

# COUNCIL ON GOVERNMENTAL RELATIONS

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TO: COGR Membership  
FROM: COGR Staff  
SUBJECT: February 2013 Update

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## **Grants Reform and OMB Circular A-21 Update – NOW AVAILABLE**

The much anticipated Office of Management and Budget (OMB) Proposed Guidance for “*Reform of Federal Policies Relating to Grants and Cooperative Agreements; Cost Principles and Administrative Requirements (Including Single Audit Act)*” has been released. The February 1, 2013 – Federal Register Notice can be found at:

<http://www.gpo.gov/fdsys/pkg/FR-2013-02-01/pdf/2013-02113.pdf>

In support of the Proposed Guidance, OMB has provided a number of documents that can be accessed at the following website:

[http://www.whitehouse.gov/omb/grants\\_docs#proposed](http://www.whitehouse.gov/omb/grants_docs#proposed)

Included on this website are a link to a Summary of Changes document (i.e., the same text as the Federal Register Notice from above), a link to the FULL TEXT (i.e., the proposed new Circular), and six additional links to various crosswalks between the current circulars and the Proposed Guidance.

This OMB initiative is formally being led by the Council on Financial Assistance Reform (COFAR). Further information on the work of the COFAR can be found at <http://cfo.gov/cofar>. OMB also will be hosting an informational WEBINAR on the proposed guidance with members of the grant community on Friday, February 8<sup>th</sup> at 11:00AM EST. A link to the webinar will be available on the [www.cfo.gov](http://www.cfo.gov) website; no advance registration is required. A recorded version also will be available for later viewing.

The Proposed Guidance, at this point, will be open for a 90-day public comment period and comments can be submitted at [regulations.gov](http://regulations.gov) under docket number OMB-2013-0001. If the 90-day public comment period is not extended, the due date for comments will be Midnight EST, May 2, 2013.

### **Initial COGR Reaction and COGR Game Plan for Responding to the Proposed Guidance**

The FULL TEXT (i.e., the proposed new Circular) is a 244 page document that consolidates Administrative Requirements (Circulars A-110, A-102, A-89), Cost Principles (Circular A-21, A-87, A-122), and Audit Requirements (Circulars A-133, A-50) into a single document. Pending a possible future review, the Cost Principles for Hospitals (*Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals*) that are in the regulations of the Department of Health and Human Services at 45 CFR Part 75, Appendix E, may be addressed at a later date.

The 244 page document is presented in a logical manner, which in COGR's view, has been completed in a format that is relatively easy to follow. The crosswalk and definition documents that are available at the OMB website are helpful supplements. The challenge will be to grind through the 244 page document and to analyze the substance and pay special attention to problematic language. This will be a major focus during the 90-day public comment period.

The February 1, 2013 – Federal Register Notice, which is a high-level summary of the proposed changes, addresses many of the comments that COGR made in its response to the February 28, 2012 – Federal Register, Advance Notice of Proposed Guidance (ANPG): *Reform of Federal Policies Relating to Grants and Cooperative Agreements: Cost Principles and Administrative Requirements (including Single Audit Act)*. On first pass, the following items are of note:

- 1) Agencies are required to keep funding announcements open for 30 days.
- 2) Added focus on agencies to comply with the Paperwork Reduction Act.
- 3) Voluntary committed cost sharing is not expected under Federal research proposals and is not to be used as a factor in the review of applications or proposals, except where otherwise required by statute.
- 4) Institutions can extend their current F&A rates for up to 4 years.
- 5) Pass-thru entities are required to pay the full F&A rate.
- 6) Effort reporting is not eliminated, but the "Examples" are.
- 7) Direct charging of administrative personnel and computing devices is allowable when directly allocable to a project.

- 8) All institutions can receive a “utility allowance” via new methods: weighting of research square footage or sub-building metering.
- 9) Agency restrictions on F&A caps are now more rigorous for an agency to obtain – though we need to better understand from OMB how this becomes transparent to our institutions.
- 10) Apparent elimination of the DS-2 and CAS as it relates to Grants.
- 11) Potential audit relief, though this is not clear. Initially, we did not see relief in regard to a prime’s monitoring responsibilities when the sub is another research university.

These are initial reactions only. Again, the test will be to analyze the detail behind the 244 page document and determine the concerns and how to effectively respond to OMB. Active engagement from the COGR membership will be imperative.

For one of the Thursday morning sessions at the February COGR Meeting, members of the Costing Committee will facilitate a discussion covering what is included, initial perceptions, and the COGR approach for responding to OMB. And for one of the Thursday afternoon sessions, OMB Controller, Danny Werfel, will present an update. After Mr. Werfel completes his presentation, he will open the floor to questions from the COGR membership.

The COGR Costing and RCA Committees have begun discussions on strategy and approach for responding to the Proposed Guidance. In addition to preliminary correspondences over the next several weeks, our Committees will meet for two days, February 19-20, prior to the February COGR Meeting. If you will be attending the Thursday morning session at the February 21<sup>st</sup> COGR Meeting, we urge you to read through as much of the Proposed Guidance as possible in advance of the meeting.

We plan to employ a similar approach to the one we used to respond to both the June 28, 2011 – Request for Information: *Input on Reduction of Cost and Burden Associated with Federal Cost Principles (OMB Circular A-21)* and the February 28, 2012 – Federal Register, Advance Notice of Proposed Guidance (ANPG): *Reform of Federal Policies Relating to Grants and Cooperative Agreements: Cost Principles and Administrative Requirements (including Single Audit Act)*. In both instances, COGR shared talking points and draft responses with the membership via postings on the COGR ListServe.

