February 2014 Meeting Report

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COUNCIL ON GOVERNMENTAL RELATIONS

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March 14, 2014

February 27 and 28, 2014 Meeting Report

COSTING POLICIES

Committee: James Luther, Chair, Duke University; James Barbret, Wayne State University; Sara Bible, Stanford University; Kelvin Droegemeier, University of Oklahoma; Cynthia Hope, University of Alabama; James R. Maples, University of Tennessee; Kim Moreland, University of Wisconsin – Madison; Mary Lee Brown, University of Pennsylvania, ACUA Liaison; Michael Daniels, Northwestern University; Dan Evon, Michigan State University; Terry Johnson, University of Iowa; Cathy Snyder, Vanderbilt University

OMB Uniform Guidance Update: February COGR Meeting Session Summary

The February COGR Meeting was heavily infused with sessions related to the OMB Uniform Guidance. The following three sessions were covered in the February Meeting and the PPT presentations for all three are available at www.cogr.edu (see Meetings | February 2014 Meeting Presentations).

COGR Perspective on the OMB Uniform Guidance (combined Costing and RCA session). Representatives from the Costing and RCA Committees led a panel discussion to provide insights and perspectives on the OMB Uniform Guidance, which was released on December 26, 2013. This was a "members only" session. The six presenters, from the Costing and RCA committees, were: Susie Sedwick - University of Texas at Austin, Mike Ludwig - Purdue University, Pamela Webb - University of Minnesota, Jim Barbret - Wayne State University, Jim Luther - Duke University, and Cindy Hope - University of Alabama.

Implementation of the OMB Uniform Guidance and other COFAR Initiatives OMB Deputy Controller (and Interim Controller), Norman Dong, provided an overview on the roll-out and implementation of the OMB Uniform Guidance. Note: Mr. Dong announced that he had accepted a new position and was leaving OMB; we will follow developments regarding Mr. Dong's replacement.

Federal Perspective on the OMB Uniform Guidance Representatives from OMB and NSF led a panel discussion to provide insights and perspectives on the OMB Uniform Guidance. Joe Ellis (on temporary assignment at OMB), Jean Feldman (NSF), and Gil Tran (OMB) provided the federal perspective on many of the specifics of the Uniform Guidance.

Follow-up sessions to the themes and topics addressed in these sessions will be scheduled, as appropriate, for the June COGR Meeting (June 12-13, 2014).

COGR Guide to the OMB Uniform Guidance: An Implementation Plan for a Major Research University

Parts of this COGR update are based on an article written by Sara Bible, Associate Vice Provost for Research at Stanford University, which was published in the March/April 2014 issue of the

NCURA Magazine. Sara is on the COGR Board and a member of the Costing Policies Committee. She is an active member of the FDP and NCURA. Sara's responsibilities at Stanford include policy development and implementation, and financial and administrative oversight for 18 interdisciplinary research laboratories, institutes and centers, and several shared equipment facilities. Other parts of this article are based on recent COGR Updates and other COGR insights to the OMB Uniform Guidance.

Now that the Office of Management and Budget (OMB) has issued the "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (Uniform Guidance) (2 CFR Chapter I, Chapter II, Part 200, et al.), institutions will need to interpret the guidance, review and revise policies and procedures, and refocus campus training programs for implementation in December of 2014. Doing this in less than a year is an enormous charge for institutions, but there are basic and methodical steps that will facilitate the challenge.

By now, a point person at your institution should be established and that person should have taken the initial steps of thoroughly reviewing the Uniform Guidance to understand what has changed. If not, it's not too late … yet! However, as soon as possible, ***we recommend that a point person be designated at your institution***. The COGR "Preliminary Assessment," published January 14th, is a helpful first look at the Uniform Guidance (see link below).

file://cogr01/Users/DKennedy/Downloads/COGR_Preliminary_Assessment_-_OMB_Uniform_Administrative_Requirements%20(4).pdf

Summaries, such as the COGR Preliminary Assessment, only are a start point. The point person at your institution should be familiar with the official guidance provided by the Council on Financial Assistance Reform (COFAR) and OMB. The complete Uniform Guidance posted in the Federal Register is available at the first link below. Additional documents, including side-by-side comparisons between the Uniform Guidance and the existing Circulars are available at the second link below. Additional information, including links to training webcasts, is available at the COFAR web site per the third link below. Finally, ***we encourage that the point person access the fourth link below and sign up for the COFAR mailing list***; this will help to ensure that your institution has the most up-to-date information from OMB and the COFAR on webcasts, status of FAQs, etc.

http://www.gpo.gov/fdsys/pkg/FR-2013-12-26/pdf/2013-30465.pdf
http://www.whitehouse.gov/omb/grants_docs
https://cfo.gov/cofar/
https://survey.max.gov/index.php/496587/lang-en

Accessing the links and printing reams of paper is an overwhelming task. While investing the time to print (and review) the complete Uniform Guidance (first link) is necessary, the side-by-side comparisons (second link) is user preference. However, we do recommend printing the side-by-side comparison titled "*Uniform Guidance Crosswalk from Final Guidance to Existing Guidance.*" This is a user-friendly 10-page comparison that shows each section in the Uniform Guidance and the source of the language (e.g., from A-110, A-102, A-21, etc.)

Next, the point person at the institution, ***supported by senior leadership and working within the infrastructure of the institution***, should consider those actions necessary to educate and communicate across the campus. The regulatory changes are so comprehensive that an "all hands on deck" mentality will be needed for successful and timely implementation of revised policies, procedures and training. Several years ago Stanford assembled a group of school and central administrators to proactively review and consider changes to current policies and to review regulatory changes, consider their impact to the research community and implement compliant solutions. The focus is on compliance while minimizing burden to faculty and administrators. The Research Policy Working Group (RPWG) meets on a monthly basis and will be vital in Stanford's implementation of the Uniform Guidance.

