 2016

2318 RAYBURN HOUSE OFFICE BUILDING

Chairwoman Comstock, Ranking Member Lipinski, and distinguished Members of the Committee. Thank you very much for holding this important hearing today, and for the opportunity to provide comments.

At the outset, let me say how much we at Mason, appreciate your efforts to address the concerns of research universities regarding the increasing complexity, burden, and cost of research regulations and how they are impacting the nation's ability to remain innovative. In particular, your bill Madam Chair, H.R. 1119, and your bill, Mr. Lipinski, H.R. 5583, make meaningful contributions to addressing concerns with the regulatory system and reducing unnecessary administrative burden for researchers and research institutions. I will comment further on both bills later in the testimony.

Research and Education at Mason

I am honored to be here today. I am Ángel Cabrera, President of George Mason University, the Commonwealth of Virginia's largest public university. Mason enrolls more than 35,000 students from 130 countries and all 50 states. We offer 208 degree programs, including 88 masters and 38 doctoral. Last year Mason conferred 8,877 degrees, with over a third of that number constituting graduate and professional degrees. Mason employs 6,500 faculty and staff to serve our growing student body.

Mason is distributed among three campuses spanning over 800 acres in Fairfax, Arlington, and Prince William counties. In addition, Mason operates a site in Loudoun County and has partnered with the Smithsonian Institute to offer a Global Conservation Studies Program at the Conservation and Research Center in Front Royal. Each of our four locations has a distinctive academic focus that plays a critical role in the economy of our region.

We are committed to providing the education and skills for our students to succeed in a globally competitive workforce. Mason's Pathway initiative with the Northern Virginia Community College has resulted in higher graduation rates, faster time-to-degree, and lower overall costs to underserved student communities. Mason has one of the best student diversity rankings, with no discernable learning gaps among student groups, while maintaining a low cohort default rate. We have created these fabulous educational opportunities while also recently achieving the Carnegie Highest Research Activity (R1) designation.

Mason's growing research portfolio includes such important areas as cybersecurity, biomedical science, bioinformatics, computational sciences, Health IT, economics, criminology, modeling and simulation, telecommunications, geospatial intelligence, neuroscience, forensics, data analytics and many more. These have led to advances producing clear benefits to society, such as a greatly improved Lyme disease test, new cancer treatments, enhanced understanding of the role of transnational crime in supporting terrorism, improved protection for our cyber-physical systems, advanced civil infrastructure monitoring techniques, and many others.

The Research Enterprise

Research and scholarship advances made by Mason researchers are moved downstream from lab-to-patent-to commercialization-to-market, generating opportunities for start-ups,

business creation, and economic development. While initially their impact may be regional, eventually they become the antecedents of next generation advances. This is how innovation occurs. Hundreds of research universities creating new knowledge that benefitted from and contribute to what is being done at other research universities, working in partnership with the private sector, each leveraging the other, all serving as precursors for the next "game-changing" breakthrough. The discovery of new knowledge feeds directly into the classroom and is critical to the academic mission. That in a nutshell, is America's research enterprise.

Madam Chair, you and some of your staff toured our Institute for Biomedical Innovation and our Virginia Serious Games Institute. You were able to talk with those conducting the research and see first-hand how research advances education, leads to jobs and improves lives. But, you saw only a glimpse of the great work being done at Mason. We have many more outstanding faculty, labs and research facilities. I would be remiss, Mr. Lipinski, if I did not extend the opportunity for you and your staff to visit us and see how Mason advances science and knowledge with the benefit of federal and other sponsor funding, and contributes to success in the nation's research enterprise.

Now, let me provide some observations on the two reports you mentioned in your letter inviting me to testify: first, the National Academy of Sciences report, "Optimizing the Nation's Investment in Academic Research"; and the Government Accountability Office report, "Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements."

The Challenge of Resources

We certainly agree with the premise behind many of the regulations in question: the need to protect the interests of taxpayers, preserve the integrity of the research enterprise, and hold institutions accountable for the management of Federal investment. As a public institution, Mason is accountable to its local community, the Commonwealth, and to the Federal government and other sponsors. One of the larger challenges we and other public research universities face is that State budgets are tied to prevailing economic conditions, which are by their nature cyclical. In constrained economic environments, State budgets do not keep up with demand, and the competition for resources becomes intense. Until public universities make a better case to taxpayers regarding the value they provide, State funding will be constrained. This is not all negative as it incentivizes campus innovation in our institutions, encouraging us to identify alternative revenue sources and find efficiencies in administration. But, what that means in practice is that Mason and other institutions like us, while trying to hold the line on tuition increases, cannot afford to hire additional administrative staff to comply with increased regulations. Increased administrative burden then falls on the researchers themselves, which reduces the amount of time they can spend in their labs doing research that advances our national innovation agenda. We have experienced firsthand the results described in the Federal Demonstration Partnership's 2012 faculty workload survey that found that ,on average, 42% of faculty research time associated with federal projects was spent on meeting regulatory requirements rather than conducting active research.

The regulatory predicament stems from the simple fact that there is no overarching authority to weigh the relative merits of each new regulation against the cumulative cost. Without being attentive to the big picture, it is hard to understand the full impact of new agency-specific regulations with their own peculiarities and requirements. It reminds me of the concept of the "Tragedy of the Commons" where all have access to a resource, but no one is responsible for its preservation. To carry that analogy to the hearing today, multiple agencies issue their regulations, but no one is in charge of reviewing them in totality and ensuring they don't overly burden the research enterprise. These agencies are staffed with hard-working, public servants dedicated to the public good. But, without a portrait of the entire regulatory enterprise, there will continue to be an inexorable march to more regulation.

Government Accountability Office Report

Let me turn to the Government Accountability effort. On a macro level, the GAO report captured the essence of the challenges Mason researchers face, with its finding that the various research agencies have different implementation requirements. Mason participated in the GAO study. We felt that GAO provided a thorough and fair process. GAO asked a series of questions, regarding budget preparation and management, documentation of personnel expenses, purchasing competition and documentation, subrecipient reporting, subaward reporting, biographical sketches, research monitoring and development, sharing research data and results, and scientific conflicts of interest. Mason's experience was consistent with those of other universities in virtually all of the areas identified. This was not surprising because when we talk to colleagues at other research universities the challenges that we face are similar regardless of the type of institution.

Let me provide some some specifics on those areas that GAO highlighted as problematic and solvable. Many of our researchers receive awards from more than one agency. This means that they have to spend an inordinate amount of time identifying and responding to different requirements regarding proposal submissions, conflict-of-interest, purchasing, subrecipient monitoring, reporting, and close out. This problem is compounded by the fact that the success rate for awards in many agencies is getting lower, while the time and cost of applying is getting higher. This paradox is discouraging faculty, many of whom balance teaching, mentoring and research loads, from pursuing more research opportunities.

Despite efforts on the part of many agencies over the past several years to target funding towards early investigators, we still see that the average age of first time Principal Investigators is alarmingly high. We are pleased that agencies have identified this problem and are taking steps to target funding at new investigators, but this alone will not address the problem. Continued efforts to eliminate redundant and unnecessary administrative requirements for our researchers will help ensure that our best and brightest continue to pursue research careers and remain active researchers once they begin to have success.

We agree with the GAO that the Office of Management and Budget and research funding agencies have made continuing efforts to reduce administrative workload and the costs for complying with select requirements. But, as GAO found, results have been limited. We endorse

the GAO's call to OMB and the agencies to identify additional areas in which standardization and flexibility promise research efficiencies.

On a more granular level, let me highlight just a few issues of the Academies report that have the most relevance to our situation.

The National Academies Report – Common Rule

First is the Notice of Proposed Rulemaking – the NPRM - on the Common Rule. We share the Academies' concerns regarding redefining all research with de-identified biospecimens as human subjects covered under the proposed Common Rule. Mason researchers in our Center for Proteomic and Molecular Medicine routinely work with biospecimens for which they have secured informed consent. However, they also obtain de-identified specimens from biological repositories, and there is no way such biospecimens could be identified in order to obtain informed consent.

What does this mean? It means that our Center, under the NPRM, might not have the variety of biospecimens they need to continue to conduct groundbreaking research that, for example, has led to a new test for Lyme disease. It means that the tremendous progress made on using the proteome to personalize treatment protocols for breast, colorectal, lung and other cancers would be slowed significantly.

