COGR

Council On Governmental Relations

An Association of Research Institutions

February 4, 2021

President Joseph R. Biden
1600 Pennsylvania Avenue N.W.
Washington D.C. 20500

Dear President Biden,

The Council on Governmental Relations (COGR) is an association of 190 of the most research-intensive public and private universities and affiliated academic medical centers and research institutes in the country. Our members account for over 95% of all basic and applied federal research awards made to the higher education community and conduct over $80 billion of research on an annual basis. COGR is a national expert on the financial and regulatory infrastructure affecting research institutions and we work closely with federal agencies to minimize regulatory burden and enhance research ethics and compliance. We are committed to fostering productive relationships between the research community and federal policy makers to ensure the most productive and effective delivery of research results to the nation.

We are excited for the commitment your administration has made to the United States' research enterprise. As you begin your term, we offer our ongoing insight and assistance on matters related to the federal research enterprise, the regulation of federally funded research, and possibilities for regulatory reform.

Many of the actions your administration has already taken are important and much appreciated. However, the long-standing general sense from the research community is that research is being overregulated and that many regulations are inefficient and unnecessarily burdensome. In addition, the emphasis on regulation and reporting has taken a significant toll on both research productivity and university budgets, as funds once available to support research activities are increasingly taxed to cover additional compliance costs.

On the pages that follow we offer suggestions regarding eleven *Opportunities for Increasing the Impact of Federal Research Dollars*, which will allow our scientists and investigators to more effectively remain on the global forefront and continue to solve the most the most challenging medical, engineering, societal, and national security challenges.

Thank you for taking the time to review our suggestions, and we look forward to working with you and your administration on these important issues. Please do not hesitate to contact me directly at wstreitz@cogr.edu to further discuss any of the issues described in this letter.

Sincerely,

Wendy D. Streitz

Wendy D. Streitz
President

CC:

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Opportunities Identified by COGR for Increasing the Impact of Federal Research Dollars

There are many opportunities for reducing the regulatory burden associated with conducting federally funded research. The eleven below are actions that we believe would have the most significant impact.

1. Reduce Federal Regulation of Research

Growing concerns about the steady increase in regulations governing federally funded research, and the associated amount of researcher time and federal and institutional funding[1] dedicated to regulatory compliance, has been detailed in numerous published reports. Three relatively recent publications, all three still considered "gold standards," are the 2014 National Science Board (NSB) report *Reducing Investigators' Administrative Workload for Federally Funded Research*; the 2016 National Academies report *Optimizing the Nation's Investment in Academic Research; A New Regulatory Framework for the 21st Century*; and the 2016 Government Accountability Office (GAO) report *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements*. Recommendations gleaned from these reports, many of which have yet to be enacted, can serve as a starting point for reducing federal regulation of research.

Since 2016, COGR has identified dozens of new regulations, policies, guidance, reporting requirements, and other burdensome mandates which have significant implications for research administration. Principal Investigators responding to the Federal Demonstration Partnership's 2018 Faculty Workload Survey "estimated that an average of 44.3% of their research time associated with federally-funded projects was spent on meeting administrative requirements rather than conducting active research."[2] Since universities are subject to a cap on facilities and administrative (F&A) cost reimbursement, every new federal regulation effectively results in an unfunded mandate to be implemented by the research university. In fact, universities are the only federal grantees that are subject to a cap on F&A cost reimbursement.[3]

> **Recommendation: Revisit these authoritative studies on reducing federal regulation of research and prioritize items that will have the most significant impact on administrative burden and cost. Further, minimize additional unfunded mandates, which particularly impact research universities because of limits on F&A cost reimbursement.**

2. Enforce a Fair and Rational Rulemaking Process, with Stakeholder Engagement

The rulemaking process permits interested parties to submit written comments in response to proposed regulations and the research community invests considerable time developing responses that convey the anticipated impact on federally funded research and development (R&D) and offers alternatives as necessary. However, public comments, while perhaps noted in the preamble to a final rule, frequently bring no substantive rule revisions. More importantly, some agencies sidestep the regulatory process by issuing guidance, FAQs, notices, etc., which effectively impose binding requirements on grantees without providing an opportunity for advance comment. This happens despite the fact that institutions contribute considerable funds of their own to federally funded research,

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[1] A 2015 study by Vanderbilt University found that research-related compliance as a percentage of research expenditures was found to range from 11 percent to 25 percent. https://news.vanderbilt.edu/files/Regulatory-Compliance-Report-Final.pdf