Stanford's Director of Training and Communication is a key member of the RPWG and aids the process by challenging the group to write policies that are clear and concise, and that both initial and ongoing training needs are thoughtfully considered and developed throughout the process. ***The RPWG members that are school representatives take the draft policies and implementation plans back to their faculty and staff for a "road test"*** to see if they are understandable and can be reasonably implemented. It is critical to obtain input from faculty and administrators on the implications of potential changes in policies and procedures before they are finalized to ensure a smooth and compliant implementation. This method has proved to be successful at Stanford for the past two decades. The extra time spent with the community prior to issuing the policy pays off when the policy is promulgated. Stanford's faculty leadership and the RPWG are poised to take on the responsibility of implementing the regulatory changes within the Uniform Guidance.

Stanford has developed a matrix of the regulatory changes that includes the following:

- A-21, A-110, or A-133 section
- Uniform Guidance section
- Current Stanford policy
- Staff member responsible for initial edits to current policy
- Impact to research community
- Implementation issues

The matrix will be used and updated beginning in the exploratory stages of the review and interpretation of the regulatory reforms and through the policy development, training and implementation phases. With a long list of changes in regulatory requirements it will be important to prioritize what policies need to be addressed early in the process as some of the regulatory changes may require changes to the chart of accounts or accounting systems.

The Federal awarding agencies are required to submit drafts of their implementing regulations to OMB by June 2014. Stanford will take these various new implementing regulations into account as its policies, procedures and training are developed and promulgated.

Fall 2014 at Stanford will be spent training research administrators on the regulatory changes and revised policies and procedures. Stanford will hold "Road Shows" for schools, departments, and central administrative units. Faculty Forums that condense the information to what is critical for faculty to understand will be held. Based on the feedback received at the various Road Shows, FAQs will be developed and published to provide additional clarification and guidance.

Road Shows will continue into Winter 2015 in order to address potential issues that are encountered as the regulatory changes and policies are implemented. The RPWG will be essential in bringing implementation issues to the forefront so that they can be resolved.

COGR is committed to being a primary resource for the COGR Membership. COGR is currently updating the January 14th "Preliminary Assessment" and expects to publish ***an expanded list of changes, including applicable analysis and action plans next month.*** After the Agency implementation plans are made available after June, COGR expects to provide comments on what those plans mean to your institution. And as we approach the December 26, 2014 implementation date of the Uniform Guidance, COGR will provide additional assessments, as needed, ***including the possibility of a "COGR Guide to the Uniform Guidance."*** The Guide would focus on the key changes between the Circulars and the Uniform Guidance with suggestions/practices/issues related to implementation strategies at your institutions.

Stanford, like other institutions of higher education, will look to the COFAR and OMB for official guidance, while COGR, the FDP, NCURA and other associations and professional development groups will provide further guidance in the implementation of the OMB Uniform Guidance. Regular and thoughtful communication is integral and COGR will play an active and lead role to support the research community.

HHS/NIH Subaccounting and Grants Closeout: Next Steps

We have written about this issue since the Fall and we expect this to be an ongoing issue throughout 2014. Background information is available in prior COGR Updates. COGR and the Federal Demonstration Project (FDP) are working actively with representatives from the Department of Health and Human Services (HHS) Office of Grants Policy and NIH to facilitate several pieces of the policy implementation.

- **Grants Closeout policy.** Per NIH Notice NOT-OD-13-120: " … *PMS will now hold payment requests for funds in subaccounts for awards that are 90 days or more beyond the project period end date. Funds requests for these awards will not be processed unless, and until, the awarding Agency has approved the payment request*." While many COGR members have expressed concern about this language, NIH has shared with us that they are proactively working with HHS and the Division of Payment Management (DPM) to address the timing for Payment Management System (PMS) unilateral closeouts and the impact on draw-down requests.

- **Proposed Due-date for Final FFR.** In a COGR request letter addressed to Dr. Sally Rockey, the NIH Deputy Director for Extramural Research, dated December 9, 2013 (see www.cogr.edu, Home page / Latest News! for a copy of the letter), we proposed that a Final FFR due-date of 180 days after award end-date, coupled with a closeout policy that sets the PMS draw-down deadline at 180 days, would be the most logical and intuitive policy. This would protect the actual science being conducted by removing any perverse institutional incentives to reduce performance periods in favor of expanding the time available to complete administrative work. NIH has shown interest in advocating for this approach.

- **Transition to NIH Subaccounts on October 1, 2014.** At an FDP meeting in January, there was a robust discussion on the administrative burden (both for universities and NIH) that could take place beginning on October 1st as existing awards are closed and reopened as "P-subaccounts." NIH is equally concerned and is proactively working with HHS and DPM to consider strategies that would minimize this burden.

- **Consistency across HHS Operating Divisions.** We are reaching out to the HHS Office of Grants Policy to coordinate representatives from at least eight of the HHS Operating Divisions (i.e., ACF, AHRQ, CDC, CMS, FDA, HRSA, NIH, and SAMHSA) with the goal of addressing strategies to ensure that the policy transition is executed in the most efficient and effective way possible. A major challenge for COGR institutions is when an Operating Division implements an approach that is inconsistent with other Operating Divisions.

- **Eliminate the Quarterly FFR and Reconciliation Process.** Our understanding is that DPM has concerns that elimination of this requirement could violate federal accounting standards – however, at least two agencies that have transitioned to subaccounts have successfully justified the elimination of the Quarterly FFR with no repercussion. We are encouraging NIH to advocate for this change, with the ultimate benefit being the elimination of a redundant and unnecessary administrative requirement.

