ASSOCIATION OF AMERICAN UNIVERSITIES

The Association of American Universities (AAU), representing 61 leading public and private research universities, would like to thank the Office of Science and Technology Policy (OSTP) for this opportunity to provide comments on the Bioeconomy Blueprint. The 21st century is an era of unprecedented advances in the life sciences, and research universities – in partnership with federal agencies such as the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Department of Energy (DOE) – are at the cutting edge of discoveries in biology and biomedicine. Genomics is transforming our approach to fields from medicine to agriculture, even as innovative partnerships between the life and physical sciences and engineering produce life-changing technologies. While AAU believes sustained, federal investment in life sciences research is critical to our nation's future, we recognize that fiscal challenges require strategic planning on how best to allocate resources. We applaud OSTP for seeking feedback from the research community to maximize our federal research investment.

AAU's responses to the Request for Information (RFI) follow. We hope that serious consideration will also be given to the comments submitted by our individual member institutions. While some of the questions lay outside the scope of our institutional perspective and expertise, and therefore were not answered, many of the issues identified have been of longstanding interest to AAU and our member institutions.

> ***Research and development:*** **R&D investments, particularly in platform technologies, can support advances in health, energy, the environment, and agriculture, and accelerate the pace of discovery in fundamental life sciences research.**
>
> **Constrained Federal budgets require a focus on high-impact research and innovation opportunities. With this in mind, what should be the Federal funding priorities in research, technologies, and infrastructure to provide the foundation for the bioeconomy?**

AAU applauds the Administration for its consistent commitment to research and development and for incorporating continued federal investment in the life sciences into the Bioeconomy Blueprint. Stable and sustained funding for scientific research underpins our nation's innovation engine; research fuels the new ideas and technologies on which our economy, health, and national security depend and generates the talent base that will drive our economy forward. Indeed, the American system of research and higher education, built upon the idea of combining research with training of young scientists and engineers, has been enormously successful. This system would be impossible without federal research funding.

Clearly, our nation must reduce federal spending and address the nation's growing debt. But we must do so in a smart and strategic way. We should not compromise our future economic growth and security through deficit reduction measures that cut spending in areas, such as scientific research and education, which are critical to our nation's ability to innovate and compete. If we want our children and grandchildren to have opportunities in the future, we need to continue to make funding for scientific research and education a national priority.

In times of fiscal constraint, questions inevitably arise about the value of our research investment and it becomes easy to focus on the short-term return on investment. As OSTP develops the Bioeconomy Blueprint, we urge you not to lose sight of the unique federal role in supporting basic, curiosity-driven research. Basic, fundamental research provides the building blocks for future innovation, economic growth, and technological advancement, although its value may be difficult to assess using short-term metrics. AAU also reiterates our support for maintaining merit review as the primary system by which research funding is awarded and scientific priorities are set. Peer review has played a central role in the success of the U.S. life sciences research enterprise, setting it apart from all other nations. We acknowledge that in a limited resource environment, meritocracy becomes more difficult to sustain as reviewers are forced into an unrealistic degree of precision when choosing between highly scored proposals, and conservatism leads them to fund potentially fewer high-risk projects and fewer innovative investigators. But the funding agencies have given this issue a great deal of thought. AAU strongly recommends that OSTP seek advice from NIH and NSF on new approaches to peer review designed to foster innovative, high-risk research, such as the NIH Transformative Research Projects program.

During times of constrained budgets, federal agencies may sacrifice investments in research infrastructure. Examples include the recent decision to eliminate the National Center for Research Resources at NIH, the disestablishment of the Armed Forces Institute of Pathology, and the loss of funding for the Arabidopsis Information Resource. But shared research resources are a crucial component of basic and translational biological research. This is particularly true as the life sciences move into an era of unprecedented large-scale projects and multidisciplinary research, with the continued revolutions in genomics and computational biology.

AAU asks that the Bioeconomy Blueprint recognize the importance of developing sustainable models for federal support of research infrastructure in the life sciences. .