We agree with the Academies' recommendation that the NPRM be withdrawn, and that a new independent national commission be established to examine and update, "the ethical, legal, and institutional frameworks for protecting human subjects", and how they might be applied to de-identified biospecimens and a range of other complex issues. The university community has weighed in on this issue and it is clear that the right path is to reconsider this and other problematic elements of the NPRM.

Export Controls

Second is the issue of Export Controls. On the surface it should be viewed as a positive development for the Department of State to transfer certain export controls from the International Traffic in Arms Regulation (ITAR) to the Commerce Department's Export Administration Regulations. The Academies' report correctly points out that universities, including Mason, continue to be concerned about efforts by the State Department to modify the definition of fundamental research in ITAR. If the result is a restricted fundamental research exemption that does not include tools and instrumentation for example, we believe that technological innovation will be significantly constrained. At Mason, a diminished definition of fundamental research could severely restrict not only the involvement of our brightest non-US students and researchers, but also the broad sharing of fundamental information that fuels innovation around the world. Multiply that throughout the research university enterprise and you can see how innovation could be stifled. The report correctly highlights the 1985 National Security Decision Directive 198 (NSDD 189) that established the principle that the products of fundamental research remain unrestricted to the maximum extent possible. This has served the US well, with no diminution of national security. With the spirit of NSDD 189 in mind, we believe the State

Department should also narrowly define "Defense Services" to clearly permit faculty collaborations with non-US students and research colleagues when such work involves only fundamental research or public domain information.

Effort Reporting

The third area I'd like to comment upon is that of Effort Reporting. In 2011 Mason was the first of four pilot schools to participate in a Payroll Certification Pilot project under the auspices of the Federal Demonstration Partnership (FDP), a cooperative initiative among 10 Federal agencies and 155 research universities focused on reducing administrative burdens associated with research.

Effort reporting is often cited as one of the most burdensome administrative requirements for researchers. Effort incurred across multiple activities is difficult to measure and track and administration is inefficient and costly. The Payroll Certification pilot project had two main goals. First, improve oversight over personnel charges to federal awards by simplifying the salary certification process. Second, enable universities to focus resources toward the efficient and effective oversight of federal awards. In short, Payroll Certification aimed to improve productivity of research without compromising responsible stewardship of federal funds.

The result of implementing Payroll Certification at Mason has been very successful. We have seen a reduction in the number of reports generated by over 85%, but have been able to improve the oversight of personnel expenses by developing a methodology that is easy to understand, aligns with project periods for certification, and targets a smaller group of certifiers (PIs). We have found that with a straightforward methodology we were able to implement with very little upfront and ongoing investment. From an administrative standpoint, we were able to redirect resources to more value added areas and our researchers are now spending less time on effort reporting and more time on research.

At a recent webinar from the Office of Management and Budget (OMB), *Promising Practices in implementation: Personnel Services,* Payroll Certification was identified as a promising strategy to provide flexibility and accrue efficiencies in ways not typically seen in more traditional effort reporting approaches.

Chairwoman Comstock, Ranking Member Lipinski, we believe Payroll Certification pilot is an example where we were able to show that more does not necessarily mean better compliance and the same principle may be applied to other regulatory areas. The FDP should continue to explore ways that the Federal agencies and research universities can collaborate to find specific ways that achieve accountability with reduced administrative burdens.

Office of Inspector General Audits

The fourth issue I'd like to comment on is OIG Audits. The Academies' report notes that there needs to be better alignment between Agency policy and the interpretation of that policy by that Agency's Office of Inspector General (OIG. When there is misalignment, universities often

have no choice but to develop overly restrictive policies and procedures based on anticipated audit findings that are often more restrictive than originally intended by the Agency.

We agree with the Academies that the OIG semi-annual reports should provide examples of innovative, cost-saving initiatives undertaken by the agencies and universities. Furthermore, for reasons of transparency, it makes sense to ask that the OIG's report the total cost of their audits of research institutions. The Academies report elaborates on this and I won't take the time here to repeat it, but providing these data would help make the public aware of the scale of the activities undertaken and the value and expense involved.

Just-In-Time Submissions

Fifth, as mentioned earlier, proposal preparation is becoming increasingly cumbersome and time-consuming with varying demands from multiple agencies. Combined with lower percentages of award winners, researchers are finding it more difficult to make the time commitment necessary to submit high quality proposals. Mason supports the Academies recommendations regarding proposal preparation efficiencies, including uniform grant proposal documents and greater use of just-in-time strategies for submission of supplementary materials. In its analysis, the Council on Government Relations noted that, in some, cases, particularly involving NSF, legislation amending the COMPETES Act may be needed. But, according to COGR, other changes, such as just-in-time submission of detailed budgets and current and pending support can be implemented though changes in agency policy.

Since we all work within a resource constrained environment, it would be much more desirable to see our resources focused on the substantive aspects of a research proposal. Given the fact that the majority of proposals are not funded, the just-in-time mechanism proposed makes sense.

Subrecipient Reporting

Sixth, Mason endorses the Academies recommendation for amending the Uniform Guidance to clarify that subrecipient monitoring applies to universities only to the extent necessary for prudent project and performance monitoring, and does not require more extensive monitoring of subrecipients' institutional compliance with all federal rules and regulations.

We understand the need to monitor more closely subrecipients who may be high risk because of their size, location or other factors, but at Mason, the majority of subrecipients are organizations such as other universities who are already monitored through the Single Audit process; we would see a significant reduction in administrative burden if we could rely on the Single Audit process to meet subrecipient monitoring requirements for these organizations.

Conflict of Interest

Seventh, Mason supports harmonizing Conflict of Interest policies across Federal agencies. The fact that agencies have issued different COI requirements both prior to and in response to the Uniform Guidance has created significant burdens for us and our sister

institutions. Differing compliance requirements regarding the reporting and management of individual and organizational COIs have become exceedingly cumbersome. What happens in reality is that Mason, and many other institutions, format their systems to comply with the most stringent requirements in some areas, and they create specialized systems for others. This is quite inefficient.

H.R. 1119 and H.R. 5583

Finally, the Academies Report calls for Congress to create a Research Policy Board, and establish a new Associate Director, Academic Research Enterprise in the White House Office of Science Technology Policy. To some extent, Madam Chair, your bill H.R. 1119, which passed the House, and your Bill, Ranking Member Lipinski, H.R. 5583, implement what the National Academies are recommending. We are grateful to both of you.

Regarding H.R. 1119, it seems to me that calling on OSTP to develop a dedicated process for harmonizing and minimizing the impact of regulations, and refocusing the enterprise's efforts on performance-based goals is eminently reasonable. OSTP is the logical leader since they already play a coordinating role among relevant federal agencies. Chairwoman Comstock, as we said in our letter to you last Sept. 21, "we believe that your bill constitutes an important step in balancing regulatory relief with accountability. Your bill is consistent with previous reports by the National Research Council and other organizations." A copy of the letter is included with the testimony.

Your bill Congressman Lipinski also has tremendous promise. H.R. 5583 adopts many of the recommendations in the Academies report. But, again, harkening back to the cumulative nature of the problem, forming a Research Policy Board would provide research universities an opportunity to share valuable input before a Notice of Proposed Rulemaking is issued so those with the rulemaking authority can understand if there is a better way of achieving the rule's goal.

Madam Chair, Ranking Member Lipinski, I think your bills will allow for broader discussion of that monster that lurks behind every rule – the law of unintended consequences. By providing a pause button, or the ability to raise a Red Flag, a means for redress, and revisiting existing rules, you have done a tremendous service to the research enterprise and the nation's future innovation.

Thank you again for the opportunity to be here today and provide comments on this important issue.

Ángel Cabrera is the president of George Mason University, the largest public university in Virginia. Serving 34,000 students and located in the Washington, D.C., metropolitan region, George Mason in 2016 moved into the highest research category as determined by the Carnegie Classification of Institutions of Higher Education.

Mason also has been selected in the top 200 of the Academic Ranking of World Universities and has been named one of the top 50 universities under 50 years old by the Times Higher Education.

George Mason University faculty have received some of the most prestigious recognitions in the world, including two Nobel Prizes in economics and the Pulitzer Prize.

Born in Madrid, Cabrera is the first native of Spain to lead an American university. Prior to becoming president at George Mason in 2012, he served as president of the Thunderbird School of Global Management in Arizona and as dean of IE Business School in Madrid.

Cabrera has been recognized by the World Economic Forum as a Young Global Leader, by the Aspen Institute as a Henry Crown Fellow, by Business Week as a "Star of Europe," and by the Financial Times as one of the world's best business school deans.