COGR is sensitive to the fact that all solutions need to be informed by the April 2012 GAO report on "*Action Needed to Improve the Timeliness of Grant Closeouts by Federal Agencies*" (see http://www.gao.gov/products/GAO-12-360).

However, COGR believes there is an opportunity to implement an HHS-wide policy that can be productive and manageable for all stakeholders, and at the same time, respects the pressures on HHS to be responsive to the GAO report. HHS was receptive to our request last Fall to implement the subaccounting methodology in a reasonable manner, and NIH has a long track record of being committed to working with our institutions. Consequently, we are cautiously optimistic these issues can be addressed in a constructive manner. We will continue our outreach to the COGR membership and keep you abreast on all developments.

Audit Update

We have included detailed summaries on the annual Audit Workplans for the HHS and NSF OIGs in the past several COGR Updates. In addition, we encourage you to regularly check the HHS (NIH) and NSF OIG websites (see links below). These sites provide access to published audit reports.

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 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.

A-133 Compliance Supplement: Suspension and Debarment - RESOLUTION

For the past several months, we have reported on this topic. At issue was a last second addition to the 2013 Compliance Supplement related to the suspension and debarment audit requirement (Part 3 - Compliance Requirements). This addition – specifically, the status of the principals (e.g., board members, corporate officers) of a vendor should be verified – was made without any opportunity for public comment. COGR communicated our concerns with OMB, CPA firms, and other stakeholders late last year. In a February 14th email to a stakeholders group, a representative from OMB referenced the following Clarification (see link and a copy of the Clarification below), which represents guidance on how A-133 auditors should address this issue:

http://www.whitehouse.gov/omb/circulars/a133_compliance_supplement_2013

Part 3- I, Procurement and Suspension and Debarment

Q: Are auditors required to report audit findings based solely on the tests for suspended and debarred principals pursuant to Part 3- I, Procurement and Suspension and Debarment, steps 6 and 7 (page 3-I-5), of the March 2013 OMB Circular A-133 Compliance Supplement?

A: No, for audits covered by the March 2013 Supplement, auditors are not required to report audit findings that relate solely to whether the principal of an entity with which the non-Federal entity has a covered transaction is suspended, debarred, or otherwise excluded. However, auditors are still required to report audit findings for non-compliance with the other suspension and debarment requirements. The 2014 Compliance Supplement will provide additional guidance for future years.

When performing the risk based approach under OMB Circular A-133 Supplement, the auditor is not required to consider audit findings or modifications of audit opinions based solely on the tests for suspended and debarred principals pursuant to Part 3I, Procurement and Suspension and Debarment, steps 6 and 7 of the March 2013 Supplement if the auditor can determine that the auditee was otherwise in compliance with the suspension and debarment requirements. For example, a material non-compliance, material weakness in internal control over compliance, or a modified opinion based solely on Part 3I, steps 6 and 7 of the March 2013 Supplement in a previously issued audit report would not preclude a program from being low risk or an entity from qualifying as a low risk auditee in the two subsequent year audits.

This modified audit guidance is being provided due to the first time inclusion of the "and principals" provision in the 2013 Supplement and the implementation challenges that non-Federal entities expressed in preparing for the audit of this requirement. However, it is important for non-Federal entities to note that this is not a new requirement and they are still required to comply with the "and principals" provision of the suspension and debarment requirements. Auditors performing fiscal year 2013 single audits are strongly encouraged to remind those charged with governance of the non-Federal entity of their responsibilities to ensure that the principals of an entity which they enter into covered transactions are not

suspended, debarred or otherwise excluded. Non-Federal entities may find that the best method to comply with this requirement is by adding a clause or condition to the covered transaction with the entity.

Furthermore, our understanding is that the requirement published in the 2013 Compliance Supplement ***will be eliminated in the 2014 Compliance Supplement***. We will track of this issue to confirm the status of this requirement in the 2014 Compliance Supplement.

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 costs, financial, or audit related topics that you would like to discuss with COGR, please contact David Kennedy at dkennedy@cogr.edu.

NIH Fiscal Notices, including an Increase in the NIH Salary Limitation to $181,500. A series of fiscal notices from NIH were released on February 10, 2014 and a summary of each was included in the COGR February 2014 Update (published February 12, 2014). The Notice addressing the NIH Salary Limitation (NOT-OD-14-052), which summarizes the increase from $179,700 to $181,500, is available at the link below:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-052.html

ARRA Recipient Reporting Ended on February 1, 2014. In the COGR February 2014 Update (published February 12, 2014), we reported that the infamous "Section 1512" reporting required under the American Reinvestment and Recovery Act (ARRA) was repealed under the enactment of the Consolidated Appropriations Act of 2014, Public Law 113-76, which was signed into law in January 17, 2014. The repeal language is specifically referenced under section 627, HR 3547. The notice to recipients can be found at the Recovery Act website (see link below). If you have related questions on open ARRA awards, we encourage you to contact a program officer from the applicable agency to confirm any additional details or requirements.
http://www.recovery.gov/arra/FAQ/Pages/RecipientReporting.aspx

NSF Survey Results on Higher Education R&D Expenditures. The NSF annual survey on Higher Education R&D Expenditures for FY2012 is now available. The "InfoBrief" report is available at:
http://www.nsf.gov/statistics/infbrief/nsf14303/nsf14303.pdf