[2] FDP Faculty Workload Survey Research Report. https://thefdp.org/default/assets/File/Documents/FDP%20FWS%202018%20Primary%20Report.pdf

[3] 2014 COGR paper on Finances of Research Universities. https://www.cogr.edu/finances-research-universities-june-2014

in large part because of the inability to recover the full F&A costs associated with such research (see 1. above). In 2014, the Obama Administration and its Office of Management and Budget undertook an ambitious project to rewrite the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*. This was a successful and important initiative, resulting in 2 CFR part 200. Further improvements were codified last August, including a provision that agencies "may impose legally binding requirements on recipients **only through the notice and public comment process** through an approved agency process, including as authorized by this part, other statutes or regulations, or as incorporated into the terms of a Federal award" [emphasis added]. (§200.105)

> **Recommendation: Reaffirm that agencies must go through a notice and public comment process for all binding requirements. Further, 2 CFR Part 200.105, which affirms the use of fair and rational rulemaking process, should be enforced, with some form of recourse when an agency fails to do so.**

3. Stand-up the Research Policy Board conceived under the Obama Administration

Acting on one of the recommendations in the National Academies report on "Optimizing the Nation's Investment in Academic Research" (see 1. above), Congress included a requirement for the OMB Director to establish a Research Policy Board (RPB) in Section 2034 of the 21st Century Cures Act. The RPB is charged with ensuring that administrative burden associated with regulations and policies is minimized, harmonizing regulations and policies across agencies, and conducting ongoing assessment of regulatory burdens, all with an eye toward optimizing the federal investment in research. In the four years since passage of the Act, this has not yet been done. Just this week, GAO issued a report recommending that OMB proceed with the creation of the RPB and that Congress extend the authorization of the RPB beyond September of this year.

> **Recommendation: The OMB Director should immediately stand up the Research Policy Board, as required by the 21st Century Cures Act.**

4. Continue OSTP Efforts to Ensure Cross-Agency Coordination of Federally Funded Research Matters

Over the last two years, OSTP has convened a cross-agency committee to ensure coordination and consistency across federal agencies on issues related to research environment safety, integrity, and productivity. Specific efforts have focused on administrative burden, safe and inclusive research settings, research security, and rigor and integrity in research. These issues are of critical importance to research institutions and the federal agencies that regulate and fund them. Convening the relevant agencies was a critical first step toward addressing these issues in a consistent and meaningful way. Their work has been thoughtfully conducted and has the potential for significant positive impact on federally funded research. We also appreciate that OSTP has recognized the value of an ongoing engagement with the academic research community by establishing an Assistant Director for Academic Engagement. Such a position helps to ensure that OSTP maintains a direct connection to the country's leading research institutions.

> **Recommendation: OSTP should continue to convene such a cross-agency group to ensure coordination and consistency of federal agencies on areas of interest to grantees. Further, OSTP should ensure that this group continues to have meaningful engagement with stakeholders.**

5. Strike an Appropriate Balance Between Advancing Science and Protecting U.S. Research

COGR and its member institutions take the threat of inappropriate foreign influence and associated research security risks very seriously. In fact, COGR has included this topic in its member meetings going back some years

now, often involving federal representatives, including from security agencies. We also recognize the benefits to the United States' science and technology leadership stemming from open research environments and productive international collaborations, and we recognize the need to ensure that research protections are evaluated in a systematic fashion that takes into consideration a risk/benefit analysis that will differ across the spectrum of research activities.

Below are specific comments that seek to strike this important balance between advancing science as quickly as possible through openness and global collaboration, while at the same time, guarding against malign interference by foreign governments.

5a. NSDD-189

NSDD-189, first issued by the Reagan Administration in 1985 and reaffirmed by subsequent administrations, sets forth *National Policy on the Transfer of Scientific, Technical and Engineering Information*. It remains the cornerstone of U.S. policy on fundamental research. It provides that "…to the maximum extent possible, the products of fundamental research remain unrestricted. … where the national security requires control, the mechanism for control of information generated during federally funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification."

The continued importance of NSDD-189 was cited in the recent report on Fundamental Research Security of the JASON group to the National Science Foundation. The JASON report noted "…NSDD-189 is still operative as our national policy….NSDD-189 indicates that when it comes to government-sponsored research of the type conducted by universities, a policy of openness should prevail, with the smallest possible number of exceptions to be carved out for those cases where security concerns dominate…The fundamental principles embraced by NSDD-189, along with much of its original wording, were subsequently incorporated into the Federal Acquisition Regulations (FAR) and are therefore the law of the land." The JASON report went on to note, however, some concerns with the implementation of NSDD-189 by various government agencies.

