July 28, 2011

Subject: 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-11-091

Dear A-21 Task Force Members,

On behalf of Duke University, I am pleased to transmit recommendations on 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). As one of the leading research institutions in the United States, Duke welcomes this opportunity to comment on concerns relating to regulatory burden, and to offer recommendations as to how these issues might be resolved.

The attached documents provide a summary of responses from several Duke University research constituencies: researchers, senior leadership, compliance managers, and experts in federal regulatory compliance. You will see a number of themes identified by faculty and research leadership, most notably the need for harmonization of federal requirements, clarification and improvement of effort management standards, allowability of certain charges related to project management activities to reduce PI burden, and specific recommendations regarding subrecipient monitoring and genomic arrays. We have provided thoughtful commentary on these issues, along with our recommendations for improvements.

Duke University has developed a unique approach to the research enterprise. The Research Administration Continuous Improvement (RACI) initiative is a task force composed of senior level leadership from various sectors of research management. Chaired by the Vice President for Financial Services, RACI provides a collaborative forum for improving research and research compliance, and for building a university-wide structure dedicated to research initiatives.

RACI has played a key role in coordinating and collecting input for the Task Force RFI. Our process included letters to Deans, research faculty and senior administrators from the Provost, Vice Provost for Research and Dean of Medicine, respectively. Additionally a series of meetings were convened that included senior researchers, the Dean’s Cabinet, department chairs and senior level business managers, and central research office directors. Individual responses were also invited from key researchers throughout the Duke research community. Attached you will find a list of the contributing parties to the Duke University response and letters from individual principal investigators.

I have also attached two letters from Duke University senior leadership. President Richard Brodhead has provided commentary regarding the burden of regulatory compliance on the institution. Dr. Tallman Trask III, Executive Vice President/Treasurer, Provost Peter Lange, and
Dr. Victor Dzau Chancellor for Health Affairs have provided their informed insights as to the financial and academic burdens imposed by the current regulatory environment.

I would be most willing to meet with the members of the task force at any time to continue discussions relating to regulatory improvements. Thank you for your efforts on behalf of the research community.

Sincerely,

James D. Luther  
Assistant Vice President  
Research Costing Compliance Officer

Attachments:  
Mémo from President Richard Brodhead  
Mémo from Dr. Trask, Provost Lange, and Dr. Dzau  
Duke University Comments and Recommendations  
Individual letters from Duke University researchers and leadership
July 28, 2011

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

Dear A-21 Task Force Members,

Thank you for inviting comments on 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). On behalf of Duke University, I welcome the opportunity to address the impact that the current requirements found in OMB Circular A-21 have on our campus. I am recommending changes that, in our view, will achieve a thoughtful balance between the federal government’s goals for accountability and transparency and the successful execution of our education and research missions.

Compliance with federal regulations and cost principles is a priority for Duke University. As stewards of taxpayer dollars, we welcome sensible, efficient and effective oversight related to our conduct of federally-supported research. However, the current regulatory system is dysfunctional and counterproductive. For years, new regulatory requirements and policies from a variety of governmental entities have been layered upon the OMB Circular framework in an indiscriminate manner. The result has been an escalation of the institutional cost of managing federally sponsored research, training and service projects. Increased requirements for cost sharing on grants and contracts, and the restrictions placed on cost recovery, have forced the University to divert institutional resources, including faculty time, away from our primary research focus and into compliance oversight. The School of Medicine has calculated that its costs for research compliance and quality assurance have increased approximately $10 million over the past 10 years. This expense adds to the larger institutional burden for research support – estimated at close to $100 million for Duke University in total – which must fill the void left by under-recovered F&A costs, research infrastructure investment, bridge funding for seasoned investigators who have lost funding in the current NIH budget environment, caps placed on salaries and administrative costs, and points lost through rate negotiations.
Financial costs do not represent the only burden. Perhaps an even greater drain is the time required of our faculty for project management support. The Duke Translational Medicine Institute alone has estimated that its investigators spend close to 30,000 hours per year on administrative tasks. Overstated regulation has had the effect of curtailing research productivity at a time when our nation relies heavily on its universities as engines of discovery and growth.

This is a critical issue for the entire Duke University community, and we welcome the opportunity to comment on specific items that should be addressed. We firmly believe that the benefits of a reduced regulatory burden will be realized in increased research productivity, improved performance by our students, and even more rapid transition of important discoveries to the marketplace. Enclosed you will find detailed comments and recommendations related to improvement of OMB Circular A-21 requirements and current restrictions. We further urge the Task Force to consider where Circular language may be clarified to the greatest extent so that the current dichotomy that exists between federal sponsors and the auditing community may be resolved.

I hope you find these suggestions useful as you continue your work to develop a sensible system for the management and oversight of federal research grants. We applaud your attention to this issue and stand ready to serve as a partner and resource in this important endeavor.

With best wishes,

Richard H. Brodhead

cc: Michael Schoenfeld
    Chris Simmons

Enclosures
July 28, 2011

Subject: 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-11-091

Dear A-21 Task Force Members,

Duke University welcomes 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). The university has a strong commitment to applying knowledge in service to society, both near its North Carolina campus and around the world.

Since 1990, sponsored research expenditures at Duke University have doubled and then doubled again. (Actual growth: 530%). In Fiscal Year 2010, sponsored research expenditures exceeded $826M. This significant growth has occurred at the same time that federal regulatory requirements and administrative cost restrictions have also grown exponentially. In addition, there have been increasing limitations on generating sufficient institutional dollars to meet new regulatory requirements. This is a common scenario among almost all of Duke University’s peer institutions, and like most of our peers, the University has taken steps to ensure compliance in spite of its growing price tag.

Duke University strongly supports the objectives of accountability and transparency, and firmly believes that compliance and regulatory oversight are essential to the conduct of federally-supported research. Duke University has developed a national model of compliance oversight and project management training designed to support compliance, while providing researchers with highly skilled support personnel to assist them in managing their federally funded projects. In the past five years Duke University has created a compliance management structure that includes over 70 dedicated compliance liaison officers, three new compliance offices, and multiple initiatives to address new and expanding federal regulations (e.g. ARRA, FISMA, Export Controls, COI, etc.)

Duke University has also implemented a comprehensive initiative to train and empower our departmental grant managers – skilled individuals with extensive compliance training – to assist our faculty who continue to struggle with rapidly escalating compliance expectations while continuing to conduct groundbreaking research.
These initiatives and responses are not without cost—costs that are not recoverable under current OMB A-21 language, but are very real to research universities which must absorb them. As an example, we estimate that improved systems for effort reporting alone cost the university $1.4 million in one-time costs and we spend upwards of $5 million annually in systems and personnel to manage and implement the certification process. Unfortunately, regulatory demands force institutions to implement systems that provide audit documentation but fall far short of appropriately equating researcher effort to sponsored project outcomes. The federal government must understand that research is never going to be measured as a standardized process. It must be measured and evaluated carefully but not by an antiquated “hourly wage” concept. This would be an acknowledgement by federal officials that the research grant making process is different than the federal procurement contracting process used with the defense industry. This aspect of the university-federal partnership is critical to reinforce because federal grants do not cover the full costs of the research; in most cases, faculty often spend far more “time” than is specifically accounted or budgeted for on the grant.

Duke University also believes in the critically important value of the highest quality research, translated to the needs of the global community. Yet we consistently receive feedback from our researchers—dedicated, internationally renowned individuals—regarding the impediments that increasing regulatory, reporting, and management requirements on federal awards place on their ability to conduct meaningful, groundbreaking research. As a senior researcher recently stated:

*I am very passionate about this issue, having witnessed the changes in this arena over the past 25 years at Duke. I believe that excessive regulatory burden is the greatest threat to the physician-scientist in the 21st century.*

We provide below a summary of the most pressing issues in burdensome compliance regulation as developed by a team of faculty, research administrators, and senior leaders at Duke University. Additional detailed documentation is included in the Duke University submission packet.