It will be a major community effort to develop this response – and in addition to the COGR Response, your institutions also will submit responses to OMB. The formal COGR Gameplan, in combination with the vast wealth of expertise that many of you have, will be crucial to an effective response – we will rely on the informal network and sharing of your observations as you independently read through the proposed new Circular. We will keep the membership posted on all developments.

### **The Federal Budget and Sequestration**

The American Taxpayer Relief Act of 2012, signed into law on January 2, 2013, averted tax increases for most taxpayers. In addition, the Act postponed Sequestration (large, automatic cuts in federal spending established in the Budget Control Act of 2011) until March 1, 2013. There are some signals from Capitol Hill that both parties may allow Sequestration to occur, at least temporarily.

Furthermore, on January 14<sup>th</sup> the OMB Deputy Director for Management issued a memorandum to all executive departments and agencies entitled “*Planning for Uncertainty with Respect to Fiscal Year 2013 Budgetary Resources*” (see link below):  
<http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-03.pdf>

As COGR reported in a note to the COGR ListServe on January 16<sup>th</sup>, the memorandum directs federal agencies to plan for possible major budget reductions for the remainder for FY2013 in case Congress fails to act on the Sequestration, scheduled to go into effect on March 1<sup>st</sup>. Adding to the uncertainty is the expiration of the FY2013 Continuing Resolution, which is effective through March 27<sup>th</sup>. The memorandum notes that unless Congress acts, the Sequestration order will require spending cuts in FY2013 alone of \$85 billion.

Of particular concern with respect to research funding is the fourth bullet point in the memorandum, which articulates OMB's guiding principles for the agencies and states: “*review grants and contracts to determine where cost savings may be achieved in a manner that is consistent with the applicable terms and conditions, remaining mindful of the manner in which individual contracts or grants advance the core mission of the agency.*”

In addition, the Department of Defense, in a memorandum issued in January, instructed the military to begin adjusting for Sequestration. With respect to DOD funding for research and development, the memo instructs agencies to clear R&D contracts above \$500 million with the Under Secretary of Defense for Acquisition, Technology and Logistics. It also instructs agencies to identify the impacts of budget uncertainty on DOD's Science and Technology accounts, which typically include basic and applied research and early-stage technology development. According to analyses from the AAAS, DOD currently stands to lose more than \$6.5 billion a year in R&D funding under Sequestration.

With this level of uncertainty in the FY2013 federal budget, it has been reported that the Administration's FY 2014 budget, normally released at the beginning of February, is unlikely to be ready until mid-March, if not later.

These developments are significant and will be a major part of the discussions at the February 21-22 COGR Meeting. We will continue to share information with the membership as we learn more.

### **NIH Salary Limitation Update**

First, the NIH Salary Limitation (which also is applicable to most HHS operating divisions) remains pegged to the Executive Salary Level II (i.e., \$179,700). The EL II will remain applicable, unless Congress changes this statutory requirement in the course of finalizing an FY2013 budget resolution. Currently, the federal budget is operating on a Continuing Resolution that is in effect through March 27, 2013.

Second, regardless of the Executive Salary Level that ultimately is enacted, there is potential for a pay adjustment to all Federal rates of pay. In two Presidential Documents printed in the Federal Register on January 3, 2013 (Vol. 78, No. 2), the President: 1) suspended any pay increases at least through March 27, 2013 (first link), and 2) via Executive Order 13635 (second link), allowed for certain rates of pay to be adjusted after March 27, 2013, effectively resulting in a

.5% rate of increase. If EL II remains the benchmark for the NIH Salary Limitation, this would increase the NIH Salary Limitation from \$179,700 to \$180,600.

<http://www.gpo.gov/fdsys/pkg/FR-2013-01-03/pdf/2013-00001.pdf>

<http://www.gpo.gov/fdsys/pkg/FR-2013-01-03/pdf/2013-00002.pdf>

Of course, the looming possibility of Sequestration and the uncertainty of any FY2013 budget resolution makes changes to the NIH Salary Limitation unclear. Until these budget issues are more settled and NIH provides guidance, institutions should continue to operate under last year's NIH guidance (NOT-OD-12-035), dated January 12, 2012:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html>

### **NIH and Costing for Core Facilities – FAQs to be Released Soon**

In the COGR Holiday Update (December 20, 2012), we provided an update on the NIH plan to revitalize its initiative to publish “*FAQs for Costing Core Facilities.*” The baseline for this NIH initiative came from a September 2010 NIH Notice Number: NOT-OD-10-138 (see link below), “*Request for Comment on FAQs to Explain Costing Issues for Core Facilities.*”

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-138.html>

In November, NIH shared with COGR a revised set of FAQs based on our community's input to the 2010 NIH Notice. Consequently, NIH asked COGR (and others from the research community) to provide feedback on the revised FAQs. COGR comments to the revised FAQs were in the form of a “red-lined version” and COGR submitted these to NIH on December 20<sup>th</sup>. The “red-lined version” (including the Cover Letter as a separate attachment) can be accessed on the COGR home page at [www.cogr.edu](http://www.cogr.edu) (see Latest News, December 20, 2012 link).

