

AAU Association of American Universities
APLU Association of Public and Land-grant Universities

July 28, 2011

A-21 Task Force
Interagency Working Group on Research Business Models
Subcommittee on Social, Behavioral and Economic Sciences
Committee on Science
National Science and Technology Council

Dear A-21 Task Force Members:

Thank you for the opportunity to provide input in response to the Task Force's June 28, 2011 Request for Information (RFI): Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Educational Institutions (OMB Circular A-21) (Notice Number NOT-OD-11-191).

Attached please find a joint response to the RFI from the Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU). Should you have any questions or require more information, please do not hesitate to contact Toby Smith at AAU (202-408-7500, toby_smith@aau.edu) or Howard Gobstein at APLU (202-478-6040, hgobstein@aplu.org).

Thank you again for your consideration of our recommendations.

With best regards,



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AAU-APLU Response to A-21 Task Force RFI

July 28, 2011

The Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU) welcome the opportunity to respond to the National Institutes of Health (NIH) June 28, 2011 Request for Information (RFI): Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Educational Institutions (OMB Circular A-21) ([NOT-OD-11-091](#)). Together, AAU and APLU represent most of the nation's large public and private research universities. Research universities strongly support the objectives of accountability and transparency, and our member institutions firmly believe that compliance and regulatory oversight are essential to the conduct of federally-supported research.

The Interagency Task Force's efforts to reform OMB Circular A-21 and the Administration's other efforts on reducing regulatory burden are of critical importance to our member institutions. Improved alignment of cost principles and regulatory policies is essential to the health of the university-government research partnership and to the efficient and productive use of federal research funding. Given increasing fiscal constraints facing our universities, it is imperative that we work to ensure efficiency in government regulation to reduce the costs of compliance and to maximize the productivity of researchers.

Our submission is designed to be complementary to the more-detailed submission from the Council on Governmental Relations (COGR); we support COGR's recommendations. Together, the recommendations from AAU, APLU, and COGR are designed to benefit the federal government, our member institutions and their faculty and researchers, and the nation as a whole. Implementation of our recommendations should allow research universities to enhance their productivity and reduce costs. Minimizing administrative and compliance costs ultimately will provide a cost benefit to the federal government and to university researchers and students by freeing up resources and time to directly support educational and research efforts. Bolstering those efforts will increase the productivity of the researchers whose discoveries and innovations will be critical to our country's future.

Our recommendations follow, in three distinct categories tiered in order of priority:

I. Top Priorities Relating to Circular A-21

1. OMB should fully enforce existing cost-reimbursement rules and prohibit federal agencies from practices and/or policies inconsistent with the federal cost principles currently outlined by Circular A-21.

A number of financial reimbursement policies imposed by federal funding agencies are inconsistent with the official OMB requirements delineated in Circular A-21. This, in turn, results in significant under-recovery of federal funds to research universities. COGR has compiled examples of federal agencies and/or programs where arbitrary agency policy results in institutions further subsidizing federally funded research programs. This list of examples can be found in COGR's November 2010 paper titled "Federal Funding Agency Limitations on Cost Reimbursement: A Request for Consistency in the Application of Federal Guidelines".

The NIH policy on Genomic Arrays, announced in May 2010, is an example where NIH identified large volume-expensive supply items (i.e., Genomic Arrays) and determined that these items generated disproportionately large Facilities and Administrative (F&A) payments. Even though OMB Circular A-21 premises that the entire F&A rate determination process be based on an “averaging” concept (i.e., some items generate more F&A, others generate less), the NIH policy disregarded this concept in the case of the Genomic Arrays policy.

We urge OMB to enforce Circular A-21 and to work with federal funding agencies to ensure that their policies and practices comply with the official federal requirements contained in OMB Circular A-21 and the subsequent 2003 OMB Policy Directive. The Negotiated F&A Rate, unless statutorily prohibited, should be accepted by all federal funding agencies on all federally-sponsored research, service and educational programs. As stated in section G.11.b of Circular A-21: “The negotiated rates shall be accepted by all federal agencies.”