**Summary Comments and Recommendations**

1. Reduce the burden of the effort certification process: Reduce or eliminate A-21’s effort certification requirement as it is currently structured in favor of a process that is more outcome based and less administratively burdensome.

2. Reduce Sub-recipient monitoring burden: Eliminate the Sub-recipient Monitoring requirement for universities that subcontract to other institutions that are themselves subject to the A-133 audit.

3. Allow the direct charging of project management support staff: Communicate to the grant community that project management support activities are an allowable direct expense when those activities can be specifically identified to an individual project.

4. Retention requirements related to imaged documents: Remove requirement that an institution must get advance authorization before substituting electronic records for original (paper) records and remove the requirement from all regulations, including the FAR (4.703), that require retention of paper documents after imaging to permit periodic validation of the imaging system.
5. Genomic arrays: NIH should reconsider and/or clarify its May 13, 2010 Notice that limits F&A recovery of Genomic Arrays.

6. Computers and similar technologies: Clarify the allowability of the direct charging of computers and similar technologies (and related supply items) that are necessary for the effective conduct of research activities.

7. Comments and recommendations on related compliance issues: Duke University offers comments on issues related to compliance burden that are not included in OMB A-21.

Principals at Duke University have also participated in the development of nationally representative comments and recommendations by the Council on Governmental Relations (COGR). Duke University endorses and supports these more detailed recommendations from COGR and those presented by the Association of American Universities. Whereas their thoughtful comments represent their broad membership base, our comments in this documentation reflect the concerns and recommendations of our faculty. It is important to note that there is consistency in identification of issues that are perceived to be most burdensome to the national research community.

We thank you for the opportunity to offer our concerns and recommendations. We stand ready to discuss these recommendations at any time, and look forward to a productive, meaningful and responsive outcome to your deliberations:

Sincerely,

[Signatures]

Peter Lange  
Provost

Victor Dzau  
Chancellor for Health Affairs

Tallman Trask  
Executive Vice President

P.S. Following is the list of Duke University faculty and staff who contributed to this response:
Duke University faculty and staff who were consulted and/or contributed to this response:

Victor Dzau, Chancellor for Health Affairs and CEO, Duke University Health System
Peter Lange, Provost, Duke University
Tallman Trask, Executive Vice President and Treasurer, Duke University

Dave Anderson, Administrative Director, Surgery
Nancy Andrews, Vice Chancellor for Academic Affairs, Dean, School of Medicine
Srinivas Aravamudan, Dean of the Humanities
Andrew Berchuck, Professor, Gynecology Oncology
Susan Bonifield, Associate Dean, Pratt School of Engineering
Ann Bradley, Associate University Counsel
Wesley Byerly, Pharm.D. Assoc Dean, Research Support Services, SOM
Robert Calderbank, Professor, Department of Electrical and Computer Engineering
Robert Califf, Vice Chancellor, Clinical Research & Director, Duke Trans. Medicine Institute
Kyle Cavanaugh, Vice President, Administration
William Chameides, Dean, Nicholas School
Julie Cole, Director, Research Costing Compliance
Sandy Connolly, Senior Associate Dean, Arts & Sciences
Art Crumbliss, Dean, Faculty of Arts and Sciences
Tom Davis, Jr., Director, Sponsored Programs & Cost Analysis
Elizabeth Delong, Professor, Duke Clinical Research Institute
Joe Doty, Vice Chair Administration, Medicine
Dan Gauthier, Professor, Physics
Scott Gibson, Executive Vice Dean, School of Medicine Administration
Catherine Gilliss, Vice Chancellor for Nursing Affairs, Dean, School of Nursing
Leigh Goller, Director, Internal Auditing
James Haggard, Associate Dean, Nicholas School of the Environment
Lloyd Hardison, Departmental Business Manager, Pharmacology & Cancer Biology
Robert Harrington, Director, Duke Clinical Research Institute
Alexander Hartemink, Associate Professor, Computer Science
Barton Haynes, Director, Human Vaccine Institute
Richard Hays, Dean, Divinity School
Rosemary Herhold, Analyst, IT, Sr., Information Technology
Brigid Hogan, Ph.D., Professor and Chair, Cell Biology
Keith Hurka-Owen, Director, Office of Research Support
Thomas Katsoulas, Dean, Pratt School of Engineering
Dan Kiehart, Professor, Biology
Mary Klotman, Chair, Department of Medicine
Sally Kornbluth, Professor, Pharmacology & Cancer Biology
Bruce Kuniholm, Dean, Sanford School of Public Policy
Cherie Lahti, Administrative Director, Duke Human Vaccine Institute
Todd Leovic, Departmental Business Manager, Immunology
David Levi, Dean, Law School
Jim Luther, Assistant Vice President, Research Costing Compliance and Federal Reimb.
Ross McKinney, M.D., Prof. & Director Trent Center for Bioethics, Humanities & Med Hist.
John Michnowicz, Executive Director, Office of Research Administration
Billy Newton, Vice Dean, Finance and Resource Planning, Medicine
Angela O’Rand, Dean of the Social Sciences
Amy Oates, Director, Academic Financial Services and Systems
Laurie Patton, Dean, Arts & Sciences
Brenda Paulsen, Administrator, Psychiatry
Joan Podleski, Director, IECP Compliance
David Rizzieri, Associate Professor, Medicine - Cellular Therapy Division
James Roberts, Executive Vice Provost, Finance & Administration
Deborah Roth, Chief Operating Officer, Duke Translational Medicine Institute
Laura Schanberg, Associate Director, Duke Pain Program, Pediatrics-Rheumatology
Mike Schoenfeld, Vice President, Public Affairs & Government Relations
Blair Sheppard, Dean, Fuqua School of Business
James Siedow, Vice Provost for Research and Professor of Biology
Christopher Simmons, Associate VP, Office of Federal Relations
Michael Sledge, Chief Financial Officer, DCRI
Michael Somich, Executive Director, Internal Audits
Molly Sykes, Senior Business Manager, Cell Biology
Tina Tyson, J.D., Chief Compliance Officer, SOM
Rick Tysor, Executive Director, Office of Interdisciplinary Programs MGM
Melissa Vetterkind, Director, Office of Federal Relations
Margaret Vigioloto, Assistant Director, Finance, DCRI - Finance
Tim Walsh, Vice President, Finance
Susan Wiley, Departmental Business Manager, Molecular Genetics and Microbiology
Valla Wilson, Director, Internal Auditing
Jo Rae Wright, Dean of the Graduate School

1. **Recommendation (Reduce the burden of the effort certification process)**

Reduce or eliminate OMB A-21’s effort certification requirement as it is currently structured in favor of a process that is more outcome based and less administratively burdensome.

**Proposed Actions**

Change OMB A-21 to allow a reporting option that relies on an assessment of the reasonableness of the effort expended/charged to the productivity/outcome of the project. This could be accomplished by modifying the Progress Report requirements and rely on the sponsor’s review of progress made as the definitive measure. This recommendation is made on the basis of two important factors: 1. University payroll systems have matured significantly over the past several decades, making it possible to accurately readily allocate effort charged to specific projects and activities; 2. The current process does not align effort expended with outcomes in any meaningful manner. If this recommendation is accepted, it is also imperative that auditors are aligned with revisions so that focus is on reasonable in support of project outcomes.