In early January, NIH provided comments to COGR regarding COGR's “red-lined version” from December 20<sup>th</sup>. And in mid-January, COGR provided one more set of comments in an effort to remind NIH that any FAQs that address core facilities should be done in a manner that is not overly broad – i.e., the FAQs should be scoped so that they are applicable to NIH core facilities only and are not applied inappropriately to institution-wide service center policies.

COGR responses to NIH have been developed by a Workgroup that includes members from the COGR Costing Policies Committee and individuals from your institutions who volunteered to be on the Workgroup. In the COGR Holiday Update we recognized those individuals and we are thankful for the expertise contributed by the members on the Workgroup. NIH currently is reviewing the additional comments from COGR and consulting with other federal officials, prior to finalizing the FAQs. As we learn more, we will update the membership on the status.

### **Accelerating Spending on ARRA Programs: NSF and NIH**

Many COGR institutions continue to await guidance from NSF and NIH as to whether or not waivers will be granted, which would allow spending on selected ARRA programs to extend beyond September 30, 2013. Agencies were required to apply to OMB for waivers on affected programs, and OMB is responsible for granting the waivers. NSF and NIH continue to await waiver approvals from OMB.

NSF awards, in particular, are affected. After careful consideration of each request, NSF determined which awards to include in its agency waiver request package to OMB. In late

September 2012, Authorized Organizational Representatives and PIs were notified by e-mail of the status of their awards. In November 2012, NSF submitted its waiver request package to OMB, and OMB has not indicated the date by which decisions would be made. For awards included in NSF's waiver package, PIs should proceed with work in accordance with the original terms and conditions of the award while continuing to responsibly accelerate when possible. NSF is prepared to stand by its determination that a compelling legal, policy, or operational rationale exists for allowing expenditures for these awards to continue beyond September 30, 2013. For awards that were not included in NSF's waiver package, all project expenditures must be completed by September 30, 2013. All expenditures must be in accordance with the terms and conditions of the award. Additional information and instructions are available in an Acceleration-specific FAQ document on NSF's Recovery Act website (see link below):

[http://www.nsf.gov/publications/pub\\_summ.jsp?ods\\_key=arrapi](http://www.nsf.gov/publications/pub_summ.jsp?ods_key=arrapi)

In the case of NIH, construction awards are at issue. Like NSF, NIH is awaiting direction from OMB. Until OMB provides direction to NSF and NIH, COGR institutions will remain uncertain as to what to expect. NSF and NIH are diligent in their outreach to OMB and we hope to receive guidance soon.

### **Department of Treasury Offset Program (TOP) and Delinquencies with the VA**

COGR has engaged with several higher education associations over the past month to learn more about possible broad concerns about the Department of Treasury Offset Program (TOP), and specific concerns associated with how the Department of Veterans Affairs (VA) recently has processed delinquencies through the TOP.

The TOP is a program administered by the U.S. Department of Treasury, Financial Management Service (FMS). Through the interaction of federal databases, payments due to an institution may be reduced, automatically, if the institution is flagged by TOP-FMS-Debt Management Services (DMS) as delinquent on a past due debt. In addition, the General Services Administration (GSA) manages a separate process, the System for Awards Management (SAM). The SAM is designed to check the TOP-FMS-DMS delinquency database, and if there is a delinquency, the SAM may flag institutions with delinquent debt and put a hold on grant awards to those institutions.

The first link below provides a link to a page published by the National Association of College and University Business Officers (NACUBO) and includes a succinct and helpful summary of the Treasury Offset Program, including advice on how institutions can receive help to locate any debt in question and understand the steps needed to resolve related issues. The two links that follow are links to web pages maintained by the TOP-FMS-DMS; one page that describes the TOP and a second page that contains "Common Questions" regarding the TOP. Also note questions regarding the TOP can be directed to the TOP Call Center at 1-800-304-3107.

[http://www.nacubo.org/Business\\_and\\_Policy\\_Areas/Accounting/Accounting\\_News/More\\_Institutions\\_Affected\\_by\\_Treasury\\_Offset\\_Program.html](http://www.nacubo.org/Business_and_Policy_Areas/Accounting/Accounting_News/More_Institutions_Affected_by_Treasury_Offset_Program.html)

<http://www.fms.treas.gov/debt/top.html>

[http://www.fms.treas.gov/debt/questions\\_top\\_pub.html](http://www.fms.treas.gov/debt/questions_top_pub.html)

Of more urgency is a recent wave of activity associated with delinquencies with the VA. For several COGR institutions, this has resulted in payment offsets on reimbursements related to research awards and/or has triggered holds on the issuance of new awards. While in some cases the debt may be legitimate, changes over the past several years in how the VA has processed GI benefits, as well as some questionable management practices (e.g., incorrect or duplicate offsets, incorrect or inappropriate mailing addresses, unclear audit trails, etc.) by the VA, have contributed to the angst at COGR institutions.

Again, NACUBO (see link below) provides helpful information, this time on VA-specific issues associated with the TOP. In the summary per the link below, NACUBO suggests that schools should email any disputes to VA's Debt Management Center (DMC) at [dmcedu.vbaspl@va.gov](mailto:dmcedu.vbaspl@va.gov).

[http://www.nacubo.org/Business\\_and\\_Policy\\_Areas/Student\\_Financial\\_Services/Student Financial Services News/NACUBO Workgroup Meets with VA Staff Expresses Concerns.html](http://www.nacubo.org/Business_and_Policy_Areas/Student_Financial_Services/Student_Financial_Services_News/NACUBO_Workgroup_Meets_with_VA_Staff_Expresses_Concerns.html)

If your institution has concerns with the TOP or concerns related to VA-specific issues associated with the TOP and the federal contacts listed above are not helpful, contact NACUBO or COGR staff.

