

# COUNCIL ON GOVERNMENTAL RELATIONS

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TO: COGR Membership  
FROM: COGR Staff  
SUBJECT: October 2012 Update

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### Grants Reform and OMB Circular A-21 Update

COGR reported in the previous COGR Update (August 30, 2012) that we expected that the Office of Management and Budget (OMB) would release a proposed new Circular soon after the Labor Day weekend. September came and went without the release of a proposed new Circular.

In a September 17<sup>th</sup> note to the COGR ListServe, we shared that COGR was informed that it would be 4 to 8 weeks before a proposed new Circular would be available to the public. In effect, the 4 to 8 weeks computes to anytime between October 15<sup>th</sup> and November 12<sup>th</sup> – i.e., before or after the Election. We can only speculate on the exact reason for the hold up and will share more as we get further confirmations. While we have been told off-the-record that a proposed new Circular would be favorable to our community, we will have to wait to see what the final version looks like.

If a proposed new Circular is released before the October 25-26 COGR Meeting, we will have a Thursday morning session to review and discuss the changes. In the August 30 - COGR Update, we shared some of our perspectives in terms of substance (i.e., what might be included), the

process that OMB would follow (e.g., 60-day public comment period), and the COGR strategy to craft a thoughtful response. Those perspectives still stand – however, at this stage, it is a waiting game. We are paying close attention to all developments and will keep the membership posted.

### **Reducing Regulatory Burden and a Request for a New GAO Review**

As we await breaking news on the release of a proposed new Circular, it is important to note other actions that have potential to be helpful to the research community. In what could be a positive initiative, Rep. Mo Brooks (R-AL), chairman of the House Research and Science Education Subcommittee, has asked the U.S. Government Accountability Office (GAO) to review regulatory actions that hinder our nation’s research universities.

Rep. Brooks asked the GAO to address three questions: 1) What federal requirements, not limited to legislative mandates, reporting requirements and regulations, create reporting burdens for research universities?, and 2) How do research university requirements under OMB Circulars A-21, A-133 and Federal Acquisition Regulation (FAR) 4.703 balance regulatory burden with accountability for federal funds?, and 3) What are the potential benefits and disadvantages of modifying requirements, including those that experts and universities have identified as most burdensome? 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)

COGR has worked with our colleagues at AAU and APLU over the past few months to share information with Rep. Brooks’ staff and to provide materials addressing regulatory burdens. Specifically, we have 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 the letter to the GAO. We expect at some point, as in past GAO reviews, the GAO staff will contact COGR for further information and discussion.

### **NIH Funding Policy Under the Continuing Resolution (CR)**

As has become typical when the Federal Government operates under a CR, the NIH has posted its funding policy under the CR. In an October 11, 2012 Notice (NOT-OD-13-002), NIH announced:

*... NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). This is consistent with our practice during the CRs of FY 2006 - 2012. Upward adjustments to awarded levels will be considered after our FY 2013 appropriations are enacted but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2012 remain in effect under the CR, including the salary limitation set at Executive Level II of the Federal Pay Scale (\$179,700), which was effective with grant awards with an initial Issue Date on or after December 23, 2011 ...*

The NIH Notice (NOT-OD-13-002) is available at:

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

## **The Federal Budget and Sequestration**

COGR institutions are starting to ask the question: “how should we prepare for the possible sequestration and severe cuts in federal research funding?” While many of those answers should come from the Administration (via the Office of Management and Budget) or from the federal agencies themselves (e.g., HHS-NIH, NSF, etc.), Federal Government officials most likely will not provide any guidance until sequestration appears to be unavoidable.

Sequestration – large, automatic cuts in federal spending – was established in the Budget Control Act (BCA) of 2011. Under the BCA, a six-member bi-partisan congressional “deficit cutting” committee was established to develop a plan to cut \$1.5 trillion from the federal deficit over the next decade. The BCA was designed to make “failure” by the six-member committee unacceptable to all parties – i.e., the consequences of sequestration would essentially have a “poison pill” for everyone. If a plan was not agreed to, this would trigger automatic cuts to defense and non-defense discretionary spending (entitlement programs, like Social Security, would be excluded from cuts). The six-member committee failed, and Sequestration is scheduled to go into effect on January 2, 2013.

If Sequestration goes into effect, the impacts would be severe. For FY2013 alone, the cuts would amount to \$55 billion in defense spending and \$38 billion in non-defense discretionary spending. Research funding, as part of the Federal Government’s non-defense discretionary spending, would suffer. In one scenario that describes how Sequestration would be implemented, the NIH could lose close to \$2.5 billion (or over 8%) of its \$30 billion budget. For additional analysis and details at the federal agency level, the American Association for the Advancement of Science (AAAS) provides helpful insights at: <http://www.aaas.org/spp/rd/>

To add to the confusing federal budget scenario is the fact that Congress recently passed a Continuing Resolution (CR), which became effective October 1<sup>st</sup>, and which funds the Federal Government through March 27, 2013. The CR has become the standard practice for temporarily funding the Federal Government, in lieu of Congress passing timely Appropriations bills. The CR puts the government on a pace to spend \$1.047 trillion in defense and non-defense discretionary spending in FY2013, the same level agreed to in the BCA of 2011. HOWEVER, Sequestration would trump the CR – the CR would stay in effect, but the automatic cuts triggered by Sequestration (\$55 billion in defense spending and \$38 billion in non-defense discretionary spending) would be applied to the \$1.047 trillion authorized under the CR.