In 2006, he was appointed special advisor to the United Nations Global Compact and was chairman of the international task force that authored the "Principles of Responsible Management Education." He has been topic leader at the Clinton Global Initiative, chairman of the World Economic Forum "Global Agenda Council for Entrepreneurship" and chairman of the Georgia Tech Advisory Board.

Cabrera serves on the board of directors of Inovio (a Nasdaq-traded biotech company), the Georgia Tech Advisory Board, the Bankinter Foundation for Innovation, the Monterrey Institute of Technology academic board, and the Northern Virginia Technology Council board, among other organizations.

Cabrera earned his PhD and MS from the Georgia Institute of Technology, which he attended as a Fulbright Scholar. He earned his BS and MS in computer and electrical engineering from the Polytechnic University of Madrid.

Cabrera is the author of numerous academic papers. His article "Knowledge-Sharing Dilemmas" (with Elizabeth Cabrera) has been cited more than 1,000 times. His book "Being Global: How to Think, Act and Lead in a Transformed World" (with Gregory Unruh) was published by Harvard Business Review in 2012.

Chairwoman COMSTOCK. Thank you, and I now recognize myself for five minutes for questions.

First, I thank all of the witnesses, and again, we appreciate you being here today despite it being a quieter day, and this is an important topic, and we appreciate all that you've been doing, and I did want to actually also echo the invitation to come down to visit George Mason if you'd like because—and in particular I really appreciate all the women that you have working on the important research, and they've spoken to my Young Women's Leadership program, and there's some really exciting cancer research going on there as well as Lyme disease, so I particularly appreciate that, although I had a lot at the videogames place too at George Mason, so that was pretty—which actually leads into some of these areas too surprisingly. So when your kids are out there playing videogames, you never know where it can lead to because there's some pretty exciting things going on at George Mason, so I always do remind everyone who gets upset about their kids playing videogames, we've got exciting scientific research that goes into medical areas and lots of other things. But I digress.

So as you mentioned, Dr. Cabrera, George Mason University recently rose in the ranks to be amongst the highest research institutions in the country with the Carnegie classification of institutions of higher education, an elite group of the top 115 research universities in the country, and congratulations on that. I think it's exciting how things are changing. I think we really see that kind of growth in so many of these areas so we're happy that you're a part of it.

Does the regulatory burden and barriers for applying for and managing federal grants make it more difficult for a smaller or less resource-rich university to become competitive, and if we really want to create this competitive ecosystem that is going to be able to do the cutting-edge research that we want, how is this regulatory burden impacting that?

Dr. CABRERA. Thank you, Chairwoman Comstock, and yes, indeed, it makes it very difficult. In fact, if you look at that cluster of 115 universities in that tier I Carnegie classification, you won't see much change from time to time. It tends to be a pretty big barrier of entry for universities that are growing like ours that are really building a research infrastructure. Our estimate is that we spend about $16 million annually to provide administrative support to our PIs to help comply with research regulations. Our estimate is that we don't recover about $2 million of that, which by the way if you compare the size of our research enterprise with Duke's, I think our ratios are require similar, and which actually seems to highlight that there doesn't seem to be much economies of scale, even as your research enterprise and looks like the burden continues to grow proportionately. So I think it does create a big barrier, not just for a big college, not just for existing large research enterprises, but for emerging ones like George Mason.

Chairwoman COMSTOCK. Could you all estimate maybe in your individual institutions, so you have $60 million for the cost, if it was streamlined like the pilot that you did, what kind of savings do you estimate you would see? And then, of course, how would

that be plowed back into the research? And then the others too, if you might address that?

Dr. CABRERA. Well, the pilot that we conducted, you can consider that it's in a relatively smaller side of the many aspects of regulation that we deal with, but our estimates that might reduce—just by that simple change, we may be saving north of $50,000 a year. So what this indicates is not just the amount of this. If you expand that kind of thinking to all the areas of regulation, those numbers very quickly add up.

Chairwoman COMSTOCK. Okay. Mr. Luther?

Mr. LUTHER. Yes. I think what I'd add to that is, the amount that departments and administrations support the research mission at Duke is significant and growing, probably $150 million, about $25 million of that that we don't recover. It's over the administrative cap.

I think the other key issue, though, is the avoided costs, right? As new policy comes down the pike, do we have to add additional staff, do we have to add additional administration and technology and business processes, because for every one of these regulations, we have to figure out how to support it centrally, how we have to roll it out to the departments, how we train this, and then ultimately can we do this in a way that doesn't further contribute to that 42 percent of the funded faculty members' time. That's what this is all about from any university's perspective is how can we do it in an efficient way so as not to distract the faculty member from doing their research.

Chairwoman COMSTOCK. Exactly. Thank you.

And Dr. Faulkner or Mr. Neumann, if you have any comments on that?

Dr. FAULKNER. I'm not currently president of the University of Texas so I don't have good, immediate numbers for you, but let me just make the point that actually was introduced by Mr. Luther that I think we would save money if we improved the regulatory environment but we would also save the invaluable time of faculty members and research investigators generally, not just faculty members. But that intellectual power, the power to carry forward research, can't be replaced. That's the indispensable asset, and in order to maintain the capacity of American research, we need to get as much of that brainpower as possible dedicated——

Chairwoman COMSTOCK. On task?

Dr. FAULKNER. But on the resource side, the dollars that institutions are putting into the support of compliance and administrative activity is quite significant and has to come from somewhere. So it competes with everything else that the institution is doing including its ability to support students including its ability to deliver quality undergraduate programs, including its ability to deliver quality graduate programs.

Chairwoman COMSTOCK. Thank you.

Mr. NEUMANN. The only thing I'll add is that we didn't focus specifically on the costs of some of these administrative requirements but rather a little more deeply at the types of things universities had to do to address them, and certainly where they found things like the payroll certification pilot where they could reduce those burdens, as Dr. Cabrera pointed out, they had significant savings

of administrative time, the researchers' time. So that's, you know, the kind of—so we tried to provide some examples of the things that universities are doing to comply with these requirements to get a sense of what's behind these numbers that we've been hearing about.

Chairwoman COMSTOCK. Great. Okay. Now I've gone over my time so I yield to Mr. Lipinski.

Mr. LIPINSKI. Thank you. Chairwoman Comstock, I'm intrigued now by the videogames at George Mason and what the connection is here.

Chairwoman COMSTOCK. Game Institute.

Mr. LIPINSKI. Game Institute. Okay. I'll have to come out and visit.

I want to say that obviously the purpose of regulations is to make sure that there's accountability, we try to rid any kind of waste or fraud but I think it's very important as Dr. Faulkner had talked about in his statement. I just want to read this from the National Academies report here. I think it's very important to make sure we focus on "Continuing expansion of the federal regulatory system and its ever-growing requirements are diminishing the effectiveness of the Nation's research investment."

As I said in my opening statement, we are unfortunately seeing the flattening out and sometimes diminishing of research dollars at the federal level, unfortunately, and we cannot afford to diminish those dollars further through regulation, and I think it's important that everyone understands what this really means, and as Dr. Faulkner talked about, the waste of time of researchers, that really is a great loss not just to those individuals but to our entire research enterprise and in our country, and so I think it's very important that we make sure that people realize that.

I wanted to have a couple of our witnesses expand on a couple of the points that were—that they made. The Research Policy Board, I want to ask Mr. Luther first, what do you see as the value of the Federal Government? Can you just expand on the value of the Federal Government working closely with institutions in developing the regulations and requirements for research?

Mr. LUTHER. Thank you. You know, as I was preparing for this and reviewing the materials, I think to many of us, both at the university level as well as at COGR, the Research Policy Board is kind of the enabler for everything else, right? There's other organizations. There's the research business models. There's the Federal Demonstration Partnership. But the Research Policy Board, the way it's been suggested, is the one group that has all of the appropriate stakeholders at the table to develop it and talk through the implementation, and what we're seeing is, that transparency of the development process as well as input into the implementation process is so critical to the efficiency of it but also to the accountability of it, the accountability going both ways to good policy as well as how can institutions do it in an effective way and meet the goals of that. And I think creation of a board like this that has the same objectives of efficient, quality policy development and implementation is so critical, and as we look specifically at the Common Rule and the biospecimens, I have absolutely no doubt that the NIH has good reasons for the position they're taking right now as they look

at this, but again, in the APLU–COGR review, there's 96 percent of the respondents both at universities and research subjects that basically are questioning this and questioning the impact this would have on research.