### **Audit Update**

The past two COGR Updates (October 2012 Meeting Report - November 16, 2012, and the COGR Holiday Update - December 20, 2012) included detailed narratives on the activities of two Offices of Inspectors General (OIG) – the Department of Health and Human Services (HHS) and the National Science Foundation (NSF). Since the beginning of the New Year, we are not aware of any new developments. However, COGR regularly checks the HHS (NIH) and NSF OIG websites (see links below) and follows other proceedings related to audit.

<https://oig.hhs.gov/reports-and-publications/oas/nih.asp>  
<http://www.nsf.gov/oig/auditpubs.jsp>

We always are interested in audit experiences at your institution so that we can update the general landscape for the membership – do not hesitate to contact us. We have the most access to HHS OIG and NSF OIG initiatives, but also are interested in activity related to the OIGs at other agencies, as well as other internal and external audit activities.

### **Update on the NRC Report on Research Universities**

The October 2012 Meeting Report (November 16, 2012) included a summary of the panel session at the October 2012 COGR Meeting. This session centered on the June 2012, National Research Council (NRC) Committee on Research Universities report: *Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Nation's Prosperity and Security*. The Full Report and the Summary version are available at the link below.

<http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=13396>

Since the COGR Meeting, NRC Committee members have begun meetings with stakeholders across the country. Dr. Peter Henderson, Director, Board on Higher Education and Workforce,

National Research Council, and the individual who directed the Study on Research Universities, shared the following update with COGR:

“We have had two very successful regional meetings so far. In November, the University of Pittsburgh and Carnegie Mellon hosted the first meeting and Chancellor Mark Nordenberg wrote a very nice op-ed in the Pittsburgh Post-Gazette afterwards that summarized the theme of the meeting. See: <http://www.post-gazette.com/stories/opinion/perspectives/mark-a-nordenberg-we-must-invest-in-innovation-to-perpetuate-pittsburghs-progress-669176/>.

On January 16, Vanderbilt hosted the second meeting which began with a terrific panel including [Tennessee] Gov. Haslam, Senator Alexander, Senator Frist, and Chad Holliday. Videos of the sessions at this meeting can be found at: <http://news.vanderbilt.edu/2013/01/nrc-meeting-jan-16/>. More meetings are scheduled for Tucson, Dallas, Detroit, San Diego, and Maryland. And, most importantly, I would like to ask you to save October 10, 2013, for the concluding national conference here in Washington, D.C. We will hold this meeting in the auditorium of the newly renovated National Academy of Sciences building.”

COGR will share periodic updates with the COGR membership as we learn more about the activities and advocacy efforts of the NRC Committee on Research Universities.

### **Other Costing Developments and Discussions**

Below are topics that are either new developments or items we have reported on in the past and continue to follow. If there are cost-related or financial topics that you would like to discuss with COGR, please contact David Kennedy at [dkennedy@cogr.edu](mailto:dkennedy@cogr.edu).

**Treatment of NSF Awards in the SEFA; 2013 A-133 Compliance Supplement.** OMB included language in the final draft of the 2012 A-133 Compliance Supplement, which would have required all NSF awards to be reported on the Schedule of Expenditures of Federal Awards (SEFA) as part of the R&D Cluster. COGR was successful in its request to OMB to eliminate the clause. However, this language was included, despite COGR objections, in the 2012 NSF Proposal and Award Policies and Procedures Guide (PAPPG). Consequently, OMB will propose the same language to be included in the 2013 A-133 Compliance Supplement. COGR continues to object to both the NSF and OMB. *If the requirement to include all NSF awards in the R&D Cluster is problematic to your institution* (for example, in terms of administrative burden, modifying accounting systems, etc.), please contact David Kennedy, prior to or at the COGR Meeting.

**New GAO Study on Indirect Costs.** The U.S. Government Accountability Office (GAO) – an independent, nonpartisan agency that works for Congress to investigate how the federal government spends taxpayer dollars – has begun a study on the indirect costs for National Institutes of Health (NIH) funded extramural research. The study is in response to a request from Senator Jeff Sessions on the Senate Committee on the Budget. Our understanding is that the GAO study will examine: a) the protocol for setting policies for covering indirect costs paid to universities, b) the amounts in indirect costs paid out to the largest universities by NIH, and c) how indirect costs vary across NIH grantees. You may recall the GAO study completed a study in 2010 (see <http://www.gao.gov/products/GAO-10-937>), which was conducted in response to the 2007 DOD indirect cap on basic research awards. While the

new study appears to be unrelated to the 2010 study, some of the same issues, most likely, will be covered in the new study.