In order for Sequestration to be averted, Congress will have to act in the lame duck session after the Election. Regardless of the Presidential Election results, President Obama will be in office during the lame duck session, and the Congress and the President will need to agree on a solution, prior to the trigger date of January 2, 2013. Some believe it is likely for Congress and the President to act in order to avoid what could be an economically devastating “fiscal cliff” – spending cuts triggered by Sequestration in combination with tax increases prompted by the end of the Bush-era tax cuts.

However, there is no certainty of what lies ahead and how Sequestration might be averted. As everyone pays close attention to the messages both leading up to the Election and those that immediately follow, this may provide clues to if and how we should prepare for Sequestration.

## Thursday Afternoon Session: The NRC Report on Research Universities – Now the Challenging Questions

Dr. Teresa Sullivan, President of the University of Virginia, Dr. James Duderstadt, President Emeritus from the University of Michigan, and Dr. Ron Ehrenberg, the Director of CHERI at Cornell University, will represent the National Research Council (NRC) Committee on Research Universities in a panel discussion in one of the Thursday afternoon sessions at the upcoming COGR Meeting. Also participating on the panel will be Dr. Brad Fenwick from the University of Tennessee.

COGR first engaged with the NRC Committee on Research Universities in late 2010. In January 2011, the Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU), and COGR wrote a joint letter to the NRC Committee and provided ten recommendations that addressed “Regulatory and Financial Reform of Federal Research Policy.” The COGR-AAU-APLU letter from January 2011 can be found at [www.cogr.edu](http://www.cogr.edu) under Educational Materials | Financial Management (see the sixth document listed).

In June 2012, the NRC Committee on Research Universities released their report: *Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Nation's Prosperity and Security*. The report was made available to the public on June 14<sup>th</sup>. The Full Report and the Summary version are available at:

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

Dr. Fenwick was asked to join the panel because of the potential synergy that his work creates. He is the author of the recently released Phase I report: *The Current Health and Future Well-Being of the American Research University*. The Phase II report, currently being developed, will address solutions and may dovetail with recommendations made in the NRC report. The Phase I report is available at: <http://www.researchuniversitiesfutures.org/>

Of the NRC's ten recommendations, four are of particular interest to the COGR Membership and two of these (Recommendations 6 and 7) were advocated by COGR to the NRC Committee:

- Recommendation 3. Strengthening Partnerships with Business
- Recommendation 4. Improving University Productivity
- Recommendation 6. Full Federal Funding of Research
- Recommendation 7. Reducing Regulatory Burdens

The panel will address the NRC's recommendations that are of most interest to the COGR membership. Some of the questions that could be raised include:

- How would faculty react to a short-term cost shifting from direct to indirect costs under a flat (or reduced) federal budget scenario?
- Is improving efficiency realistic when regulatory burden continues to grow, agencies demand more reporting and transparency, and after we already have spent the past decade cutting costs and eliminating administrative positions?
- How forthcoming can we be, especially public institutions, about addressing the significant federal subsidy we contribute to federally-sponsored research and the role tuition and other revenue sources may play under this dynamic?

- How can we strengthen partnerships with business when we are scrutinized for inappropriate financial conflicts of interest, and at the same time, accused by industry of being inflexible on access to intellectual property rights?

Over the course of the next year, NRC Committee members will be meeting with stakeholders across the country to seek further input and advocate for implementation of the recommendations. Some of the discussions that ensue from the panel discussion at the COGR Meeting could be helpful to the NRC Committee members as they engage with other stakeholders.

### **Audit Update - OIG Workplans and Other Developments**

Inspectors General offices release their annual audit workplans at this time of the year. At the same time, COGR schedules annual meetings with several of the Office of Inspectors General (OIG) to discuss their workplans and gain additional insights. We are scheduled to meet with staff from the HHS OIG and the NSF OIG in two separate meetings prior to the October COGR Meeting. We will share perspectives from these meetings at the upcoming COGR Meeting and provide more details in the next COGR Update.

The HHS OIG Workplan for FY2013 is available at the link below. Part V – Public Health, includes audit initiatives specific to NIH. While the published Workplan is a helpful overview of the areas in which the HHS OIG considers could be high-risk, it is important to note that it is a general blueprint only. The Workplan will expand and contract as the HHS OIG does ongoing risk assessment, reacts to Congress, and determines where to best direct its limited resources.

<https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf>

The NSF OIG Workplan for FY2013 is not yet available. Normally, their Workplan is released in November. We will keep the membership posted on developments related to the release of the NSF OIG Workplan.

The published Workplans and any discussions that COGR has with OIG staff should piggyback on a number of topics that already are of interest. Below are those topics that are either new developments or items we have reported on in the past and continue to follow.