While agencies such as DOD have reaffirmed NSDD-189 relatively recently, it has not been reaffirmed at the highest government levels since 2001. Maintaining an open fundamental research environment is essential to advancing scientific and technological progress, and innovations that are so critical to our national and economic security. Given the importance of open fundamental research, we urge the Biden Administration to again reaffirm NSDD-189 as national policy.

Recommendation: Reaffirm NSDD-189 as national policy.

5b. Section 117 of the Higher Education Act

Section 117 of the Higher Education Act of 1965 requires reporting of contracts with and gifts from foreign sources by U.S. institutions of higher education that, either individually or in the aggregate from a single source, are valued at $250,000 or more in a calendar year. The Department of Education (ED) is responsible for implementation.

1) Information Collection Requirements.

For many years ED paid little attention to this requirement, collecting information submitted through an E-App to Federal Financial Student Financial Aid reports semiannually without further instruction to institutions. This lax enforcement made for an unclear compliance environment, partly due to the lack of clear guidance from ED. In 2019, after repeated requests for clarification by higher education associations, ED issued an overly broad information collection request (ICR), greatly expanding the information required to be reported under Section 117. Because of the significance of the changes being made, they should have been implemented through a more robust negotiated rulemaking process. The resulting requirements are extraordinarily broad and unnecessarily burdensome to institutions, and in some cases inconsistent with the statute. Furthermore, starting last July the information is collected via an electronic portal that, while an improvement over the prior process, is still quite onerous to use. We understand the importance of full and accurate reporting and are committed to improving compliance. However, we urge the Biden Administration to review the current reporting requirements with respect to actual statutory requirements and stakeholder concerns and improve the electronic portal to minimize user burden.

Recommendation: Require the Department of Education to withdraw the Information Collection Request and instead engage in negotiated rulemaking on Section 117 compliance with the stakeholder community.

2) Notice of Interpretation

In November of 2020 ED published a Notice of Interpretation of the Department's enforcement authority for failure to adequately report under Section 117 (85 FR 72567). In the Notice ED asserts that it has enforcement authority for compliance under both Titles IV and VI of the HEA.

This assertion is legally dubious given that Section 117 expressly assigns enforcement authority to the Department of Justice. Also, given its claimed legal effect, it appears to require rulemaking under the Administrative Procedure Act as a "legislative rule." Finally, Section 117 is promulgated under Section 1 of the HEA and has no relationship to Title IV. In effect, ED's interpretation could inappropriately convert all federal reporting requirements for institutions of higher education into Title IV requirements.

Recommendation: Given the serious legal flaws, the Biden administration should rescind the Notice of Interpretation.

3) True Copies NPRM

On January 13, ED published a proposed rule on its website that would require submission of "true copies" of gift and contract agreements subject to Section 117 reporting requirements. The true copies requirement originally had been included in the ICR but was deleted by OMB with an indication that it would be subject to a separate rulemaking. It was never officially published in the Federal Register.

Submission of true copies would be extremely burdensome to institutions, with substantial resource

implications. It also raises serious confidentiality concerns. Other means of assuring compliance such as including Section 117 reporting in annual institutional audits are more effective and less burdensome than requiring true copies submissions.

> **Recommendation:** We **urge the Biden Administration to make it clear that the NPRM has no official status and will not move forward.**

Under the previous administration, ED adopted a very adversarial tone with regard to Section 117 and universities which was neither productive, nor did it further the objectives of the statute. A new, more collaborative approach would be beneficial. Copies of all documents referenced above may be found on the ED website and many will demonstrate the adversarial nature of the engagement. COGR continues to be ready and willing to work in a collaborative and productive manner with the current administration to improve reporting and compliance in a meaningful way.

5c. DOD Cybersecurity Maturity Model Certification

On September 29, DOD issued an interim DFARS rule Assessing Contractor Implementation of Cybersecurity Requirements (85 FR 61505). The rule implements DOD's Cybersecurity Maturity Model Certification (CMMC) project.

The rule requires all organizations included in the Defense Industrial Base (which includes COGR member institutions) to obtain at least a CMMC Level 1 certification. The Level 1 certification (Basic Cyber Hygiene) requires all DOD contractors to have current NIST SP 800-171 DOD Assessments on file with the DOD (DFARS 252.204-7019). This includes at least a Basic Level Self-Assessment. Without such an assessment, offerors cannot be considered for award. The rule was effective November 30.