And so again, I'm sure the NIH has good reason for the position they're taking, but again, if universities and other stakeholders are the table to evaluate this and participate in it, it would be a much more transparent and accountable process.

Mr. LIPINSKI. Thank you.

Dr. Faulkner, do you have anything you want to add on that?

Dr. FAULKNER. Well, that was a beautiful speech that Mr. Luther just gave. Let me just add two points, though. One is, I'd like to emphasize the word "anticipatory," which is—it's used in that report, and I believe I'm speaking accurately about the sentiments of the committee who wrote the report that they believe that the ability to anticipate new issues and to be able to work those issues before they really have to reach regulatory implementation is the key to maintaining a sane and functional overall regulatory burden, and that's one of the things that we wanted to achieve with the RPB.

And I had a second point, which has flown out of my mind, so I'll just turn my microphone off.

Mr. LIPINSKI. That happens to me all the time.

Dr. Cabrera, do you have anything to add? You don't have to.

Dr. CABRERA. No, just to emphasize—and I think the way you articulated question, I couldn't agree more with that preamble and since I don't think none of the recommendations from these reports question the importance of good regulation, of good accountability, and no one is, I guess, advocating for weak accountability. On the contrary, I think the words that even both of your bills use, you know, harmonize, streamline, eliminate duplication, improving coordination, those are the right directions to take in all these efforts and that can only be done with these coordinating bodies like the ones that your bill endorses.

Mr. LIPINSKI. Well, if I can take a little more time, I wanted to at least briefly touch on something else that Dr. Faulkner raised about the Inspector General. The 1978 Inspector General Act says the purpose of the IG also is to promote economy, efficiency and effectiveness in the administration of programs, and you touched upon that in your statement. Can you expand on that? Obviously you don't think that—or it seems to me that you are saying that that's not always the understanding that the IG brings to part of what their job is.

Dr. FAULKNER. Well, I think that the committee fully recognizes the need for the Inspectors General to focus on waste, fraud, and abuse. What we also recognize, however, is that the research enterprise in the United States as it's implementing in the research partnership with academic institutions already has a large volume of audit involved in it. Every institution is audited every year on its research activity. The history of Inspector General engagement with the research enterprise is not one that has yielded large trophies in terms of recovered funds. There are, of course, isolated cases where problems have been explored and where remediation has been required, but that's not the ordinary story. A more com-

mon story is that Inspectors General and the agency that they're supporting or engaged with have different interpretations of what federal policy ought to be or federal practice ought to be in financial management of research grants, and the dispute which is essentially between two federal actors, will get fought out on a battle ground in an institution that then has to spend large amounts of money to go through the process of the audit that's being used to fight the battle. This, in our judgment, is not really constructive. The battle between the federal players should be fought out here and not there.

And we do recognize also that in the charter that you read, Representative Lipinski, there is a direct reference to giving the responsibility to the Inspectors General for the improvement of efficiency and effectiveness and we're simply asking for a rebalancing of the approach in this area where there's already so much audit activity to pay attention to that part of the mission.

Mr. LIPINSKI. Does the two months' summary salary issue at NSF fall into this?

Dr. FAULKNER. Well, that's been one of the areas where there's a dispute between the IG and the agency itself over what the policy should be. They have to settle what the policy is and we carry it out.

Mr. LIPINSKI. Thank you very much, and I thank the Chairwoman for being here. I know you didn't have to be here this morning, so I appreciate it.

Chairwoman COMSTOCK. We appreciate the professor too being here with his expertise.

Let's see. I wanted to see if we could maybe draw a picture for us. I'm thinking when I visited George Mason, Dr. Luchini I guess was named one of the 40 most brilliant people in the world working on Lyme disease research, I think some cancer research, because the nanotechnology is kind of coming together in some ways, or Dr. Petricoin, who was also with us on some of those visits. How is their day and time—because when I think of having the asset of one of the 40 most brilliant people in the world working on these important diseases and chronic conditions that we want to cure and find, you know, new information on, how is their day impacted? How is their work impacted because of these regulations? Maybe if you can give us a picture of what Dr. Luchini or Dr. Petricoin have to do as a result of these regulations, that helps sort of give us the urgency of, we want them on task, and having seen some of those brilliant things that they're working on, I really don't like the thought of them having to do much else besides put their brains to this good work.

Dr. CABRERA. Sure. Dr. Luchini, by the way, is one of those thousands of bright scientists from outside of the United States that every year choose to come and join our universities because this is where the tools and the environments that they think were they can have the biggest impact, and her recognition indeed was not just as a top scientist but as a top young scientist, and this is very important because I believe when I talk to our faculty, it is young scientists that suffer the burden of these regulations more directly and more personally. I'm guessing that people like Dr. Petricoin and well-seasoned scientists have somehow developed their own

survival routines, on how to deal with all these things, and they figure out a way to do it.

My concern is that the younger scientists may see this as yet another unsurmountable barrier to do what they want to do, which is to spend time in the lab trying to explore how to best test people for Lyme disease or how to come up with a new personalized treatment for cancer. So just like I mentioned earlier that I believe that this complex regulatory machinery creates a burden for young universities that are building the research infrastructure at a more micro level, it does the same for younger researchers.

Chairwoman COMSTOCK. No, that's great, and seeing how she inspires the students too and to get to capture their imagination and stay in working in this, I think we need bring the Uber economy to the scientific research, right? Get a little bit more flexibility.

Okay. We wanted to cover some of the things that others who aren't here might have covered.

Dr. Faulkner, the centerpiece of the Academies report is the creation of a self-funded Research Policy Board to include members of both the research community and government agencies. Did the study committee have any concerns that it would be just another layer of bureaucracy? Because as we come in and look at these things, that's what I'm trying to figure out, you know, what is the ideal picture of a day in the life of these researchers and how we're going to provide accountability without interrupting the important work? So as we come up with these solutions, how can we make sure we're not adding more bureaucracy instead of peeling it back?

Dr. FAULKNER. Well, I think that's a good question, Madam Chairwoman. The goal certainly is not to add a layer, and I believe that with the design we've laid out, that would not happen. This is not an approval body. It's not I think in the line of what would be required to get things done, but it is meant to be a coordinating body, and as I emphasized earlier, an anticipatory body.

One of the points that Representative Lipinski made earlier is that the volume of regulatory activity has grown over time and continues to grow. We can bet that it's going to continue to grow because as research goes on, it uncovers issues that require attention. We can all sit here today and recognize that in the years ahead, we're going to have to more regulatory activity that addresses some of the genetic issues that are clearly in the field of view right now.

So we know that as research goes on, new issues come into the picture. We need more coordination and some capacity for the whole community, the researchers' side and the funders' side, to get together and try to find ways to get to the optimal regulatory picture, which is going to take continuous editing as we have to bring in the capacity for additional things, and perhaps we can develop other devices that speed up or simplify or lower the cost of some of the things we're already doing.

So I guess the answer I would give you is, we desperately need the coordination, and the coordination and the anticipation is the key to keeping this as sane as we can keep it going forward.

Chairwoman COMSTOCK. You know, one of the things that I've heard from researchers as we talk about particularly in the area of medical research and some of the rapid pace that things are developing, the doctors, you know, if you're in any particular field,

you can't possibly know everything that's going on that's out there, and we all get in our silos and all, and they talk a lot about—I mean, some of the researchers and technology people now—we've had—in my area we see people who are very engaged in the technology committee are merging into the medical area and wanting to, you know, use technology with medicine and find ways to get information out there, and they talk a lot about having more transparency, which is very different from how our medical research is done today. You know, you're in a study, you don't know all the other things that are going on in the patients, and we don't have this transparent process, you know, for good—I know there are reasons why we don't but I have seen people now in the medical area talk more about just getting more of this information out there, you know, just having it all out there for everyone to kind of come in and look at and, you know, you kind of have that check and balance by having information out there instead of having to have all these boards, having, you know, all this regulatory process that you really get it out there and you have the vast public being able to check it. You know, it's like a spell check system out there because everybody else gets to look at what you're doing and saying hey, did you connect this with this and, you just have a lot more people in there helping you, and is there—and I know, I'm not articulating this very well—but this is what I had expressed to me in some way from the technology side of this is, how do we open this up a lot more and change that way of thinking in research that it's just going to be open source type of information. Is it something that you all have discussed in some way or heard about too? Just any of you to address.

Dr. FAULKNER. Shall I try?

