COUNCIL ON GOVERNMENTAL RELATIONS
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MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS
WASHINGTON MARRIOTT HOTEL
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COSTING POLICIES

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COSTING POLICIES

Committee: John Shipley, Chair, University of Miami; James Barbret, Wayne State University; Susan Camber, University of Washington; James Luther, Duke University; James R. Maples, University of Tennessee; Kim Moreland, University of Wisconsin – Madison; Eric Vermillion, University of California, San Francisco; Mary Lee Brown, University of Pennsylvania, ACUA Liaison; Dan Evon, Michigan State University; Cynthia Hope, University of Alabama; Terry Johnson, University of Iowa; Casey Murray, University of Chicago

1. Thursday Morning Session – The Audit Landscape: Case Studies on Federal Office of Inspectors General (OIG) Audit Initiatives and Other Audit Discussions

The Thursday morning session presented by the Costing Policies Committee was a panel discussion covering a variety of audit topics. The panelists included Eric Vermillion, Associate Vice Chancellor – Finance at the University of California, San Francisco, Jim Luther, the Assistant VP – Finance and Research Compliance at Duke University, and Kimberly Ginn, a Senior Manager at Baker Tilly Virchow Krause, LLP.

Eric and Jim shared their experience with the Administrative & Clerical audits at their institutions, and Eric, Jim, and Kim each addressed the topics of effective communications with auditors and minimizing audit risk. David Kennedy, the Director of Costing Policies at COGR, provided the broad overview of the current Federal OIG focus areas. Below is a summary.

- **The Planning Process, the Team, and Overall Audit Management are Crucial to Success.** All three panelists emphasized the importance of the institution's planning process, the team in place, and the need to implement solid audit management practices. Having a strategic plan in advance of the audit, with a response team that is informed of the audit status and that can be mobilized quickly, is an important asset during the audit process. Documentation is critical – the auditors will keep all documentation they have asked for, and when they come back to an issue that was addressed months (or years) ago, you must be able to reference the same documentation they are referring to. The institution's web site is easily accessible by auditors and should be scrutinized for information that could be unfairly misconstrued. Maintaining regular contact with senior audit staff (e.g., Regional Directors) can help to preempt miscommunications. When auditors request interviews with faculty, it is important for other university personnel to be present. Finally, assembling a broad-based team from different offices at the university is a "must have" in order to have the most effective audit response team available.

- **Will Pre-Audits or Pre-Screening Create Institutional Risk?** In one case study, the institutional strategy was to pre-screen and accumulate all potential audit findings, prior to the arrival of the OIG. All potential findings were shared with the auditors upon their arrival. This was a "calculated risk" approach because once the institution decided to pre-screen, the institution believed they were obligated to share all findings with the auditors,

even if the findings were unfavorable. However, this open approach built trust with the auditors and helped to contribute to a successful audit. Hypothetically, in cases where inappropriate charges are found, the institution could be well-served to look for "offsets" – i.e., situations where a direct charge was not made, but could have been. More generically and in situations where there is not a pending audit, "mock" audits conducted by the Internal Audit department often are a good practice. However, when Internal Audit discovers findings, the institution must have a process for addressing the findings.

- **What Specific Items Were Looked at in the Prior Administrative & Clerical Audits?** Both labor and non-labor title codes charged to NIH projects were looked at by the HHS OIG auditors. "Clerical" title codes were the obvious target on the labor side, and the Circular A-21, Section F6b(3) object codes (e.g., office supplies, postage, local telephone, and memberships) on the non-labor side. Also, object codes listed as "miscellaneous/other", as well as transactions associated with overseas programs, were likely candidates for review. While direct charging of "personal computers" was not mentioned in the case studies, it was raised as a possible area of audit risk. The extent to which any of the items in question were charged to a "major project" could be a mitigating circumstance – however, what constitutes a "major project" often is a subjective measure and the auditors may not be agreeable (e.g., in one case study, the auditors maintained that the Cancer Center was not a "major project"). On the other hand, prior agency/budget approval appears to have been a helpful mitigating circumstance. Finally, the "direct charge equivalent" (or DCE methodology) is a mechanism used in the F&A rate calculation to create a downward adjustment to the F&A rate in situations where direct charging occurs – this may be an effective point to raise to auditors.