**Burden/Cost**

At Duke University, an extremely conservative estimate of the annual cost associated with the effort management process approximates 75 FTEs and $5.3M (other estimates, depending on the definition of effort reporting/management range from $10M - $15M in total annual cost). This estimate includes a proportion of FTEs that coordinate the collection of effort certifications, time associated with faculty and staff that are required to certify, personnel costs in central offices, and related technology costs. This estimate does not include associated space and other costs for staff to conduct these activities or the mandatory training and communication that is distributed to thousands of faculty and staff on an annual basis. Furthermore, Duke incurred a one-time initial implementation cost in FY09 of over $1.4 million. Note that the estimated $5.3M cost is for a process that is not directly correlated with improved research outcomes.

Lastly, it is important to mention that this cost is not reimbursable from sponsors as Duke University’s F&A rate exceeds the 26% administrative cap.

This burden is particularly difficult in a complex academic medical center where:

- a) there is significant interrelatedness between projects and
- b) when one bedside interaction with a hospital patient is extremely difficult to capture accurately in an effort system. In this situation, the faculty member may simultaneously be exerting effort in support of clinical care, in support of the academic mission (because there may be a graduate accompanying the faculty member), and the research mission (because the patient may also be clinical trial subject).

Effort reporting is extremely burdensome and costly, and is not correlated to project outcome in a manner that justifies its cost.
2. **Recommendation (Reduce Sub-recipient Monitoring burden)**
Eliminate the Subrecipient Monitoring requirement for universities that subcontract to other institutions that are subject to the OMB A-133 audit.

**Proposed Actions**
Universities that enter into subcontracting relationships with other domestic institutions subject to OMB A-133 should not be subject to expanded standards of accountability for the compliance actions of these subrecipients.

**Burden/Cost**
More than 60% of the Duke University 300 subcontractors are peer institutions that are subject to the OMB A-133 audit. This 60% represents more than 80% of our subcontract volume on an annual basis. Duke University therefore, expends most of its time monitoring subs that the federal government, by virtue of its direct grants to the institution, has deemed in a risk category that they feel is reasonable.

OMB A-133 and the associated annual supplement define audit guidelines, provide a framework for evaluation of risk and risk areas at prospective subrecipient institutions and even provides follow-up systems to determine if risk has been mitigated. Therefore, it seems logical to rely on these audits to provide a reliable, consistent framework for monitoring subrecipient compliance.

Duke University has developed a sophisticated business process and web-based system for gathering information on our potential subrecipients, evaluating this data, and adjusting contract terms and conditions as a result of this initial risk assessment. The university also monitors financial and programmatic compliance during the life of the funded project and conducts additional review at closeout. The Office of Sponsored Programs is responsible for reviewing OMB A-133 audits for all subrecipients, and ensures that updated information regarding risk is conveyed to the pre-award offices on a regular basis. Multiple forms, complex electronic workflow and three shared databases are required to support the current SRM process. The cost of developing the current assessment process and IT tools approximated 5 FTEs from central offices and the technology development group over a 15 month timeframe. In addition, at least three pre-award office staff members review, assess, and negotiate subrecipient agreements based on risk. The post-award office (OSP) issues formal letters advising each subrecipient of expected compliance requirements, and also issues an internal “rate of burn” letter to advise departments of financial progress at mid-point of each subaward. The Research Costing Compliance office provides extensive monitoring and training to ensure that subrecipient monitoring is appropriately applied. As stated above, this extensive effort would be appropriate only to a small subset of the university’s subrecipient pool if those subject to OMB A-133 were removed from subrecipient monitoring. Duke could then adjust its process to focus on those at highest risk.

The new business process was designed to reduce burden by applying a technical solution but with federal auditors recent focus, we spend an inordinate amount of time documenting the process instead of focusing on those subrecipients that are not subject to the A-133, and therefore are likely at higher risk.
3. **Recommendation:** Allow the direct charging of project management support staff.

**Proposed Action**
Communicate to the grant community that project management support activities are an allowable direct expense when those activities can be specifically identified to an individual project.

**Rationale:**
OMB A-21 current reference to “clerical and administrative” was developed over 20 years ago and was generally focused on “secretarial activities” that supported broad administrative functions and could not readily be allocated to a specific project. Examples might include typing correspondence, filing, purchasing basic supplies, incidental travel arrangements, and general office duties. Although these functions remain essential to general administrative operational support, the nature of project management administrative responsibilities and their specific application to sponsored activities has dramatically changed.

Over the past four decades, a new profession of research support staff has emerged, with its own body of knowledge, professional credentials, professional associations, and professional standards. These skilled technicians may be found across the globe as professional project managers, and it is these individuals that form the project management support structure that is critical in effective management of sponsored activities. Their functions can be readily identified with project management support and their contributions are critical in relieving faculty of burdensome compliance and financial management duties. Unfortunately, current OMB A-21 language is often interpreted to prohibit the direct charging of these otherwise allocable compliance and project administration functions. We recommend that project management support activities be classified as an allowable direct expense when those activities can be specifically identified to an individual project.

Duke University faculty are frustrated by the competing demands of managing increasingly complex projects and the limitations on directly charging project management support to their funded projects. These activities include, but are not limited to, research protocol and compliance support, recruitment and hiring of staff, management of complex financial and programmatic reporting requirements and related project financial oversight. These are essential components of contemporary research projects and programs and in many instances, they are performed by researchers, or possibly by students and post doctoral fellows, pulling these research personnel away from their research responsibilities.

**Burden / Cost:**
The 2007 *Faculty Burden Survey*, conducted by the Federal Demonstration Partnership, reports that the significant growth of compliance requirements and commensurate project management responsibilities are overwhelming faculty, and having a measurable impact on their ability to focus on scientific productivity. The 2007 FDP *Faculty Burden Survey* revealed that, of the time that faculty committed to federal research, 42 percent was devoted to pre and post-award administrative activities – not to active research.
The recommended change would acknowledge the changing dynamic of project support functions, address the ever increasing regulatory and project management burden on faculty, and provide skilled technical support to enable researchers to become increasingly more productive and accountable. By funding personnel to perform project management tasks, sponsors will be paying a lower rate of pay than faculty researchers currently receive, thus leading to efficiencies in both science and administration.

Direct charging of allocable project management support personnel empowers support for individuals who would perform these functions in a much more cost effective manner than the PI.
4. **Recommendation (Eliminate paper retention requirements for imaged documents)**

**Proposed Actions**

a) Remove requirement that an institution get advance authorization before substituting electronic records for original (paper) records.

b) Remove requirement from all regulations, including the FAR (4.703), that require retention of paper documents after imaging to permit periodic validation of the imaging system.

**Burden/Cost**

Under the current regulations, many universities are required to maintain a massive amount of paper documentation in the unlikely possibility that it is related to a federal contract. One example, which is extremely costly, is the requirement when applied to the procurement cycle. To provide some high level numbers to this statement, although Duke University has less than $7 million dollars in contract procurement spend (excluding payroll, fringe and related F&A), we are required to maintain supporting documentation for more than $1.5 billion of procurement spend to ensure we were meeting the FAR requirement. This occurs because as an accounts payable invoice is received, the central office has no way of knowing whether the document is related to a federal contract, a student group, the health system, the football team, or any other unit within the university. Per FAR 4.703, we are required to retain the paper document for one year after scanning. This requires clerical support, filing cabinets, office supplies, rental space, etc. all to ensure that the ½% of potential contract related spend is retained in support of a potential audit.

As we expand the imaging solution to other business process cycles, such as travel and grants processing (proposal through closeout), we will continue to incur significant costs even though our contract volume ($20M) is small compared to the rest of our institutional business ($3B).

**Background**

Technology has improved over the recent years so that imaging solutions are full featured and searchable, secured, and add significant value to the business process while often reducing transaction cost. They allows an institution to workflow documents, share documents via corporate systems such as a general ledger, and most importantly maintain/retain the documents in an electronic format so that the original paper documents can be disposed of, as well as the associated file cabinets.