GAO Releases the First of Two Studies on Indirect Costs. The first of two GAO studies that COGR has been following is available. The report titled: "*NIH Should Assess the Impact of Growth in Indirect Costs on Its Mission*" can be found at: http://www.gao.gov/products/GAO-13-760. And, as we have reported, a second GAO study was requested by Congress in June 2013. The House Energy and Commerce Committee's Subcommittee on Oversight and Investigations, chaired by Rep. Tim Murphy (R-PA), sent a letter to the GAO asking the agency to review indirect costs on grants issued by NIH. In light of the release of the first study, it is uncertain if this affects whether or not the second study still is necessary – Representative Murphy will need to determine how he wants to proceed. We are paying attention to all developments.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: David Winwood, Chair, University of Alabama at Birmingham; Mark Crowell, University of Virginia; Alexandra McKeown, The Johns Hopkins University; Cordell Overby, University of Delaware; Patrick Schlesinger, University of California, Berkeley; Kevin Wozniak, Georgia Institute of Technology; Catherine Innes, North Carolina State University; Valerie McDevitt, University of South Florida; Fred Reinhart, University of Massachusetts; John Ritter, Princeton University; Wendy Streitz, University of California

Patent Trolls and Related Issues Continue to Command Attention

The COGR February Update summarized federal and state legislative initiatives aimed at addressing patent "trolls." Discussions are continuing among various stakeholder groups including higher education on the various Senate bills that have been introduced (see http://www.aau.edu/publications/article.aspx?id=14999 for more information). Also we understand at least 20 states now have introduced legislation aimed at addressing "bad faith" assertions of patent infringement.

On February 21 the White House held a patent stakeholders meeting at which National Economic Council Director Gene Sperling, Commerce Secretary Penny Pritzker, and Deputy U.S. Patent and Trademark Office (PTO) Director Michelle Lee reviewed Administration initiatives "designed to combat patent trolls and further strengthen our patent system and foster innovation." The speakers reviewed progress on five initiatives announced last June, and announced three new executive actions.

In his opening remarks, Sperling presented a case for forceful action against what he characterized as an abrupt increase in abusive patent practices by patent assertion entities. But in describing the Administration's position, he acknowledged legitimate differences among different sectors on the range of legislative proposals for curbing abusive practices. He called on stakeholders to come together to forge workable compromises.

Following the public session, Deputy Undersecretary Lee moderated a roundtable on patent reform legislation attended by representatives from 25 invited organizations, including universities, to present and discuss their views on key legislative issues. Each group was asked to provide a statement on its top three priorities; the statement submitted by AAU can be found at http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=15025 . The roundtable revealed significant differences of view, but the discussion also suggested a receptivity among the parties to seeking ways to narrow those differences to achieve legislative compromises.

The five executive actions announced last year were promoting transparency in patent ownership, promoting patent clarity, providing information for consumers about patent litigation, greater outreach to stakeholders by PTO including expansion of the PTO Edison Scholars

program; and review of the scope of ITC exclusion orders (see COGR June 2013 Meeting Report). The new executive actions include "crowdsourcing" prior art, providing more robust training to patent examiners, and providing inventors with pro bono assistance (see http://www.whitehouse.gov/the-press-office/2014/02/20/fact-sheet-executive-actions-answering-president-s-call-strengthen-our-p). PTO has approached AUTM about identifying volunteers to participate in the strengthened training program.

The February COGR meeting included a session on patent trolls. Among the speakers was Paul Schneck, Chairman of Rembrandt IP Management, LLC. Mr. Schneck described Rembrandt's model as identifying a few fundamental patents with a high likelihood of infringement, and working with the patent holders to develop a strategy to address the issues. While a patent assertion entity, this business model contrasts with more typical troll behavior involving sending out large numbers of demand letters to potential infringers. Mr. Schneck expressed the view that the perceived recent increase in patent litigation was to be expected given PTO's reduction of the application backlog as well as changes in the complexity of products and the market. Patents are property and enforcement of patents is similar to that of any property owner taking steps against trespasses. He queried why the scope of copyright protection has been expanded while that of patents seems to have eroded. He noted also that much of the attempts to reduce patent litigation could be viewed as cartel-like behavior on the part of large companies resisting new innovation. The bottom line is that a one size fits all view of patent assertion entities is not appropriate.

COGR Comments on PTO "Attributable Owner" NPRM

The February Update discussed the Notice of Proposed Rulemaking (NPRM) issued by PTO on January 24 (79FR4105) that would require identification of "attributable owners" in patents and patent applications. The Update noted some potential concerns, and that we expected to comment jointly with other higher ed. associations.

The COGR CIP Committee discussed the NPRM at its February meeting. We identified the following concerns:

1) The requirement to disclose exclusive licensees could in some cases have a chilling effect on the ability of our member institutions to commercialize their inventions;
2) basing the requirement in terms of enforcement entities "necessary to be joined in a lawsuit in order to have standing to enforce the patent…." involves conclusions of law which are the province of the courts, not PTO;
3) the continuing duty to identify attributable owners, especially ultimate parent entities, could substantially raise the cost of compliance since our institutions are not necessarily familiar with corporate structures (and also may result in inadvertent non-compliance since corporate transactions may not be public in the various time periods specified);
4) the exemption from the disclosure requirements for state agencies raises the prospect of an uneven playing field between some public institutions and other public and private institutions; and
5) given the pending Congressional legislation, PTO rulemaking at this time seems premature.

6) PTO also asked for comments on allowing patent applicants and owners to voluntarily report licensing offers and related information to PTO to be made available to the public in an accessible online format. While we support the concept of making this information as accessible as possible, many of our member institutions already are subject to a requirement to post such information on a public website maintained by the National Science Foundation (http://www.research.gov/acasection520). We have some skepticism as to whether having such information also available on a PTO website would yield much by way of positive results.