**Reducing Regulatory Burden and a Request for a New GAO Review.** As we have reported in previous COGR Updates, Rep. Mo Brooks (R-AL), chairman of the House Research and Science Education Subcommittee, asked the U.S. Government Accountability Office (GAO) to review regulatory actions that hinder our nation’s research universities. COGR worked with our colleagues at AAU and APLU to share information with Rep. Brooks’ staff – specifically, we discussed effort reporting, subrecipient monitoring of entities already subject to the A-133 audit, and paperwork retention requirements under FAR 4.703. Each of these was addressed in his letter to the GAO. As in past GAO reviews, we expect GAO staff will contact COGR for further information and discussion. Rep. Brooks’ letter to the GAO is available at:

[http://science.house.gov/sites/republicans.science.house.gov/files/documents/Letters/100312\\_brooks\\_GAO.pdf](http://science.house.gov/sites/republicans.science.house.gov/files/documents/Letters/100312_brooks_GAO.pdf)

**NSF Survey on R&D Expenditures – FY2011 InfoBrief Available.** The National Science Foundation, National Center for Science and Engineering Statistics (NCSES), announced in November that the InfoBrief for the FY 2011 Higher Education R&D Survey (HERD) is available. The report can be found at:

<http://www.nsf.gov/statistics/infbrief/nsf13305/nsf13305.pdf>

**NIH Funding Policy Under the Continuing Resolution (CR) – Special Attention on NCI.** The Federal Government is operating under a CR, which became effective October 1<sup>st</sup> and funds the Federal Government through March 27, 2013. NIH posted its funding policy under the CR in Notice NOT-OD-13-002 on October 11, 2012 (see link below). The Notice reflected standard NIH policy for the previous six years where NIH issues non-competing research grant awards generally up to 90% of the previously committed level. However, at least one NIH Institute, the National Cancer Institute (NCI), has issued non-competing awards that includes 6 months of funding at the previously committed level. This is inconsistent with the guidance under NOT-OD-13-002. We have contacted OPERA on this topic and they are working with NCI to clarify the NCI funding policy under the CR.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-002.html>

**Grant Reporting Information Project (GRIP).** We reported in the October 2012 Meeting Report (November 16, 2012) that GRIP is an initiative currently being led by the Recovery Accountability and Transparency Board (RATB) to explore implementing an ARRA-type reporting model for all federal grants (note, contracts are not part of GRIP). The initiative is in a proof-of-concept/pre-pilot stage and should be considered preliminary. The results of the pre-pilot will help determine if GRIP should be expanded to a full pilot. The RATB expects to release a report that provides findings from the pre-pilot – that report could be available soon. Future development of the GRIP initiative will be subject to critical review by many stakeholders and possible outcomes cannot be predicted at this time. COGR is paying close attention to all developments related to GRIP, including discussions involving a “Universal Award ID” initiative and issues associated with federal payment systems.

**Implementation of the NSF Award Cash Management System (ACM\$).** The NSF has shared the following update: “Starting in January 2013, ACM\$ will be implemented early at 38 research organizations. These organizations will begin using ACM\$ after the submission

of their final Federal Financial Report to NSF. ACM\$ will be implemented at all NSF awardee organizations in April 2013.” Additional information is available at:

[http://www.research.gov/research-portal/appmanager/base/desktop?\\_nfpb=true&\\_pageLabel=research\\_node\\_display&\\_nodePath=/researchGov/Generic/Common/WhatisACM.html](http://www.research.gov/research-portal/appmanager/base/desktop?_nfpb=true&_pageLabel=research_node_display&_nodePath=/researchGov/Generic/Common/WhatisACM.html)

### **HIPAA Privacy Rule Changes**

The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) issued the final rule that modified the HIPAA Privacy, Security, Enforcement and Breach Notifications Rules as required under the Health Information Technology for Economic and Clinical Health Act (HITECH Act) and the Genetic Information Nondiscrimination Act. The final rule was published in the Federal Register on January 25, 2013 (78FR5566). The effective date of the rule is March 26, 2013; the compliance date for covered entities is September 23, 2013.

When the proposed modifications were offered for comment on July 14, 2010 (75FR40868), COGR focused its response to those issues that directly affected the research enterprise. The final rule modifies numerous aspects of the Health Insurance Portability and Accountability Act (HIPAA) provisions and covered entities, as defined by HIPAA and their business associates will need to review all the changes. Information can be found at the OCR website at: <http://www.hhs.gov/ocr/privacy/index.html>

#### **Sale of Protected Health Information**

In its comment, COGR supported the proposed exceptions to the rule with regard to the sale of protected health information (PHI). OCR has adopted the statutory exceptions from authorization requirements for the sale of PHI for public health activities and research, including PHI provided in limited data sets. The OCR asked for information about the costs associated and we urged OCR to not attempt to identify specific cost categories and rely on established cost and audit regulations to ensure a reasonable cost-based fee for the preparation and transmittal of PHI and with further definitions this is the approach OCR has taken in the final rule.

#### **Combined Authorization**

One central concern for the research community, OCR proposed to allow combined authorizations for conditioned and unconditioned research activities and noted in the summary of comments included with the final rule the almost unanimous support for this change. OCR has adopted the amendment to allow combined authorization provided that the authorization clearly differentiates the conditioned authorization (e.g., participation in the clinical trial) and unconditioned (e.g. tissue banking of specimens) and allows the individual to opt in to the unconditioned activities. Again, there is an exception to compound authorization for psychotherapy notes and the unconditioned authorization must be an opt-in provision.

#### **Future Use**

OCR asked for advice on its current interpretation with regard to authorization for future research uses of PHI. In the proposed rule the OCR outlined possible modification to its

interpretation which required any future research use authorization to be study specific which made it difficult to develop research databases or repositories. In response to the comments received, OCR “modif[ies]” its prior interpretation in that authorizations for future research use must address the core elements and statements currently required but OCR no longer interprets the “purpose” provision to require a study specific authorization. Rather, the purpose description “must adequately describe such purposes such that it would be reasonable for an individual to expect that his or her PHI could be used or disclosed for such future research.” OCR states that covered entities may rely on an IRB-approved consent for future use obtained prior to the effective date of the rule if it reasonable informed the individual and was combined with a HIPAA authorization.