Many institutions have made progress in this area in the procurement cycle and are now considering an expansion of the use of technology, including the entire grant cycle from proposal through closeout. Other opportunities include the travel/reimbursement business process, procurement card, check request, etc.

OMB A-110 (2 CFR 215.53, para c) states that “Copies of original records may be substituted for the original records if authorized by the Federal awarding agency.” DHHS has identified a process to transition to electronic records (OGAM AT 99-1), but very clearly states in the “Purpose and Background” section that institutions should “be aware that Federal contract documents are subject to FAR 4.703(c)(3), which states, "the contractor or subcontractor retains the original records for a minimum of one year after imaging to permit periodic validation of the
imaging systems." Recent discussions with cognizant officials at DHHS have confirmed this interpretation.

Institutions should be permitted to meet document retention guidelines in any manner they deem reasonable with the understanding that it is their ultimate responsibility to provide backup documentation as required to substantiate all expenditures, proposals, agreements, etc. This documentation, whether paper or electronic, must be available and legible for the appropriate retention period.
5. **Recommendation:** NIH should reconsider its May 13, 2010 Notice that limits F&A recovery of Genomic Arrays.

**Proposed Actions**

a) NIH should rescind its May 13, 2010 Notice (NOT-OD-10-097) that limits F&A recovery on Genomic Arrays purchases. If this is not possible, then

b) NIH should clarify what the Notice does and does not apply to.

   a. The *Notice* should not apply to “Sequencing Reagents”, which are incredibly facility and administration intensive and often require facilities with specialized equipment, IT support, HVAC, and associated technicians.

   c) NIH should raise the threshold.

**Background / Burden / Cost**

We endorse COGR’s response dated May 27th, 2010 and July 11, 2011.

Specifically focusing an F&A reimbursement policy to a single vendor purchased event is inconsistent with A-21 premise of an “averaging concept” and it is inconsistent with the reality for the true life cycle costs associated with Genomic Arrays. Because of the expedited implementation, multiple items associated with GA’s were “swept” into this cap, including Sequencing Reagents that are facility and administratively intensive and require specialized equipment, HVAC, IT support, etc. With regard to the life cycle issue, the purchase is just one-step in the broader and very expensive continuum related to the processing. Furthermore, there are numerous cases where the university incurs far higher F&A costs than the negotiated rate for a particular purchase or grant, but no opportunity is presented to recover these costs. The 26% cap, cap on F&A for subcontracts, and artificial limitations by sponsors on reimbursement are but three examples.

Permitting NIH to arbitrary implement this cap opens the door to any situation where there is a real or perceived disproportionate administrative burden. Moreover, it does it in a manner than it extremely burdensome, operationally, for an institution to implement in a timeframe that a university could not realistically include in the F&A negotiation in an attempt to support equitable reimbursement.
6. Recommendation: Clarify the allowability of the direct charging of computers and similar technologies (and related supply items) that are necessary for the effective conduct of research activities.

Proposed Actions
We endorse COGR’s position and agree that OMB should write a “Memorandum to Agency Heads, Representatives from the Regulatory and Audit Community, and Research Universities and Institutions” that states research communications, tools, and similar equipment (and related supply items) that are necessary for the efficient and effective conduct of research activities are allowable as direct charges to Federally-sponsored research, service and educational programs, effective immediately. Furthermore, we agree that necessary adjustments to A-21, section J.18 should be made to support this communication and the audit community should be directed to utilize the proposed changes as the sole basis for determining allowability.

Burden/Cost (paraphrased from COGR response)
Technology, and how it is used in the conduct of research, has changed dramatically since Circular A-21 was introduced. Despite many changes to the Circular over the past two decades, text specific to current technology has not been updated in the Circular; in fact there is still reference to “telegrams” and other outdated modes of communication. Research communications equipment/devices and other “research tools” including laptop and desktop computers, printers, video equipment, cell phones, other equipment/devices that are used to conduct the research and to facilitate data processing/data transfers/etc. between research colleagues, and other “research tools” are necessary for the efficient and effective conduct of research activities.

The current requirement in Circular A-21, Section J.18, that requires these types of equipment and tools to be treated as “general purpose” and specifies them as “unallowable as direct charges” (Section J.18.b(1)) ignores the important and direct role they play in research. When research communications equipment/devices and other research tools can be supported as direct benefit to a federally sponsored program, they should be an allowable charge to the project, subject to cost allocability principles defined in Circular A-21. In the case where the item(s) do not meet the institution’s threshold for capitalization, the same principle should be applied and the item(s) should be an allowable charge to the project.

Implementation of this change will provide faculty and investigators with easier access to the research communications, tools, and similar equipment (and related supply items) that are necessary to conducting their research activities.
7. Comments and recommendations on related compliance issues

The research community is greatly encouraged by the potential benefits of Executive Order 13563, *Improving Regulations and Regulatory Review*, issued by President Obama on January 18, 2011 which discusses the need for addressing current and future regulatory burden. Unfortunately, that promise has not been fully realized as there are several proposed/pending regulatory changes that could potentially increase regulatory burden in spite of the recent Executive Order. Individually these may appear to be minor, but collectively they have the potential of imposing further compliance costs to federal recipients. These items are Conflict of Interest, Human Subjects, and ARRA Reporting expansion. In addition, Federal Information Security Management Act (FISMA) provisions which have already been applied to federal contracts are resulting in increased research compliance costs.

**Conflict of Interest**

The proposed rule now under final consideration contains several components that could significantly increase the demand on both institutional and researcher resources. As examples, the proposed rule mandates required training for investigators, which must be successfully completed every two years without evidence that this will ameliorate COI problems; the threshold for potential COI has been cut in half, which will increase the administrative burden of performing institutional review; the need to certify that all conflicts have been identified and managed prior to expenditures of grant funds means that COI staffing must be increased to assure just-in-time management plans, and software to identify all investigators on every award must developed or purchased; and proposed requirement that institutions provide a remediation plan to NIH when a conflict is retrospectively discovered. Currently, institutions have only to assure NIH that a conflict has been managed, reduced, or eliminated.

In a recent article published in the *Report on Research Compliance*, Dianne Dean, the director of the NIH Division of Grants Compliance and Oversight in the Office of Policy for Extramural Research Administration, answered questions and comments regarding the proposed changes, acknowledging that the proposed requirement for institutions to operate a public database listing conflicts had generated the most feedback, (Source: *Report on Research Compliance*, December, 2010). A database of this type will be expensive and provide little information that won’t be available through the public database to be maintained as part of the *Physician Sunshine component of the Affordable Care Act*.

These are only a few examples of the significant additional measures that institutions must take to ensure compliance with the proposed rule.

**Human Subjects – Regulatory Consistency** *(Paraphrased from COGR)*

Duke University is one of the foremost medical research institutions in the world. Because of the amount of research activity, it is profoundly affected by differing regulations and policies
among federal agencies. The protection of human research subjects requirements have changed significantly by the accumulation of agency-specific specifications and suffers under duplicative conflicting reviews by federal agencies. The Department of Health and Human Services (HHS) human subject protection regulations at 45 CFR part 46 serves as the basis for all Federal human subject protection regulations and policies. This is accomplished through the implementation of Subpart A as the “Federal Policy for the Protection of Human Research Subjects,” informally known as the “Common Rule.” Adopted by 15 federal departments and agencies in 1991 the Common Rule is codified with identical language in the separate regulations of those departments and agencies. Some but not all agencies have adopted the other Subparts of 45 CFR 46 providing additional protections for specific subject groups. The Food and Drug Administration, has a separate set of regulations that regulate clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices. In addition to meeting the basic regulations protecting human subjects, the Health Insurance Portability and Accountability Act of 1996 (HIPAA, recently amended by the Health Information Technology for Economic and Clinical Health Act, HITECH) requires additional reviews and approvals to ensure the privacy of individually identifiable health information in the conduct of research.