Chairwoman COMSTOCK. Sure.

Dr. FAULKNER. I think actually you're addressing the question of the sort of review and self-correction of science as it occurs. You know, historically we've published things in journals and people read the journals and they may do verifying or testing experiments or other kinds of activity of their own. As the scientific enterprise has gotten more complicated, and as information technology has dramatically improved, the possibility exists of providing larger amounts of information including original data, which by and large has not been part of that publication proceeding activity over the years. So I think there is a lot of discussion in the scientific world about whether by being more open with a larger fraction of what investigators have produced including their original data we might not be ahead. The Academy committee really didn't address that issue. We're addressing not the question of review for validity of scientific work; we're talking about true regulation, I mean, financial regulations, what you can do with human subjects and that sort of thing. So our work was all on the other side here.

Chairwoman COMSTOCK. Okay.

Mr. LUTHER. If I can add to that, you know, there is, I think it's a 2013 OSTP requirement that for federal agencies with over $100 million in annual expenditures, there's a public access process, and I think the rollout of that is going to be ripe for something like a Research Policy Board because that regulation requires that for all peer-reviewed publications that all supporting digital data as well

as all the metadata be made available. It requires that it's stored for long-term preservation and publicly accessible to search, and it requires—with a goal of maximizing the potential to create the new business opportunities. And I think that's wonderful, right? The Federal Government has funded this research, it's data that can be leveraged to do other wonderful things, but as we look at how we're going to execute on that, one example that we've discussed with a faculty member is that the imaging data related to one mouse is terabytes upon terabytes upon terabytes of data, and that would have to be made publicly available with metadata and supported for future research, wonderful idea, but how we do that and how we execute on that and how it happens and orders of magnitude. We've talked to peers out in the Midwest that do weather research. Well, the quantity of weather research and the data they create or the space program is just orders of magnitude. So the concept is wonderful but the idea behind a Research Policy Board that's where all the players at the table are working towards the same strategic goal and thinking through how to operationalize that is what's so critical because if the regulation just comes out and says do it, it's the faculty member that's going to have to, that's going to know the data. We as administrators are going to try to help but we don't have the tool set, and it will create an immense amount of burden.

Dr. CABRERA. Just to add to that, I mean, the possibilities that are created by new technologies are simply phenomenal in terms of access to data and immediacy of that data, not having to wait the number of months and sometimes years that a traditional publication cycle would enforce. The key and I think some of the biggest debates we're having in scientific communities is how to balance that desire for immediacy in access with the power of the peer-review process, which is really one of the central pillars of the scientific enterprise and not lose that because that's one of the most important sort of research quality control processes that we've developed throughout the years.

Chairwoman COMSTOCK. Great. Thank you. And I will yield to Mr. Lipinski.

Mr. LIPINSKI. I think we've covered many things here. I just want to see if there's anything—I'll open up. Usually the Chair probably would do this, but are there any—anything that any of the witnesses would like to add that they think we haven't covered here that are important to get on the—to get on the record? Any additional—Dr. Cabrera?

Dr. CABRERA. If any—the only thing, I think it's been said, but I just wanted to emphasize the tremendous amount of consensus and agreement that the NAS report has generated, so this is not just an isolated point of view. I think it really reflects the point of view of the research universities of this country.

Mr. LIPINSKI. Thank you.

Mr. LUTHER. I was just going to add that I think the GAO report set out, you know, to really look at the university community's concerns and in a sense validated those concerns, and if agencies take action based on our recommendations, we think they can continue to make some progress in this area which, you know, we did identify a couple of areas that really do need further look, you know,

in terms of streamlining, standardizing some of these requirements and delaying some and doing things that make more sense based on the risk like, you know, the purchase requirement. So I think that would be really important. I'm glad that you're holding this hearing, and I think having this will ensure that agencies will take action based on our recommendations.

Mr. LIPINSKI. Thank you.

Mr. Luther?

Mr. LUTHER. Yes. Thank you. I would just like to say I hope you sense the commitment from universities, certainly from our comments as well as, you know, the communications that COGR and AAU and FDP and many of the other organizations have had. It's all about the commitment to support the research and make it better, and we do things internally. In fact, at Duke, we have in essence kind of a research policy board internally that reviews policies. We have a couple of senior leaders that meet every Tuesday morning and have met for about the last ten years to look specifically at research issues, and it's a combination of financial, administration and faculty leadership, and it's there to address those issues, to address the resource needs and so forth.

And then my final comment would be, as I mentioned in my opening statement, there are lots of examples of highly functioning relationships of where we've worked through things, the uniform guidance with NIH, we've had NIH, NSF and DOD. We've had some really positive discussion about the closeout process and subaccounting. But as I mentioned, much of that is very relationship-based. There's a handful of absolutely wonderful people that are just as committed, if not more than we are, to work through this. We would hope that that research board, research policy board, is structured that same way, to have the committed individuals that are accountable that push the objectives of good, effective policy.

Dr. FAULKNER. I think we've done well with the subject today, so I won't add anything further.

Mr. LIPINSKI. I completely agree. I thank the witnesses for your testimony. I think all of you did a very good job of explaining the real need for regulatory relief when it comes to academic research and the regulations. So thank you all for your testimony.

Chairwoman COMSTOCK. Thank you. And I also thank the witnesses for their testimony, and Mr. Lipinski for joining me here today and bringing his expertise to bear here.

It is really exciting to hear from people on the front lines, and I invite you to continue the dialog with us on how we can best help you best utilize the resources that we're providing and make sure we have the best policies in place for you to be able to do the good work that your researchers are doing because there is so—you know, I think we are on the cusp of some really incredible research developments that are out there, and we want to make sure we are putting the best policies we can in place, so we have no pride of authorship on our end. We'd love to have you come and help us improve that. You know, we're looking at Mr. Lipinski's bill too, so I think we want to make sure we have the best ideas in place. So we really, really appreciate your expertise and talent and the importance of attracting that talent and making sure we have the best talent here working and working on task.

So I thank you, and the record will remain open for two weeks for additional written comments and any written questions from Members who are here or not able to be here.

So thank you again, and the hearing is adjourned.

[Whereupon, at 11:17 a.m., the Subcommittee was adjourned.]

Appendix I

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Dr. Larry R. Faulkner

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

"Academic Research Regulatory Relief: A Review of New Recommendations"

Dr. Larry R. Faulkner, President Emeritus, The University of Texas at Austin

Question submitted by Rep. Barbara Comstock, Chairwoman, Subcommittee on Research and Technology

1. The Academy report makes several recommendations for Congress on resolving issues between inspectors general and agency opinions in audits of universities. The Inspectors General for the National Science Foundation and Department of Health and Human Services sent a letter to the National Academies expressing their concerns about some of the recommendations in the draft report about how their comments were characterized.

    a. Can you elaborate on what the issue is for universities with how IGs and the agencies are handling routine audits? Did the final report address or correct any of the concerns expressed by the IGs?

RESPONSE:

Research institutions are subject to frequent federal audits as part of their acceptance of federal research funds. There is a growing concern, however, that there is a lack of shared understanding between agencies and their own IGs with regard to expectations regarding financial policies and procedures. Universities have become battlegrounds for disputes that are essentially matters of federal policy. When agencies, Inspectors General, and research institutions have shared understandings and interpretations of the rules and regulations governing financial expenditures, there are fewer disagreements about the expenditure of federal funds and there is far less wasted effort across the institutions and government. Without a shared understanding, an environment is created with competing assertions and findings. Consequently, we recommend that the responsibilities of the Inspectors General be rebalanced so that appropriate consideration is given both to uncovering waste, fraud, and abuse and to advising on economy, efficiency, and effectiveness.

With regard to the concerns expressed by the IGs following the release of Part 1 of the committee's report, the final report includes revisions to Chapter 6 ("Regulations and Policies Related to the Financial Management of Research Grants") that incorporate minor editorial corrections, including clarification of the relationship between offices of inspectors general and their agencies and the difference between audits and investigations.

2. The centerpiece of the Academy's report is the creation of a self-funded Research Policy Board, to include members of both the research community and government agencies. Did the study committee have any concerns that it could become just another layer of bureaucracy? And how can that be avoided?

   RESPONSE:

   The goal of this new entity – and of the new framework overall – is not to increase bureaucracy, but to provide a mechanism that will forestall the creation of duplicative and incongruous regulations, streamline and harmonize existing regulations, provide a means to eliminate outdated or ineffective regulations, and serve as a forum in which the regulatory issues of the future can be thoughtfully anticipated. Anticipation of issues and coordination of efforts are the keys to an efficient regulatory environment.