**NSF OIG and Data Analytics** - We are aware of several COGR member institutions that are engaged in audits premised on a new audit approach that the NSF OIG describes as “data analytics.” COGR shared this with the membership in COGR Updates late last year after we met with NSF OIG staff. Under this approach, the NSF OIG asks institutions for an electronic version of the General Ledger, specifically, NSF funds and accounts. Based on various analytical techniques, auditors look for indicators that suggest audit risk or need for additional information. Our initial understanding was that between 10 and 20 institutions would be audited in FY2012 using the new methodology.

Some institutions have raised concerns to COGR with the new audit approach, both in terms of substance (e.g., relevance of the issues raised by the auditors) and process (e.g., unclear protocols for providing responses to findings). We are exploring ways in which COGR can best be engaged in addressing these concerns.

**HHS OIG and Equipment Reviews** - One of the new items in the HHS OIG Workplan for FY2013 is a review of NIH grantee claims associated with equipment purchases. The HHS OIG recently posted an audit report specific to this audit initiative. There were no findings in this particular audit, though institutions may want to review the audit report to gain insight into this HHS OIG audit initiative. The audit report can be found at:

<https://oig.hhs.gov/oas/reports/region5/51200074.asp>

**HHS OIG Administrative and Clerical Audit, \$2.9 Million Finding** - The previous COGR Update (August 30, 2012) included a commentary on the history of the HHS OIG audit program, *College and University Indirect Costs Claimed as Direct Costs*. Also included in the COGR Update was a summary of the most recent report, posted by the HHS OIG on July 19, 2012. In that audit, the HHS OIG recommended that the University “*refund \$2,977,548 to the Federal Government*” and “*enhance oversight of charges to Federal awards to ensure consistent compliance with Federal regulations.*”

The issues raised in the audit report are broad. The audit report opens up discussions on the use of job titles and the actual duties and activities associated with a job title; allowable activities for direct charging; consistency of effort reporting with what has been directly charged; the functional use of space in a lab and its correlation to which awards are charged; composition of recharge and specialized service facility rates; graduate student compensation and compliance with NIH limitations; allocability and reasonableness decisions and methodologies utilized by the institution; and the appropriate level of central oversight and review of direct charging practices and the corresponding documentation required.

In the audit report, the University objections are noted, including objections to the HHS OIG methodology for extrapolating results and to the HHS OIG conclusion that the University has weaknesses in its internal controls. The HHS OIG recommendations are not final. An official from the HHS Division of Audit Resolution, Office of Grant and Acquisition Management, is responsible for making final determination on the HHS OIG recommendations. Go to <https://oig.hhs.gov/oas/reports/region4/41101095.asp> for the HHS OIG audit report.

One observation by COGR is that the significant cost disallowances and recommended refunds throughout the history of this HHS OIG initiative primarily have been associated with HHS Region 4 – this region covers Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. As appropriate, we will attempt to learn more about the status of the Administrative and Clerical audit program during our meeting with HHS OIG staff.

**2012 A-133 Compliance Supplement.** This was released in July. COGR was successful in its request to OMB to eliminate a clause in the Compliance Supplement that would have required all NSF awards to be reported in the R&D cluster (also see update in next section). The 2012 A-133 Compliance Supplement is posted at:

[http://www.whitehouse.gov/omb/circulars/a133\\_compliance\\_supplement\\_2012](http://www.whitehouse.gov/omb/circulars/a133_compliance_supplement_2012)

COGR regularly checks the HHS (NIH) and NSF Office of Inspectors General (OIG) websites (see links below).

<https://oig.hhs.gov/reports-and-publications/oas/nih.asp>

<http://www.nsf.gov/oig/auditpubs.jsp>

We also 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.

### **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 2012 A-133 Compliance Supplement and the NSF PAPPG** - The 2012 A-133 Compliance Supplement, prior to its release, had a clause that 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, despite COGR objections to the same clause being included in the draft version of the 2012 NSF Proposal and Award Policies and Procedures Guide (PAPPG), the final version of the 2012 NSF PAPPG included the clause. COGR's position is that there are examples of programs within each NSF directorate where an R&D classification is inappropriate. For Financial Statement reporting, F&A rate development, and classification on the SEFA, selected programs may more appropriately be considered instructional/educational/ other sponsored activities and not R&D. If institutions are required to make a classification on the SEFA that they believe is incorrect, they effectively are being asked to compromise their accounting practices. COGR will continue to pursue this issue and keep the membership updated.

**SWAP Agreements are Determined by OMB and ONR to be Allowable** - We included a detailed update on this topic in the previous COGR Update (August 30, 2012). In summary, the Office of Naval Research (ONR) and the Defense Contracting and Audit Agency (DCAA) had disallowed interest expense in the F&A rate for at least three institutions based on what they considered inappropriate debt financing arrangements. COGR and the institutions involved argued that the financing arrangements in question (SWAP agreements) are legitimate financing arrangements, result in significant cost savings, and are not disallowed according to current OMB policy. After providing documentation to OMB and ONR and participating in a conference call that included four COGR member institutions, COGR, and representatives from OMB, the Department of the Treasury, and ONR, ONR reconsidered its position concerning SWAP agreements. OMB concurred and interest expense associated with SWAP agreements has been determined to be allowable.

