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Carnegie Mellon University  
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Emory University  
Georgia Institute of Technology  
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Indiana University  
Iowa State University  
The Johns Hopkins University

Massachusetts Institute of Technology  
McGill University

Michigan State University  
New York University  
Northwestern University

The Ohio State University  
The Pennsylvania State University  
Princeton University

Purdue University  
Rice University  
Rutgers University – New Brunswick

Stanford University  
Stony Brook University –  
State University of New York

Texas A&M University  
Tulane University  
University at Buffalo –

State University of New York  
The University of Arizona  
University of California, Berkeley

University of California, Davis  
University of California, Irvine  
University of California, Los Angeles

University of California, San Diego  
University of California, Santa Barbara  
The University of Chicago

University of Colorado Boulder  
University of Florida  
University of Illinois, Urbana-Champaign

The University of Iowa  
The University of Kansas  
University of Maryland, College Park

University of Michigan  
University of Minnesota, Twin Cities  
University of Missouri, Columbia

The University of North Carolina at  
Chapel Hill  
University of Oregon

University of Pennsylvania  
University of Pittsburgh  
University of Rochester

University of Southern California  
The University of Texas at Austin  
University of Toronto

University of Virginia  
University of Washington  
The University of Wisconsin - Madison

Vanderbilt University  
Washington University in St. Louis  
Yale University

October 22, 2019

Kelvin K. Droegemeier, Ph.D.,  
Director  
Office of Science and Technology Policy  
Executive Office of the President  
Eisenhower Executive Office Building  
1650 Pennsylvania Avenue  
Washington, DC 20504

Dear Dr. Droegemeier:

The Association of American Universities (AAU) is pleased to respond to the White House Office of Science and Technology Policy (OSTP) [Request for Information](#) on the Bioeconomy. America's leading research universities transform lives through education, research, and innovation. AAU's member universities earn the majority of competitively awarded federal funds for university research that improves public health, addresses national challenges, and contributes significantly to our economic strength, while educating and training tomorrow's visionary leaders and innovators. AAU's sixty-two member universities collectively help shape policy for higher education, science, and innovation; promote best practices in undergraduate and graduate education; and strengthen the contributions of leading research universities to American society. AAU's responses to the RFI are rooted in our universities' decades-long experience conducting federally funded basic research, the bedrock of discovery which leads to translation, product development, and commercialization and critical to making the U.S. the world leader in innovation.

AAU commends OSTP for their work with the National Science and Technology Council (NSTC) to form the Joint Committee on Research Environment (JCORE). JCORE's four subcommittee's will help American innovation move forward by addressing "some of the most critical areas for action to ensure America's researchers, scientists, and engineers can reach their full potential."<sup>1</sup> AAU and our members welcome engagement with JCORE and stand ready to partner and support the committee's work.

### **Federal Investment in the U.S. Bioeconomy**

Predictable federal investments in U.S. research and development help sustain and grow the U.S. economy and will be vital to the future transformation and expansion of the U.S. Bioeconomy. One example demonstrating the value of this investment is the Human Genome Project, a federal-industry-academic partnership whose foundational discoveries in analysis, tool creation, data storage, and sharing helped launch the modern bioeconomy. Scientific advances, such as those from the Human Genome Project and other smaller

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<sup>1</sup> [Update from the National Science and Technology Council Joint Committee on Research Environments](#), White House Office of Science and Technology Policy, July 9, 2019

research projects, can take decades for their impact to be fully realized. For example, it took several decades before the neuroplasticity in animal models, first cited in academic papers<sup>2</sup> in the 1960s, was translated into improved treatment and recovery for human stroke survivors. Strong federal investments in knowledge and understanding help provide fertile soil for innovation.

A recent report by the Aspen Institute finds that “federal R&D funding – which encompasses foundational research – as a percentage of GDP has fallen steadily since the 1960s. In the 1980s, industry began out spending the federal government in R&D, and that gap has steadily widened ever since, creating a reliance of private investment for research.”<sup>3</sup> The case for federal government R&D funding – particularly basic research – is simple: no one else aside from the federal government will invest at the scale necessary for the U.S. to be the global leader. Basic research frequently does not directly reward the original investor in the short term. In the private sector, it is difficult to make a business case to support theoretical research that might not lead to a marketable product or result in directly company profits even after years of effort.”<sup>4</sup> Therefore, it is essential that such research be supported by the federal government and that these investments be accompanied by federal investments in scientific infrastructure – laboratories, information technology, and education. Such investments are critical to maintaining American leadership in research and discovery.