These are important changes for the research community, but all covered entities must review the entirety of the final rule to ensure that they are meeting the HIPAA requirements.

### **NSF Reporting Through Research.gov**

As we reported in the October meeting report, Jean Feldman, head of the NSF Policy Office, joined the membership on Thursday morning to provide a wide-ranging up-date on a number of issues including and the implementation of the Research Performance Progress Report (RPPR) on Research.gov. At that time Feldman outlined the staggered implementation strategy for the Research Performance Progress Report (RPPR) on Research.gov.

In a *Dear Colleague* letter dated January 10, 2013 (NSF 13-041), NSF announced that beginning March 18, 2013, investigators will be required to submit annual, final and interim project reports through Research.gov. FastLane became unavailable for reporting on February 1, 2013. Recognizing the potential for confusion, NSF is extending overdue dates for reports scheduled to be past due between January 31 and April 30 to allow for the transition to Research.gov. Investigator need to be aware that reports prepared but not submitted in FastLane after February 1 will need to be re-entered in Research.gov. The FastLane Project Reporting System will become unavailable on March 15.

### **NIH Seeks Community Advice on Use of Chimpanzees**

The National Institutes of Health (NIH) issued a Request for Information (RFI) to seek the public’s response to the recommendations offered by the NIH Council of Councils’ Working Group on the Use of Chimpanzees in NIH-Supported Research. The Working Group was convened to consider the recommendations offered by the Institutes of Medicine (IOM) in its NIH-commissioned study on Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity (December 2011). The NIH Working Group submitted its report on January 22, 2013. The IOM report is available at: <http://iom.edu/Reports.aspx> - search for chimpanzees; the NIH Working Group report is available at: [http://dpcpsi.nih.gov/council/working\\_group\\_message.aspx](http://dpcpsi.nih.gov/council/working_group_message.aspx) - along with links to submit comments. Comments are due no later than March 23, 2013.

In the interim, NIH continues to operate under the policy issued on December 21, 2011 (NOT-OD-12-025) which halted the funding of any new or other competing projects (renewal and revisions) for research involving NIH-owned or supported chimpanzees. Ongoing research using NIH-owned or -supported chimpanzees was reviewed on a case-by-case basis to determine whether the work met the IOM principles and criteria. Projects not meeting those principles and

criteria were to be phased out in a manner that preserved the value of research already conducted.

### **NABR Survey on Rats, Mice and Birds**

The National Association for Biomedical Research (NABR) has asked its membership to complete a survey to assess the impact of inclusion of rats, mice and birds under the Animal Welfare Act and to estimate the overall cost of compliance. The survey is available for NABR members through contacting NABR at info@nabr.org. On December 20, 2012 at the end of the last session of Congress, Rep Gerald Connelly (R-VA) introduced HR 6693, *To amend the Animal Welfare Act to provide for the protection of birds, rats, and mice, and for other purposes*. The bill would include within the definition of an "animal" for purposes of compliance with the Animal Welfare Act a bird, rat of the genus *Rattus*, or mouse of the genus *Mus* that is being used, or is intended for use, as a pet or for research, testing, experimentation, or exhibition purposes. In anticipation that the bill will be reintroduced in the new session of Congress, NABR has prepared a confidential survey to assess the impact of such an expanded definition. The information will provide important information for Congressional members concerning regulatory and financial burden including estimates of the number of these species currently in U.S. research.

We urge COGR members who are members of NABR to consider completing the survey.

### **HHS Asks for Comments on New DEC Clauses**

On January 10 the Department of Health and Human Services (HHS) proposed to add two new clauses to its Acquisition Regulations (HHSAR), covering Patent Rights and Data Rights in Exceptional Circumstances. The clauses would be used in contracts where HHS has approved a Determination of Exceptional Circumstances (DEC) to provide contractors with other than normal Bayh-Dole invention rights (*78FedReg2229*).

The notice states that the purpose is to ensure that providers of proprietary materials will retain their preexisting rights to materials and inventions in which the provider has a proprietary interest when a DEC has been executed. It will help ensure that pharma companies, academia, and others will collaborate with HHS in identifying, testing, developing, and commercializing new drugs, therapeutics, diagnostic, prognostic and prophylactic measure affecting human health. Using these clauses will provide “solid legal protection for the proprietary rights of providers to ensure providers will collaborate...and provide access to their promising proprietary material(s)...” It also avoids the need for individual Federal Acquisition Regulations (FAR) deviations whenever a DEC is executed. The proposed patent rights clause allocates rights to subject inventions to the providers, although it allows contractors to request greater rights. It also provides contractors with normal Bayh-Dole rights to “Class 2 and 3” subject inventions as defined in the DEC (subject to a license to the provider for “Class 2” inventions). While not specified in the notice, this general framework previously has been used by NIH in DEC’s (e.g. CTEP program; Class 1 (A) inventions are those that use or incorporate the materials; Class 2 (B) inventions do not use or incorporate the materials but are conceived or first reduced to practice in studies utilizing the materials; Class 3 (C) inventions are a result of research utilizing the invention but outside of the scope of the agreement. See COGR May 2010 Recent Developments).