**NSF Survey on R&D Expenditures – FY2010 Results and Changes for the FY2012 Survey** - The National Science Foundation, National Center for Science and Engineering Statistics (NCSES), recently released results from the FY2010 Higher Education Research and Development (HERD) Survey. The FY2010 report represents the first year of the new survey format and includes new data points such as expenditures funded by Nonprofit

organizations and a more detailed breakdown on Institutional Funded expenditures (i.e., unrecovered indirect costs, cost sharing, and internal research projects). The report can be found at: <http://www.nsf.gov/statistics/infbrief/nsf12313/>

Changes to the FY2012 Survey are focused on fine-tuning definitions for Institutional Funded research (e.g., internal awards, start-ups, bridge, seed, tuition assistance). Using the FY2012 Survey as the vehicle, NCSSES staff is attempting to better understand inconsistencies in how Institutional Funded research is reported. It may behoove COGR and the research community to better understand who at your institution collects and reports this data, what is included, and why some institutions report unusually low numbers in comparison to other institutions. We will follow up with your institutions, as appropriate.

**NSF Award Cash Management System (ACM\$)** - The new system initially was to go live in January, 2013. The date has been pushed back to April, 2013. Staff from the NSF Division of Financial Management have been active in their communications to the research community, and will continue to provide updates to the community.

**OMB Grant Reporting Information Project (GRIP)** - This OMB initiative, described by some as “ARRA reporting for all Federal funds,” is a new OMB initiative currently in “pilot” stage. The pilot includes several Federal agencies and grant recipient institutions. Some COGR institutions will be involved in the pilot. The COGR Costing Committee is scheduled to meet with Federal officials who are involved with GRIP at the Costing Committee’s Wednesday, October 24<sup>th</sup> meeting. We will share what we learn with the COGR membership during the Committee Reports on Friday morning of the COGR Meeting

### **New FAR Rule Proposed on Basic Safeguarding of Contractor Information Systems**

On August 24 a proposed new FAR rule on Basic Safeguarding of Contractor Information Systems was published (<http://www.gpo.gov/fdsys/pkg/FR-2012-08-24/pdf/2012-20881.pdf>). The proposed rule cites the Advance Notice of Proposed Rulemaking (ANPR) proposed by DOD on March 3, 2010 (75FR9563) for the DFARS (Case 2008-D028, “Safeguarding Unclassified Information”). COGR and AAU extensively commented on the proposed DFARS rule (see COGR April 2010 Update and May 2010 Recent Developments), which was never implemented. The FAR Notice states that public comments on the proposed DFARS were considered in drafting the proposed FAR rule.

The proposed rule sets forth requirements for the basic safeguarding of contractor information systems that contain or process information provided by or generated for the Government. It partly extends the Federal Information Security Management Act (FISMA) requirements that address information security for information and information systems that support the operations and assets of federal agencies (including those managed by contractors). The FISMA focus differs from the previous proposed DFARS rule. That rule proposed to amend the DFARS 252.204—7000 clause to protect unclassified DOD information not cleared for public release that was provided by DOD to contractors or collected, developed, received, transmitted, used or stored by contractors in support of a DOD activity. However, the Basic Safeguarding requirements in the proposed FAR rule are virtually identical to the basic safeguarding of unclassified DOD information requirements in the DFARS rule previously proposed.

The previous proposed DFARS rule exempted fundamental research contracts, unless the contract required access to or generation of DOD information to perform the fundamental research. However, in our comments we expressed concern that this language was ambiguous, and would lead to indiscriminate application of the expanded 7000 clause by DOD to university research contracts. We also expressed concerns about the vagueness of certain terms used in the ANPR, and the costs and burdens to contractors, particularly of the requirements at the “enhanced safeguarding” level that the ANPR set forth (the proposed FAR rule does not include enhanced safeguarding requirements).

The proposed FAR rule applies to all contracts (including those for commercial off-the-shelf items), and does not contain an exception for fundamental research. It also contains some of the same vague terms (e.g. “best level of security available”) that we objected to in the DOD ANPR. Most COGR member institutions have at least first level information technology security measures in place within the systems that they normally use for storing and processing data that require protection which may meet most of the Basic Safeguarding requirements. However, we are concerned about the broad potential scope of the information subject to these requirements. The experience of our member institutions over the past 10 years is that individual agencies have tended to broadly expand FISMA requirements to information developed under federal contracts regardless of whether the information is a deliverable under the contract or otherwise collected directly on behalf of the agency. Examples include data exchanged among researchers generated under a federal contract that is not required by the contract or a contract deliverable. This issue has been discussed in sessions as a number of COGR meetings over the past several years. Obviously affording such a broad scope to the requirements significantly increases the compliance burden for contractors. For example, in the case of our member institutions, desktop or personal electronic devices that individual researchers use under a covered contract would have to be inventoried and assessed to ensure that they are utilizing the appropriate FISMA-compliant technologies.