In implementing this Common Rule, agencies have taken strikingly different approaches. Research organizations are required to maintain a Federal-Wide Assurance (FWA) that demonstrates operational compliance with the current federal regulations. Nonetheless, agencies have inserted additional requirements in their implementation. The Department of Navy has recently expanded the training requirements for administrative personnel despite the training requirement that is part of the FWA process. The most time-consuming and redundant procedure is the requirement to submit for an additional review a research protocol describing the human subject research component that has been reviewed and approved by the applicant institution’s IRB or, in some cases, by the peer review panels established to recommend the funding of research projects. This duplicate review delays awards and creates ambiguities over which institution or agency is ultimately responsible for the conduct of the human subject research. Agencies assure us that the institution retains responsibility and authority, but the agency will often require changes in the protocol that are inconsistent with institutional operations. Additional unique reporting, training, and operational requirements create confusion and occasional conflict in maintaining compliance with the regulation or policy.

The Council on Governmental Regulation (COGR) has identified a significant increase in the costs to institutions associated with the conduct of human subject research. During the period 1995 to 2000, costs related to human subjects’ protection increased an average of 263% percent. The FY 2000 costs did not include mandatory training in human subjects protection – a new requirement in 2000 – estimated at that time by several large universities to be over $500,000. The COGR survey was repeated for AY2002 and AY2003, with average increases of more than 40%. COGR has recently polled a small group of large institutions with affiliated academic medical centers, and they report costs from $400k to $1.2 million for their human subject protection programs.

Our belief is that the Common Rule requirement should be the standard for all research with human subjects. For institutions meeting the requirements of their approved FWA, research protocols for human subjects research should not undergo a full Federal agency review.
Similarly, if institutions hold a current FWA which requires training of various members of the human research participate protection program, they should not have to meet additional unique training requirements. The additional requirement consumes researchers’ time which is more productively spent in conducting research. Harmonization would allow researchers more time to devote to actual scientific work.

As proposed changes to the Common Rule are considered, the above concerns should be given full review and attention.

ARRA Reporting Expansion

In support of the American Recovery and Reinvestment Act of 2009 (ARRA) reporting and oversight, the University employed a specialized team composed of four experienced individuals to manage these awards, and developed a comprehensive in-house tracking and management IT system to support these efforts. If ARRA standards are applied to all federal awards, the resource demands on faculty and staff at Duke University would be exponentially increased.

Duke University endorses and supports the following statement issued by the Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU), and the Council on Governmental Relations (COGR) on H.R. 2146, the Digital Accountability and Transparency (DATA) Act of 2011.

Joint Statement from AAU, APLU and COGR: The nation’s research university community is deeply concerned about the potential impact of HR 2146, the Digital Accountability and Transparency Act of 2011, on our nation’s innovation capacity. This legislation would impose substantial new costs on universities’ research enterprises, significantly reducing productivity with little benefit to the nation.

Scientific research is, by its nature and by already-existing laws, regulations, and reporting requirements, a transparent and accountable process. The Recovery Act imposed substantial added paperwork and other administrative burdens on scientists and administrators, with little evidence that they produced significant and useful information for the public or policymakers. The time and resources expended could have been devoted to actual research and education. Yet H.R. 2146 seeks to perpetuate these additional requirements.

In fact, preliminary data being collected by the Federal Demonstration Partnership suggests that the paperwork and other administrative costs of the Recovery Act reporting requirements for just under 100 research institutions alone were $87 million, or about $7,900 per research award. If these costs are extended throughout the entire federal research enterprise, they could amount to hundreds of millions of dollars each year. The public rightfully demands that its tax dollars be spent usefully and wisely. Money is wasted, however, when researchers and administrators are forced to spend their time making needless calculations and filling out forms.
Both Congress and the Administration have been taking action to reduce the burden of unnecessary or unproductive regulation on the American economy. This legislation goes in exactly the opposite direction, and it should be rejected.

**Federal Information Security Management Act (FISMA)**

In October 29, 2008, the HHS CISO issued a memo to clarify FISMA application that stated, “FISMA (Federal Information Security Management Act) applies to grantees only when they collect, store, process, transmit or use information on behalf of HHS or any of its component organizations.” A short time after this memo, FISMA terms appeared in RFPs for contracts from component organizations of the HHS. Duke, as well as many other universities across the country, has been negatively affected by these terms. The regulatory burdens include, but are not limited to, those summarized below:

**Broad interpretation of a federal system** – Data associated with federally funded research generally resides on the same information systems as data associated with non-federally funded research. These systems are fully integrated into the existing computing infrastructure of the lab or unit performing the research. Yet, with the signing of a contract, these existing systems are transformed to “federal systems”. They require different controls from that the rest of the computing environment. It is difficult to isolate these systems to apply these controls, as they must be used concurrently for non-federal contract research. The award of the contract forces two difficult choices: create a separate environment and duplicate systems, or apply a level of controls that is goes beyond what is required to meeting existing federal and state law, reducing the usability and flexibility of the systems to persons with no involvement in the work.

**Decentralized nature of computing in academic setting** – Persons with subject matter expertise reside in many different units within a university. A researcher with a specific expertise may be awarded a contract. Her lab resides in one department and she uses expensive microscopes, systems and tools to perform that research. The next contract or subcontract will likely be awarded for a very different research purpose in a completely different lab. It is difficult to apply FISMA controls in a unit by unit basis, and it is equally difficult to consolidate computing resources (which much be shared with projects with no FISMA requirements). Applying a regulation that most appropriately pertains to the computing environment of an entire federal agency to disparate labs in a university setting is very difficult and costly.

**Overlapping regulations** – There has been an enormous effort to bring systems used in academia into compliance with HIPAA and HITECH due to the frequent use of PHI in human subjects research. The contract does not change the nature of the data, yet the FISMA control requirements are significantly different and require much greater expense to the research enterprise. This is undue regulatory burden. It is also important to note that the current effort to revise the “Common Rule” for human subjects research includes a proposal to create a uniform standard for the maintenance of PHI in the context of research. Those rules are being created to simplify the IRB review process, but FISMA
has the potential to complicate it instead, if the institution needs to assure that both the new common rule and FISMA standards are met.

**Small volume of contracts and subcontracts** – unlike a federal agency which processes federal information as a standard business function, academic institutions process and maintain data associated with a relatively few federal contracts and subcontracts. Therefore, the cost of implementing controls cannot be offset with volume.

**Lack of clarity** – There is a lack of transparency in the determination of how the FISMA risk ratings are determined (High, Moderate, Low). Contracts for similar types of research originating from different government receive different FISMA ratings. It is also difficult to determine what FISMA level should be flowed-down to subcontractors and on what basis the rating can be challenged.

The regulatory burdens come with significant costs. Because FISMA costs were not considered in the indirect rate funding negotiation, FISMA is an unfunded mandate. Some of the compliance costs, include, but are not limited to the following:

**Certification and Accreditation costs** – Certification and Accreditation (C & A) is a process that helps ensure that federal systems are meeting security requirements. If Duke has 25 different systems used in research which require FISMA controls the testing costs alone cost over $500,000 annually.

**Subcontractor compliance costs** – Subcontractors from other universities often provide subject area expertise to answer important research questions. Each time a subcontractor is employed, an evaluation of whether the subcontractor can meet the FISMA terms must be performed. In addition, the prime contractor is responsible for monitoring FISMA compliance for the subcontractors.