We believe that OMB should write a “Memorandum to Agency Heads” that reaffirms the official requirements from OMB Circular A-21 and the 2003 Policy Directive on Financial Assistance Program Announcements, requesting that all agencies review and provide a report back to OMB on their compliance with Circular A-21 within 90 days. If there are specific programs or practices that are identified by the agencies as not adhering to the A-21 requirements, the agency would be required to include in its report a plan to phase in adjustments in these policies that will ensure their future compliance.

2. OMB should ensure that rate setting practices by government negotiators are consistent and fair across all institutions.

The Government Accountability Office (GAO), in a 2010 report entitled “[University Research: Policies for the Reimbursement of Indirect Costs Need to be Updated](#)” (GAO-10-937), recommended that OMB “identify methods to ensure that the rate-setting process is applied consistently at all schools, regardless of which agency has rate cognizance. This would include identifying ways to ensure that differences in cognizant rate-setting agencies’ approaches, goals, policies, and practices do not lead to unintended differences in schools’ rate reductions for indirect costs.” In support of GAO’s recommendation, COGR made a more detailed set of recommendations in its May, 2011 paper entitled “Improving the F&A Rate-Setting Process with the Federal Government.” We support consistent and fair rate setting practices generally, and GAO’s and COGR’s recommendations more specifically. To ensure that there are not such discrepancies, we request that OMB conduct a comprehensive evaluation of current rates to see if unwarranted disparities exist in rates and the associated negotiation processes between public and private institutions, institutions with different cognizant auditing agencies (i.e. the Department of Health and Human Services Division of Cost Allocation (DCA) versus the Department of Defense’s Office of Naval Research), or among the four respective DCA regional offices. If unwarranted discrepancies are found based upon this review, OMB should develop a plan to see that they are immediately and fairly addressed.

Additionally, we recommend that OMB establish a formal mechanism and process by which universities that feel that they were treated unfairly or arbitrarily in their rate negotiations could appeal the decision of their cognizant rate setting agency.

3. *OMB should immediately remove other inequities in current reimbursement policies across institutions. Accordingly, the option to receive the Utility Cost Adjustment (UCA) should be extended to all institutions.*

Prior to July 1, 1998, many institutions performed special studies to allocate utility costs, since research buildings consume power at a much greater rate than non-research buildings. These studies were often a matter of contention during F&A rate negotiations with federal agencies, and were disallowed in the 1998 revisions to Circular A-21. The special studies were replaced by a Utility Cost Adjustment (UCA), which was granted at that time only to those 65 institutions that had completed a utility cost study in their most recently negotiated F&A rate proposals. The 1998 revisions stated that in 2002, OMB would consider allowing other universities to use the UCA, but OMB has never taken any further action on this matter. As a result, hundreds of universities are unable to recover the very real, higher utility costs associated with research buildings. In its September 2010 report on university F&A costs, the GAO recommended that “The Director of OMB...clarify the roles and responsibilities of federal agencies (including DOD, HHS, and OMB) in accepting applications and reevaluating the eligibility of schools to receive the utility cost adjustment.” We concur with the GAO that the option to receive the UCA should be extended to all universities.

4. *Researchers should be allowed to charge some level of administrative and compliance support directly to their federal grants and contracts.*

A revision to Circular A-21 in 1993 prohibited faculty from directly charging clerical and administrative staff support (except for awards deemed as major projects) for the administrative aspects of their research responsibilities. This revision effectively mandated that clerical and administrative support could be recovered only through the F&A rate mechanism. The combined impacts of this ability to recover administrative and clerical support only as an indirect cost with new compliance mandates have been significant. In particular, some of the response to the federal regulatory changes fell directly on the faculty, drawing them away from their direct research, education, and mentoring responsibilities. Indeed, the survey of faculty by the Federal Demonstration Partnership (FDP) in January, 2007 shows that faculty members were spending 42 percent of their federally funded research time on compliance and administrative matters associated with grants.