(Note: review of the website indicates that about 50 COGR member institutions subject to the requirement (NSF research support and at least $25M in total federal research grants in the most recent fiscal year) have not as yet complied with the requirement to submit their tech transfer URLs to the website. We urge all COGR members to comply with the requirement).

PTO held a public hearing on March 13 on the NPRM. COGR presented testimony at the hearing making the five points noted above. Other witnesses expressed mixed views. Some were strongly opposed to the NPRM. Similar concerns to ours were expressed about the need to preserve confidentiality in licensing (one witness expressed the view that requiring U.S. companies to disclose their strategic business plans would particularly benefit foreign competitors). Strong concerns also were expressed about the costs of compliance and whether the benefits justified the burden, particularly for small innovative businesses. Supporters cited increased economic efficiency resulting from a more transparent competitive landscape and the need to curb abusive patent suits. PTO plans another public hearing in San Francisco (Hastings College of Law) on March 26. PTO also has extended the period for public comment to April 24 (79FR9677).

COGR Discusses Commercialization and Entrepreneurship Initiatives with OSTP

Colleen Chien, Senior Advisor for Intellectual Property and Innovation, OSTP and Charina Choi, a White House Fellow at the Office of Science and Technology Policy (OSTP), visited with CIP at the February meeting. This followed on a meeting the day before of COGR staff and the CIP Committee Chair with Ms. Choi and Doug Rand, Assistant Director for Entrepreneurship, at OSTP.

OSTP basically is concerned with encouraging a better return on investment for the $140B federal R&D portfolio. They understand and support the importance of discovery research, but they are seeking ways to "open up" the federal R&D portfolio by providing more connection points for federal R&D assets, including data, intellectual property, and equipment/facilities.
The Administration is strongly supporting an open data policy. This includes raw research data (available on www.data.gov - the website includes over 120,000 agency datasets) as well as federal or federally-supported technologies (the website includes available technologies from federal labs via the Federal Laboratory Consortium). They are seeking new models of connection and gateways, and to form new partnerships (e.g. with AUTM and BIO). They want to provide mechanisms to link entrepreneurs with technologies, and to link potential public users

with federal or federally-funded equipment. The proposal in the PTO NPRM to provide voluntary licensing information is an example.

Among the problems are lack of a common taxonomy, different formats which hinder the ability to search smartly, the need to interface with various data entry processes (e.g. by federally funded principal investigators), and accessibility (i-Edison data as well as the AUTM licensing survey were cited as examples). There's also the familiar issue of how to measure "success" in these kinds of activities. Identification of best practices is a priority.

In the meetings we pointed to existing efforts along these lines, such as the AUTM Global Technology Portal. We also mentioned the NSF website that contains tech transfer URLs (of which they seemed unaware). However, we noted that the efficacy of simply posting this kind of information has not been clearly demonstrated (i.e. not clear that many deals have resulted). We also cautioned that opening up federally funded equipment for general public use may raise issues of competition with the private sector (and is prohibited in some states) and in the case of universities also may have tax implications. We also brought up StarMetrics (of which they also seemed unaware).

The OSTP initiatives are examples of the themes of openness and transparency which recently have characterized this Administration. However, much of what was discussed either has been tried before or raises potential policy issues (e.g. equipment use). We expect to engage in continuing discussions with OSTP on these matters.

Omnibus Funding Bill Includes "Made in America" Provision

The FY '14 Omnibus Funding bill includes a provision inserted by Rep. Fattah (D.--PA) that directs the Secretary of Commerce to produce a report on job repatriation and manufacturing growth. More specifically, it directs Commerce "to issue a report specifying the legislative and regulatory authorities available to ensure that the Federal Government reaps the maximum benefit from intellectual property developed as a result of Federally funded research. The report (due within 6 months) shall describe how the agencies funded in this division could use these authorities to ensure that agency research discoveries yield commercial technologies that are manufactured domestically. The report shall additionally include specific recommendations for improving domestic intellectual property transfer and retention, and advancing related domestic manufacturing derived from such intellectual property…"

This language is an improvement over Rep. Fattah's original bill (H.R. 614), which among other things raised the possibility of recoupment of royalties from commercialization of federally-funded research. While we have no issue with the concept of encouraging more domestic manufacturing, the domestic manufacturing requirement already is included in the Bayh-Dole Act. We contacted Commerce/NIST to point this out, and to offer help in developing the report. We also mentioned the difficulty of finding domestic sources, and that our member institutions occasionally have experienced difficulties in obtaining waivers of the domestic manufacturing requirement from funding agencies. NIST indicated willingness to engage in further discussions on these issues with COGR.

Other CIP Updates

1) **Anti-Bayh Dole Provision to be Dropped from Manufacturing Innovation Bill** - The December 2013 Update mentioned the NIST Manufacturing Innovation Network initiative, and the anti-Bayh-Dole provision included in the supporting legislation ("Revitalize American Manufacturing and Innovation (RAMI)"--S. 1468 and H.R. 2996). It noted that we had raised concerns about this provision with NIST, and that NIST would work with Congressional staff to modify or eliminate the provision. We understand that NIST now has delivered revised language to the Congressional staff. In addition, on February 26 AAU and APLU sent a letter to the Senate sponsors supporting the RAMI legislation contingent on a change to subsection 3.h. to make Bayh-Dole applicable to the centers for manufacturing innovation established under the program. (For a copy of the letter see http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=15034).

2) **NETL Foreign National Approval Requirement Discussed with Senior DOE Management** - The February Update discussed the requirement that a number of universities have received from the DOE National Energy Technology Lab (NETL) that all foreign nationals performing research on NETL-funded work be submitted to DOE for approval, even if the research is fundamental and whether or not the foreign nationals have access to NETL-provided information. The Update noted that a number of universities have objected in letters to NETL, and that the matter had been raised informally with DOE headquarters.