On the one hand the proposed clauses merely implement approved DEC's and do not change the DEC approval process. Background discussions with NIH indicate that they are intended for use in testing of proprietary materials largely by for-profit service providers, and not for research contracts with universities. (NIH also alleges that universities are among those reluctant to provide proprietary materials without these protections). On the other hand, the clauses seem to promote the notion of class DEC deviations. COGR has a long history of concern about use of DEC's, which in our view are supposed to be used in truly exceptional circumstances on a very limited individual basis.

Further concern is caused by the proposed Rights in Data—exceptional circumstances clause. While for the most part similar to FAR Rights in Data clause 52.227-14, it contains a significant publication restriction in (d)(4), allowing government contracting officers to delay public disclosures of data or publications for up to 6 months. While one would not expect many publications to result from contracts for testing services, such restrictions if applied to universities are potential “deal breakers.” The clause also requires approval of the contracting officer to assert copyright in all data other than journal articles (c)(1). Universities typically will accept only Alternate IV of the general FAR Rights in Data clause 52.227-14, which permits universities to assert copyright generally. (The clause also purports to cover computer software which might be potentially patentable, which also is an anomaly in the basic FAR clause). We plan to prepare a comment letter to NIH discussing our concerns. Comments are due on or before March 11.

### **Penn Plans Conference on Export Controls and Higher Education**

The University of Pennsylvania is planning to hold a conference on the Impacts of Export Controls on Higher Education and Scientific Institutions. The conference will be held March 26—27 at Penn. In addition to Department of Commerce representatives and other federal officials, members of the Commerce (PECSEA) and State (D-Tag) Advisory Committees will participate as well as university, national lab and industry representatives and legal experts. COGR, AAU and NAS or NSB representatives will participate in a panel dialogue on export controls and the scientific community. Given the ongoing export control reform initiative and other recent developments in export controls we expect this will be an important conference. The registration site is located at <https://regstg.com/Registration/Introduction.aspx?rid=5f8f37d0-deb4-48d7-b6ad-3c0c22e7375a>.

### **Final Rules on Micro Entity Patent Status May Not be Favorable to Universities**

We mentioned in the COGR Fall 2012 Update that COGR together with other higher ed. associations had submitted comments to the U.S. Patent and Trademark Office (USPTO) on the proposed rules (77*FedReg*31806) for the new micro entity patent status provided by the America Invents Act (AIA). In our comments we had noted two concerns; one involved ambiguity in the proposed rules over micro entity applicant eligibility when the patent applicant is an institution of higher education itself rather than the (faculty) inventor(s), and the other a question as to the eligibility of university foundations for micro entity status.

USPTO issued final rules implementing micro entity status on December 19, 2012 (77*FedReg*75019). Unfortunately the rules make it unlikely that universities will be able to avail themselves of this status with its 75% fee reduction. USPTO indicated that it believes the legislative history indicates the intent was to limit micro entity status to “a subset of small

entities, namely, “truly independent inventors.” It also indicated that the legislative history includes a reference to micro entities as inventors and not the assignees of inventors. Thus for establishing micro entity status under 35 U.S.C. 123(a), it appears applicants regardless of whether they are natural persons or other entities must meet the statutory limits on previous patent applications (no more than 4) and income (no more than 3 times the median household income for the preceding calendar year as reported by the Bureau of the Census). With regard to 123(d) eligibility which we had understood was supposed to include institutions of higher education as a separate category, the rules state that the statutory criteria “ordinarily would not be met by an institution of higher education that is itself an assignee—applicant.” Applicant institutions still are subject to the same limitations. Additionally, with regard to our suggestion to include university foundations as within the definition of eligible “institutions of higher education,” PTO states in the final rules that the AIA does not authorize USPTO to include other organizations within the definition of institutions of higher education in the statute (which is based on the Higher Education Act of 1965 Section 101(a)).

A subsequent discussion with a USPTO representative confirmed that the intent is to strictly limit eligibility for micro entity status. However, in our view this is inconsistent with the intent of 123(d) in the AIA as well as assurances we previously were given in discussions with USPTO. We also are aware that a number of university counsels do not share our interpretation. We previously had viewed the advantages of micro entity status to universities as probably more apparent than real (see COGR June 2012 [Meeting Report](#)). However, if our interpretation is correct, the effect of the final USPTO rules is to render 123(d) virtually meaningless. USPTO representatives will meet with the COGR CIP Committee in February to further discuss this issue as well other issues related to the March 16 implementation of the new “first inventor to file” patent system. We will keep the COGR membership informed.

### **USPTO Requests Comments on Possible Patent Small Claims Proceeding**

On December 18 USPTO asked for public comments on whether the U.S. should develop a small claims proceeding for patent enforcement (*77FedReg74830*). If such a need is determined to exist, the notice also asks what features this proceeding should possess. According to the notice, the concept has been discussed by various groups for over 20 years. COGR has been approached by patent practitioners about the idea.

The CIP Committee believes there could be pros and cons for universities with this concept. In any event the subject seems more appropriate for AUTM to address. The notice asks for comments on a long list of specifics to which COGR is not well-positioned to respond. We will follow up with AUTM. Comments are due March 18.

### **USPTO Holds Webinar on Genetic Diagnostic Testing**

As noted in the COGR 2012 Holiday [Update](#), the AIA (Sec. 27) mandated USPTO to conduct a study of ways to provide independent, confirming genetic test activity where gene patents and exclusive genetic test licenses exist. The legislation specified several factors for USPTO to consider and required a report to Congress within 9 months of enactment of the AIA.