> ***Moving life sciences breakthroughs from lab to market:*** **It is a challenge to commercialize advances in the life sciences because of the risk, expense, and need for many years of sustained investment. The Administration is interested in steps that it can take directly, but is also interested in encouraging experimentation with new private sector-led models for funding commercialization of life sciences research.**
>
> **What are the barriers preventing biological research discoveries from moving from the lab to commercial markets? What specific steps can federal agencies take to address these shortcomings? Please specify whether these changes apply to academic labs, government labs, or both.**

Several studies in the past few years have found that the current system of university technology transfer under the Bayh-Dole Act of 1980 is working well, especially in comparison to universities' low technology transfer activities before passage of the law. These studies include an October 2010 report by the National Research Council Committee on the Management of University Intellectual Property: *Managing University Intellectual Property in the Public Interest*, National Academies Press, October, 2010, pp. 4 & 73-74. Additional reviews of university technology transfer include the 2001 report, *NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interests are Protected*, and the 2003 report by the President's Council of Advisors on Science and Technology, Technology Transfer of Federally Funded R&D Clearly, ***the current legal framework for university technology commercialization established by the Bayh-Dole Act of 1980 and its implementing regulations is effective and should be maintained.***

While great strides have been made in university technology transfer since the enactment of the Bayh-Dole Act, working with industry and the federal government, there is still a great deal that our universities can do to improve. In responding to the OSTP and National Economic Council's RFI concerning the commercialization of university research and proof of concept centers in May, 2010, AAU made a number of recommendations to help overcome barriers to moving new ideas from the lab to the marketplace. Below we reiterate and expand upon some of the key points we made in that response because we believe they are equally applicable here.

- ***Finding Resources to Support Commercialization by Universities:*** One of the greatest challenges in university of technology commercialization is finding funds to support the infrastructure for commercialization and technology transfer, particularly early stage (gap and proof of concept) funding for new inventions. Technology transfer imposes significant costs on universities at a time when they are already under significant financial stress due to the economy and resulting declines in state support, endowments, and donor giving.

  The intent of commercialization by universities should be to transfer technology for further development and effective application to ensure broad public access and increased social welfare. The lack of adequate institutional and/or government resources for commercialization activities, however, may have driven some university technology transfer offices (TTOs) to focus disproportionately on revenue generation as opposed to moving new knowledge into the public domain for the public good. This situation creates the wrong incentives for optimizing technology transfer. While many TTOs operate at a loss, at times, commercialization generates net revenues. However, universities should not pursue commercialization of research primarily for this purpose. Universities, government, and industry have a responsibility to find new ways of providing university technology transfer operations with necessary support so that these operations have the correct incentives to be successful in achieving their broader mission.

  To ensure that revenue generation does not drive negative behaviors that can impede technology commercialization, universities must evaluate the indicators that they use to judge the effectiveness and quality of their technology transfer and licensing operations. Indicators that have traditionally been used to measure successful commercialization efforts at universities (e.g. patents, licenses, and revenue generation) have been overused, misapplied, or are sometimes inappropriate surrogates to measure the effectiveness of efforts by universities to commercialize research. Many of our institutions are aware of these issues and are seeking to develop better measures. Our association, as well as others including the Association of University Technology Managers (AUTM), is also taking steps to develop better commercialization effectiveness measures.

- ***State Policies*** Some states forbid equity participation in companies (i.e. startups) by state institutions, while others have policies limiting involvement of faculty in such activities due to their status as state employees. There also may be tax and funding issues associated with states that can be problematic. Additionally, states may have specific policies about use of state "facilities" for commercial activities which affect public universities. We encourage the Obama Administration to work with the nation's governors to examine the impediments these laws and regulations may create for economic innovation and growth, as well as possible solutions.