Equally important to ensuring substantive federal investments to support the U.S. bioeconomy is maintaining a mechanism that provides predictable, consistent, and sustained funding. The Congressional appropriations process continues to labor to pass the required annual appropriations measures by the end of each fiscal year. “Since 1997, Congress has never passed more than a third of its regular appropriations bills on time, and usually has done considerably less than that: for instance, for six straight years (fiscal 2011 through 2016), not a single spending bill was passed by October 1. Instead, Congress increasingly has bought itself more time by relying on continuing resolutions, or CRs. CRs typically extend previous agency research funding levels, but only for existing programs; they’ve lasted as little as one day and as long as the rest of the fiscal year (a “full-year CR”).<sup>5</sup> Delays in finalizing federal funding levels can leave highly ranked research proposals and discovery opportunities at the federal research agencies, i.e. the Department of Defense, the Department of Energy, the National Science Foundation (NSF), the National Institutes of Health (NIH), the National Aeronautics and Space Administration (NASA) and the Department of Agriculture (USDA), unfunded for months at a time due to restrictions on new grant awards. This delay in full appropriations funding slows the rate of basic scientific discovery.

### **Clearing Regulatory Bottlenecks**

OSTP is in a unique position to help clear regulatory bottlenecks to innovation caused by duplicative and often burdensome paperwork that grantees and universities submit to comply with agency regulations, sub-regulations, policies, and guidance. We believe there is opportunity for reforms that will streamline federal requirements, ensure high standards for research conduct, and fully leverage federal funds to maximize the benefit from taxpayer investments. The regulatory burden for researchers and academic staff is significant with the accretion of regulations often resulting in unnecessary and duplicative reporting requirements. Despite previous efforts to address these growing regulatory burdens, the number of requirements with which researchers and universities must comply does not seem to be

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<sup>2</sup> Chemical and Anatomical Plasticity of Brain, By Edward L. Bennett, Marian C. Diamond, David Krech, Mark R. Rosenzweig, *Science*, 30 Oct 1964: Vol. 146, Issue 3644, pp. 610-619

<sup>3</sup> “[An Innovation Challenge for the United States](#)” Aspen Cybersecurity Group, The Aspen Institute, 2019, p.10

<sup>4</sup> *ibid*, p.11

<sup>5</sup> Pew Research Center, “Congress has long struggled to Pass Spending Bills on Time” Fact-Tank, News in the Numbers, January 16, 2018

waning. AAU appreciates OSTP's role as an agent for change and its work across federal research agencies to seek meaningful regulatory reform.

In August 2018, the NIH, USDA, and the Food and Drug Administration (FDA) released a report on "[Reducing Administrative Burden for Researchers: Animal Care and Use in Research](#)" which highlights some of the unintended consequences of delaying reform. The three agencies convened a working group, as required by the 21st Century Cures Act,<sup>6</sup> to identify and revise inconsistent policies and redundant reporting regarding the care and use of laboratory animals.

The August report outlined forthcoming modifications to existing policies, including the enhancement of existing options to streamline protocol review, elimination of USDA's three-year registration renewal, and harmonization of USDA and NIH policies to require triennial review of planned animal activities. Additionally, the report indicates the agencies' plans to spend the next two years completing their review and beginning implementation.

AAU aligns itself with the views expressed by the Federation of American Societies for Experimental Biology's (FASEB) [response](#) to the 2018 report acknowledging that, while the report "recommendations are steps in the right direction, they are an inadequate response to the charge set forth by the 21st Century Cures Act." An additional two-year delay in operationalizing the Report's recommendations is not optimal. AAU supports FASEB's interim recommendations to the working group to mitigate the risks of ongoing uncertainty among institutional leaders concerning animal research guidelines including:

- ) Publication of a Frequently Asked Questions (FAQs) document to address and clarify common inquiries, including those submitted to FASEB during its March 2019 webinars on the topic; and
- ) Regular posting of an NIH Office of Laboratory Animal Welfare blog, consistent with those of other institutes and centers.