Allowing researchers to charge some level of administrative and compliance support directly to federal grants, perhaps in the form of an allowance that would allow a Principal Investigator (PI) to directly charge expenses to hire staff to support project management activities on a particular award, would both make these costs more transparent and allow faculty to spend more time on research and teaching versus administrative duties associated with existing and future compliance and reporting requirements.

5. ***The expectation of “Effort Reporting” should be discontinued and replaced with institutionally designed compliance-based approaches that meet accountability standards for “Payroll Distribution” systems. An “outcomes-based” approach that demonstrates to agency officials that faculty, investigators, technical staff, students, and other personnel are actively engaged in the proposed research can be an appropriate foundation for institutional systems.***

Effort reports show the percentage of total effort that individuals contribute to university activities. Faculty commit to devote a certain fraction of their work time to specific projects funded by the federal government, and must regularly certify that they are devoting this amount of time to those activities. Effort reporting has been widely criticized for imposing significant cost without adding value. For example, according to the [Federal Demonstration Partnership](#), “...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.”

AAU and APLU believe that government research agencies should focus on ensuring that the work required by a specific grant is performed and that payments made for the work are appropriate. But attention should not be focused, as is currently the case with effort reporting, on ensuring that a certain level of effort is devoted to that grant and that this is distinguishable from time faculty spend on other activities and responsibilities for which they are also being paid. We believe that current effort reporting requirements can be eliminated without any detriment to the accountability or oversight of the research enterprise for four reasons:

1. *It is redundant.* Requirements that faculty provide regular progress reports to funding agencies concerning fulfilling the requirements of their federal awards are already in place. These reports serve the same function as effort reporting, but do so more effectively because they better align with incentives for faculty performance such as research accomplishments, success on subsequent grant proposals, and promotion and tenure. Ultimately, assessing if the work requirements of a grant are completed – not specifically accounting for time spent working on the project – is the most important mechanism for ensuring that taxpayer dollars are being well spent.
2. *It is unnecessary.* Faculty researchers rarely spend less time than they initially commit to federally funded research. Indeed, as acknowledged by the OMB A-21 Clarification Memo of January 2001, faculty routinely spend more time than they committed to.
3. *It lacks precision.* Effort reporting is incompatible with an academic research environment in which researchers do not work on billable hours and researcher responsibilities such as student supervision often cannot realistically be billed reliably to a single project. A strong argument can be made that the most effective researchers are very good at multitasking and combining their research efforts so that they are synergistic in nature. As a result, their work on one project may lead to significant advances on a different project. This makes separating and distinguishing the specific time spent on one award versus the other for the purpose of accurate accounting difficult if not impossible.

4. *It is expensive and wasteful of government funds.* The federal government must spend money in the auditing of effort reports and associated administrative processes. It adds considerably to universities' administrative costs and takes faculty away from their research and education responsibilities.

To ensure fiscal accountability, AAU and APLU support the recommendation made by COGR that an outcomes-based alternative to effort reporting be developed. For example, reports from an institution's payroll distribution system could be produced and attached to existing agency progress and final reports. The reports would include a listing of the personnel being paid from the project, the amount paid for the reporting period, and a statement by the PI that the salaries funded by the project are reasonable relative to the work performed for the reporting period. Progress reports and final reports are already designed to address the important scientific/technical questions and challenges that are inherent to fundamental research and the project's objectives – outcomes are demonstrated to agency officials and program officers when faculty, investigators, technical staff, students, and other personnel are actively engaged in the proposed research and conducting those activities that are unique to scientific discovery.

6. *Reduce subrecipient monitoring requirement for other entities, like research universities, that receive federal awards.*

Many collaborative research projects involving investigators at different institutions require that subawards be made to other partnering institutions. In these instances, the prime award recipient is also required to "monitor" the business practices and internal controls at the subrecipient institution. While there may be value to monitoring subrecipients that are not established recipients of federal funding, to monitor other research universities that regularly receive federal awards and also have to report is a wasteful exercise and can be significantly reduced.