Assuring adequate cybersecurity is critically important to our institutions. University researchers have been among the national leaders in developing programs and mechanisms for cybersecurity protection. However, there are serious implications for fundamental research at our institutions. The DFARs framework is predicated on the protection of Controlled Unclassified Information (CUI). But fundamental research, by definition, does not involve CUI. The result is a conceptual problem in needlessly applying the interim rule framework to fundamental research with serious practical consequences. DOD should not subject fundamental research to requirements that are intended to secure information that fundamental research does not entail, and that run counter to the free exchange of knowledge that forms the very basis of fundamental research.

> **Recommendation: We have urged DOD to exclude fundamental research from CMMC requirements and recommend the issuance of clear guidance that fundamental research should not be subject to the CMMC.**

6. Harmonize Conflict of Interest Requirements

Institutions recognize the importance of ensuring that science is conducted objectively without bias, and they respect the need for regulations that ensure researchers appropriately disclose financial interests that may introduce such bias. However, regulation in this area should be consistent across federal agencies to promote compliance and minimize administrative burden. NSF's standards for grantee conflict of interest policies provide

a potential template that could be adopted by multiple agencies. The NSF requirements provide overarching standards for such policies without being overly prescriptive, thus permitting institutions to tailor their policies to individual circumstances. A December 2020 AAMC report "Measuring the Impact of the Public Health Service Regulations on Conflicts of Interest" points out the high cost to benefit ratio associated with the Public Health Service (PHS) regulations in this area (42 CFR Part 50, Subpart F), and makes suggestions for improvements that could be gained by standardizing to certain NSF requirements.

Recommendation: Maximize cross-agency consistency in COI requirements in a risk-based manner, as opposed to a blanket "one size fits all" approach.

7. Remove Unnecessary Barriers to Research Using Human Fetal Tissue

The Department of Health and Human Services Notice of Proposed Rulemaking (NPRM) *"Establishment of Safeguards and Program Integrity Requirements for Health and Human Services-Funded Extramural Research Involving Human Fetal Tissue,"* which imposes additional consent requirements for research using human fetal tissue, is currently on hold pursuant to the January 20, 2021, "Regulatory Freeze" Memorandum. The consent requirements imposed by the NPRM do not strike an appropriate balance between subject protections and permitting this important research to continue. Rather, the NPRM effectively bars research using deidentified fetal tissue obtained from elective abortions by imposing onerous consent and audit requirements that destroy confidentiality protections form women who have had abortions. Additionally, the NPRM ignores the fact that there are longstanding statutory requirements in place under of 42 USC §§ 289g-1 & g-2, which ensure that consent is properly obtained from donors for fetal tissue used for transplantation research and prohibit purpose-donated tissue or tissue donated for the promise of consideration.

Along these same lines, the NIH "Requirements Regarding Proposed Human Fetal Tissue Research" (NOT-OD-19-128) placed onerous justification burdens on research using human fetal tissue (HFT) cells, cell cultures, and derivatives from elective abortions and established the NIH Human Fetal Tissue Research Ethics Advisory Board (Board). All COGR member institutions recognize the primacy of the ethical conduct of research. These NIH restrictions, however, provided no additional ethical protections, but rather serve as an unnecessary deterrent to research using even attenuated products such as secondary cell cultures obtained from vendors and animal models incorporating HFT. The impact of these burdensome requirements and their restrictive application by the Board are amply demonstrated by the FY2020 Board Report, in which the Board reported finding that only one of the fourteen research proposals reviewed met the requirements for funding. As noted above, the provisions of 42 USC §§ 289g-1 and g-2 and the requirements at 45 CFR § 46.206 provide appropriate ethical protections, while permitting this extremely important research to continue.

Recommendation: Rescind the HHS NPRM and NOT-OD-19-128 and rely instead on existing statutory requirements regarding the requirements for the use of fetal tissue in research and obtaining consent from fetal tissue donors.

8. Harmonize HHS and FDA Rules on Protection of Human Subjects

The 21st Century Cures Act of 2016 called for the Secretary of Health and Human Services (HHS) to harmonize the differences between HHS and FDA regulations regarding protections for human subjects in research. Although the HHS Common Rule for the protection of human subjects was substantially revised in 2018, the FDA has not yet modified its human subject protection regulations (21 CFR Parts 50 and 56) to align with these

requirements to the greatest extent possible. More rapid progress to harmonize these rules will reduce administrative burden, while continuing to ensure the protection of the health, safety, and welfare of research participants.