### **Supporting the Bioeconomy Workforce**

AAU commends OSTP's examination of the needs and possible solutions for the training and continued development of a skilled bioeconomy workforce. Investment in STEM education is a national priority to bolster our nation's competitiveness, particularly in the biological sciences. As an association of research universities who collectively award over 60 percent of undergraduate STEM degrees and award 43 percent of all research doctoral degrees in the U.S.,<sup>7</sup> AAU's comments focus on our leadership of transformational projects to bolster and improve the scientific workforce.

#### *AAU Undergraduate STEM Education Initiative*

Since 2011, AAU has engaged in an initiative<sup>8</sup> to improve the quality and effectiveness of undergraduate teaching and learning in science, technology, engineering, and mathematics (STEM) fields at its member institutions. AAU aims to influence the culture of STEM departments at AAU universities so that faculty members are encouraged to use teaching practices proven to be effective in engaging students in STEM education and in helping students learn, particularly at the first year and sophomore levels. Promoting excellence in undergraduate STEM at major research universities is necessary to ensure that we have the STEM-literate workforce and general population required to propel the nation forward into the twenty-first century and beyond.

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<sup>6</sup> The report is in accordance with Title II, Section 2034(d) of The 21st Century Cures Act, [P. L. 114-255](#)

<sup>7</sup> <https://www.aau.edu/sites/default/files/AAU-Images/AAU-By-The-Numbers/Education.pdf>, AAU 2019

<sup>8</sup> <https://www.aau.edu/education-community-impact/undergraduate-education/undergraduate-stem-education-initiative-3>

### *AAU PhD Education Initiative*

To improve the educational experience of current and prospective doctoral students in all disciplines and in recognition of the full range of career pathways available to PhD graduates, AAU launched a PhD Education Initiative in 2018.<sup>9</sup> The initiative aims to influence the culture and behavior at the department level to make doctoral education more student-centered, to foster increased inclusion of current and prospective doctoral students from diverse backgrounds, and to provide PhD students with the knowledge, skills, and abilities to be successful in careers both within and beyond academia. The initiative's objective is to make the full range of PhD career pathways visible, valued, and viable for all students and place individual students and their diverse educational and professional goals, needs, and challenges at the center of the graduate education experience. The initiative seeks to advance recommendations made by the National Academies of Science, Engineering and Medicine in its 2018 report, "Graduate STEM Education for the 21st Century".<sup>10</sup>

AAU also suggests NIH restart the [Broadening Experiences in Scientific Training](#) (BEST) program as a pipeline for trainees to develop valuable bioengineering skills, particularly through hands-on experience with bioengineering machinery. Responding to the realization that biomedical research trainees pursued a diverse range of career opportunities, NIH began BEST in 2013 with the goal of examining methods to enhance training opportunities for early career scientists and better preparing them for a variety of career options. A consortium of seventeen universities worked to improve career development for all involved in biomedical training. NIH funded ten awards at the program's inception in 2013, seven awards in 2014 and has since not renewed applications for the program. A commitment to supporting a sustainable and robust workforce requires sustained funding for programs which help train early career scientists and prepare them for a variety of career options in the dynamic biomedical workforce landscape.

In 2006, AAU [released a report calling for the creation of a new National Defense Education and Innovation Initiative](#) that highlighted the need for major investments in domestic research and talent development. The report envisioned modern-day investments similar in magnitude to federal investments in science during the years following the launch of Sputnik in 1957. It is thanks to this forward-looking leap in investment that we have the Defense Advanced Research Projects Agency, NASA, and the National Defense Authorization Act. AAU urges Congress to consider the report's recommendations<sup>11</sup> which are still salient to bolster our nation's security, strength, and competitiveness on an ever-changing global stage.

AAU supports the proliferation of programs such as the Engineering Biology Research Consortium (EBRC) [Industry Internship Program](#). U.S. colleges and universities and participating biotechnology companies partner with the goal of better preparing tomorrow's leaders for careers outside academia and to enhance students' laboratory skills and understanding of technical applications. Engineering and synthetic biology requires use of expensive machinery that is often changing so rapidly that academic institutions can find it difficult to keep pace with new innovations. Partnerships with industry can more easily provide access and training to the technology necessary to train tomorrow's leaders.