7. *Cost sharing:*

- a) *Create a mandatory cost sharing exemption for research institutions.*

Mandatory cost sharing requirements, while appropriate in selected situations, generally are inappropriate for federally-sponsored research and educational programs. A [recommendation by the National Science Board](#) encourages mandatory cost sharing requirements only for a small subset of National Science Foundation (NSF) programs – specifically, programs for which it has been determined that an institutional commitment is critical to long-term program success, as well as programs built on partnerships with industry and state and local governments.

The Department of Energy has a long history of requiring a mandatory cost share commitment with its industry partners, and unfortunately, has regularly imposed similar requirements on research institutions. The President's Council of Advisors on Science and Technology, in a 2010 report, recommended that universities be exempted from cost-sharing requirements. While it may be an appropriate expectation of for-profit industry enterprises, to require the same commitment from university partners ignores both the public policy role and the non-profit status of research universities. Universities have a limited number of funding sources, some of which (e.g., tuition) should appropriately be dedicated to support their education mission and not to subsidize costs associated with research. Exempting research universities from mandatory cost

sharing requirements would be an important step forward. OMB should provide a policy clarification referencing Circular A-110 and the prohibition of mandatory cost sharing, except in those situations where the requirement is necessary for long-term program success or otherwise mandated by statute.

b) Prohibit voluntary committed cost sharing on all federally-sponsored research and educational programs.

Program officials often “encourage” institutions to pledge voluntary cost sharing commitments (or waive F&A costs as an alternative measure). This can be done either in a formal program announcement, or off-line, during a negotiation of the award budget. This practice leads to an uneven playing field where institutions with the most resources have an unfair advantage. Ultimately, this practice results in the draining of institutional resources, an environment of unhealthy gamesmanship, and a degradation of the peer-based merit review system. OMB addressed this issue in 2003 – OMB Policy Directive on Financial Assistance Program Announcements, June 23, 2003. NSF went further by implementing a new policy in January 2011 that prohibits voluntary cost sharing on all NSF programs, based on a [2009 recommendation by the National Science Board](#). We believe that OMB should reinforce the 2003 Policy Directive, and that all agencies should adopt the NSF policy.

8. Leverage financial reporting requirements to ensure transparency and accountability without imposing undue cost and excess burdens on research universities.

A number of financial reporting requirements mandated by the American Recovery and Reinvestment Act (ARRA) and the Federal Funding Accountability and Transparency Act (FFATA) impose excessive requirements on research universities that could be remedied while maintaining transparency and accountability. Attempts to extend these requirements to all federal research grants – such as the requirements called for by H.R. 2146, the Digital Accountability and Transparency Act (DATA) introduced by Rep. Issa (R-CA), currently being considered in Congress – must be carefully evaluated for the additional costs and requirements they will impose.

We specifically recommend the following with regard to these federal reporting requirements:

a) Carefully assess the impacts of extending existing American Recovery and Reinvestment Act (ARRA) reporting requirements to all federal research grants; do not put in place any additional reporting requirements that duplicate existing reporting already required by federal agencies. We understand and support the need to create uniform federal data reporting standards and systems across federal agencies to ensure accountability and transparency. We are concerned, however, that current legislative proposals aimed at trying to address these issues, such as the DATA Act, add additional reporting requirements, burdens and costs on universities, but provide no mechanism by which to phase out already existing and duplicative reporting requirements required by federal agencies. If additional reporting measures are put in place by either the Executive Branch or Congress, they should ensure that other preexisting and duplicative reporting requirements are phased out. Moreover, a mechanism should be put in place to help pay

for the changes that universities must make to update their reporting systems to comply with any new reporting requirements.