3. Regarding the Academy report's recommendation of creating a new Research Policy Board, did the Committee consider instead utilizing any existing forums for making recommendations on regulations? For example, the National Science and Technology Council (NSTC) or the National Science Board?

   RESPONSE:

   The committee did indeed consider utilizing existing forums, including the National Science Board (NSB), but did not find such forums to have the capacity to bridge the diverse agencies and institutions that constitute the government-academic research partnership. In the particular case of the NSB, the committee found that while the board "serves as advisors to both the President and Congress on policy matters related to science and engineering," its responsibility to and alignment with the National Science Foundation limits its ability to provide the comprehensive approach to government-wide regulation that is needed to foster a sensible regulatory system. In addition, the NSB has other responsibilities and does not have the strong relationship to the Office of Information and Regulatory Affairs (OIRA) that the committee believes to be necessary. For the most part, the existing federal apparatus is focused on policy matters other than regulation, including priorities for research funding, new facilities, and national technical staffing needs. The RPB is aimed at effectiveness in the actual operation of the federal-academic research partnership.

4. In your testimony you note that many federal regulations were in response to incidents of misconduct or mismanagement. What responsibilities do universities have for ensuring good stewardship of research and what recommendations does the Academy report make for the research community? For example, your testimony mentions sanctions, what would be an appropriate process for determining penalties?

RESPONSE:

The report recognizes that universities have an obligation to demand the highest standards on an individual and an institutional level. The committee's second overarching

recommendation speaks entirely to institutional responsibilities and suggests that the Research Policy Board might assist in the development of an appropriate policy to hold institutions accountable for transgressions:

RECOMMENDATION TWO: To advance the government-academic research partnership research institutions must demand the highest standards in institutional and individual behavior. This can only be achieved if universities foster a culture of integrity among academic leaders, faculty, postdoctoral trainees, students, and staff, and institutional administrators, and mete out appropriate sanctions in instances where behavior deviates from the ethical and professional norms of the institution and of the academic research community. Universities that deviate from or fail to enforce the norms of behavior should sanctioned. The committee recommends that a newly established Research Policy Board should collaborate with research institutions on the development of a policy to hold institutions accountable for such transgressions.

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

"Academic Research Regulatory Relief: A Review of New Recommendations"

Dr. Larry R. Faulkner, President Emeritus, The University of Texas at Austin

Question submitted by Rep. Daniel Lipinski, Ranking Member, Subcommittee on Research and Technology

1. Most of the existing Boards that are populated by both federal agencies and non-governmental stakeholders are really focused on a single agency, or a small and targeted group of agencies. The Research Policy Board as envisioned by the National Academies would have representatives from all 8 or 9 agencies that fund academic research. Is there one current board in particular that is the most relevant precedent for such an entity that develops policies and advises across so many diverse mission agencies? How might that look in practice so that it doesn't get bogged down with so many different entities trying to hash out common agreement? What are the benefits or possible drawbacks of a board that includes only three federal agencies, as proposed for example in H.R. 5583?

   RESPONSE:

   The most relevant model for the Research Policy Board is that used by the Securities and Exchange Commission (SEC) for the operation of the Financial Accounting Standards Board (FASB), which has functioned successfully for over four decades. FASB's authority is derived entirely from the SEC, but FASB operates on private-sector funding. It is a government-enabled, private-sector entity with a staff to coordinate the flow of business and supporting project teams that are assembled from time to time to address extant policy matters. This model should be adapted to establish the Research Policy Board we recommend.

   While the RPB, as conceived, would fulfill the need for an active forum bridging the public-sector and private-sector partners, there is a need for a federal officer whose focus is the healthy functioning of the government-academic research partnership. To fulfill this role, the committee recommended the creation of the position of an OSTP Associate Director, Academic Research Enterprise. It would be the responsibility of this individual to coordinate the federal research policy and regulatory process and to routinely integrate and organize input in a broadly representative fashion among federal research agencies, the RPB, and other representatives of institutions of higher education and their representative associations.

   This officer would routinely coordinate with senior agency staff including those in the Office of Management and Budget (OMB); research funding agencies; NSB, Chief Financial Officers Council; Council of Inspectors General on Integrity and Efficiency; President's Council of Advisors on Science and Technology; National Science and Technology Council (NSTC), and other agencies as appropriate.

I cannot comment on the benefits or possible drawbacks of a board that includes only three federal agencies. As we noted in our report, the specific operational functionality of the RPB and the mandate of the proposed associate director will be defined through debate and negotiation.

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

"Academic Research Regulatory Relief: A Review of New

Recommendations" Dr. Larry R. Faulkner, President Emeritus, The

University of Texas at Austin Question submitted by Rep. Elizabeth Esty

Thank you, Chairwoman Comstock and Ranking Member Lipinski for holding today's hearing to review recommendations put forth by the National Academies and the U.S. Government Accountability Office (GAO) on ways to alleviate regulations on academic scientific research.

Yale University, one of the world's premier academic institutions, is grateful for Congress' commitment to substantial funding for university research. Yale is also committed to the highest standards of ethics in conducting research as well as full accountability for the use of public funds that are invested in university research.

At the same time, the extensive body of rules and reporting requirements is both expensive and a drag on research. Yale and the university community have long called for smarter, more efficient regulation that would enable the research community to be more productive and to save money. A Research Policy Board would give stakeholders a chance to work cooperatively with federal agencies to rationalize rules before they are adopted.

A review of compliance spending was recently undertaken at Yale. Yale tracked the budgets of the offices that had lead responsibility for implementing federal rules for the conduct of research, such as environmental health and safety, conflict of interest, privacy, among others. It was determined that offices charged with compliance rose, on average, 9% per year for 10 years. I suspect that other universities had a similar experience.

1. I am trying to understand why we have not solved this problem sooner, because the imperative to balance accountability and efficiency seems obvious. What has impeded past efforts to streamline compliance burdens? Can you speak to how the Research Policy Board would help?

RESPONSE:

As noted in our report, the increase in federal regulations is well recognized and has many sources. In part, it may be due to the momentum and inertia of a regulatory process that provides little opportunity to review, evaluate, and eliminate unneeded regulations. This is a concern far beyond the research enterprise, as is manifested by decades of initiatives to reduce paperwork and streamline regulation across the federal system. In the particular case of scientific research, the increase in regulation stems, in part, from specific research concerns. Public perception of the risks of some research procedures, materials, or outcomes motivates the accretion of regulations. Episodic investigator misconduct, sometimes associated with investigator or institutional conflicts of interest—and the real

sufficiently—have

also led to new regulations.

The regulatory landscape is complicated by the fact that the involvement of the federal government in the research enterprise is not overseen by a single office. Unlike in some countries, the U.S. government does not confine its funding of research within a single ministry. Rather, it supports and oversees research via a diverse and decentralized array of agencies and offices with different missions, mandates, budgets, and institutional profiles.

The challenges of complying with duplicative and conflicting regulations have not been lost on federal sponsors of academic research. Agencies have frequently undertaken efforts to reduce regulatory burden.

However, the absence of a body responsible for monitoring and optimizing the health and functioning of the nation's investment in basic and applied research causes serious problems. Congress, the Administration, funding and regulatory agencies, research institutions, and the public lack a means of communicating with one another about their concerns and expectations regarding the regulation of research. Also lacking are the data needed to assess whether the government–academic research enterprise is operating as well as it might and the extent to which existing and proposed regulations, guidance documents, and policies are aiding or hindering that end. In the current regulatory framework, agencies face barriers to harmonizing research regulations and policies for optimal effectiveness. The committee believes that an integrated entity formally connected to the federal policy-making process is necessary to address the scale and complexity of current and future regulatory needs.

The RPB, as a high-level forum that facilitates substantive dialogue about and collects and analyzes data on existing and proposed regulations, will ultimately result in less bureaucracy as the members of the partnership, working together, streamline and harmonize those regulations governing the conduct of research.