**FISMA controls implementation** – At a Low risk level, FISMA has over 140 control requirements. Although these controls are worthy, even at a low base-line, internal cost analysis show it would cost at least $1,000,000 to bring one single large unit into compliance. Smaller institutions without many contracts find these costs exorbitant. Only large institutions can afford to employ these controls, which limits competition. In addition, unlike federal systems which are used to continually process data, federal contracts or subcontracts have an end date. Therefore the useful life of any hardware and software solutions used to implement controls would likely have to be recouped over the life of a single contract. Investment in such tools diverts money from research, and is not an efficient way to spend IT security dollars.
July 14, 2011

A-21 Task Force  
National Science and Technology Council Interagency Working Group on Research Business Models  
Email: A-21_Task_Force@mail.nih.gov

Dear A-21 Task Force Members,

In response to NOT-OD-11-091, I would like to express my support for the response and recommendations put forward by the Council on Government Relations and Association of American Universities.

As the Director of the Duke Translational Medicine Institute, which supports more than 1000 research faculty, the reduction in administrative burden is critical to our ability to conduct efficient and effective biomedical research.

Effort reporting is a particularly burdensome activity. With NIH funding decreasing, investigators are required to submit more applications and obtain funding through a greater portfolio of research programs than ever before. These larger portfolios multiply the amount of time researchers spend on tracking, monitoring, and certifying their effort.

For example, a single investigator may hold funding on ten separate NIH or industry-funded research projects. Each of these projects has different start and end dates. Each time a new project is funded, the investigator must determine the amount of time he/she will be able to allocate, and potentially reduce time on a different grant, including communicating with other investigators and administrative staff. He/she must also track his/her time actually spent on the project and provide certification of this effort. If we assume that the investigator dedicates three hours per project to these activities, it adds up to 30 hours per year. While this may seem small for a single investigator, when one considers the composite time for all investigators involved in our institute, in this example, the total amount of time devoted approaches 30,000 hours of administrative time per year. Stated another way, this represents more than 14 FTEs per year – a substantial burden to our institute.

I appreciate this opportunity to provide input and look forward to the outcome of this initiative.

Sincerely,

Robert M. Califf, MD, MACC  
Vice Chancellor for Clinical Research  
Director, Duke Translational Medicine Institute  
Donald F. Fortin Professor of Cardiology  
Duke University School of Medicine
A-21 Task Force
National Science and Technology Council Interagency Working Group on Research Business Models
Email: A-21_Task_Force@mail.nih.gov

Dear A-21 Task Force Members,

I am responding to the Request for Information (NOT-OD-11-091). I would like to add my support for the recommendations put forward by the Council on Government Relations and Association of American Universities.

As the Chair of a basic science department that supports research faculty, postdoctoral fellows, and students, the reduction in administrative burden is critical to our ability to conduct efficient and effective biomedical research and train future generations of researchers.

There are many administrative regulations imposed on academic institutions and faculty as described in the COGR/AAU report. These regulations increase the amount of time that researchers are required to spend on administrative activities which takes time away from scientific efforts and academic work. Each regulation adds to the administrative activities, and faculty become frustrated and discouraged by the amount of time shifted from productive bench work to administrative paperwork.

A simple example of this regulatory burden is the requirements necessary to purchase computers for research labs. Based on Circular A-21, computers are treated as “general purpose” and are unallowable as direct costs to a research project. In the current scientific environment not only are computers necessary tools to accomplish daily work, technologies are critical to the productivity as well as communication of research results. With the Circular A-21 restrictions, researchers are constrained to sharing computers, using out-dated systems, or utilizing personal funds to procure new technology. Computers and future technology should be in the same category as scientific supplies and equipment.

With NIH and other funding sources reducing funds available to basic research, investigators are required to submit an increasing number of applications to obtain funds to sustain their programs. Each grant application multiplies the amount of time researchers are occupied with seeking funds. Additionally, the lack of success in obtaining funds for many of our researchers has slowed research progress and impacted our ability to support the next generation of investigators. Institutions have had to shift valuable resources from science to administration to
manage the increasing administrative regulations. The confluence of decreased research support and increased compliance burdens has significantly constrained our scientific progress.

I appreciate the willingness of the Interagency Task Force to consider changing the OMB Circular to reduce the administrative burden and costs associated with compliance requirements and look forward to the outcome of this initiative.

Sincerely,

[Signature]

Brigid L.M. Hogan, PhD
Professor and Chair
July 14, 2011

OMB Circular A-21 Task Force
NOT-OD-11-091
Request for Information: Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Educational Institutions (OMB Circular A-21)
Email: A-21_Task_Force@mail.nih.gov

Dear A-21 Task Force Members,

I am writing to show my full support for the important work of the administrative burden task force and to offer my perspective as a researcher and a provider of research administration infrastructure. The Duke Clinical Research Institute (“DCRI”) is the largest academic research organization in the world with almost 1300 staff and 228 faculty. The DCRI is a global clinical trial coordinating center with over 700 clinical trials completed in 64 countries involving the participation of over one million patients that have resulted in more than 6800 publications in peer-reviewed journals and over 800 manuscripts published annually.

This critical review is particularly relevant to the DCRI as we are increasingly concerned that the research engine is in danger of being consumed by the fear of non-compliance and audit findings and by the assumption of costs that are beyond our resources. I do not suggest any sacrifice of integrity in research, but we live by a double-edged sword when the best and brightest scientific minds sacrifice 40% of their productivity to prepare and route forms in order to assure various stakeholders that the many aspects of compliance have been satisfied. Researchers feel very strongly about this, and I am compelled to respond to this well-intentioned request for input on reduction of cost and burden associated with OMB Circular A-21 compliance. This review is appropriate because A-21 may unintentionally be responsible for the growth of the current research administration infrastructure burden.

A-21 sought to promulgate standards for cost application in order to promote fiduciary ethos and consistent costing. Many of the principles are sound and addressed efficiently the notion that certain administrative costs were more easily allocated through application of a reimbursement rate, particularly in times that predated the sophisticated enterprise systems of today. Nevertheless, A-21 methodology falls short of adequately reimbursing the true costs of research when administrative reimbursement rates are artificially capped. The formation of A-21 methodology pre-dated many of the compliance and reporting requirements that have matured since then; there was no thought given to the best way to reimburse the infrastructure costs necessary to administer these requirements because the infrastructure did not exist. Departmental and central administration staff did not support researchers at the same levels that are necessary today.

Both central and departmental research administration ranks have grown exponentially in recent years, and other university revenue sources support this growth. Departments are
charged with providing services to ensure compliance and other departments are charged with ensuring that those departments comply. Some of the most time-consuming administrative burdens result from maintaining expensive and duplicative effort reporting systems, departmental administrative and project management support for investigators, particularly with respect to guidelines, regulations and financial compliance, departmental staff support for federally mandated central university accountability reporting, and administrative staff support for OIG and agency audits of university systems and individual research projects.