- **Beware of Extrapolation Methodologies.** It is significant to note that in one of the Administrative & Clerical audits the auditors extrapolated their small sample results to a large universe, and in any audit the findings may well be extrapolated. In the past, federal auditor methodologies that were not statistically sound could be an important defense to the institution. However, in the case of the HHS OIG, recently they have focused on more statistically sound methodologies, which makes it more difficult for an institution to challenge monetary damages. Another area of note is that monetary damages should always be limited to the audit period. For example, if the auditors sampled transactions for the period 7/1/07 through 6/30/09, it would be inappropriate to extrapolate monetary damages to any time prior to 7/1/07 or after 6/30/09.

- **Audit Resolution may be a "Crap-Shoot."** In the case of audits conducted by the HHS OIG, who is responsible for audit resolution at the federal level is unclear. Outside the HHS OIG office, HHS houses an Audit Resolution office. However, one expert in the audience observed that the Audit Resolution Office does not seem to have the resources or capability to undertake resolution of all OIG audit findings. In at least one of the Administrative & Clerical audits, the Division of Cost Allocation (DCA) was designated as the point office for audit resolution under the premise that indirect costs were the issue-at-hand, and therefore, the DCA was the appropriate point office.

The Administrative & Clerical audit initiative being led by the HHS OIG is significant. COGR is aware of 7 of the 8 institutions that have been selected and we will pay close attention as these audits unfold.

In the broad overview presentation, prior to the panelist's presentations, other audit areas were introduced, including Recharge Centers, Supplemental Compensation, Effort Reporting, Federal Pass-Through Funding, and Tuition and Fee Charging Practices. While not discussed at length in the Thursday morning session, all of these topics have been addressed in more detail in COGR Updates over the past four months. Some of these audit areas are either in a pilot stage or effectively are completed (e.g., Labor and Effort Audits by the NSF OIG) and COGR will continue to follow all developments. We encourage you to contact David Kennedy at dkennedy@cogr.edu if your institution has been contacted by an audit agency, and we will keep all correspondences confidential.

2. Thursday Afternoon Session – Coping with Regulatory Burden: Making the Case for Regulatory Relief and an Update on the National Academies Study

The final Thursday afternoon session was a panel presentation covering diverse perspectives on regulatory and financial relief for research universities. The panelists included Denise McCartney, Associate VC for Research Administration at Washington University, Susan Camber, Associate VP for Financial Management at the University of Washington, Dr. Peter Henderson, Study Director at the National Academies, and Michael Fitzpatrick, Associate Administrator at the Federal Office of Information and Regulatory Affairs (OIRA).

Denise and Sue each presented an institutional case study that emphasized the compliance and financial tribulations associated with federal regulations. Denise targeted the "disharmonious" policies of NIH and NSF applicable to the Responsible Conduct of Research (RCR), while Sue pointed to the challenges of implementing an Effort Reporting system. In both case studies, Denise and Sue reiterated that our community is committed to compliance and we take our stewardship responsibilities seriously. However, the compliance and financial burdens are unrelenting and cumulative. By easing the burden, this could lead to greater administrative efficiencies, enhanced investigator productivity, and reclaiming the research competitive edge of the United States.

Prior to the presentations by Denise and Sue, David Kennedy, the Director of Costing Policies at COGR, provided an overview of the recent regulatory and financial reforms advocated for by COGR and COGR's association partners, the American Association of Universities (AAU) and the Association of Public and Land-grant Universities (APLU). The recommendations to the National Academies can be found on the home page of the COGR web site (see www.cogr.edu, "Latest News" and January 28 link). Each of these reform recommendations have been shared with the National Academies with the hope that they may help shape their ongoing "*Study on Research Universities*".