- ***Conflict of Interest:*** Increased economic engagement inevitably raises the likelihood of more financial relationships between institutions and their researchers and the companies with which they engage. In fact, one gauge of the effectiveness of commercialization is the growth of such relationships. Current perceptions that such relationships are inherently suspicious or invariably lead to unmanageable conflicts of interest must be changed. Both policymakers and the public must understand that these relationships are positive and necessary for universities to achieve greater success in commercializing their research. At the same time, it is critical that as federal agencies move to regulate potential conflicts of interest, they do not put in place regulations which inadvertently discourage appropriate interactions among research faculty, universities, and industry. We understand that conflicts of interest must be closely monitored and kept in check. However, an overly strong focus on elimination, rather than management, of conflict of interest by federal agencies would produce a chilling effect on universities' willingness and ability to engage in economic development and be directly counter to the Administration's interest in increasing commercialization by universities. As purveyors of objective knowledge, universities have their own built-in interest in managing conflicts of interest, or perceptions of such conflicts, to ensure that the integrity of research findings are not compromised.

- ***Reconsider the current cap and other restrictions on the reimbursement of university administrative costs:*** To address the issue of resources and in accordance with a recommendation made by the Government Accountability Office in September 2010 (see: University Research: Policies for the Reimbursement of Indirect Costs Need to be Updated, GAO-10-937, September 8, 2010, http://www.gao.gov/new.items/d10937.pdf), we urge the government to reexamine the existing 26 percent cap on reimbursement of university administrative costs. Costs of supporting commercialization are not allowed as direct costs of research in traditional federal research grant mechanisms. Currently, some of these costs, namely patent costs and related expenses, may be charged to universities' administrative cost pools for purposes of facilities and administrative (F&A) cost reimbursement. However, since the administrative components of F&A are capped and subject to pressures to support increased costs of regulatory compliance, there is little flexibility to support other activities such as patent and other costs related to commercialization. Removing or lifting the cap would help to ease current financial pressures universities face as a result of growing compliance demands and free up resources for other areas. Additional resources could also be freed up if certain costs, such as those associated with human subject protection, were allowed to be directly charged to grants.

- ***Provide for supplemental grants to support the translation of research with a high potential for commercialization:*** The federal research agencies have recently focused on developing new translational research programs. While we believe such programs can play an important role in helping to transfer research into the marketplace, effectiveness at translating research for commercialization is not necessarily the same as translational research. Indeed, there are many good ideas with significant commercialization potential already being generated from existing and more traditional federal research programs. The problem is that researchers and universities do not have resources available to support the proof of concept work, market analysis, and mentoring needed to translate these ideas from the university laboratory to the marketplace.

To address this situation, we recommend that the Administration consider the establishment of new "Translational Supplemental Awards." These awards would be made by the major federal research agencies to support proposals jointly submitted by an existing principal investigator and the university TTO or another appropriate institutional research or technology commercialization official. These awards would be made at the tail end of federally funded awards to support next stage research for projects that show strong clinical or market potential. We believe that providing such awards would both incentivize researchers to think about the potential commercial applications of their research and help to change the culture of the federal research agencies in ways that would help facilitate the commercialization goals of the Administration.

- ***Modify the R&D tax credit:*** The Administration is already on record in support of making the existing R&D tax credit permanent, a goal we support. In addition, we encourage the Administration to seek modifications to the R&D tax credit so that it provides a greater incentive for such investments instead of penalizing companies that invest in university research by not granting them full credit for research performed outside of the company, as is currently the case.

- ***Create additional tax incentives to promote commercialization:*** We encourage the exploration of additional ways in which the tax code could be used to encourage early stage investment in university technologies and to reward companies that license university technologies. For example, tax credits or deferral of taxes for angel investors in emerging companies can help spur additional investment at a critical period in a company's development.

- ***Seek new ways to reduce or supplement the growing expenses involved in patents:*** While we realize that increasing the degree to which universities obtain patents does not necessarily result in increased commercialization, patenting costs are increasingly becoming a barrier to commercialization by universities. We recommend consideration of new methods to support such expenses, perhaps along the lines of the competitive allocation process that is currently being used in the United Kingdom. One example might be to develop a separate commercialization rate supplement based on a set of indicators of commercialization success compared to total federal research dollars received.

What specific changes to Federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs would help accelerate commercialization of federally-funded bioeconomy-related research?