I enthusiastically support the majority of the proposed changes that are endorsed by the Council on Governmental Relations and the Association of American Universities, and I am most supportive of initiatives that reduce the costs involved in supporting the research community as opposed to those that move the cost from one bucket to another. True cost cutting initiatives will benefit government agencies and universities by a reduction in infrastructure and a repurpose and refocus upon scientific results. In particular, I lend my support to the following initiatives that I believe will result in a better balance of scientific results and administrative efficiency:

- Harmonize the myriad submission systems, regulations and reporting requirements of various agencies in order to reduce the time that faculty and staff spend navigating and staying current with the many different requirements. As one small example, preparing other support pages for Department of Defense grants is inconsistent with and more burdensome than a National Institutes of Health grant.
- Consider a standardized submission protocol where agencies review only the science and invite a select group of investigators to submit a full submission package.
- Reduce the burden associated with pre-award subrecipient monitoring for university collaborators that are subject to OMB Circular A-133. It may take days and even weeks to collect and organize small business plans, certs and reps, subcontract checklists, certificate of current cost and pricing data, copies of F&A rate agreements, budgets, institutional signatures and other agency or project-specific forms for each collaborator.
- Endorse a proactive and comprehensive approach to effort management that begins at proposal submission and continues throughout the award rather than a back-end effort reporting system of central reconciliation and reporting. The current effort reporting system involves expensive software to reach large numbers of remotely located faculty and adds no value. Other enterprise systems manage and record salary charges.
- Eliminate the NIH salary cap or remove the requirement that it be separately accounted for as cost sharing. Accounting for salary amounts over the cap is administratively prohibitive, drains investigator and staff time, and requires reporting systems to eliminate the distortion to the overall effort picture.
- Recognize that investigators must have administrative and project management support to successfully navigate the rules, regulations and reporting requirements that were not
required when A-21 was written and that universities cannot solely fund this level of support.

- Clarify and ease export control and publication restrictions that interfere with the ability of investigators to collaborate and promulgate scientific results.
- Refocus metrics on the science and results rather than on accounting procedures. It seems that we have lost something in the translation of A-21 when we measure compliance by the number of cost transfers in a given period.

As the director of the DCRI, I can assure you that our research faculty choose to serve in the public domain with all of the commensurate responsibility that engenders. We do not seek to minimize our responsibility or our public accountability; we take pride in thought leadership and quality of science, and we espouse academic and ethical principles and overall integrity. We value the public trust, and we will continue to take great care to ensure that our faculty and staff uphold those principles.

I appreciate the opportunity to provide my input to the Task Force, and I am hopeful that the results of this review will provide a more effective and efficient environment in which to conduct research.

Sincerely,

[Signature]

Robert A. Harrington, MD
Richard S. Stack, MD Distinguished Professor
Division of Cardiology, Department of Medicine
Director, Duke Clinical Research Institute
Duke University Medical Center
July 22, 2011

Dear A-21 Task Force Members,

Together with the faculty and administration of Arts and Sciences, I would like to endorse heartily the recommendations put forward by the Council on Government Relations and Association of American Universities in response to NOT-OD-11-091. We have polled our faculty on this matter and include their email responses in Appendix A.

Specifically, we would like to note the following undue burdens that were mentioned by our respondents:

1) Effort reporting takes time, is impossible to gauge, and frequently has no relationship to the actual work done. Such added burden is also difficult in multiple site research.

2) In regard to NIH caps and cost-sharing, Arts and Sciences does cost-share faculty summer supplements. Cost-sharing creates a financial burden for Arts and Sciences, particularly with salaries that exceed the caps. Administrators in Arts and Sciences must take more time to create alternative arrangements in those cases.

3) There is a disadvantage to placing clerical or related work to direct charges on individual grants, because it takes dollars away from research. While administrative staff support is a necessity of a grant and provides support to a PI and allows the PI to focus her/his time on the research, charging such support as direct rather than indirect cost reduces the dollars available for research. (This is not generally true for umbrella grants such as TUNL and HEP).

4) Subrecipient monitoring creates an added layer of work which most grant recipients feel is unnecessary, except in egregious cases of subrecipients not fulfilling the contract.

5) The current constraints put on the purchase of computers absolutely curtail research. In respondents’ minds, they should be treated as any other form of equipment.

6) Faculty in general are happy to use American carriers, but would appreciate a clearer set of guidelines about possible exceptions.

In general, the overall administrative burden of Effort Certification provides neither added accountability nor added value to the research. In many cases, it detracts from both. We are glad that you are becoming aware of the problems created by these particular procedures and appreciate your openness to feedback.

Yours sincerely,

[Laurie L. Patton]

Attachment

LLP:mj
July 26, 2011

A-21 Task Force
National Science and Technology Council Interagency Working Group on
Research Business Models
Email: A-21_Task_Force@mail.nih.gov

Dear Task Force Members,

Please accept this letter as evidence of my strong support for the recommendations submitted by the COGR/AAU. As the Chair of the Department of Biostatistics and Bioinformatics at Duke University School of Medicine, the proposals set out will likely dramatically improve our efficiency.

Two areas are of particular importance and are responsible for inefficient and unproductive use of faculty and administrative time. First, the effort management/certification system is unrealistic. Given the variability in effort dedicated to projects over time and the fact that faculty generally work on related projects in terms of concepts and requirements, it is virtually impossible to correctly separate effort into discrete components. The overhead involved in assuring compliance with an implicitly undefined mandate is an unjustifiable burden.

A second area of concern is the rigorous requirements that must be satisfied in order to direct charge the cost of computers and software. The process for justifying the exclusivity of the hardware and/or software to the particular project or to appropriately justify the percent usage in order to document the record and obtain university approval represents an unreasonable barrier to the purchase of necessary tools of the trade. Our faculty in the Biostatistics and Bioinformatics Department are heavily dependent on such tools, which are dedicated to specific projects.

Additionally, I am especially interested in the efforts to harmonize human subjects regulations and policies within the NIH and across federal agencies. As a department that is involved in the conduct of substantial research involving human subjects, we are acutely aware of the variances in policy among the agencies.

For example, it is sometimes difficult to ascertain the necessity of Data and Safety Monitoring Boards, a function very relevant to our biostatistical faculty. It would be extremely helpful to have a standard policy across the agencies. These Boards are a critical element in the assurance of human subjects safety.

It would also be helpful to develop a national standard for training in human subjects safety. Currently, if our faculty serve as a subcontractor with another institution, they must undertake the training modules from the prime institution, despite the fact that they have successfully completed our institution's training requirements. A standard policy from the federal government would allow for institutions to create reciprocity agreements, decreasing the amount of time investigators must spend on duplicative training activities.

Thank you for this opportunity to provide feedback on ways to reduce administrative burden associated with compliance requirements.

Sincerely,

Elizabeth DeLong, PhD
Chair, Department of Biostatistics and Bioinformatics
July 20, 2011

OMB Circular A-21 Task Force
NOT-OD-11-091
Request for Information: Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Educational Institutions (OMB Circular A-21)

Task Force Members,

On behalf of the faculty and research administration personnel of the Department of Medicine, thank you for the opportunity to comment on the need to reduce the cost and burden of policy and procedure related to OMB Circular A-21. We appreciate the national recognition these issues have received and look forward to the results of your work.

The Department of Medicine at Duke has a long and rich tradition of conducting basic, clinical, and translational research. My faculty member’s investigations are focused on improving human health through the discovery and application of new knowledge. My research administrators understand this mission and strive to provide our faculty the best administrative support possible. Unfortunately, much of the support our research administrators provide to our faculty is not focused on completing the aims of their research. Instead, it is spent on compliance activities, many of which could and should be simplified and standardized. Instead of performing work that is focused on completing research, all too often our research administrators spend their time interpreting and applying a myriad of complex (and sometimes conflicting) rule sets that are based on individual agency guidelines. We strongly believe there are opportunities to improve in this regard and suggest the following concepts be used to build a frame of reference as you complete your review:

- Commit to simplifying all of the administrative requirements needed to support research administration activity. The current framework is much too cumbersome for the vast majority of research awards. We strongly suggest the business requirements of OMB Circular A-21 be reviewed in context of the complexity (burden and corresponding cost) required to meet the requirements. Said another way, if the benefit of the A-21 requirement exceeds the cost to implement, we should ensure the requirement is as simplified as possible for implementation and application. Simplification of administrative requirements enables institutions to better understand the business needs they represent so they can implement them accordingly.