After the first three presentations, Peter Henderson provided an update on the "*Study on Research Universities*." This initiative was started in response to a bipartisan request by Senators Lamar Alexander (TN) and Barbara Mikulski (MD) and Representatives Bart Gordon (TN) and Ralph Hall (TX) for a study focused on the health and competitiveness of our nation's research

universities. Peter shared that the Study is proceeding rapidly and that it is likely a final report will be issued this summer. While it is still too early to share results or insights on the final report, he did indicate that the report will address topics related to the Mission, Governance, Management, Finances, and Regulation of Research Universities. The Study can be followed at: http://sites.nationalacademies.org/PGA/bhew/researchuniversities/index.htm

The final presentation was made by Michael Fitzpatrick from OIRA. OIRA is the regulatory policy office for the White House and operates as part of the Office of Management and Budget. Michael works directly for Dr. Cass Sunstein, the Administrator of OIRA. Michael described how President Obama's Executive Order 13563 (January 18, 2011) reaffirmed and advanced President Clinton's Executive Order 12866 (September 30, 1993). Executive Order 13563 ordered that the regulatory system of the country must allow for open public participation and must identify the most innovative and least burdensome tools for achieving regulatory relief, while not sacrificing important health, safety, or environmental protections. OIRA is committed to implementing the principles of Executive Order 13563 and Michael sent an encouraging message that COGR and its member institutions should activity engage OIRA on this topic. The links below provide access to Executive Order 13563, the Implementing Guidance for Executive Order 13563, and Executive Order 12866 as issued in 1993.

http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order

http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-10.pdf

http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf

COGR expects to accept Michael's offer to stay engaged with OIRA, and when appropriate, to schedule joint COGR-OIRA-Agency meetings in those situations where a regulatory issue requires direct intervention. Furthermore, as agencies respond to Executive Order 13563 and request public comments specific to regulatory review through the Federal Register, COGR will respond accordingly (see discussion in the Research Compliance and Administration section of this Meeting report).

3. F&A-Compliance-Regulatory Reform Update

COGR has reported on reform initiatives for the past nine months. The Thursday afternoon session described in the previous section highlighted two pieces of the puzzle – the National Academies Study and the Obama Administration's commitment to achieving regulatory relief through the Office of Information and Regulatory Affairs (OIRA). Both could be positive developments.

We anticipate that the COGR focus on F&A-Compliance-Regulatory Reform will continue well into 2011. Some of our activities will be coordinated closely with our association partners at AAU and APLU, while others will emanate from COGR and be carried through by COGR. The COGR Costing Policies Committee has a full agenda specific to a number of reform-related topics and will continue fine-tuning the agenda over the course of the year. Included on the list are items that have been completed, as well as those that are works-in-progress:

- **COGR Policy Paper: *"Federal Funding Agency Limitations on Cost Reimbursement: A Request for Consistency in the Application of Federal Guidelines."*** The paper can be accessed at www.cogr.edu under "Latest News" on the COGR home page (see December 14 link), or by clicking on "Educational Materials / Financial Management." There are two documents – the first is the policy paper and the second is the appendix. Both are password protected, so you will need to enter your user name (normally, this is your email address) and password information. If you cannot gain access, click on the "Log-In | Register" tab in the upper right-hand corner of the home page and follow the directions for access. The paper identifies financial reimbursement policies imposed by Federal funding agencies that are inconsistent with official federal guidelines and result in the significant under-recovery of federal funds by research institutions. The Appendix to the paper includes a sampling of Federal agencies and/or programs where arbitrary agency policy results in additional financial burden for research institutions. The paper also includes a request for the Office of Management and Budget (OMB) and the funding agencies to undertake specific action items.

- **Consistent Application of the 1.3-percent Utility Cost Adjustment (UCA).** This was addressed in the September 2010 GAO Study, "University Research*: Policies for the Reimbursement of Indirect Costs Need to be Updated"* (GAO-10-937). OMB Circular A-21, Section F4. states: "*Beginning on July 1, 2002, Federal agencies shall reassess periodically the eligibility of institutions to receive the UCA.*" COGR's position is that the 1.3-percent UCA should be extended to all institutions – since many of the highest volume research institutions in the country already receive the 1.3-percent UCA, the shift of dollars from direct to F&A would be minimal.

- **Consistency Between DCA and ONR Negotiation Models.** This topic also was addressed in the September 2010 GAO Study. The advocacy strategy on this issue is being defined. However, there could be an opportunity to identify those federal rate negotiation practices that either exist or that would be desirable, and upon identifying these practices, document them and seek out a meeting with the appropriate Federal officials.