Responses by Mr. John Neumann

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

"Academic Research Regulatory Relief: A Review of New Recommendations"

Mr. John Neumann, Director, Natural Resources and Environment Team, Government Accountability Office

Questions submitted by Rep. Barbara Comstock, Chairwoman, Subcommittee on Research and Technology

1. **In your testimony, you mention that attempts were made to streamline research regulations in a 2011 executive order and in the 2013 adoption of the OMB Uniform Guidance, a consolidation of federal research regulations, but that reductions in burden were limited. Why did these actions fail to make a difference in regulatory burden on universities?**

As we reported in June 2016, OMB and research funding agency efforts to streamline research requirements have made a difference in universities' administrative workload and costs in several of the areas we reviewed.[1] However, these reductions have been limited, in part because (1) efforts to standardize requirements have not fully addressed variations in agency implementation of certain requirements, such as agencies' forms and systems for collecting project budgets and biographical sketches; (2) funding agencies have not fully examined pre-award requirements to identify those—such as requirements for detailed budgets—that can be postponed; and (3) some requirements—such as those for obtaining multiple quotations for small purchases—limit universities' flexibility to allocate administrative resources toward oversight of areas at greatest risk of improper use of research funds. Our June 2016 report made several recommendations for OMB and funding agencies to identify additional areas where requirements can be standardized, postponed, or made more flexible, while maintaining oversight of federal funds.

2. **The GAO report did *not* recommend the creation of a new Research Policy Board, but rather utilizing the NSTC's Research Business Model (RBM) working group. In your opinion, is the RBM working group capable of achieving the same ends, perhaps working with external stakeholders?**

We believe that RBM is capable of serving as a coordinating body for agencies to implement the recommendations made in our June 2016 report. RBM's charter calls for it to examine opportunities and develop options to unify and streamline agency research grants administration practices, and to assess and report periodically on the status, efficiency, and performance of the federal-academic research partnership. In addition, RBM's charter calls for it to consult and coordinate with external stakeholder groups that include university representation, such as the Federal Demonstration Partnership and other private-sector groups. We also reported in June 2016 that RBM efforts have resulted in standardization of some selected requirements, and officials at NSF, NIH, and OSTP who co-chair RBM told us that the group is well suited to pursue further efforts to standardize requirements and to report on its efforts.

---

[1]GAO, *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements*, GAO-16-573 (Washington, D.C.: June 22, 2016).

In addition, to the extent that the recommendations from our June 2016 report coincide with the goals to be addressed by a new board, we believe that RBM is capable of achieving the same ends as a new board. However, proposals such as the Research Policy Board include goals that go beyond our recommendations, such as facilitating discussions about emerging fields of research that may require new or revised regulations or policies. Because our report did not consider such goals, we cannot say whether RBM is capable of achieving them.

Question submitted by Rep. Daniel Lipinski, Ranking Member, Subcommittee on Research and Technology

1. **The GAO recommended that agencies continue to collaborate and work toward streamlining requirements through OSTP's Research Business Models interagency working group, and the agencies seemed to concur. The stakeholder community feels very strongly that they need to be at the table to ensure the reforms are effective and appropriate. The National Academies recommended a Research Policy Board that would include both the federal funding agencies and key stakeholders. What findings from GAO's report should the committee consider as it evaluates the need for a Research Policy Board? What are key similarities and differences between the existing Research Business Models interagency working group and the Research Policy Board recommended by the National Academies? Are you aware of similar such boards across the government from which we might learn any lessons or best practices? Do you have any specific recommendations with respect to the Research Policy Board recommendation in the National Academies report?**

As we reported in our June 2016 report, according to OMB staff and funding agency officials, there are statutory and other limitations to agencies' ability to streamline requirements—limitations that could also apply to the efforts of a new body, such as the Research Policy Board proposed by the National Academies. For example, funding agencies must comply with differing statutory or other requirements, which can result in differences in their requirements for grantees, and there are differences in the types of research or recipients agencies fund that can limit their ability to standardize requirements. There are other limitations to agency efforts to streamline pre-award requirements through the use of preliminary proposals, such as in cases of solicitations or research grant programs in fields with a small number of scientists who are likely to apply, or where the large majority of applicants go on to submit full proposals.

The Research Policy Board recommended by the National Academies includes goals that are similar to RBM's charter, which calls for it to unify and streamline agency research grants administration practices and to assess and report periodically on the status, efficiency, and performance of the federal-academic research partnership. The Research Policy Board would also differ in several respects from RBM. For example, the National Academies proposed establishing a new position in the Office of Science and Technology Policy to serve as a principal federal contact point for the Research Policy Board. In addition, the Board would have a different structure than RBM. As the National Academies described it, the Board would be "a government-enabled, government-linked, private-sector entity" similar to the Financial Accounting Standards Board. We did not evaluate proposals for new research policy bodies as part of our June 2016 report. As a result, we do not have specific recommendations with respect to the structure or functions of such a body.

Question submitted by Rep. Elizabeth Esty

1. **Funding agencies, as well as universities, have a clear responsibility to account for the ethical conduct of research and the responsible use of federal funds. At the same time, university research is a job creator. It is the source of many startup companies, as I have seen in Connecticut with the launch of Achillion, Alexiox, Arvinas, Kolltan, and dozens of other companies based on Yale inventions. My colleagues and I often talk about reducing the burden on jobs creators. Shouldn't we think about the compliance burden on universities in the same way? That is, shouldn't we seek to ease the burden on universities as job creators?**

We did not evaluate the effect of administrative research requirements on universities' ability to create jobs. However, the administrative workload and costs of complying with these requirements can negatively affect universities' ability to efficiently conduct research, as we reported in June 2016. To the extent that such research leads to economic growth, greater efficiency in the use of federal funding for research could lead to improved economic outcomes.

Responses by Mr. Jim Luther

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

"Academic Research Regulatory Relief: A Review of New Recommendations"

Mr. Jim Luther
Associate Vice President for Finance & Compliance Officer, Duke University

1. Mr. Neumann's testimony mentions that attempts were made to streamline research regulations in a 2011 executive order and in the 2013 adoption of the OMB Uniform Guidance, a consolidation of federal research regulations, but that reductions in burden were limited. Did these actions have any impact for your universities, negative or positive?

Similar to the GAO comments, I would suggest that from Duke and COGR's perspective, *Executive Order 13563, Improving Regulation and Regulatory Review*, issued in January 2011 has not had the intended level of positive impact on federal research regulations and burden reduction. The principles of this Executive Order with respect to limiting burden, maximizing net benefits and identifying alternatives to regulation, as well as the suggestion of outreach prior to issuing proposed rulemaking and coordination among agencies are often not applied in the rulemaking process to the extent envisioned. Were agencies to adhere to these principles in a more accountable manner, both with respect to regulations and to policies that carry the force of regulation, regulatory burden could have been significantly reduced, but agencies have not been expected to demonstrate their adherence to the principles. With respect to retrospective analysis of existing rules, as detailed in Executive Order 13563, the recommendations put forward regarding retrospective review does not apply to the major policies and guidance issued by research funding agencies, although significant opportunity exists.

With the Uniform Guidance, we believe that OMB and several key policy leaders from funding agencies did seek to apply these principles, to reduce burden and to enhance flexibility. OMB and these select leaders did regularly engage stakeholders during the regulatory process. However, in this case, the impact was somewhat limited because the act of combining the eight disparate circulars was not, in itself, going to reduce regulatory burden on universities in a meaningful way. The magnitude of this change, regardless of the technical implications on individual regulatory requirements, required significant business process analysis and change, training and education, and in some cases, changes to technology. One area of significant opportunity related to effort reporting, but the lack of specificity, likely as a means to enhance flexibility, coupled with concerns about Inspector General audits, has some institution's forgoing or delaying reforms that could reduce burden. Further, long-standing concerns with respect to subrecipient monitoring were not addressed; and new requirements, such as the micropurchase threshold, threaten to cancel out gains with respect to reducing burden. In summary, the engagement throughout the UG development process was very collaborative, but the true value to the university research community has yet to be determined.

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

"Academic Research Regulatory Relief: A Review of New Recommendations"

Mr. Jim Luther
Associate Vice President for Finance & Compliance Officer, Duke University

Question submitted by Rep. Daniel Lipinski, Ranking Member, Subcommittee on Research and Technology

1. Most of the existing Boards that are populated by both federal agencies and non-governmental stakeholders are really focused on a single agency, or a small and targeted group of agencies. The Research Policy Board as envisioned by the National Academies would have representatives from all 8 or 9 agencies that fund academic research. Is there one current board in particular that is the most relevant precedent for such an entity that develops policies and advises across so many diverse mission agencies? How might that look in practice so that it doesn't get bogged down with so many different entities trying to hash out common agreement? What are the benefits or possible drawbacks of a board that includes only three federal agencies, as proposed for example in H.R. 5583?

