COGR Committee Reports & Hot Topics



October 25, 2024



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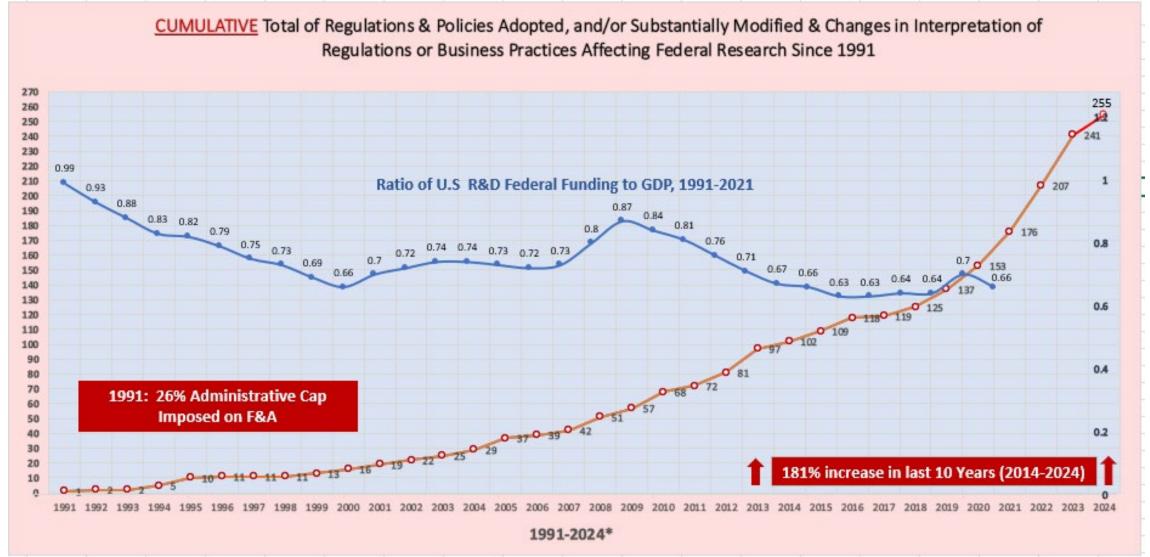
COGR Treasurer

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Jeffrey Silber, Cornell University

Senior Director, Sponsored Financial Services

Aggregated Regulatory Requirements Impacting Federally Funded Research Since 1991



Source: https://www.COgr.edu/cogr-list-regulatory-changes-1991-0

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MARCIA MCNUTT

For a More Competitive US Research Enterprise, the Work Begins Now Here's what we need to do to keep American science strong.

The US scientific enterprise has for decades been a juggernaut for innovation, economic growth, and lasting national security and prosperity. However, as the head of a premier US science organization, I am growing increasingly alarmed by worrying trends that threaten to undermine our

rate of investment in R&D is growing at twice that of th United States, and China is now on track to surpass US investments. That investment is also producing more research output-for example, China's global share of drugs in phase I to III trials has grown from 4% in 20 to 28%. And China is not the only country making th...

"Addressing Red Tape" | Issues in S&T, Fall 2024

ADDRESSING RED TAPE

Matt Owens

The partnership between the federal government and academiresearch institutions has served the United States exceptionally Technology Policy should establish a position for well over the decades. Scientific and engineering discoveries and innovation have bolstered national security, health, and economic growth. Today, however, the necessary and wellintended—but inefficient and risk intolerant—regulation of this partnership impedes research, researchers and their institutions, and taxpayers' research investments.

The Council on Governmental Relations closely tracks, analyzes, documents, and comments on federal research regulations. In the past 10 years, the number of new and modified federal requirements and substantial updates to policies, business practices, and interpretations has grown by 181%. Many of these regulations address the same core issues, but in a disjointed manner across multiple agencies. This regulatory trajectory is unsustainable if the United States is to retain its leadership in science and innovation.

To cut red tape encumbering federally sponsored research, the following actions should be taken.

First, the most consequential action the federal government can take is to stand up the Research Policy Board authorized b unforeseeable. This is an impossible and self-defeating the 21st Century Cures Act. No one federal agency can address approach that can divert resources needed to mitigate the the bloat and disaggregation of the current regulatory system. As recommended by a 2016 National Academies report, the Research Policy Board would be housed at the White House Office of Management and Budget (OMB)—where all federal regulations ultimately are approved—and serve as a primary policy forum for discussing ways to streamline and harmonize research regulations. In 2021, the nonpartisan Government

Accountability Office reaffirmed the recommendation to OME Governmental Relations. to establish this body.