- **Recovering Research Compliance Costs through a New Research Compliance Cost Pool.** While eliminating the 26-percent Administrative cost pool limitation continues to be the COGR position, recovery of research compliance costs through a new research compliance cost pool could be an alternative solution. As appropriate, COGR will document the benefits and challenges to this methodology and how it could be implemented at the federal level.

- **The DS-2 and Effort Reporting.** In the "10 Recommendations" that COGR-AAU-APLU provided to the National Academies, the second recommendation was entitled: *"Eliminate regulations which do not add value or enhance accountability."* The recommendation stated that at least two requirements, Effort Reporting and Cost Accounting Standards, neither add value nor enhance accountability. Furthermore, both of these regulations could be eliminated without any detriment to the accountability or

oversight of the research enterprise. Further advocacy on this topic will require a number of additional considerations.

- **Direct Charging of Administrative Personnel when Appropriate.** OMB Circular A-21, Section F6b(2) provides some latitude by stating: "… *Direct charging of these costs may be appropriate where a major project or activity explicitly budgets for administrative or clerical services and individuals involved can be specifically identified with the project or activity*." One could interpret the language in F6b(2) that when a project is not a "major project", direct charging could be justified if there is an appropriate basis for doing so. Appropriate situations may include those where compliance and administrative support can be identified easily with the project (regardless of the size of the project) and where this support will have the impact of increasing investigator productivity. In some situations, support personnel could be shared among investigators and recharge rates could be developed to support the direct charges to research projects.

The right balance of pro-action, persistence, patience and flexibility is necessary to advance the reforms for which we are advocating. We will engage the membership and keep you updated on all aspects of the reform initiatives.

4. 2011 COGR Survey of F&A Rates and Development of the 2012 Survey

The 2011 COGR Survey of F&A Rates was sent to the COGR ListServe on February 9th. It is a 2-page survey that should be relatively easy to complete. We request that you complete the survey by March 21st. If you did not receive the survey, contact David Kennedy at dkennedy@cogr.edu. Some of the highlights of the survey are:

- **Historical F&A Rates, beginning with FY2006**. After the 2011 survey is completed, we will send reminders throughout the year and ask you to send updates to COGR if you negotiate new F&A rates.

- **Most Recent Proposed and Negotiated Components**. If you recently submitted an F&A rate proposal, but have not negotiated your F&A rate, we will ask you to fill-in the proposed components – the negotiated components can be completed at a later date.

- **Comparison between the Most Recent Proposed (Calculated) Components and "Old" Components**. We are recommending that the "old" components (calculated, not negotiated) fall into the FY1997 to FY2001 timeframe. We have asked for both the Administrative and the Facilities components, and our initial goal is to document the changes in the Administrative components. Specifically, changes in the G&A, DA, and SPA components.

- **Administrative Components Analysis**. Ultimately, COGR would like to analyze changes to the calculated administrative rates, as well as related issues on administrative efficiency. This section of the survey asks for institutional perspectives on the impact of burden, and also provides an opportunity to address effective administrative practices.

In addition, we would like to get a head start on the 2012 survey – specifically, what special and timely topics should be targeted? For example, the 2012 survey could address F&A and space survey methodologies, DS-2 updates, fringe rates, recharge centers, and other topics.

In the COGR Update (dated February 7, 2011) and in the February 9th note to the COGR ListServe, the Costing Policies Committee invited COGR members to participate in the development of the 2012 Survey. Four individuals accepted the offer and we met Friday morning during the COGR meeting to begin sharing ideas. One intent with future surveys is to maintain Historical Rates and the Proposed and Negotiated components on a "real-time" basis. Other target areas will be addressed by the survey development team. We will conference call and meet over the rest of the year and will keep the membership posted on developments – we welcome any ideas you may have.

5. ARRA Update

The seventh cycle of ARRA Section 1512 reporting will be initiated on April 1, 2011. While we continue to receive updates and inquiries from COGR members, the volume of ARRA-related concerns appears to have ebbed. However, several recent developments are worth noting.