- b) *Within Federal Funding Accountability and Transparency Act (FFATA) requirements: 1) raise the subreporting threshold from \$25,000 to the simplified acquisition threshold; 2) use the OMB – rather than the FAR – definition of “subcontract,” which will eliminate procurements from FFATA coverage and continue to provide disclosure of the entities that have a role in the fulfillment of the programmatic objectives; 3) only report first tier; and 4) make reporting annual.***
 - c) *Eliminate duplicative reporting requirements, such as the Federal Financial Report, when it can be established that an agency maintains the necessary information in its internal systems.***
 - d) *Assess the additional burden that will be imposed on universities by expanded Form 1099 Reporting Requirements.***
 - e) *We value the need for voluntary reporting systems that help to inform our understanding of the outcomes of federal investments in scientific research.* While we highly discourage making institutional participation in programs such as STAR METRICS mandatory, we encourage flexibility in federal reporting statutes and accompanying federal reporting requirements to allow institutions that voluntarily choose such alternative reporting mechanisms to opt out of other mandatory reporting requirements. Such opt-out provisions should work to ensure that the data being reported in such voluntary programs are comparable in nature to those required by statute and that they are made publically accessible to ensure transparency.**
- 9. *As a part of its ongoing review of federal regulations called for by President Obama in Executive Order 13563, we urge OMB’s Office of Information and Regulatory Affairs (OIRA) to give additional attention to regulations and reporting requirements affecting research universities and their faculty.***

While we understand that it is beyond the scope of this task force to review the existing 26 percent cap on administrative reimbursements to universities, *the cap makes universities unique in that they are the only performers of federally funded research and development (R&D) that are restricted in how much they can be reimbursed by the federal government for federally mandated compliance requirements.* Other research organizations, including not-for-profit research laboratories and private industry, have no such limitations on their ability to recoup such compliance costs associated with the conduct of government sponsored R&D.

The 26 percent cap on administrative reimbursements has forced an increased level of financial efficiency on universities with respect to administrative expenditures. With respect to compliance with federal regulations, however, these regulations limit the ability of universities to save on costs, even when universities believe such regulation is unnecessary or excessive. In many instances, universities expend their own institutional funds to finance the costs required to comply with federal regulatory and reporting requirements. This makes it all the more important

that the government, and specifically OIRA, do everything possible to ensure that regulations and reporting requirements applied to our universities and their research faculty are as efficient and streamlined as possible. Specifically, we encourage OIRA to: a) work with the university community to develop reasonable compliance cost elements that can be used to help evaluate the specific cost of regulations and to help assess their benefits compared to their actual costs, and b) work with the National Science and Technology Council (NSTC) Research Business Models (RBM) Subcommittee and all federal research agencies to conduct a careful examination of research regulations and reporting requirements in an effort to:

- Eliminate unnecessary or duplicative regulations outright, or exempt universities and other federal funded researchers from them;
- Harmonize regulation across federal research agencies to avoid unnecessary duplication and redundancy;
- Tier the regulation to levels of risk rather than assuming that one size fits all;
- Refocus regulations on performance-based goals rather than on process as appropriate; and
- Adjust certain regulations to better fit the academic research environment.

We address specific regulations we believe should be examined as a part of this effort in the final section of our response, and recommend other mechanisms to ensure ongoing review of regulations in the section immediately below.

II. Priorities with Regard To Regulatory Reform and Reducing Compliance Costs

10. Designate a high level official within OMB's OIRA to serve as a Federal Ombudsman, responsible for addressing university regulatory concerns and for seeking ways to increase regulatory efficiency.

This official 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, in accordance with recommendation number nine above and would also have responsibility for reviewing specific "simplification requests." The Ombudsman, along with a designated representative from the White House Office of Science and Technology Policy (OSTP), should lead an interagency group charged with regularly reviewing regulations affecting research universities (discussed below). The Ombudsman will be a critical point of contact to ensure frequent and effective contact between the federal government and the research university community.

11. The National Science and Technology Council (NSTC) RBM Subcommittee should report directly to the NSTC Committee on Science. RBM, with the OMB Ombudsman, should review university regulatory concerns and A-21 issues on an ongoing basis.

The RBM Subcommittee has served as an effective mechanism for addressing research universities' concerns and issues relating to how research across all academic disciplines is managed and administered. Recently, this subcommittee was moved within NSTC from directly reporting to the NSTC Committee on Science to instead reporting to the NSTC Subcommittee on Social, Behavioral, and Economic Research, which in turn reports to the Committee on Science.