AAU generally supports the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, although we have been seriously concerned both about recent legislative attempts to increase the percentage set-aside for this program, as well as the lack of funding for proof of concept research to help the program succeed. We highlight this latter issue here, but our full position may be found at: http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=11944 SBIR and STTR are important to helping research cross the "valley of death," but SBIR and STTR funding presumes there is already sufficient evidence that a particular research advance or technology has enough commercial value to attract further investment for commercialization. Often times, however, there is not the funding available within our universities, or from other sources, to push these technologies to this point.

We propose the development of a targeted program focused on funding earlier stage proof of concept research across research agencies and scientific disciplines. Such a program would not only help more projects cross the "valley of death," but would also help enhance the infrastructure (e.g. expertise, personnel) and facilitate the cultural change necessary for universities to better support this kind of transfer. At least two models for such a program already exist:

- The European Research Council (ERC) has just announced a new proof of concept funding initiative to help bridge the gap between ERC-funded research and the earliest stage of marketable innovations. [1] These awards will be up to around $215,000 for individual researchers, equivalent to about one percent of ERC's budget.[2]
- The Wallace H. Coulter Foundation has established Translational Research (for individual researchers) and Translational Partnership (for institutions) Awards for proof of concept research in biomedical engineering.[3] The Translational Researcher Awards are made in amounts of approximately $100,000 per year, while the university grants have duration of five years at over $500,000 per year.

A proof of concept funding award program should have several key attributes. Like the Coulter Awards, they should be focused on both individual researchers and on institutions. Both individual and institutional funding should be subject to rigorous evaluation by carefully assembled panels of local experts in translational and proof-of-concept research. Unlike traditional research awards, the award criteria should include not just scientific merit, but also a demonstrated willingness and capability of a university in engaging project management boards comprised of industry, start-up, venture capital, technical, financial, and business/market experts. Additionally, successful applicants for this funding should be required to prove:

- agility in managing translational projects stressing market-relevant milestones,
- ability to conduct rigorous oversight and management of such projects, and
- willingness to withdraw funding from projects failing to reach essential milestones so that funding can be re-allocated to projects with more potential.

As under the Coulter model, title to inventions should remain with the institution, which is free to follow its normal invention licensing policy.

We envision several ways in which such a program might be implemented:

1) *Translational Supplemental Awards*—As discussed above, Federal research agencies would make these awards to support proposals jointly submitted by an existing principal investigator and the university technology transfer office or other appropriate institutional research or technology commercialization official.
2) *Institutional Translational Center Awards*— Larger grants to universities aimed at helping them to establish a culture that promotes the acceleration of innovative ideas into the marketplace should be supported by federal agencies. We are pleased to see that the National Heart, Lung, and Blood Institute (NHLBI) has recently announced its intent to publish a new Funding Opportunity Announcement to help to foster the creation of just such centers to

[1] http://erc.europa.eu/pdf/ERC_PR_Proof_of_Concept.pdf
[2] http://news.sciencemag.org/scienceinsider/2011/03/europe-nudges-top-scientists-to.html
[3] www.whcf.org/partnership-award/overview

"…address the problems that hinder the critical, early steps necessary to translate novel scientific advances and discoveries into commercially viable diagnostics, devices, therapeutics, and tools that improve patient care and advance public health." (see: Notice of Intent to Publish a Funding Opportunity Announcement for the NHLBI Centers for Accelerated Innovations, NOT-HL-11-157, NIH Guide). We believe that the model that is being established by the NHLBI has great potential to significantly accelerate commercialization and should be replicated by other NIH Institutes.

3) *Modification of SBIR/STTR Program*—The SBIR/STTR program could be modified in a way that would provide agencies with flexibility to use a certain proportion of funds set aside for SBIR/STTR to directly support additional proof-of-concept work at universities; specifically, new demonstration projects that would support proof-of-concept grants to universities and their faculty members. This flexibility is aimed mainly at allowing agencies such as the National Institutes of Health (NIH) and NSF to devote a proportion of their STTR funds for even earlier stage proof-of-concept research or prototype development research, the type of research that is best conducted in the settings where discoveries and innovations perceived to have commercial application are first developed, as opposed to later stage product development or for more applied pre-commercial research.