We expect to submit comments on the proposed FAR rule jointly with AAU expressing concerns about the costs and burdens. One suggestion might be to limit the scope of the clause by changing the phrase “generated for” to “delivered to.” Alternatively, the definitions in the proposed rule could be expanded to include a definition of “generated for” which makes clear that the information must be a deliverable under the contract and/or a contract requirement. This would help limit the applicability of the proposed FAR rule to incidental data that might be developed under the contract but not generated directly on behalf of the agency. We also will suggest that contracts for fundamental research be exempted except in unusual circumstances, as in the DFARS rule previously proposed.

In addition, while not a matter for comment at this time, the proposed FAR rule references ongoing efforts by the National Archives and Records Administration in the implementation of Executive Order 13556 “Controlled Unclassified Information” (75FR68675; 11/9/10). It indicates that the requirements may be altered as necessary to align with any future direction arising from those efforts. We also are concerned that the expanded DOD 7000 clause may resurface at some point. We need to pay continued attention to these issues.

We are still considering possible comments and discussing the proposed rule with other interested organizations. Comments are due October 23.

## **Patent Reform**

### **1. COGR Joins Other Associations in Comments on Proposed Implementation of “First Inventor to File”**

The COGR Fall 2012 Update discussed the proposed rules published by the U.S. Patent and Trademark Office (PTO) on July 26 (77FR43742) to implement the conversion of the U.S. patent system from “first to invent” to “first inventor to file,” pursuant to the America Invents Act (AIA). We noted a potential major issue for universities in the proposed Examination Guidelines (77FR43759). In order for the one-year grace period for public disclosures in the AIA to apply (102(b)(1)(B) and (2)(B)), the proposed rules state that the subject matter disclosed must be identical. Insubstantial changes or obvious variations to the subject matter disclosed are not covered by the grace period (and thus do not fall within the shield provided by the grace period prior art exception). This essentially guts the grace period for scientific publications that the higher ed. associations fought hard to maintain throughout the patent reform process.

COGR joined the six other higher ed. associations that have worked together on patent reform in comments to PTO on the proposed rules on October 5. In our comments we strongly objected to the narrowing of the grace period. We expressed the view that the language in the proposed Examination Guidelines was a gratuitous and unwarranted extrapolation of the statutory language, which constituted substantive rulemaking beyond PTO’s authority. We noted that we would not have supported the AIA had this interpretation been advanced during the patent reform process, and that PTO’s interpretation appeared inconsistent with the legislative history. The language in the Examination Guidelines seems almost to invite someone who finds the disclosed invention problematic to copy the disclosure in a scientific publication, introduce a “mere insubstantial change” or “trivial or obvious variant” and publish the resultant product, perhaps just on a website, to establish patent-defeating prior art under 102(a) of the AIA. This eviscerates the clear intention of the grace period to encourage early publication consistent with the mission of universities to broadly disseminate new knowledge. We suggested alternative language that would interpret the (ambiguous) AIA grace period language in a way that maintains an effective grace period for academic publications.

Another major concern discussed in our comments was the proposed treatment of authorship of grace period disclosures. The Examination Guidelines appear to adopt a default position that a publication having more authors than the subsequent patent application has inventors will be categorically rejected by PTO as being a grace period inventor disclosure, leading to a rejection of the patent application. To overrule such a rejection would require an “unequivocal” statement from inventors and an absence of any evidence to the contrary. We pointed out that the rules for authorship of scholarly publications are different from rules for determining inventorship under patent law. Publications often feature multiple authors, not all of whom necessarily are inventors for purposes of subsequent patent applications. We suggested the default position should shift, allowing an inventor affidavit at the time of application to affirm a grace period disclosure and to be reversed only by subsequent irrefutable evidence. This procedure would accord Office procedures with the realities of academic publishing and the intent of the grace period. It also is more consistent with the basic premise in AIA 102(a) that a person is entitled to a patent unless PTO can demonstrate that the applicant(s) did not meet the statutory requirements.

We do not know why PTO adopted the narrow grace period interpretation or the stringent view of authors vs. inventors in the proposed Guidelines. There has been some speculation that PTO is seeking to obtain strong feedback from the academic community as to the importance of the grace period. In any event, a copy of our comments has been posted to the COGR website.

## **2. COGR Elects Not to Comment on Proposed New Patent Fee Schedule**

On September 6 PTO proposed a new patent fee schedule, implementing its new fee-setting authority under the AIA (77FR55028). The proposed schedule sets or adjusts 352 patent fees. According to the notice, the proposed fee schedule seeks to balance PTO's aggregate revenue and costs. It seeks to provide sufficient revenues to implement a sustainable funding model for PTO operations and optimize patent timeliness and quality. It also sets fees to further three key policy goals: fostering innovation, facilitating effective administration of the patent system, and offering patent prosecution options to applicants. It cites the PTO's 2010-2015 Strategic Plan and the Administration's *Strategy for American Innovation* (<http://www.whitehouse.gov/innovation/strategy>).

The COGR CIP Committee discussed the proposed fee schedule. While most fees are increasing, it was noted that with the new microentity status (see Fall Update) the effects on universities will be relatively small (and those nonprofit organizations not eligible for microentity status can still file as small entities). The committee agreed that there was no need for COGR to comment on the proposed fees. (Note: PTO has not yet responded to our comments on microentity status eligibility that we submitted in July and are summarized in the Update). Comments are due November 5 if COGR member institutions wish to consider submitting individual comments.