Second, the White House Office of Science and associate director for the academic research enterprise, as recommended in the same National Academies report. This senior position would be a principal federal contact for the Research Policy Board, oversee and facilitate the general health of the research partnership, and work closely with OMB's Office of Information and Regulatory Affairs (OIRA) to manage overall regulatory burden. The position would also work with the OIRA administrator to issue an annual report on regulatory issues and actions affecting the partnership.

Third, regulators must calibrate regulation to risk. Research is never risk-free, and the most effective regulations are calibrated to address known and major anticipated risks without stultifying creativity and innovation. Excessive regulation occurs when risks are overstated and/or the government seeks earnestly to anticipate and eliminate *all* risk, no matter how minor or most severe risks.

Together, these commonsense actions would establish a more effective regulatory oversight framework and help to rebalance and strengthen the research partnership that is vital to US science, innovation, and competitiveness.

COGR

Matt Owens is the president of the Council on

https://issues.org/state-of-the-science-mcnutt/



COGR Mission Statement, Tagline & Logo



Current Mission Statement (2014)

COGR is an association of leading research universities, affiliated medical centers, and independent research institutes. We are the national authorities on the financial and regulatory infrastructure, and the corresponding compliance requirements associated with managing federal research grants and contracts within research institutions. We provide information, analyses, advice, policy perspective, and historical context to our members in the areas of research administration and compliance, financial oversight, and intellectual property. COGR communicates the viewpoint and concerns of its members and fosters productive relationships between the research community and federal policymakers, advocating for innovation and change that avoid unnecessary regulatory burden.

COGR IS A LEADING ADVOCATE FOR POLICIES THAT SUPPORT:

- · the conduct of research at the highest standards;
- · sound and informed decision-making on issues critical to the research and higher education community; and
- maximum benefit from investments in research conducted at its member institutions.

COGR SERVES ITS MEMBERSHIP BY:

- seeking to balance appropriate levels of accountability with fair recognition of the interests of all parties in research policies and practices;
- promoting policies and practices in research and training that fairly reflect the mutual interests and separate obligations of universities and federal and other sponsors;
- conducting objective and timely analysis of financial, compliance, administrative and intellectual property issues in research for the benefit of its members, their sponsors and other higher education associations; and
- working with governmental agencies and other organizations to develop a common understanding of the impact that policies, regulations and practices may have on the research of its membership.

COG

COGR is the national authority on federal policies and regulations affecting U.S. research institutions.

Mission

To empower an unparalleled U.S. academic research ecosystem by advancing sound federal policies and regulations that are vital to U.S. science and innovation leadership and our nation's health, security, and prosperity.

COGR Mission Statement Approved Unanimously by the Board of Directors on September 13, 2024



Purpose

Founded in 1948 to address the need for sensible federal research policy, COGR provides a unified voice for U.S. research universities, affiliated medical centers, and independent research institutions. Through our expertise and advocacy, our work strengthens the research partnership between the federal government and research institutions and furthers the frontiers of science, technology, and knowledge.

We advocate for effective and efficient research policies and regulations and are guided by the need to:

- Promote and protect high standards and accountability in research;
- Maximize the impact of taxpayers' investment by minimizing administrative and cost burdens; and
- Balance the interests and obligations of researchers, research institutions, research sponsors, and other federal partners.

Impact

We leverage our professional staff and member institution expertise to build consensus and advocate for sound federal research policies and regulations.

We achieve this by:

- Communicating the impacts of federal policies on research and researchers and their institutions;
- Providing expert analyses and comments to federal agencies to optimize policies and their implementation; and
- Bringing together senior research leaders from our member institutions to build relationships, share experiences and ideas, and promote effective research administration practices.





Advancing Effective Research Policy

Mark Your Calendars!

Next COGR Meeting - Virtual

February 25-28, 2025

Registration will Open in December

Costing and Financial Compliance (CFC)



- Sarah Axelrod, Harvard University (Chair) •
- **Kimberly Croft,** *Massachusetts Institute* of Technology*
- Casey Erickson, University of Washington*
- Jeremy Forsberg, University of Texas at Arlington
- **MC Gaisbauer,** University of California, San Francisco*
- Vivian Holmes, Massachusetts Institute of Technology

- Michael Legrand, University of California, Davis*
- Nate Martinez-Wayman, Duke University*
- Julie Schwindt, University of Mississippi Medical Center*
- Jeffrey Silber, Cornell University
- Maria Soliman, University of Iowa*
- **Renotta Young,** *Columbia University**
- Cindy Hope, COGR Director

* at-large committee members





Costing & Financial Compliance (CFC)

- Committee Changes
- Primary Focus UG (still)
- Ongoing and Other Topics



Costing & Financial Compliance (CFC)



Uniform Guidance

- Cross cutting with Contracts & Grants Administration (CGA)
- \circ COGR 1st, 2nd, 3rd, 4th, 5th, looks & advocacy
- Meetings with OMB
- Impacts of Agency Implementations
- Priority issues
- Next steps