4) *Built into new programs*—For example, the new Cures Acceleration Network within the proposed NIH National Center for Advancing Translational Sciences might consider this model in developing its strategies and programs.

In summary, as the federal government focuses on facilitating the movement of basic research discoveries into the private sector, we urge that attention be paid to the need for early-stage proof-of-concept research at universities. Such research will better prepare discoveries to move effectively and efficiently into the marketplace, as well as providing universities and individual investigators with the resources to more fully incorporate considerations of commercial viability into their research enterprise.

Workforce development: **Investment in education and training is essential to creating a technically-skilled 21st century American bioeconomy workforce.**

The majority of doctorate recipients will accept jobs outside of academia. What modifications should be made to professional training programs to better prepare scientists and engineers for private-sector bioeconomy jobs?

AAU recently submitted extensive comments to the NIH Working Group on the Future of the Biomedical Workforce on the topic of life sciences training and career opportunities, which may be found here: http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=12706 We hope that OSTP will coordinate its efforts with this group, led by Princeton President Shirley Tilghman, in considering potential modifications to training programs to better align with career opportunities in the new bioeconomy. While we recognize that the Bioeconomy Blueprint goes beyond the biomedical into broader applications of life sciences, it is an inescapable fact that the vast majority of biologists are trained at some point through NIH training mechanisms or in NIH-funded laboratories.

The stated goal of NIH-supported training is to produce independent investigators eligible and able to obtain NIH research awards. If that is, in fact, the objective of such training, one could argue that these programs are not entirely successful. Perhaps the better approach is not to try to manage supply and demand, but rather to manage expectations and redefine the measures of "success." NIH, research institutions, and faculty involved in training share in the responsibility to provide students and postdoctoral trainees with realistic assessments of future employment prospects, through provision of accurate data on employment placement, award competition, and career opportunities. All stakeholders in the biomedical research community need to work together to eliminate the stigma that any career outcome other than an R01-funded academic investigator represents failure. While it may not be NIH's role specifically to create programs that train students and postdocs for non-research or non-clinical careers, such a role may fit the broader aims of the Bioeconomy Blueprint. Thus, NIH and other agencies should ensure flexibility in training mechanisms to allow trainees to explore non-traditional careers or gain additional skills and experiences. One example might be adjusting the payback policy on National Research Service Awards (NRSAs) to expand beyond engagement in research. In addition, to provide a future foundation for evaluating the supply and demand question, the government must find a way to capture information about career outcomes on all of the trainees it supports, regardless of funding mechanism.

What roles should community colleges play in training the bioeconomy workforce of the future?

AAU works closely with other higher education associations, including the American Association of Community Colleges. As we address the challenges facing American higher education, we are fortunate to have as a foundation colleges and universities that offer an extraordinary variety of quality educational and research experiences without a centralized system that stifles educational innovation. We must take advantage of our diverse and flexible system to meet the current opportunities and challenges in the life sciences, and community colleges are an important component of our higher education enterprise.

What role should the private sector play in training future bioeconomy scientists and engineers?

Doctoral training is of great interest to AAU, as our institutions collectively award more than half of all doctoral degrees nationwide. As a general principle, AAU believes there is a strong federal interest in ensuring that enough of our most talented college graduates go on to earn doctoral degrees. If they do not, the country's innovative capacity and economic competitiveness will be weakened. Like the federal investment in basic research, the federal investment in doctoral education fills a critical gap that neither states nor industry can fill. Talented students who receive doctoral degrees are a highly mobile national resource, and state governments often are reluctant to invest in fellowships for students who might not remain in their state. Similarly, corporations may find doctoral fellowships difficult to justify when they cannot be certain that a student will join the company after attaining the degree. Furthermore, industrial support of training programs in the wake of NIH's new rules on conflicts of interest might prove difficult for universities to manage.