To strengthen and advance the U.S. bioeconomy workforce, collaboration is a necessity. Federal agencies are in a unique position to align their grant mechanisms to leverage collaborations across

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<sup>9</sup> <https://www.aau.edu/education-community-impact/graduate-education/phd-education-initiative>

<sup>10</sup> "A Call for Systemic Change" National Academies of Sciences, Engineering, and Medicine. 2018. Graduate STEM Education for the 21st Century. Washington, DC: The National Academies Press

<sup>11</sup> National Defense Education and Innovation Initiative, AAU January 26, 2006

disciplines and geographic areas. AAU supports the development of a greater number and better-connected industry-academic consortia to share ideas, equipment, and platforms. Coordination and partnership between key federal agencies can attract talent and encourage geographic diversity of engagement in the bioeconomy. For example, the [Life Sciences Collaborative Access Team](#) (LS-CAT) provides macromolecular crystallography resources for those with a need to determine the structure of proteins. LS-CAT was formalized in 2002 with seed money from the State of Michigan through the Michigan Core Technology Alliance. Northwestern University was selected as the managing partner and personnel from the DuPont-Northwestern-Dow Collaborative Access Team (DND-CAT) started work on the design of the facilities. Eight AAU member universities are current members of LS-CAT.

Access to state-of-the-art x-ray diffraction facilities at Argonne National Laboratory's Advanced Photon Source are available to LS-CAT members and have led to the discovery of the physical structure of a KRAS protein, a frequently mutated isoform in human cancers. As a result of this industry-academic-government partnership, three drugs are in advanced development to improve survivability for lung cancer and color rectal cancer patients based on KRAS crystallography research.<sup>12</sup>

### **Attracting and Retaining Talent**

A key to maintaining America's scientific and technological preeminence is to attract, educate, and retain domestic and foreign talent at all skill levels. Attracting and retaining scientific talent is a critical element of our national security and economic competitiveness. Therefore, we guard against measures that would unnecessarily harm the flow of foreign research talent to our shores. American science has remained on the cutting edge of innovation because U.S. academic institutions attract, educate, and retain the best and brightest foreign researchers. U.S. visa and immigration policies should convey a welcoming message and encourage talented students and scholars from around the world to come to this country and actively contribute to advancing American science and the U.S. economy. The combination of insufficient numbers of American students prepared for STEM careers and fewer international students studying and staying in the U.S. to work represents an ominous trend that has significant implications for America's competitiveness.

AAU requests federal agencies work to reduce the increasing time between visa application and issuance and ensure timely visa extensions and visa renewals for those in education and research. Visa processing delays have resulted in students deferring admission to their academic programs, missing the beginning of the academic year, and unexpected delays to continuation of their studies. [AAU's statement](#) submitted as part of a House Judiciary Immigration Subcommittee hearing<sup>13</sup> further outlines the impact of some of the delays international students and scholars are facing.

In addition, potential changes in federal policy that would narrow the scope or foundational purpose of the Optional Practical Training (OPT) program, which allows foreign students time-limited, practical work experience immediately upon completion of their academic studies, would also negatively impact U.S. interests to attract and retain foreign talent particularly as [other nations](#) seek to expand access to experiential opportunities. In the [Fall 2018 International Student Enrollment Hot Topics Survey](#) compiled by the Institute of International Education (IIE), uncertainty regarding visas and access to experiential learning are noted as two contributing factors to the declining number of international students enrolling for the first time at U.S. colleges and universities. 94 percent of survey respondents indicated it

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<sup>12</sup> EBioMedicine. 2019 Mar; 41: 711–716. Published online 2019 Mar 7, KRAS-mutant non-small cell lung cancer: Converging small molecules and immune checkpoint inhibition, Helen Adderley, Fiona H. Blackhall, and Colin R. Lindsay

<sup>13</sup> "[Policy Changes and Processing Delays at U.S. Citizenship and Immigration Services](#)," House Judiciary Immigration Subcommittee Hearing, July 16, 2019

is not just one reason, but rather multiple factors that contribute to falling new student enrollment numbers.<sup>14</sup>

### **Bioeconomy Infrastructure Challenges and Opportunities**

To continue to advance the U.S. bioeconomy, advanced manufacturing facilities are critically needed. For universities and industry, these cutting-edge facilities are costly and challenging for one organization to independently build and maintain. Given the emergent need to quickly develop synthetic biology manufacturing capacity to keep pace with other nations, AAU encourages OSTP and federal agencies to expeditiously explore construction funding mechanisms and partnerships to help close the U.S. capacity gap and strengthen U.S. competitiveness.