"Best Available Data" (with "lag") Methodology and the A-133 Audit. A small number of institutions utilized an ARRA Section 1512 reporting approach that has come to be known as the "best available data" (with "lag") methodology. In several situations, this method has been questioned by A-133 auditors. For example, using the initial October 2009 reporting period, the institution may have reported data through September 15, rather than September 30. The important justifications for this approach were that this would provide the American public with the most accurate snapshot of ARRA activity and that the underlying OMB "cumulative" data model provided for an automated correction mechanism. In an email to COGR dated September 17, 2009, a representative from OMB stated that OMB reviewed a COGR description of the "best available data" methodology and OMB was "fine" with the COGR description of that approach (note, the COGR description did not specifically refer to the "lag"). However, in a recent discussion with COGR, OMB clarified that while "best available data" is an acceptable principle, the "lag" is not. In that same discussion, OMB also indicated that it is their opinion that if an institution used the "lag" approach, an A-133 audit finding should be limited to an "immaterial" finding. COGR is in the process of getting further clarification from OMB.

GAO Review of NIH Recovery Act Grants. We have been contacted by several member institutions and our understanding is that the five institutions that received the highest dollar volume of NIH ARRA funding have been selected by the GAO for this review. The GAO review is not an audit, but instead, a study that addresses the impact of the ARRA funding. The GAO review will target ten faculty members and they will send a web-based questionnaire to them with specific questions on jobs, impact on science, impact on the University and impact on the local community. The Office of Sponsored Programs also will be getting a questionnaire that probes the central office responsibilities related to ARRA reporting. The GAO was charged in the ARRA legislation to conduct these types of reviews and has done so since the onset of ARRA. We expect this review will turnaround relatively quickly, and we will keep the membership posted.

GAO Review of ARPA-E Awards. We have been contacted by one member institution that they have been selected by the GAO for this review. Again, the GAO review is not an audit, but instead, a study that addresses the impact of the ARRA funding. Like the GAO review of NIH awards, we expect this review will turnaround relatively quickly, and we will keep the membership posted.

COGR is monitoring these items and is interested in feedback from the membership. In addition, we encourage you to contact COGR staff if you have questions or if there are situations that you believe require OMB and/or RATB clarification or action.

6. 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.

NIH Genomic Arrays (GAs). COGR remains actively engaged with the GA issue (see prior COGR Update letters to the membership for detailed discussions). While COGR's position remains that the policy issued on May 13, 2010 should be retracted, that outcome is unlikely. However, we expect NIH shortly will issue Frequently Asked Questions (FAQs) and/or policy modifications. While modifications will be a compromised solution, we believe they will improve the current version of the policy.

NIH Salary Cap. The legislative authority for the NIH Salary Cap is determined in the annual appropriations legislation for NIH – since 1990, the legislation has required that the NIH salary limit be tied to the Level I salary rate of the Federal Executive Schedule for compensation. Under the most recent two-week Continuing Resolution, the FY2010 appropriations requirements remain in effect and the NIH salary limit is required to be tied to the most current Level I rate. The most current Level I rate was published by the Office of Personnel Management (OPM) in January 2011 (see link below). Due to the freeze on federal salaries, the Level I rate stayed at $199,700, and hence, the NIH salary limit stayed at $199,700. When (if) appropriations legislation is passed for FY2011, the expectation is that the NIH salary limitation will continue to be tied to the Level I rate, in which case, the $199,700 cap will remain applicable. The OPM Executive Schedule can be found at:
http://www.opm.gov/oca/11tables/pdf/ex.pdf

NIH Request, Costing on Core Facilities. COGR submitted a response letter to NIH concerning the NIH request for comments on "*FAQs to Explain Costing Issues for Core Facilities.*" A copy of the COGR letter can be found on www.cogr.edu (see the home page, "Latest News", December 8, 2010). NIH intends to release a final version of the FAQs later in the Spring and we expect to have access to NIH as they formulate the final version. COGR appreciates the detailed and thoughtful input that a number of you shared with us – we were able to incorporate many of your comments into the COGR response letter.