What role might government, industry, and academia play in encouraging successful entrepreneurship by faculty, graduate students, and postdocs?

In an April 19, 2011 letter sent to the Secretary of Commerce, over 135 university presidents and three major higher education associations, including AAU, committed to working with industry,

private foundations, venture capitalists and local, state and federal governments to promote entrepreneurship, to accelerate the technology commercialization, and to institute policies and programs that support regional economic development. A copy of this letter can be found at: http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=12084

Two areas highlighted in the letter focused on promoting innovation and entrepreneurship among students and faculty. To enhance student entrepreneurship, the university presidents that signed the letter committed to:

- Build upon and expand courses aimed at teaching entrepreneurship, provide new opportunities for experiential learning, run student business plan competitions, support student clubs, and sponsor programs that put multidisciplinary student teams to work solving real world challenges.

- Create new programs and grow existing activities to encourage undergraduates, graduate students, and post-doctoral students to pursue careers as innovators and entrepreneurs.

- Develop new cross-college, cross-disciplinary programs that connect business with science, math, technology and engineering fields.

- Extend campus-based entrepreneurship programs to reach young people in underserved and low-income areas by involving community colleges in consortia for training and mentoring in innovation and entrepreneurial activities.

To encourage faculty innovation and entrepreneurship, the presidents noted that, among other things, they use financial incentives, faculty industry sabbatical leaves, campus prizes and other forms of recognition, To further promote successful faculty entrepreneurship, they committed to:

- Expand efforts to encourage, recognize and reward faculty interest in research commercialization by providing incentives and encouraging engagements with industry, entrepreneurs and venture partners.

- Create or expand programs that connect faculty and students to the resources they need: industry partners, entrepreneurial mentors, translational research and "proof-of-concept" funds, accelerator facilities and venture creation services.

- Encourage streamlining and reduction in reporting and compliance requirements, which would allow faculty to increase time spent on proposal writing and research.

The presidents also called upon the federal government to refrain from enacting policies, such as overly stringent rules on conflict of interest that would discourage faculty willingness to work with industry or to commercialize innovative new research discoveries.

We believe the ideas presented in the university presidents' letter represent reasonable and sound ideas for promoting and supporting student and faculty entrepreneurship. We would encourage the federal government and industry to find ways that they can help support universities that are making such efforts.

Reducing regulatory barriers to the bioeconomy: **As President Obama has stated, our regulatory system must ''identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends'' and ''protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.''**

What specific regulations are unnecessarily slowing or preventing bioinnovation? Please cite evidence that the identified regulation(s) are a) slowing innovation, and b) could be reformed or streamlined while protecting public health, safety, and the environment.

AAU recently joined with the Association of Public and Land-grant Universities (APLU) and the Council on Governmental Relations (COGR) in assembling a white paper on the issue of Regulatory and Financial Reform of Federal Research Policy, which was submitted to the National Research Council committee examining the future of research universities. We suggest that this white paper would be useful to OSTP in preparing the Bioeconomy Blueprint: http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=11666

We firmly believe that compliance and regulatory oversight are essential to the conduct of federally-supported research. Rationalizing the federal regulatory infrastructure is essential to the health of the university-government research partnership and to the efficient and productive use of federal research funding. Research universities strongly support the objectives of accountability, transparency, and implementation of important policy and regulatory requirements. However, the current regulatory climate has become dysfunctional – regulations do not align closely with true risk, and new regulatory mandates are unfunded due to the 26-percent cap on reimbursement of administrative costs. It is a growing fiscal challenge for universities to manage unfunded mandates as institutional budgets are being reduced, administrative cost reimbursements are being suppressed, and cost-sharing requirements are increasing.

Quantifying the burdens associated with specific regulations is difficult, though we provide anecdotal information in Appendix A of the above referenced white paper. The larger issue is the accretion of regulatory burdens and the increase in overall compliance costs over time.