AAU also supports OSTP's goals of increased scientific rigor and reproducibility. To that end, federal facilitation of collaborations regarding data standards as well as computational frameworks to validate effective designs would be helpful. Challenges of data management including storage, usability, and interoperability have increased exponentially in the past few decades. The National Library of Medicine's development of analysis tools to mine electronic health records to help discover adverse drug reactions, identify promising drug targets, and detect transplant rejection earlier is an excellent example of the federal government leading and providing a critical tool. As technologies including software change very quickly, significant effort is needed to adapt existing methods as not to lose access to valuable data which may have been collected and stored using legacy standards.

While the U.S. looks to promulgate and develop new types of infrastructure, such as biofabrication facilities and cloud storage platforms, access to basic scientific resources continues to be a critical component of the infrastructure required for translational research. Stem cells, fetal tissue cells,<sup>15</sup> and animal models (particularly non-human primates), are important resources. Non-human primates are especially important to assist with understanding brain function<sup>16</sup> and expanding our knowledge of devastating neurological diseases such as Alzheimer's. For example, an estimated 5.7 million Americans are currently living with dementia while costs are rising to provide care for Americans with Alzheimer's disease (an estimated \$277 billion dollars in 2018).<sup>17</sup> To find effective treatments and remedies to this very complex disease, improving access to key scientific resources to help translate research is vital.

### **Data Policies and Safeguards**

Data access, preservation, and management are complex and emerging areas of the research infrastructure. AAU is keenly interested in data standards and universities agree it is beneficial to make data from federally funded research accessible to both the public and others in the research community to accelerate scientific discovery by making data more open to scrutiny and re-analysis. Data access has only been complicated by the vast expansion of human bioinformatics – which span the gamut of genomic sequencing, protein analysis, bioimaging and electronic health records.

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<sup>14</sup> "[Fall 2018 International Student Enrollment Hot Topics Survey](#)," Institute of international Education, November 2018: 5

<sup>15</sup> <https://www.aau.edu/key-issues/aau-submits-joint-letter-expressing-concern-over-additional-limits-fetal-tissue-research>, AAU 2019

<sup>16</sup> The Critical Role of Nonhuman Primates in Medical Research *Journal of Pathogens and Immunity*. 2017; 2(3): 352–365. Published online 2017 Aug 23

<sup>17</sup> 2019 Alzheimer's Disease Facts and Figures, Alzheimer's Association <https://www.alz.org/alzheimers-dementia/facts-figures>

We call OSTP's attention to our December 10, 2018 response to NOT-OD-19-014, Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research.<sup>18</sup> AAU was joined by our partner associations, the Association of Public and Land-grant Universities (APLU) and the Council on Governmental Relations (COGR) in commenting. The response to NIH's proposed data plan noted:

- ) Data preservation and management standards are still evolving across the scientific research enterprise. Best practices around long-term data preservation and access are still being defined in some disciplines. If a university is required to ensure long-term access to and preservation of data, it is important that there be a mechanism to update and change how existing data is stored and plans for continued preservation.
- ) It would be helpful for NIH to provide guidance on what types of "newly created repositories" would be accepted. We would also suggest that NIH create its own data repository to host any NIH-funded research data. This would be especially useful for disciplines that do not already have "community repositories."
- ) Most importantly, we strongly encourage the harmonization of data policies and required elements of data management plans within the NIH and across federal agencies in order to more fully to leverage research capabilities.

There is an urgent need for federal guidance to make big data sustainable, interoperable, accessible, and usable by the broader scientific community. Data standards and tools are critical to that endeavor. AAU appreciates that NIH recognizes the need for large scale data generation and developed its STRIDES initiative. However, at the federal level, gaps remain for standard setting and operationalization. This may be due in part to the salary restrictions and the lengthy civil service hiring process. OPM processes have been outpaced by the need for elite technology talent. NIH remains at a competitive disadvantage. The FDA faces similar challenges in recruiting and retaining scientific talent to assure the reliability and safety of products resulting from bioengineering.

### **Clarity on Safeguards and Need for Agency Harmonization**

Universities have long partnered with the federal government and industry to conduct research. As part of a portfolio of research, universities comply with existing controls and additional vetting for research projects which involve controlled technologies, dual use research of concern (DURC), or otherwise sensitive data or information. Research projects – such as those which are classified, export controlled, or otherwise identified as dealing with Controlled Unclassified Information (CUI) – have limitations, restrictions, and additional vetting requirements for foreign students and scholars. Universities work diligently to comply with federal regulations and a complex set of security controls when conducting such research.