Health Resources and Service Administration (HRSA) and Letter of Credit Accounts. HRSA is an operating division under the Department of Health and Human Services (HHS).

While its reach to the university community is not as extensive as other research funding agencies, many COGR members have some level of HRSA funding. Under ARRA, HRSA (and all other HHS operating divisions) was required to establish an award-by-award drawdown mechanism, rather than utilizing a pooled letter-of-credit account. It now appears that HRSA is applying the grant-by-grant drawdown mechanism to selected non-ARRA programs. COGR has engaged with HRSA, HHS, and OMB on this issue and will keep the membership posted on developments.

DOD 35-percent F&A Limitation. This statutory requirement will remain in effect as long as DOD continues to operate under a Continuing Resolution. We remain cautiously optimistic that when (if) FY2011 appropriations legislation is passed, the F&A limitation language will either be eliminated or modified to state that the limitation no longer applies.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Wendy Streitz, University of California, Chair; Elaine Brock, University of Michigan; Charles Louis, University of California, Riverside; Cordell Overby, University of Delaware; Susan Sedwick, University of Texas, Austin; Marianne Woods, University of Texas at San Antonio; Catherine Innes, University of North Carolina, Chapel Hill; Alexandra McKeown, The Johns Hopkins University; Jennifer Murphy, George Mason University; John Ritter, Princeton University; Kevin Wozniak, Georgia Institute of Technology

7. Panel Discusses Export Control Developments

A panel consisting of Kevin Wolf, Assistant Secretary of Commerce for Export Administration; Phillip Kuhn of the Commerce Office of Export Enforcement, and Jahna Hartwig, Hopkins/APL, a member of the State Department Defense Trade Advisory Group (DTAG) discussed recent developments in export controls.

- **Reform Initiative.** Mr. Wolf discussed the current reform initiative (see COGR February '11 Update). He noted that the previous system was a "Cold War artifact," and not designed for today's security environment, where interoperability and collaboration are critical. He described the new control structure as more user friendly and facilitating the migration of items among tiers and control lists. The eventual goal (for which legislation will be required) is to harmonize the system into one control list under the jurisdiction of a single regulatory agency, with one IT system and one form of license application. He indicated that the President and Sec. Gates are directly involved in the reform initiative. The final rules for the FR notices published in December are planned to be issued in April, with additional revisions to USML categories rolled out over the next few months. A copy of Mr. Wolf's remarks will be posted to the COGR website.

- **I129 Deemed Export Certification.** With regard to the USCIS Form 129 deemed export certification (also discussed in the COGR Update), Mr. Wolf mentioned a recent GAO study of the visa process. The study found a huge imbalance between the number of visas granted to foreign visitors in H1B and other special occupation visa categories vs. the very small number of deemed export licenses issued for such visitors. GAO recommended that as part of the visa process assurance be obtained that the receiving entity is knowledgeable about the export control regulations and would obtain the necessary license authorization to allow the foreign visitors' access to controlled technologies or information. For this reason the certification was added to the I129, after some editing by Commerce of the version USCIS initially proposed last February. (Note: the GAO report, *Improvements Needed to Prevent Unauthorized*

Technology Releases to Foreign Nationals in the U.S., was released on March 7; GAO-11-354. The overall recommendations correspond to those made in previous GAO reports).

- Mr. Wolf stated that the objective is to "force people to think about" what if any access foreign visitors will have to controlled data or technology before they are brought in. **The certification requirement is effective as of February 20**. In response to a later question about due diligence, Mr. Wolf indicated that the I129 is not intended to be a "permanent compliance form," and that petitioners should complete the certification to the best of their knowledge at the time. **There is no requirement that the certification be updated should circumstances change**. Mr. Wolf also indicated that Commerce is trying to get DHS to publish a set of FAQ's, and suggested that questions be sent to DHS (if no response, he said the questions should be sent to him). (Note: NAFSA has published a Practice Advisory on the I129, which is available at http://www.nafsa.org/resourcelibrary/default.aspx?id=25004. There also is a helpful NACUA Note, which has been sent to the COGR listserv).