While we are able to identify several regulations for outright elimination, it is often difficult to isolate or object to one regulation or category of requirements. Instead, it is the proliferation of those requirements and their uneven and unsynchronized implementation across many federal agencies that create a compliance miasma. In this environment, universities are often forced to institute one agency's compliance requirements across an entire campus, even where they don't make sense, and to sift through each agency's specific rules and develop different compliance mechanisms all aimed at the same ultimate purpose.

What specific steps can Federal agencies take to improve the predictability and transparency of the regulatory system? (Please specify the relevant agency.)

We would again refer you to the above cited white paper on regulatory reform related to university research, which details issues with inconsistent application of federal regulations. Because of this inconsistency, universities have sometimes taken an especially conservative approach to federal

regulatory compliance, in part to ensure they avoid the hefty penalties that would be levied if an Inspector General-ordered audit found them in noncompliance. This conservatism has also increased costs, with some universities even failing to take advantage of regulatory exceptions for fear of regulatory non-compliance.

The federal government needs to help universities ensure they are complying with regulations in the most efficient way possible. It also needs to assist universities in helping assess the costs associated with regulation. Finally, working with universities, a serious attempt should be made by the Federal government to better account for, track, and reduce regulatory costs. Specifically to improve transparency and predictability of the regulatory process, AAU would recommend:

- ***Harmonize regulations and information systems between agencies and statutes where reasonable and eliminate unnecessary duplication and redundancy*.** University research is funded by 25 different federal agencies, each with a unique approach to regulatory implementation. While regulations concerning areas like human subject protections, animal welfare, export controls, select agents, responsible conduct of research, and financial conflicts of interest all serve important public policy goals, unique interpretations and implementations across agencies are difficult to manage, create inefficiencies, and increase costs. Additional challenges occur when rules applicable to grants (established by OMB) are inconsistent with rules applicable to contracts (established under the Federal Acquisition Regulations Councils).

- ***Eliminate regulations which do not add value or enhance accountability***. At least two requirements, Effort Reporting and Cost Accounting Standards, neither add value nor enhance accountability. As characterized by the Federal Demonstration Project, Effort Reporting "is based on effort which is difficult to measure, provides limited internal control value, is expensive, lacks timeliness, does not focus specifically on supporting direct charges, and is confusing when all forms of remuneration are considered." Cost Accounting Standards require institutions to disclose in writing accounting policies that are already documented in other institutional systems. Both of these regulations could be eliminated without any detriment to the accountability or oversight of the research enterprise. As other valueless regulations are identified, there should be a formal process in which each can be reviewed and made eligible for elimination.

- ***Ensure that regulations are meeting their goals in terms of performance, rather than simply in terms of process***. Research universities support the objectives of implementing important policy and regulatory requirements – research institutions take their stewardship responsibilities seriously. However, when implementation of regulation is premised on overly prescriptive measures issued by agencies, and subject to audit by federal and local auditors, institutional management of regulation becomes grossly complex and expensive. "Performance-based regulatory compliance" focuses on regulatory outcomes (e.g., research animals are treated in a humane manner) rather than intermediate measurements (e.g., all holding areas must meet specific dimensions). A regulatory approach that is based on performance-based standards offers universities greater flexibility to achieve regulatory goals and results in a more rational and cost- effective regulatory infrastructure.

- ***Designate a high level official within OMB's Office of Information and Regulatory Affairs (OIRA) to serve as a Federal Ombudsman, responsible for addressing university regulatory concerns and for seeking ways to increase regulatory efficiency***. This individual should be empowered with broad responsibilities to manage and minimize regulatory burdens applicable to research universities and institutions. The Ombudsman would assist in harmonizing and streamlining federal regulations, and would also have responsibility for reviewing specific "simplification requests." Under the auspices of the National Science and Technology Council (NSTC), the Ombudsman – along with a designated representative from OSTP – should lead an interagency group charged with regularly reviewing regulations affecting research universities. This interagency group could be organized as a new subcommittee of the National Science and Technology Council (NSTC) Committee on Science, or as part of the existing Research Business Models Subcommittee. Through an application process, research universities or university associations could submit proposals to "fix" or eliminate rules that either add no value or promote inefficiency and excessive regulatory burden.