This new placement does not reflect RBM's mission which ultimately should address the development of successful and effective business models for the management of scientific research across all disciplinary fields. The RBM subcommittee should not be stove-piped under a subcommittee within a specific research discipline. We therefore urge that RBM be moved back to reporting directly to the Committee on Science.

Further, RBM is an ideal forum to manage an interagency group charged with ongoing review of A-21 issues and research regulations and reporting requirements. The Ombudsman recommended above will be a critical part of this process. 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. This ongoing dialogue should be mutually beneficial and help ensure efficient use of federal funds.

12. Through the use of Executive Branch Authority, provide targeted exemptions for research universities similar to protections provided for small entities under the Regulatory Flexibility Act (RFA).

The RFA requires agencies to prepare and publish a regulatory flexibility analysis describing the impact of a proposed rule on small entities. In addition, agencies are encouraged to facilitate participation of the affected entities by holding conferences and public hearings on the proposed rule. The RFA encourages tiering of government regulations or the identification of "significant alternatives" designed to make proposed rules less burdensome. Through an Executive Order or the use of other Executive Branch authority, we urge the administration to extend RFA requirements to include organizations engaged in conducting federally sponsored research.

As an example, the Chemical Facilities and Anti-Terrorism Standards (CFATS) capture universities in the same class with chemical manufacturers and industrial agricultural corporations, requiring identical policy and procedure implementation and reporting despite the fact that these requirements do not adequately address specific security risks unique to the university campus and laboratory settings.

13. Delete Cost Accounting Standards from A-21.

The Cost Accounting Standards sections are redundant and duplicative of other sections of Circular A-21. Elimination of the sections containing these standards from Circular A-21 will not compromise accountability, and will simplify the Circular at the same time. Research Universities should be exempted from Cost Accounting Standards coverage, as applicable to both grants and contracts. OMB should facilitate this exemption with the appropriate Federal entities.

14. Ensure that agency audits and reviews are not duplicative of the A-133 audit under the Single Audit Act, and provide an appeals process for institutions that believe that a proposed audit or review is duplicative.

Research universities spend significant money on an annual basis to complete their A-133 audit as required under the Single Audit Act. Results of the A-133 audit provide assurance to federal

agencies that an institution's internal controls, oversight, and compliance infrastructure are adequate to manage federal funds. While agencies should conduct program expenditure audits in those situations deemed necessary, many agency audits and reviews are duplicative of the audit work completed in the A-133 audit. OMB should ensure that agencies rely on the audit work performed in the A-133 audit and minimize duplicative audit coverage. In situations where an institution believes that a proposed audit or review is duplicative of work covered in the institution's A-133 audit, the institution should have access to an OMB-managed appeals process.

15. Require a Cost of Compliance analysis as a part of the Unfunded Mandates Reform Act (UMRA) requirements for any proposed regulations that will be required of any entity subject to the Single Audit Act. The Congressional Budget Office (CBO) should estimate the cost impact of proposed legislation on research institutions without regard to annual dollar thresholds.

It is often not a single regulation that creates compliance challenges for universities, but rather the stacking of regulations over time. Yet federal agencies rarely reevaluate, eliminate, or redesign regulatory schemes to reduce the burden of compliance for universities. In fact, because the overall costs associated with many individual regulations do not exceed the \$100 million threshold currently included in the UMRA, agencies often need not provide any form of analysis of the expected costs of new research regulations.

As part of the review required under UMRA, OMB/OIRA should require an agency to complete a compliance benefits-cost analysis and/or cost-effectiveness analysis and an analysis of the availability of federal funds to help pay for the mandate for any proposed new regulation or policy that will be required of any institution that is subject to the Single Audit Act. The CBO should include research institutions (entities subject to the A-133 audit) in its estimates of overall impact of any proposed legislation, without regard to an annual dollar threshold in the case of research institutions. The development and implementation of the compliance cost analysis elements should be conducted in consultation with representatives of the affected communities including colleges, universities, academic medical centers, independent research institutes and other research-performing organizations. Research institutions should be allowed to recover the costs for meeting the federally mandated unfunded compliance costs either through a direct charge or through a research compliance cost pool that would be an addition to the institution's F&A rate.