## **3. Other AIA Implementing Rules**

The Fall Update mentioned that on August 14 PTO published a series of other final implementing rules for the AIA (77FedReg48612), including changes to implement *inter partes* and post-grant review, the inventor's oath or declaration and supplemental examination provisions, the transitional program for business method patents, and trial rules of practice. The new rules were effective September 16. We elected not to comment on these rules when proposed last February (see COGR Spring 2012 Update). After discussion with the other higher ed. associations, we also decided not to comment on the final rules.

## **Myriad Gene Patent Case Heads Back to the Supreme Court**

The Fall Update noted that in August the Federal Circuit Court of Appeals affirmed its previous holding in the case of *AMP et.al. v. Myriad Genetics, et.al.* The case had been remanded by the Supreme Court back to the Federal Circuit for reconsideration in light of the Supreme Court's decision in *Mayo v. Prometheus*. The Federal Circuit again split 2—1, with the majority opinion holding that the case solely involved whether the claims to isolated BRCA DNA were patent eligible. In the majority's view, "creating a new chemical entity is the work of human transformation, requiring skill, knowledge, and effort" and thus meets the criteria for patent eligibility. The opinion also noted that finding the isolated DNA molecules ineligible for patents would upend "the settled expectations of the inventing and investing communities," as well as long-established PTO practices.

The plaintiffs again have appealed to the Supreme Court, arguing that the Federal Circuit did not correctly apply *Mayo v. Prometheus* and other precedents. In their view patenting human genes, even in isolated form, allows corporations to control DNA occurring naturally in the human body. If it takes the appeal, the Supreme Court could determine ultimately both the validity of gene patenting and patenting of diagnostic claims based on isolated DNA. While COGR has declined to participate in any *amicus* in the case, as discussed in many previous Meeting Reports and Updates, we will continue to follow and report on developments.

### **White House/Commerce Co-Host Entrepreneurial University Event**

The Fall Update mentioned the plans to hold an event following on the commitments made by university presidents to promote innovation and entrepreneurship under the auspices of the Commerce Secretary's National Advisory Council on Innovation and Entrepreneurship (NACIE). Commerce and the White House jointly hosted the event on October 1. It was entitled "The Innovative and Entrepreneurial University: Higher Education, Innovation and Entrepreneurship in Focus."

The morning session hosted by Commerce featured panels on "Student and Faculty Innovation and Entrepreneurship," "University Technology Transfer and Industry Collaboration," and "Universities and Regional Economic Development." The afternoon session hosted by the White House included panels on "The Next Phase of University-Driven Innovation and Entrepreneurship," and "The Future of American Innovation and the University." The most senior Administration official present was Acting Commerce Secretary Rebecca Blank.

COGR was not invited to participate. However, reports from participants indicate there was little opportunity for feedback or interaction during the sessions. The event does demonstrate the strong focus of the current Administration on encouraging universities to promote innovation and entrepreneurship.

### **CDC/APHIS Revise Select Agent/Toxin Regulation - Workshop Registration by October 16**

The Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) and the US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) published the final biennial review and revised rules concerning the *Possession, Use and Transfer of Select Agents and Toxins*. Separate but coordinated notices appeared in the October 5, 2012 *Federal Register* (77FR61084, HHS/CDC; 77FR61056, USDA/APHIS). The rules have staggered effective date – certain provisions are effective December 4, 2012; the remaining provisions are effective April 3, 2013. Institutions using select agents and toxins will want to review the provisions to ensure compliance as required.

CDC and APHIS have implemented a tiered listing of select agents and toxins (SAT) designating 11 SAT as Tier 1 agents requiring enhanced security measures. This change in the SAT list responds to comments collected from the public in December 2011 and the recommendations included in the of the Federal Experts Security Advisory Panel (FESAP) report, *Recommendations Concerning the Select Agent Program* (November 2, 2010, Revised December 20, 2010 and January 10, 2011, Foreword added June 13, 2011). In addition to the 11 Tier 1 SAT, 3 agents have been added to the list and 13 removed or excluded from the regulations. The scientists on your campuses will be in a stronger position to offer observations on the changes to

the SAT list. COGR focused its comment on the proposed rule to the changes to the administrative regulatory requirements proposed by CDC/APHIS.

**SAT Workshop Registration Required by October 16, 2012** - The Federal Select Agent Program will broadcast webcast-only workshop on Friday, November 16th from 9:00 AM to 5:00 PM that will cover the changes to the select agent regulations, occupational health, information and physical security, personnel suitability, Bioterrorism Security Risk Assessment Form (FD-961 form), and changes to the Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1). **YOU MUST REGISTER BY OCTOBER 16 TO PARTICIPATE.** Information and registration links for the workshop are available at: <http://www.selectagents.gov/>.