   A number of senior research vice presidents at COGR member universities now have raised the issue directly with senior DOE management. We understand DOE management has acknowledged the problems the requirement creates for universities, and is discussing the issue with NETL. The NETL policy is based on the revised DOE Order 142.3A, but no other DOE facility appears to interpret the revised order as requiring foreign national approval for fundamental research conducted on campus at universities. We hope to report a positive resolution soon.

3) **DOD Promises Clarification of Revised DFARS 7000 Clause** - The February Update noted that DOD/Defense Procurement Acquisition Policy (DPAP) had advised COGR that additional language was being drafted to provide further guidance to DOD contracting officers on the recent DFARS 7000 clause changes. DPAP recently advised COGR that while little progress has been made, they expect to have additional guidance published in the Procedures, Guidance and Information (PGI) for DOD contracting officers by the end of April. DDR&E has been very helpful in working with us to urge DPAP to provide clarification.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: James Tracy, Chair, University of Kentucky; Lois Brako, University of Michigan; Pamela Caudill, Harvard University; Michael Ludwig, Purdue University; Susan Sedwick, University of Texas, Austin; Pamela Webb, University of Minnesota; Kathleen Delehoy, Colorado State University; Walter Goldschmidts, Cold Spring Harbor Laboratory; Suzanne Rivera, Case Western Reserve University

NSF Issues Revised Terms and Conditions

As is its custom (and appropriate next step), the National Science Foundation (NSF) revised all its assistance-related *Award Terms and Conditions* to implement the changes made to the *Proposal & Award Policies & Procedures Guide* (PAPPG). The revised Terms and Conditions will apply to all new NSF awards and funding amendments to existing NSF awards issued on or after February 24, 2014. In addition to clarifications and other changes made to the conditions, the significant change involved supplementing the Program Income Article with information on the annual program income reporting requirement. If you identify a term or condition that is inconsistent with the PAPPG, let us know (cblum@cogr.edu) and we'll seek clarification. The Award Terms and Conditions are available electronically at: http://www.nsf.gov/awards/managing/award_conditions.jsp?org=NSF.

NSF and NIH Whistleblower Protections

Within days of revising its *Award Terms and Conditions*, NSF issued a revision on March 7, 2014 to provide for the expanded whistleblower protections. The National Institutes of Health (NIH) revised its Award Conditions on March 7, 2013 to extend the same coverage and the agencies took different approaches.

As we reported in December, 2013, grantees of the Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) received notification that the institution is required to "comply with, and inform all employees of the "Pilot Program for Enhancement of Contractor Employee Whistleblower Protections," effective July 13, 2013. This particular regulatory requirement amending the statute at 41 USC §4712 passed as part of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 (Pub. L. 112-239, enacted January 2, 2013).

NSF's March 7, 2014 revision of the entire suite of *Award Terms and Conditions* adds a provision that simply notifies the awardee of the applicability of 41 USC §4712 as amended by PL 112-239. NSF's provision is effective March 7, 2014.

NIH issued Notice NOT-OD-14-068, *Notice of Implementation of Pilot Program for Enhancement of Employee Whistleblower Protections* on March 7, 2014 and provides greater

detail on the provisions in 41 USC §4712 including the key requirement in the "pilot program" to inform employees **working on federal grants and contracts** in writing of the employee's whistleblower protections as described and defined in § 4712. The notification to employees must be in the predominant language of the workforce. The NIH requirement is applicable (effective) on all awards issued on or after July 1, 2013.

There's the difference. The NIH requirement is retroactive to July 13, 2013; NSF's requirement is effective prospectively from March 7, 2014.

Given the applicability of the notification requirement as defined by NIH – "all employees working for contractors, grantees, subcontractors and subgrantees on federal grants and contracts" – institutions need to provide the notification to employees who were employed since July 13, 2013 on federal grants and contracts of the protections. We have raised our concern with NIH about the ability of institutions to identify and notify individuals – students or employees – who are no longer enrolled at or employed by the institution. It would seem the best approach for institutions to use to achieve compliance is to make and document a good-faith effort to provide the notification to former students and employees who worked on NIH grants and contracts.

In the case of current NIH-funded students and employees and – we would extend the NIH applicability to NSF awards – current NSF-funded employees, notifications should be provided and the requirement will continue going forward until modified or, in the case of NIH, January 1, 2017. These provisions flow down to subawardees. The applicable section of the Code of Regulations can be found by searching the US Code Title 41, Public Contracts; Subtitle I, Federal Procurement Policy; Division C, Procurement; Chapter 47 (available at: http://uscode.house.gov/browse/&edition=prelim).

The good news? The agencies with NIH as representative are defining who needs to be notified more narrowly than our original interpretation – it applies only to those employees working on a federal contract or grant. Both NIH and NSF have established the requirement and have left the manner and/or mechanisms to be used for implementation by the awardees up to the institution. With the NIH and NSF implementation and in reviewing the statutory language, it seems clear that this notification requirement applies to any Federal contractor, subcontractor or grantee, thus, it will be applicable across agencies, eventually.

We continue to believe any institutional response should consider the most effective way to notify its employees of the whistleblower protection. Not markedly different from other such labor requirements – Employee Assistance Programs (EAP) or Drugfree Workplace notifications – an institution could provide this information – a brief summary with a link to §4712 – in a regular, annual communications to the institutional community or more narrowly to individuals employed on federal contracts and grants. You may notify more individuals than necessary but a broad, documented notification can help ensure compliance.