Costing & Financial Compliance (CFC)



Ongoing and Other Topics

- F&A Survey Capstone Report in Progress
- HHS Removal of Salaries Over the Cap in IDC
- Timeliness of F&A Cost Rate Negotiations
- F&A in the News



Research Ethics & Compliance (REC)



- **Deborah Motton,** University of California, President's Office (Chair)
- Kristin Bittinger, Harvard University*
- Theresa Colecchia, Johns Hopkins University
- Grace Fisher-Adams, California Institute of Technology*
- Karen Hartman, Mayo Clinic*
- Jennifer Lassner, University of Iowa
- Jonathan Miller, University of Alabama Birmingham*

- **Stacy Pritt,** *Texas A&M University**
- Brian Smith, University of California, San Francisco*
- Geeta Swamy, Duke University
- Ara Tahmassian, Harvard University*
- **Debra Thurley,** *Pennsylvania State University**
- Tracy Wilson-Holden, Case Western Reserve University*
- Kristin West, COGR Director

** at-large committee members*



REC Hot Topics



- OSTP <u>Policy</u> and <u>Implementation Guidance</u> re. Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) Framework
 - Meeting with ABSA president elect
- Dept. of Justice <u>NPRM on Provisions Pertaining to Preventing Access to U.S.</u> <u>Sensitive Personal Data and Government-Related Data by Countries of Concern or</u> <u>Covered Persons</u>
 - Developing comments
- Implementation of <u>Public Health Service Policies on Research Misconduct Rule</u>
 - Potential joint survey with ARIO and coordination on materials
- Implementation Update for Data Management and Access Practices Under the Genomic Data Sharing Policy (<u>NOT-OD-24-157</u>)
 - Requires compliance with NIST 800-171
- NSF <u>RFI on Research Ethics</u>
 - Developing comments



in #COGROct24

Research Security & Intellectual Property (RSIP)

- Jennifer Ponting, University of Chicago (Chair)
- **Tom Burns,** Johns Hopkins University*
- Hannah Carbone, California Institute of Technology*
- Allen DiPalma, University of Pittsburgh
- Sophia Herbert-Peterson, Georgia Institute of Technology
- Kelly Hochstetler, University of Virginia*

- Michael Moore, Augusta University*
- Bruce Morgan, University of California, Irvine*
- Dan Nordquist, Washington State University*
- **Kenneth Porter,** University of Maryland*
- Todd Sherer, Emory University
- **David Winwood,** *Wake Forest University Health Sciences**
- Kevin Wozniak, COGR Director

* at-large committee members



Updates from Bureau of Industry and Security

- RSIP establishing a collaborative dialogue with the BIS
 - Be on the look out for even more comment letters and outreach activity!
- BIS issued over 40 amendments and new regulations in the past fiscal year.
 - Driven by national security concerns and the overall geopolitical climate
 - Regulations are less focused on updating the existing Control Lists model (CCL)
 - Additional rulemaking scheduled for December 2024
- BIS confirmed their support of Fundamental Research and related exclusions



Clarification that AES Registration is NOT required for Items listed on the Commerce Control List and carried with you under the TMP or BAG license exceptions, to China, Russia and Venezuela.

Dell Everywhere Pollev.com/cogrstaff949 Ask a question from your seat!



in #COGROct24

Contracts & Grants Administration (CGA)



- Stephanie Endy, Brown University (Chair)
- Maggie Ewell, George Mason University*
- Jeffrey Friedland, University of Delaware*
- Michael Glasgow, University of Connecticut*
- Walter Goldschmidts, Cold Spring Harbor
 Laboratory*
- Stephanie Gray, University of Florida

- **Charles Greer**, University of California, *Riverside*
- Lisa Mosley, Yale University
- **Twila Reighley**, Michigan State University*
- Craig Reynolds, Van Andel Institute
- Jennifer Rodis, University of Wisconsin-Madison*
- **Pamela Webb**, University of Minnesota*
- Krystal Toups, COGR Director

** at-large committee members*





Uniform Guidance:



Other significant discussions since June:

- Common Forms (Agency Implementations NASA, NIH, DOE)
- DARPA OTA web site
- New Trafficking in Persons FAR (DOD, GSA, & NASA, 48 CFR 22 & 52)
- Public Access Policies (NIH, DOE) Agency Adoption
- RTCs

Next:

- Managing Externally Funded Research Programs update - volunteers needed!
- CGA Open House



Poll Everywhere

Pollev.com/cogrstaff949 Ask a question from your seat!

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Join us for COGR's Upcoming Virtual Meeting February 25-28, 2025!

Registration will open in December