In its comment on the proposed rules, COGR expressed its disappointment that the establishment of the Tier 1 SAT with related enhanced security requirements did not include a similar tiering of the remaining SAT on the list to allow for a truly risk-based security matrix for all agents. The rules, as proposed by CDC/APHIS, heightened security across the entire SAT list. For example, we called for the removal of a new section that expanded the documentation and reporting associated with transfers of excluded levels of SAT. We did not prevail in that argument. CDC/APHIS require that a registered individual or entity exercise and document due diligence in affirming that a potential recipient has a legitimate need for a toxin of a type or in an amount that is excluded under the provisions of 73.3(d)(i). New reporting is required if an entity detects a known or suspected violation of Federal law or becomes aware of suspicious activity related to the transfer.

We expressed deep reservations concerning the definition of a “restricted person” proposed by CDC/APHIS and are pleased that the definition is excluded from the final rule. We questioned the proposed requirement that the responsible official must “have their principal duty station at the physical location of the entity” [73.9(a)(6)] to ensure compliance and a quick response to incidents. The final rule requires the official to have a physical presence at the registered entity but, in the commentary accompanying the final rules, CDC/APHIS acknowledge that on campuses with several registered laboratories it would be “counterproductive” to have different responsible officials assigned to each laboratory. The co-location requirement is tempered in the commentary by noting that the responsible official be able to respond “in a timely manner” to incidents on campus.

The proposed training requirement for the responsible official was not implemented in the final rule but the security risk assessment required of all individuals with access to SAT will only be valid for three years, reduced from five. The assessment will need to be renewed in a narrower window.

Additional changes to the security requirements including information security are included in the final rule as well. The requirements addressing the security plan retain a suitability assessment for personnel that requires procedures that limit access to Tier 1 SAT to those individuals that have undergone the Federal security risk assessment, receive an institutional (entity) pre-access suitability assessment and are subject to the institution’s ongoing suitability assessment. CDC/APHIS elected to broadly state the requirement to provide flexibility to the regulated entities and promise additional guidance (to be posted to <http://www.selectagents.gov/index.html>).

CDC/APHIS pledge to provide updates to the guidance (FAQs) on the National Select Agent Registry website to assist the community in implementing the revised rules (at: <http://www.selectagents.gov/>). Institutions engaged in SAT research must review the changes and ensure they continue to maintain compliance with the new regulations.

### **National Institutes of Health's New Grants Policy Statement**

The National Institutes of Health (NIH) published a revised NIH *Grants Policy Statement* (NIHGPS, rev. 10/1/2012) applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2012 as a standard term and condition of award.

This revision does not introduce any new material for the first time. Rather, it incorporates requirements, clarifies policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the NIHGPS dated 10/1/2011. Most have been announced in the NIH Guide. The document is available at: ([http://grants.nih.gov/grants/policy/nihgps\\_2012/index.htm](http://grants.nih.gov/grants/policy/nihgps_2012/index.htm)) and a summary of the significant changes that are available at: [[http://grants.nih.gov/grants/policy/nihgps\\_2012/Significant\\_Changes\\_NIHGPS\\_2012.doc](http://grants.nih.gov/grants/policy/nihgps_2012/Significant_Changes_NIHGPS_2012.doc) ]

### **National Institutes of Health Proactive FCOI Compliance Oversight**

On September, 21, 2012, NIH's Division of Grants Compliance and Oversight announced a Proactive Financial Conflict of Interest (FCOI) Compliance Program to assess institutional implementation and compliance with the 2011 Revised Federal FCOI regulatory requirements (NOT-OD-12-159). Institutions were required to be in compliance with the regulatory requirements no later than August 24, 2012. The Proactive FCOI Compliance Oversight Program (FCOI Compliance Program) will assess grantee compliance with FCOI requirements and assist grantees in fully implementing their FCOI policies by providing assistance in the form of constructive feedback.

The announced initial phase will build on a review and evaluation of the publicly accessible FCOI policies (required by the regulations) for a sample of NIH grantee institutions. The names of the sampled institutions will remain confidential. If deficient areas are noted by NIH, institutions will be notified and expected to formally address and resolve all identified issues. As with other such proactive initiatives, NIH will share the results of its review to assist other institutions in achieving compliance.

### **National Institutes of Health FCOI and Travel**

COGR has expressed its concern to NIH with NIH's Frequently Asked Questions (FAQs) that define the scope and applicability of the regulations with regard to disclosures of reimbursed and sponsored travel. As the community is aware, the PHS regulatory definition of "significant financial interest" includes reimbursed and/or sponsored travel, thus requiring disclosure by investigators. The FAQs address disclosure and the subsequent review and determination in several places.

The current FAQs E.1 requires disclosure by investigators of reimbursed and sponsored travel for the preceding twelve months. COGR challenged the FAQ asserting that, unlike Section (1)

of §50.603 Definitions “Significant Financial Interest” which sets parameters for time (i.e., “the twelve months preceding, or “upon receipt of income”) for disclosure for remuneration, Section (2) concerning reimbursed and sponsored travel does not include a timeframe for identifying significant travel. We argued that the disclosure requirement is contemporaneous, i.e., travel must be reported if it occurs while the regulation is applicable to that investigator (e.g., when an application is submitted), and no later than 30 days after its “acquisition.” It seemed to modify the regulations. We recommended that FAQ E.1. be modified by deleting the section – “(1) Investigators who are planning to participate in PHS-funded research must disclose their SFIs over the previous twelve-month period to their Institution no later than at the time of application for PHS-funded research.”