Institutions need to provide notification to students employed on contracts and grants. Whether or not students are considered employees should be determined by the institution – we are not likely to get further clarification from the agencies. A simple approach for both employees and students is providing notification to anyone paid from a contract or grant. At this juncture,

compliance need not be complicated but as institutions prepare such broadly distributed documents, including the information on whistleblower protections should bring the institution into compliance.

Pornography

On February 27, 2014, the National Institutes of Health (NIH) issued an amendment to its *Notice of Legislative Mandates for 2014* (published February 10, 2014 as NIH Notice NOT-OD-14-053) to include an additional legislative mandate regarding the *Restriction of Pornography on Computer Networks*. The restrictions states that "None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography." (Notice NOT-OD-14-062, February 27, 2014).

As we discussed at the recent COGR meeting, NIH reviewed its award portfolio and identified those projects that potentially allocated funds to support computer networks – defined, in part, by NIH as "infrastructure that allows two or more computers to communicate with each other." The institute/centers were asked to examine the projects and report to the Office of Extramural Research on whether the projects met the definition and, thus restrictions, of the statutory provisions.

Our colleagues at the University of California discovered that this restriction is not entirely new. Similar language appeared in the Consolidated and Further Continuing Appropriations Act, 2012 PL 112-55 (November 2011) and the Consolidated and Further Continuing Appropriations Act, 2013 PL 113-6 (March 2013). So why now? The provision as it appeared in the earlier Appropriations Acts applied to a limited number of agencies. The Consolidated Appropriations Act of 2014, PL 113-76, added the Departments of Labor, Health and Human Services (HHS) and Education, among others.

Thus, NIH took "proactive" steps to meet the statutory restriction. The apparent approach chosen by NIH – linking the restriction to projects specifically designed to maintain and establish a computer network – may be the more manageable scenario for research institutions. As the network is established as a part of the project, appropriate provisions can be made to block access to pornography. We suspect affected grantees will receive further information from NIH. In the absent of further direction, institutions should make and document a good-faith effort to block access to materials it, the institution, defines as within the definition of pornography.

DURC Institutional Policy May be Forthcoming

One thing is certain – predicting when new or proposed regulations may be issued is unpredictable. But it has been suggested that the final US Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC) may emerge earlier (rather than later) this year.

You will recall that a proposed policy was issued in February 2013 for comment. In general, the proposed policy deals with the 15 select agent and toxins and seven threatening outcomes or effects of research conducted with those agents and toxins that were identified in the March 29,

2012 Federal policy. The government sought comment on scope in terms of agents and toxins, applicability meaning all research or federally funded research, feasibility, burden and how the policy could be implemented at institutions. The current select agent/toxin regulations govern the safety and security of the agents themselves. This policy is focused on the management of the information or outcomes of the research. A copy of the proposed policy is available at: http://www.phe.gov/s3/dualuse/Pages/default.aspx - the US Government **S3 – Science, Safety and Security** website.

COGR joined with the Association of American Universities (AAU) in offering comment. We supported the limited scope of the policy and argued that the government should not consider expanding the scope to a broader class of experiments or agents. The proposed scope matches the current Select Agent & Toxin Regulations and will make compliance significantly more manageable while meeting the goals of mitigating the risk of the misuse of research outcomes.

We sought clarification or assurance that the training and responsible officials can track with the institutional select agents policies and procedures and asked for greater detail on how and when institutions communicate with the Federal sponsors. We are concerned about how disputes will be adjudicated and reminded OSTP of the recent Government Accountability Office (GAO) findings that overlapping and duplicative inspections, in the GAO review case, increases the burden of compliance on the regulated community. We noted that increasing the regulatory burden can have the effect of driving scientists away from this critical research.

As we anticipate the issuance of this final policy, we'd like to begin gathering examples and models of effective practices from institutions that are conducting similar types of reviews. In June 2012, we had a very informative panel at the COGR meeting with presentations by Duke University and the University of Wisconsin-Madison and will make the information present available again.

We'd like to continue that discussion by gathering additional information from any COGR member that has instituted activities whether through its Institutional Biosafety Committee (IBC) or another mechanism to 1) raise awareness of investigators including training; 2) collect information and conduct reviews; and 3) and develop policies or procedures to manage DURC. Our goal is to develop a short list of effective practices for institutions to consider when the policy becomes final. We believe that all institutions should consider the scope of their research and think about areas outside select agents and toxins that are vulnerable to misuse. Areas like food safety, infrastructure engineering, etc. hold opportunities for misuse. While note covered by the proposed policy, we believe engaging in an awareness and, as appropriate, training program may be in the best interests of the research enterprise.

If you would like to contribute information, contact Carol Blum (cblum@cogr.edu) with attachments, links to institutional websites, and/or questions about how to begin the process of education, awareness and training. For institutions using select agents and toxins covered by the policy, we welcome your observations on what new policies and procedures you would implement in light of the policy if finalized as proposed.

NSB Administrative Task Force Reports

Arthur Bienenstock, Stanford University and chair of the National Science Board Task Force on Administrative Burden, and Kelvin Droegemeier, University of Oklahoma and vice chair of the NSB and member of the Task Force (and COGR Board member), reported on the findings and recommendations in its report, *Reducing Investigator's Administrative Workload for Federally Funded Research*, which was approved, subject to final edits, by the NSB at its February meeting. The final document will be released in early April. Drs. Bienenstock and Droegemeier spoke from slides summarizing the report and recommendations.

Through its open and collaborative process of information-gathering initiated in December 2012, the Task Force found areas of investigator administrative burden that echo similar surveys, including the Federal Demonstration Partnership – financial management, grant proposal processes, outcome reporting, time and effort reporting, and processes involved in the use of human subjects and animals in research.