- Commit to standardizing as many common administrative processes among funding agencies (institutes within the NIH) as possible. For example, the processes to submit funding applications, report technical progress, certify activity, and provide financial reporting should all be standardized. The current variation in these processes creates a significant learning/training burden for both the funding agency and recipient organization personnel. These variations also
create opportunity for misinterpretation of requirements which leads to resources being spent on reconciliation instead of research. Standardizing common administrative processes is achievable and makes sense; doing so will strengthen the integrity of the process.

Again, we make these suggestions to help develop a framework to complete your review. We are confident you will receive many individual technical suggestions for improvement. We encourage you to evaluate each of these suggestions with simplification and standardization as part of your reference for improvement. As Chair of a very large and diverse Department, my experience is clear; simple and standard instruction yields the most compliant and complete action.

Finally, on behalf of the faculty and research administration personnel in the Department of Medicine, we sincerely appreciate the opportunity to comment and provide information for this review. Please contact me at your convenience if I can provide additional information or answer any questions you develop during this review. We are very hopeful that the results of this review will provide more streamlined and efficient administrative process to support our research mission.

Sincerely,

Mary E. Klotman, MD
R. J. Reynolds Professor and Chair
Department of Medicine
Date: July 22, 2011

To: OMB Circular A-21 Task Force
NOT-OD-11-091
Request for Information: Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Education Institutions (OMB Circular A-21)
Email: A-21_Task_Force@mail.nih.gov

From: Michael L. Somich, Executive Director, Office of Internal Audits
Leigh P. Goller, Director, Office of Internal Audits
Valla F. Wilson, Director, Office of Internal Audits
Joan M. Podleski, Director, Office of Institutional Ethics and Compliance

Subject: Request for Information: Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Education Institutions (OMB Circular A-21)

The Office of Internal Audits provides objective controls, compliance and business process evaluations across functions and departments at Duke. The Office of Institutional Ethics and Compliance facilitates monitoring programs to evaluate and ensure compliance with laws and regulations. These offices work together to evaluate and assess risks in the Duke environment, recommend business process changes to improve internal controls and/or compliance outcomes. In the course of our work, we evaluate business processes in light of desired outcomes or specified objectives, considering effectiveness, efficiency, resourcing and the balance between the risk level and risk mitigation strategy. We regularly observe inconsistency among third-party regulations, imbalances between compliance expectations and good business practices, and inefficiencies in building business processes based on external audit expectations and monitoring requirements for regulations rather than prudent use of resources.

Specifically, our experience yields several observations relative to revisiting OMB Circular A-21 regulations to explore opportunities to strengthen the research enterprise, increase accountability between the federal agencies and their institutional partners, reduce non value-add administrative burden and encourage medical and scientific professionals to explore research opportunities.

1. **Administrative burden is not aligned with the institutional or transaction risk level.**

   The rigid nature of provisions within OMB Circulars A-21, A-110 and A-133 and interpretations of those provisions do not provide flexibility at the institutional level. Federal agencies and the respective cognizant auditors apply the provisions without consideration of the differences among institutions or the relative materiality of certain types of transactions. Additionally, the complexity of the processes to support compliance may
greatly exceed the relative risk to the funding agency of inappropriate use of research funds. As a result, every institution must design, implement and maintain administrative infrastructure, oversight and monitoring for elements small and large alike. In the course of audits or monitoring evaluations, we make recommendations to streamline business processes and enhance resource utilization. Process owners often want to make business process changes to promote efficiency, however, the most efficient process design may not align with some aspects of compliance expectations.

To illustrate the imbalance of the administrative burden and assessed risk level: one institution may have a robust and thoroughly tested electronic document retention system, including high-standard electronic back-up procedures; another institution may rely solely on paper files for all supporting documentation. Although the risk of loss or document fraud is insignificant at the first institution, it is required to retain original hard copy supporting documentation for at least one year. Conversely, at the latter institution the risk of loss by natural disaster is far greater than the probability of electronic storage failure, yet this second institution is not required to keep a “back-up” copy of all supporting documentation. The risk of loss or failure is lower at the first institution, yet it incurs a higher administrative burden to comply with federal regulations.

2. Inappropriate reliance on transaction testing versus business process validation.

Risk-based internal auditing and compliance monitoring represent best practices for providing assurance as the reliability and predictability of business process results. Risk-based evaluations focus on the strength of business processes to prevent or detect undesirable or inappropriate outcomes for those areas representing the most significant financial, operational or compliance impact. If process owners expend time and effort to build and maintain strong business processes, the results will be reliable and predictable within a modest or reasonable tolerance for human error.

The Office of the Inspector General’s annual work plan and OMB Circular A-133 audit work program do not evaluate the strength of business processes. Rather, both encourage federal auditors and public accounting firms providing A-133 attest services to evaluate the aggregate accuracy of financial records based on a small and potentially non-representative sample of transactions. For many institutions, fewer than 100 sample transactions determine the extrapolated accuracy of several hundred thousand transactions. Transaction testing is a valuable tool to validate the effectiveness of thoroughly understood business processes and internal control environments. Without that important context, transaction testing and results extrapolation is nothing more than a numeric representation of a small portion of the population. In worst case scenarios, inappropriate interpretation of test data can lead to additional administrative burden by creating business processes and monitoring efforts to identify transactions that may not represent a significant or material portion of the population. Additionally, transaction testing at an interim point in time (i.e., before fund close-out) may not account for the positive impact of detective controls later in the process or timeline that would mitigate the effect of interim testing errors.

If federal regulations set forth principled expectations for business practices, and auditing bodies evaluate the strength of institutional business practices in light of relative risk factors, then an institution would not build business processes to anticipate and protect itself against arbitrary results from sample transaction testing. Similarly, third-parties can validate the
reliability of institutional risk assessment by evaluating the effectiveness of its overall compliance program and institutional culture supporting compliance.

3. **Inconsistencies among federal regulations and agency interpretations increase the likelihood of error and inhibit effective auditing and monitoring.**

Institutional business processes must vary to accommodate differing expectations among federal regulations and multiple agency interpretations and additive guidance. Internal auditors promote consistency and predictability of business processes and related internal controls as a way to strengthen outcomes and reduce inefficiencies. However, in the cases where federal regulations and agency guidance vary, business processes must be designed to accommodate, comply with and monitor exceptions to these variations. The flexibility needed in such processes makes strong, systematic controls more difficult, leading to a higher level of reliance on human input, thereby increasing the risk of error. These variations also lead to increased administrative costs across all process levels, including systems design and training of both research and financial support staff with no added value to the research process.

Risk-based internal audits and external compliance audits (agency sponsored or A-133) are inherently more difficult to perform when these variations exist. In some cases the variations conflict, introducing yet another complexity that challenges accurate and reliable audit conclusions. Without accurate and reliable audit conclusions, the value of auditing of any kind is limited. In any case, the audit must be designed and conducted to follow each permutation to its conclusion, creating redundant and time-consuming audit procedures and reducing the reliability of any conclusion to apply to the population.

Effective auditing is core to institutional oversight and public confidence. Harmonized federal regulations and agency guidance will improve audit quality and increase the reliability of audit results and recommendations for improvement or remediation.

All industries, entities and institutions continue increasing their reliance on audit and monitoring as partners to promote best practices, strengthen operations and increase accountability. Internal audit and institutional compliance programs are core elements at Duke and many other research institutions. Audit and compliance programs built around and supporting effective business processes and a culture of compliance will strengthen and streamline the research enterprise and its administrative components. Federal regulation reform and harmonization will promote simpler and more easily controlled administrative processes. They will also allow for more effective and efficient auditing and compliance monitoring programs, returning greater dividends to federal agency sponsors.