To my knowledge, there is not necessarily an existing board that advises across diverse agency missions. However, I would suggest that the focus should not be the "agency" and the agency's mission, but instead the focus should be "research" and how university research is regulated, as the regulation of research across agencies has many commonalities. The OMB Uniform Guidance which is adopted by agencies in regulation and policy, governs how federal funding for research is managed by institutions and agencies; common research terms and conditions derived from the guidance are often adopted by multiple agencies although not all; the Common Rule for the protection of human subjects has been adopted by more than a dozen federal agencies; federal regulations for the treatment of animal research are applicable across multiple agencies; most agencies have conflict of interest policies; they have similar, but not the same, pre- and post-award requirements; similar, but not the same, systems for managing proposal submission and funding. It should be noted that very substantial gains can be made by streamlining and harmonizing these similar, yet different, requirements, processes and systems. Universities input via a Research Policy Board, coupled with appropriate and accountable oversight, could lead to more streamlined and harmonized requirements and significant burden reduction.

In terms of not getting bogged down with many agencies identifying common agreements, I think the focus should be on identifying commonalities and relying on the federal-university partnership to identify the best model or practices as well as those that create unnecessary administrative work as a starting point for discussions, and help ensure the implementation of regulations that are effective, efficient and fit with the realities of the university research environment.

I think the community has read H.R. 5583 as explicitly including three federal agencies but not necessarily limiting the Board to that number. The three agencies listed, NIH, NSF and DOD, are the

largest federal funding agencies for academic research and therefore have the greatest impact on the administrative workload, or level of burden, of investigators and institutions so there are certainly benefits to discussions with these agencies. The top six includes DOE, NASA and USDA and according to Science and Engineering Indicators, these six agencies provide over 92% of academic expenditures for science and engineering research and development. H.R. 5583 also proposes the use of ad hoc working groups "to address particular regulations, policies, and guidance documents reviewed or identified by the Board...that are under development or targeted for reform." These ad hoc groups could allow for discussions with additional agency officials and university experts on issues identified by the board.

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

"Academic Research Regulatory Relief: A Review of New Recommendations"

Mr. Jim Luther
Associate Vice President for Finance & Compliance Officer, Duke University

Question submitted by Rep. Elizabeth Esty

Thank you, Chairwoman Comstock and Ranking Member Lipinski for holding today's hearing to review recommendations put forth by the National Academies and the U.S. Government Accountability Office (GAO) on ways to alleviate regulations on academic scientific research.

Yale University, one of the world's premier academic institutions, is grateful for Congress' commitment to substantial funding for university research. Yale is also committed to the highest standards of ethics in conducting research as well as full accountability for the use of public funds that are invested in university research.
At the same time, the extensive body of rules and reporting requirements is both expensive and a drag on research. Yale and the university community have long called for smarter, more efficient regulation that would enable the research community to be more productive and to save money. A Research Policy Board would give stakeholders a chance to work cooperatively with federal agencies to rationalize rules before they are adopted.

A review of compliance spending was recently undertaken at Yale. Yale tracked the budgets of the offices that had lead responsibility for implementing federal rules for the conduct of research, such as environmental health and safety, conflict of interest, privacy, among others. It was determined that offices charged with compliance rose, on average, 9% per year for 10 years. I suspect that other universities had a similar experience.

1. Did your Committee examine whether universities, out of concerns about being audited by an Inspector General, go beyond the requirements of federal rules, and interpret research regulations and requirements that are overly conservative and, as a result, unnecessarily expensive? How can Congress provide assurances to universities that they will be held harmless if they meet the policies established by funding agencies?

The Council on Governmental Relations, in partnership with its university members, has identified over 100 actions that have the potential to reduce the administrative work associated with sponsored awards and many of our members are currently working through this checklist. COGR has not explicitly looked at the role of OIGs. However, I can say that as a result of recent NSF OIG audits, where more than a dozen universities followed agency policy and guidance only to have costs disallowed by the OIG, some institutions are likely hesitant to use the flexibility made available through the Uniform Guidance. As an example, many institutions are likely hesitant to replace existing effort reporting systems, many of which were implemented at great cost to the institution, with payroll verification or other, less labor-intensive options because of the uncertain OIG environment.

A potentially effective opportunity for Congress to "provide assurances to universities that they will be held harmless" is referenced in Section 8 of H.R.5583 - University Regulation Streamlining and Harmonization Act of 2016 that addresses the OIG's role in audits. Developing a mutually beneficial and accountable relationship between universities, the OIG's and policy offices in this area are critical to the effective and compliant use of the taxpayer dollar.

Responses by Dr. Ángel Cabrera

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

"Academic Research Regulatory Relief: A Review of New Recommendations"

Dr. Ángel Cabrera, President, George Mason University

Question submitted by Rep. Barbara Comstock, Chairwoman, Subcommittee on Research and Technology

Question:

Can you share any of the lessons learned from the pilot and audit that would help inform the Committee on whether a wider roll-out of the pilot would ensure efficiency and integrity?

Reply:

George Mason was pleased to participate in the Federal Demonstration Partnership pilot of Payroll Certification and demonstrate firsthand that we could simplify and streamline the oversight of direct salary/wage charges while not incurring additional risk. By reducing administrative burden we were able to free up time for our researchers to spend more time on their research and also allow us to redirect administrative resources to more value-added activities. During the pilot we continually reviewed the procedures and systems supporting payroll certification, and made adjustments as needed to refine the process. During the pilot audit, the NSF Inspector General recommended areas for improvement that we appreciated and took very seriously. Some of the items such as IT security were not related directly to the Payroll Certification implementation, but were being addressed by our institution. Other recommendations related to the payroll certification system specifically were in the process of being (or had previously been) addressed.

Our biggest lesson learned from the experience is that when you develop a logical and intuitive policy and procedure there is an opportunity to reduce administrative burden for faculty while being a good steward of federal funds and not increasing risk to the institution. Since Principal Investigators better understood the payroll certification methodology because it aligned with a project budget and the timing was consistent with other reporting requirements, it allowed for a more effective review tool. In addition, we were able to redirect administrative resources to other activities such as regular reconciliation of project finances and improved reporting tools for Principal Investigators.

Appendix II

Additional Material for the Record

STATEMENT SUBMITTED BY COMMITTEE RANKING MEMBER
EDDIE BERNICE JOHSNON

OPENING STATEMENT

Ranking Member Eddie Bernice Johnson (D-TX)

House Committee on Science, Space, and Technology
Subcommittee on Research and Technology
"Academic Research Regulatory Relief: A Review of New Recommendations"
September 29, 2016

Thank you Chairwoman Comstock and Ranking Member Lipinski for holding this hearing.

This is an important topic; one our Committee has been closely monitoring for a few years now. In pursuit of competitively awarded federal research grants, universities and their faculties are spending an unprecedented amount of resources and time bogged down by paperwork.

In response to this excessive burden on grant-seeking researchers and their institutions, I supported a recent bill introduced by Ranking Member Lipinski, and an earlier proposal by Chairwoman Comstock aimed at reducing the administrative burden on federally funded academic research while ensuring accountability and integrity in the conduct of this research. These bills represent a good effort to be directly responsive to the input and testimony of the true experts, including the panel before us today. I want to thank both Members for their leadership on this issue and the witnesses for their efforts.

Of course this is not a new issue. Research funding agencies and OMB have undertaken many collaborative efforts of their own to streamline grant requirements. However, despite years of such efforts, our work continues. It remains an ongoing challenge for us to strike a balance between conducting legitimate oversight of how scarce federal research dollars are spent, and allowing researchers the freedom to do what they do best. But we must keep at it.

University investigators push the boundaries of human knowledge in all areas of science and engineering. They also provide world-class training for the next generation of scientists, engineers, and technologists. The more time researchers spend dealing with mountains of paperwork, the less time they can dedicate to advancing science and molding the minds of our future leaders.

Today we will hear from experts in academia and the Government Accountability Office about the unintended consequences of well-intentioned regulatory requirements surrounding the process of awarding federal research grants.

I'm interested to hear from our panelists about where agencies can better streamline, harmonize, and coordinate their requirements across the research enterprise. I also want to hear what areas, if any, should be addressed legislatively, including updating old laws. When I think of our world-renowned scientists spending hours filling out forms and checking boxes, I can't help but think that our federal dollars could be better spent.

I want to thank the witnesses for being here this morning. I look forward to the testimony and discussion, and I yield back.

○