A set of the NSB-approved recommendations call for a return to a focus on science requiring only those elements in applications that are essential to evaluating the merit of the research and making a funding decision and requiring reports that focus on science outcomes with data requests limited to those essential for assessment of performance. The NSB supports some of the HHS proposed reforms to the human subjects research regulations including the use of central Institutional Review Boards (IRBs), eliminating continuing review of a subset of protocols and an expansion of exempt categories. The Board endorses recommendations for expedited review of minimal risk research and eliminating the duplicative review of institutional-approved research during the peer review process. The NSB calls for an evaluation of the management of animal research by all stakeholders to identify policies and guidance that increase administrative workload without improving or enhancing the care and well-being of animals used in research. The Board calls on research institutions to review their IRB and Institutional Animal Care of Use (IACUC) processes with the goal of improving efficiencies and streamlining processes and recommends that Federal agencies and research institutions work together to develop and disseminate model programs and effective practices that achieve these and other recommendations made by the NSB.

A number of the recommendations offer focused proposed changes that can have a significant effect on the research enterprise. The NSB calls for the Office of Management and Budget (OMB) to identify mechanisms that permit the use of payroll certification rather than time and effort reporting to meet any audit requirements. The Board recommends mechanisms that ensure uniform and consistent audit and financial practices and calls for an evaluation of the recently-revised PHS/NIH financial conflicts of interest policies to assess cost and effectiveness. The NSB does not recommend adoption of PHS/NIH models by other Federal agencies. The Board requests the re-examination of the application on research institutions of safety and security regimes designed for industry with the goal of identifying appropriate alternatives. Such alternative approaches could ease the burden of a number of regulatory regimes like the Chemical Facilities Anti-Terrorism Security CFATS) requirements.

Finally, the NSB calls for a permanent structure – interagency, inter-sector committee – to develop and implement new requirements and develop a priority candidate list of regulations and policies, and guidance for elimination, modification or harmonization to reduce the administrative workload on investigators and their home institutions. We will report on the final recommendations when available.

Regulatory Burden Subject of Numerous Committees and Task Forces

As the NSB issued its report on investigator administrative burden, other complimentary efforts began to take shape. The Consolidated Appropriations Act of 2014 (PL 113-076) signed on January 17, 2014, directs NIH to track and measure administrative burdens on grantees. In the Joint Explanatory Statement posted by the US House Committee on Rules as an elaboration of the provisions in the Appropriations Act, NIH is to "establish a workgroup that includes coordination and participation of universities, not-for-profits, and institutes receiving support from the NIH to develop a method to track and measure the administrative burden on entities participating in NIH supported activities with the goal of developing a plan to reduce such administrative burden as practicable."

In addition to the NIH workgroup effort, the Appropriations Act provides funds to support a study by the National Research Council (NRC) on the effects of regulations and reporting requirements on colleges. This study had been authorized by the Higher Education Opportunities Act of 2008 (HEOA). Section 1106 of HEOA directed the Secretary of the Department of Education to enter into an agreement with the NRC to determine the number and scope of Federal regulations and reporting requirements with which higher education institutions must comply. At the time, Congress failed to appropriate funds to support the study.

The recent Appropriations Act provides $1 million for the study. In addition to the number and scope of the regulations, NRC will be directed to estimate the time and costs to institutions required to comply with the regulations and reporting requirements and to make recommendations for consolidating, streamlining, and eliminating redundant and burdensome Federal regulations and reporting. The study is due in one year.

Federal regulatory burden received separate attention from the US Senate in late November, 2013. On November 18, 2013, US Senate Education Committee members Lamar Alexander (R-Tenn.), Barbara Mikulski (D-Md.), Richard Burr (R-N.C.), and Michael Bennet (D-Colo.) announced the formation of a task force to examine burdens on institutions of higher education. The Task Force on Government Regulation of Higher Education is directed to conduct a comprehensive review of federal regulations and reporting requirements affecting colleges and universities and make recommendations to reduce and streamline regulations, while protecting students, institutions and taxpayers. The task force is co-chaired by Nicholas Zeppos, chancellor of Vanderbilt University, and William Kirwan, chancellor of the University System of Maryland and includes 14 college and university presidents and higher education experts. The American Council on Education will provide organizational assistance.

One of the US Senate Task Force members, Margaret L. Drugovich, President of Hartwick College, joined the COGR membership at the meeting to describe Hartwick College's recent report assessing the costs of regulatory compliance at the College. A small liberal arts and

sciences college in mid-state New York, with 1500 students, Hartwick found it was governed by the regulations and policies of 28 federal agencies, 15 state and 4 local government agencies, 7 accrediting bodies, 3 athletic conferences and 43 hospital and medical organizations in support of its nursing program. The list would be similar and likely longer for any research-intensive institution but demonstrates the reach and impact of government regulatory requirements.

Looking just at the time and associated costs of completing the reporting requirements, Hartwick found that the College's 110 non-instructional employees spent more than 7,200 hours completing reports at an approximate cost of $300,000 or 7% of Hartwick's non-aid budget. More than one-third of that time was spent reporting on its 1,500 students to the US Department of Education on Pell grant eligibility, direct loan processing and Clery Act Crime logs.

Dr. Drugovich reminded the meeting participants that meeting these compliance requirements are replicated at every institution of higher education and have a direct impact on the institution's ability to provide resources to meet compliance in other areas, notably research. The US Senate Task Force has been challenged by its Senate organizers to come up with a short list of specific reforms that can be made by the Department of Education without Congressional action; a list for Congress that require statutory changes; and big ideas about what is needed to encourage innovation in higher education. Dr. Drugovich's study will inform the work of the Senate Task Force as it begins the process.

The Washington-based associations are monitoring all these studies and working to getting the review of specific research regulations as a part of these various considerations.