In a August 23, 2012 response to COGR’s request, NIH upheld its position arguing “ FAQ E.1.states NIH’s policy determination with respect to the requirement found in 42 CFR 50.603(2) of the 2011 revised financial conflict of interest regulation, consistent with the requirements of the Significant Financial Interests found in 42 CFR 50.603(1). ... Further, it is important to note that this disclosure requirement applies to the Investigator’s spouse and dependent children.”

Subsequent to this communications, NIH added a new FAQ, FAQ E.31, which restates and reinforces the requirement for disclosure of reimbursed and sponsored travel for the preceding twelve months. FAQ 31 was posted to the website on August 24, 2012. It is notably that the inclusion of travel by an investigator’s spouse and dependent children was not included in the new FAQ.

COGR asked for a reconsideration given our belief that NIH’s determination has resulted in a regulatory change contrary to good guidance practice as directed by the Office of Management and Budget in its bulletin *Agency Good Guidance Practices* (published in the *Federal Register* on January 25, 2007, 72FR3432). OMB makes clear that guidance documents such as FAQs may not impose a legally binding requirement – guidance cannot change or make regulation. Guidance can explain how an agency believes a regulation applies but, because of guidance’s legally nonbinding nature, guidance should not include words like “shall,” “must,” or “required.” We will keep the membership informed of the progress of our discussions.

### **National Science Foundation’s New PAPPG**

The National Science Foundation (NSF) issued the revised Proposal and Award Policies and Procedures Guide (PAPPG, available at: [http://www.nsf.gov/pubs/policydocs/pappguide/nsf13001/nsf13\\_1.pdf](http://www.nsf.gov/pubs/policydocs/pappguide/nsf13001/nsf13_1.pdf). As we noted in an email to the membership on October 4, Jean Feldman will be at the COGR meeting on Thursday, October 25 at 10:00 AM to describe and discuss the changes to the PAPPG. We encourage you to review the Guide and come to the meeting with your questions. The new version of the PAPPG, effective for proposals submitted, or due, on or after January 14, 2013.

NSF sought comments from the community on the planned revisions and COGR responded in a letter in July 2012. As we reported to the membership in the June COGR Meeting Report, one of the principal areas of change to the PAPPG is the incorporation of the National Science Board’s (NSB) recommendations concerning merit review. In addition to the revisions related to merit review, NSF addressed the consistent application of the negotiated F&A rates, exclusions to the F&A, NSF General Counsel review of unmanageable conflicts of interest, the inclusion of all

NSF programs in the R&D cluster in A-133 audits and a number of other changes and clarifications.

Of those areas that COGR requested clarification or changes, NSF modified language concerning the applicability of F&A rates on participant costs. In the draft NSF disallowed F&A on participant costs. In the final version NSF notes that, in general, it will not pay F&A on participant costs but NSF may establish or negotiate with applicants an allowance for indirect costs if circumstances warrant it. Our request to eliminate the cluster of all NSF programs into the Research & Development (R&D) cluster for purposes of the A-133 audit was not made in the final version; nor was our request for modification of NSF Office of General Counsel review of unmanageable conflicts of interest. NSF eliminated requirements linked to Life Sciences Dual Use Research of Concern and expanded the certification regarding federal tax obligations. Other minor requests related to field research with vertebrate animals, the citations for products (publications) made by COGR were not implemented in the final version of the PAPPG.

NSF is offering applicants additional information and resources to meet the new merit review criteria at its website (<http://www.nsf.gov/bfa/dias/policy/meritreview/>) and is planning a webcast in November to discuss the PAPPG revisions (for those of you unable to attend the COGR meeting, you should send an e-mail to [policy@nsf.gov](mailto:policy@nsf.gov) to be notified when this webcast is available)

### **National Science Foundation Transition to Research.gov**

In early 2013, the National Science Foundation (NSF) will completely transfer all project reporting from FastLane to Research.gov. In support of the transition, we will begin piloting the new service in Research.gov beginning in October. Once we have fully implemented project reporting through Research.gov, Principal Investigators (PIs) and co-PIs will use Research.gov to meet all NSF project reporting requirements, including submission of Annual, Final and Interim Project Reports and the Project Outcomes Report. The new Project Reporting Dashboard in Research.gov will make it easier for PIs, co-PIs, and Sponsored Project Office (SPO) staffs to see which reports are due or overdue, and will provide access to all reports submitted to NSF.

### **National Science Foundation New Grants.gov Application Guide**

A revised version of the *NSF Grants.gov Application Guide* is posted to the NSF website and is available at: [http://www.nsf.gov/publications/pub\\_summ.jsp?ods\\_key=grantsgovguide0113](http://www.nsf.gov/publications/pub_summ.jsp?ods_key=grantsgovguide0113).

This document is applicable to all applications submitted, or due, to NSF via use of Grants.gov on or after January 14, 2013. Please refer to Page 2 of the Guide for a summary of the significant changes, clarifications and other changes. Any questions regarding the new Guide should be submitted electronically to [policy@nsf.gov](mailto:policy@nsf.gov)