Universities regularly establish Technology Control Plans (TCPs) and other risk mitigation initiatives to ensure the security of research and protection of intellectual property and to maintain compliance with federal regulations, laws, and contract terms. In instances where proprietary research is being conducted, institutions regularly employ non-disclosure agreements. Institutions have in place clear and comprehensive policies regarding whether and how they will undertake export-controlled research activities. This includes applying for export control licenses when required and creating Technology Control Plans (TCPs) to protect technology from unauthorized access. Most AAU institutions have one or more staff members with specific responsibility for ensuring compliance with export controls.

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<sup>18</sup> <https://www.aau.edu/key-issues/aau-aplu-cogr-submit-joint-comments-nih-proposed-provisions-data-management-and-sharing, AAU 2018>

Institutions conducting classified research also have specially trained Facility Security Officers (FSOs), who oversee security specific to this research.

Recently, increasing concern regarding compromised research has led to a proliferation of interactions with federal science and security agencies. AAU welcomes these conversations, however, the lack of coordination among federal science and security agencies and communication between them and universities regarding safeguards from undue foreign influence must be addressed. Uncoordinated actions, disparate policies, and conflicting information and communication cause confusion for universities and their research faculty. Coordinated efforts to clarify and harmonize requirements for researchers across all federal research agencies will lead to a more effective approach to protect the security of the U.S. research enterprise.

For example, NIH, NSF, DOD, and the Department of Energy appear to be working to clarify outside funding disclosure requirements for faculty, but those efforts seem to be uncoordinated and could lead to an array of different requirements. Similarly, the DOD, DOE, and Department of Commerce are talking about new steps needed to protect key technologies, but the separate agencies are not coordinating on definitions of those technologies. We are pleased to see that the NSTC JCORE is working to coordinate these agency policies and harmonize where possible.

### **Suggestions for Enhancement**

Along with our request for increased agency coordination regarding disclosure requirements and definitions on emerging technologies, we request that OSTP consider recently submitted comments on National Institute for Standards and Technology's SP800-181B.<sup>19</sup> Our comments included requests for clarification of:

- The criteria and processes for designating critical programs and high value assets outside of federal information systems;
- The parameters that will ensure consistency among federal agencies in the application of such designations and thus the 800-171B requirements;
- The flexibility and discretion that agencies and institutions will have in determining which controls truly fit with the unclassified information in question given the context of the research being conducted; and
- The cost mitigation strategies that agencies and institutions might pursue to ensure that appropriate security is maintained without diverting limited resources from vital research objectives.

Lastly, AAU encourages OSTP to explore new mechanisms for federal agencies to assist basic researchers with patent applications. Two models to consider are expanding NIH's Research Evaluation and Commercialization Hubs (REACH) program, and patent support. The REACH program currently has nine centers. The effort utilizes industry-style project management to arrive at technologies that are poised to launch. These centers are a unique public-private partnership whose objective is to change how to identify and develop innovations with scientific and commercial potential.

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<sup>19</sup> AAU, COGR, EDUCAUSE, APLU, and ACE comment letter in response to NIST Request for Public Comment on SP 800-171B, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations: Enhanced Security Requirements for Critical Programs and High Value Assets <https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/Science-Security/NIST%20800-171B%20Comments%20ACE%20AAU%20APLU%20COGR%20EDU%2008-02-19.pdf>, 2019

To assist in smoothing the way for patent applications, NIH, as a follow-on cost of grant funding, providing matching funds to universities seeking patents. Providing such patent funding, matched by an institution, would galvanize the movement of critical innovations into the marketplace to serve the public good. Patents are particularly essential for technologies that require long and costly development – and have high failure rates – and/or that require government regulatory approval. On average, developing a novel prescription treatment costs \$2.6 billion and takes approximately 11 years, and patent protections are what give companies the confidence to invest those vast resources to bring new treatments to patients.<sup>20</sup> Growth of the bioeconomy is in the national interest and it depends in part on an effective and robustly supported technology transfer process.

AAU thanks OSTP for the opportunity to submit comments and consideration of our views and to partner on matters of national importance.

Sincerely,

A handwritten signature in black ink that reads "Mary Sue Coleman". The signature is written in a cursive, flowing style.

Mary Sue Coleman  
President  
Association of American Universities

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<sup>20</sup> See, e.g., [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3458588](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3458588)