> **Recommendation: Require the FDA to harmonize its regulations with the 2018 HHS Common Rule.**

9. Allow the NIST NPRM to Proceed, Affirming the Bayh-Dole Act

On January 4, NIST issued a proposed rule (NPRM) revising the regulations on rights to federally-funded inventions and the licensing of government-owned inventions (86 FR 35)). The NPRM implements some of the findings of the NIST Return on Investment (ROI) Initiative, with comments due April 5. COGR and other higher education groups strongly supported the ROI Initiative, which was aimed at fostering and encouraging the transfer of federally funded innovations to the marketplace. The NPRM makes a number of changes and updates to the implementing regulations (37 CFR 401) for the Bayh-Dole Act (35 USC 200 *et seq*), which governs rights in inventions made with federal assistance.

The Bayh-Dole Act is widely viewed as having been extremely successful in facilitating the commercialization of federally funded inventions. The proposed revisions in the NPR are timely and responsive to the goals and objectives of the ROI Initiative. These include a clarification that "march-in rights" should not be exercised by agencies exclusively on the basis of business decisions by contractors regarding the pricing of commercial goods and services arising from the subject inventions. This essentially restates the understanding most stakeholders have had of the intended and proper application of march-in rights since the implementation of the Bayh-Dole Act over 30 years ago. For the government to intervene in these decisions could have a considerably adverse effect on the ability to commercialize inventions.

> **Recommendation: We urge the Biden Administration to affirm both the Bayh-Dole Act and the changes proposed in the NPRM.**

10. Harmonize and Share Costs Associated with Public Access to Scientific Data Requirements

During the Obama Administration, OSTP released a memorandum, *Increasing Access to the Results of Federally Funded Scientific Research,* directing each federal agency with annual research and development expenditures exceeding $100M to develop a plan to support increased public access to the results of federally funded research. The plan would include access to any results published in peer-reviewed scholarly publications and the underlying digital scientific data. While our members generally support making the results of research more broadly available, there are considerations that need to be thoughtfully addressed. For example, the costs associated with proper data governance, management, and sharing are significant and should not be borne exclusively by research institutions. If it is a federal requirement that data be subject to findable, accessible, interoperable, and reusable (FAIR) standards for lengthy periods of time, it would be appropriate for the government to be a partner in making this happen. Otherwise, these requirements will result in another case of an unfunded mandate implemented by the federal government. The problem is amplified when there is inconsistency in public access requirements from one agency to the next, and even from different organizations within an agency, ultimately placing new cost and administrative burden on federal funding recipients. In addition, new repositories can be costly to establish and maintain; it could be helpful if these were hosted by federal research agencies.

Recommendation: Harmonize public access requirements to the maximum extent practicable and invest in the establishment and maintenance of new repositories where they are needed. And as new cost and administrative burdens are identified, a mechanism is needed to ensure research institutions are not solely responsible to implement unfunded mandates (also see 1. above).

11. Reduce the Barriers to Performing Research on Cannabis

With 35 states legalizing the use of cannabis for medical, and in many cases, recreational use, the need for scientific data has never been greater. However, research on cannabis is extremely challenging. Not only do researchers have to deal with the challenging and costly hurdles presented by the DEA regulations associated with a Schedule I substance, but they are also limited to using cannabis provided by one federally approved supplier, which means they are unable to conduct research on the products actually being used by the public. There are steps the administration could take to remove or reduce the Schedule I barriers, including reducing the regulatory requirements for bona fide research, or perhaps creating a research "carve out." Rescheduling cannabis entirely would have an even greater impact on the ability to conduct research and would reflect the increasing trend of state law. Barring such action, at a minimum, the number of approved growers approved should be increased to improve the variety of cannabis available to researchers. DEA indicated in a 2016 Federal Register Notice that it would expand licensing to additional growers. Since then, there have been over two dozen applications, but no action by DEA, despite Congressional requests.[4] FDA and NIH have also indicated support for a greater diversity of cannabis for research purposes, including from state authorized dispensaries.[5]

Recommendation: Reduce the barriers to research associated with cannabis being a Schedule I substance and increase the sources of cannabis available to researchers.

[4] See July 25, 2018, letter from a bipartisan group of six Senators. https://utahpolicy.com/index.php/features/featured-articles/17651-hatch-harris-follow-up-with-sessions-doj-regarding-medical-marijuana-research

[5] See August 27, 2019 letter from NIH Director Collins and FDA Acting Commissioner Sharpless to Senator Schatz. https://www.politico.com/f/?id=0000016d-188c-d466-a36d-de8d31490001