The report was due last June. USPTO held two public hearings on the matter last year. In August USPTO notified Congress that given the complexity and diversity of the opinions, comments and suggestions provided in the previous hearings, an additional public roundtable was needed.

The roundtable was held on January 10, and was webcast. A great diversity of views again was expressed. We understand that USPTO had prepared a draft report some time ago that included a recommendation that agencies should more aggressively use Bayh-Dole march-in rights to address potential misuse of publicly funded patents in this area rather than imposing restrictions on patentable subject matter. Witnesses from NIST and NIH at the roundtable made strong statements against encouraging greater use of march-in. However, Professor Rai of Duke University Law School (formerly an administrator at USPTO) suggested that agencies should use march-in to “nudge” bad performers to “do the right thing.” Other witnesses mostly addressed medical and socioeconomic issues associated with genetic diagnostic tests. A final witness suggested USPTO should do nothing pending the Supreme Court decision in the *Myriad* case (see 2012 Holiday Update).

It is not clear what USPTO will make of this input. However, in our view the march-in option would set a very bad precedent. It also is not clear on what basis agencies would make determinations as to what constitutes bad behavior. We will continue to follow developments.

### **Final Amicus Brief to Supreme Court Submitted in *Bowman v. Monsanto***

We discussed this case in the December 2012 Update. COGR had decided against participating in an *amicus* brief filed by WARF joined by a number of higher ed. associations and universities. While the brief was not specifically submitted in support of Monsanto, in urging the Federal Circuit decision be affirmed it supports Monsanto’s position.

17 universities as well as AAU, APLU and AUTM joined WARF in the brief. The case involves infringement of patented self-replicating technologies, in this case through a farmer’s unauthorized planting of second generation soybean seeds. The brief argues that allowing first buyers to make identical copies without compensating the patent holder would impair the ability of universities to transfer and market such technologies.

A highly critical article in the Chronicle accuses the brief participants of “Standing Up for Big Ag” and undercutting their own researchers. It cites a brief submitted by two nonprofit organizations alleging that researchers at two universities were forced to abandon their research on similar seeds because the company insisted on the right to block publication of the results. The Chronicle article accuses the participating universities of putting money ahead of freedom of scientific inquiry. See <http://chronicle.com/blogs/bottomline/in-standing-up-for-big-ag-are-universities-undercutting-their-own-researchers/>

The case involves fundamental issues of patent law, namely whether the “patent exhaustion” doctrine should apply to these kinds of technologies. The USG also submitted an *amicus* brief in support of Monsanto’s position, on the grounds that the farmer’s activities constituted the making of newly infringing seed. As noted in the previous Update, we understand these concerns. However, we did not believe the case met our criteria for *amicus* participation, particularly the need for a high level of consensus in the university community and avoidance of negative public perceptions. Subsequent developments appear to confirm the soundness of this position and the COGR criteria.

## **Startup Act To Be Reintroduced in Congress**

We previously discussed the “Startup Act,” originally introduced by Senators Warner and Moran in December of 2011 with a “2.0” version (S. 3217) introduced last June (see COGR June 2012 [Meeting Report](#); the House counterpart (H.R. 58930) was introduced by Rep. Grimm (R.--NY). As we previously noted, there was much in the proposed legislation that COGR and the other higher ed. associations supported, including provisions on STEM immigration and favorable tax treatment for startups. However, we were concerned about certain provisions in Section 8 of the bills on Accelerating Commercialization of Taxpayer-Funded Research. The original version of the bill included a new “Collaborative Commercialization Grants” program, to be administered by the Department of Commerce. This program would have provided funding to research institutions that choose to allow their faculty to use university technology transfer programs other than those based at their home institutions to commercialize technologies they develop. The program would be funded by taxing the research budgets of other agencies.

In the 2.0 version, the grant programs in the original program were replaced with Commercialization Capacity Building grants and Commercialization Accelerator Grants. The bill indicates that the latter grants should be awarded “to support institutions of higher education pursuing initiatives that allow faculty to directly commercialize research in an effort to accelerate research breakthroughs.” As we noted, this language is vague and its meaning unclear.

We understand that a new version of the legislation is likely to be introduced prior to the COGR meeting, presumably by the same sponsors. While we have not seen the actual language, we understand that draft revisions retain these grant programs, and may continue to include problematic language.

The original Startup Act Sec. 8 provision was based on the faculty “free agency” concept originally proposed by the Kauffman Foundation. At the 2013 Kauffman State of Entrepreneurship luncheon held in Washington on February 5, Robert Litan, now Director of Research for Bloomberg Government (formerly Kauffman VP), in his concluding remarks delivered a ringing endorsement of the free agency concept in which he decried the “monopolistic” practices of university tech transfer offices. We strongly believe that allowing faculty to commercialize their own research results potentially would create significant issues for universities relating to conflict of interest and public accountability since federal research awards are made to the university and not the individual faculty members. Moreover, universities often work with faculty in supporting faculty startups which might not be the case under such a model. The concept is premised on beliefs about tech transfer offices that the data does not support, and which indicate a lack of understanding of their purpose and operations. We have repeatedly discussed these concerns with policymakers in the legislative and executive branches, and will continue to do so especially should the concept again find expression in the next version of the Startup Act.