Additionally, the Paperwork Reduction Act (PRA) requires that all proposed regulations be analyzed for the paperwork that they require, and that paperwork be reduced to a minimum. Regulations creating new paperwork requirements must be cleared by OMB. Unfortunately, agency projections of the paperwork burden are often underestimated and do not recognize how new reporting requirements will be paid for. (ARRA reporting requirements and the recently proposed NIH reporting requirements related to financial conflicts of interest are two notable examples.) In situations where new requirements are not effectively controlled to minimize cost burden, institutions should be allowed to establish a cost reimbursement mechanism in which the incremental costs can be recovered as a direct charge to the federal award.

16. Establish protocols to address statutorily-mandated regulatory concerns.

When statutorily-mandated requirements create unintended regulatory burdens for universities, a fast-track approach to amending the law would be a useful tool that could help to minimize burdensome regulations.

III. Specific Regulatory Requirements that Should Be Targeted for Reform:

17. Select Agents:

- a) Tier different agents (pathogens or biological toxins that pose potential risks to public health and safety) according to their risk, as documented by the American Society for Microbiology and recently recommended by the Federal Experts Security Advisory Panel.
- b) Reform inventory requirements to avoid meaningless vial counting.
- c) Harmonize laboratory inspections by multiple agencies of jurisdiction.

18. Human subjects research:

- a) Harmonize human subjects protections between the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA).
- b) Eliminate Health Insurance Portability and Accountability Act (HIPAA) requirements from research, or harmonize HIPAA regulations with OHRP regulations.
- c) Tier human subjects research for exemption from Institutional Review Board review. Minimal-risk studies, like many in the social sciences, should not require the same level of review as clinical trials.
- d) Research organizations are required to maintain a Federal-Wide Assurance that demonstrates operational compliance with current federal regulations. If universities meet those requirements, research protocols for human subjects research should not need to undergo a full federal agency review or meet additional unique training requirements.

19. Export controls:

- a) Eliminate new regulations requiring deemed export certification for certain visa applications (I-129 form).
- b) Harmonize ITAR, EAR, and OFAC definitions and regulations.
- c) Tier export control lists to risk, removing much of what is currently on these lists or reclassifying to lower their control levels.
- d) For purposes of enforcement of deemed export control laws under the Export Administration Regulations (EAR), require that individuals have “knowledge or intent” that controlled information will be exported or transmitted without proper authorization. This requirement had, in fact, previously existed until it was removed in 1994 by the Department of Commerce, which has oversight over the EAR.¹

20. Conflict of Interest:

- a) Newly proposed conflict of interest guidelines from NIH should be carefully evaluated for their full impact before being implemented. If such guidelines require public posting

¹ These amendments were published in 59 Fed. Reg. 13,449 (Mar. 22, 1994) and are codified at 15 C.F.R. § 734.2(b).

of faculty-industry relationships, even when potential conflicts are being effectively managed, they will create public confusion and unnecessary work, and have a potential chilling effect on university-industry interactions.

- b) Eliminate negative patent reports, which require form completion even when there are no intellectual property concerns.
- c) Direct OSTP to convene agencies to develop a conflict of interest policy like the Misconduct in Science Policy, which articulates general goals and objectives.

21. Chemical Facilities Anti-Terrorism Standards (CFATS) :

- a) Create exemptions for research universities, as recommended earlier. When this is not possible, tier according to actual levels of risk.
- b) Establish separate but robust standards, protocols, and procedures for assessing vulnerabilities and improving the security of chemicals of interest, to ensure that rules, such as those being implemented under the CFATS, are best crafted to ensure security in a university setting.

22. Animal Research:

- a) Eliminate duplication of NIH study section and Institutional Animal Care and Use Committee (IACUC) review of protocols
- b) Improve coordination between multiple agencies and jurisdictions in terms of inspection timing, protocol review, etc.
- c) Consider phasing-in adoption of the proposed new Guide for the Care and Use of Laboratory Animals by NIH in terms of cage sizes and other new requirements.