- **Enforcement—Roth Case.** Mr. Kuhn discussed Commerce/BIS's general approach to export enforcement and provided some information on the case involving Professor Roth of the University of Tennessee. He reviewed in some detail the recent decision of the 6th Circuit Court of Appeals on Professor Roth's appeal of his conviction (see Update). Mr. Kuhn cited the opinion as holding that if a defense project ultimately contemplates a defense use, the technologies are defense articles at any stage of the project. In response to a later question about phased projects, Mr. Kuhn suggested that we provide our views to the State Department if we have concerns about the implications. Mr. Kuhn also stated that the opinion indicates that liability for export violations does not require proof of knowledge of specific sections of the law or regulations; just a general knowledge that the activities may be violations. More generally, Mr. Kuhn indicated that 99% of enforcement visits to universities do not involve specific allegations of wrongdoing but are for the purpose of developing a general sense of what is going on. BIS may or may not contact universities in advance. Mr. Kuhn concluded with 3 tips to universities; 1) have a general protocol in place; 2) don't lie—it destroys credibility; and 3) don't cover up; voluntary self disclosures always are better.

- **DTAG Proposals**. Ms. Hartwig discussed the revisions proposed by the DTAG to the ITAR definitions of "defense services," "public domain information," and "fundamental research." One proposal is to add to the definition of "defense services" in ITAR Part 120 a statement that "the conduct of fundamental research using only public domain information does not constitute a defense service." The proposed definition of fundamental research would follow NSDD 189, with additional definitions of basic and applied research based on the FAR. The

DTAG also proposed to add FAQ's to the defense services definition. The suggested FAQ on collaborative research with non-higher education entities involving foreign persons may raise concerns. Ms. Hartwig indicated that the President's Export Control Reform Task Force is considering the ITAR definitions, including the DTAG proposals. Something is expected to be published soon. A copy of Ms. Hartwig's presentation will be posted on the COGR website.

8. Universities with DOD Contracts Receive Defense Security Directive

We have been informed that a number of universities who are "cleared contractors" under the DOD National Industrial Security Program have received a directive dated February 11 from the Defense Security Service (DSS) on protecting classified information on their IT systems. The directive responds to the WikiLeaks disclosures. It reminds cleared contractors that classified information regardless of whether it may have been posted or disclosed on public websites remains classified. Cleared contractor employees accessing the web on unclassified systems may not access or download classified documents even if publicly available through WikiLeaks or other websites. This includes accessing or downloaded such documents on personal computers.

Questions have been raised by COGR member institutions as to the scope of "cleared contractor employees" covered by the directive. We have discussed this issue with a number of universities with cleared facilities. The advice we received is that this directive does not apply to the main campus even though a small number of personnel there may hold government clearances. The guidance only pertains to government and contractor facilities that possess a facility clearance. If the facility is involved in a security violation that involves an individual (who holds a clearance) that accessed any WikiLeaks information from an unclassified computer, the facility would follow the guidance in the directive. The bottom line: If a cleared employee anywhere on campus accesses Wikilinks on an unclassified system, and views or downloads a classified document, it is considered a security violation and is reportable to the DSS. If a non- cleared employee or student accesses Wikilinks on a computer located other than a cleared facility no action is required. If a non-cleared employee or student accesses Wikilinks on a computer located at the cleared facility that is considered a security violation and is reportable. In this interpretation, "cleared contractor employees" means only cleared employees of the contractor, not all employees of a cleared contractor.

Obviously a broader interpretation of the directive in a campus environment would raise a host of issues. While not definitive, we suggest that pending any further guidance, COGR institutions may wish to consider following the interpretation above.

9. Committee Discusses Commercialization Issues with NIST Counsel

The COGR February 2011 Update discussed the Commerce Department's efforts to seek commitments from universities to enhance their commercialization activities. The COGR Contracts and Intellectual Property Committee (CIP) met with Henry Wixon, Chief Counsel at NIST, to further discuss these activities and related developments.

- **New NIST Associate Director.** NIST has appointed a new Associate Director for Innovation and Industry Services. According to the announcement, the new AD position for Innovation and Industry was created as part of the first major realignment of NIST programs in 20 years. The change was designed to improve the agency's efficiency in delivering both forefront research results and the measurement, standards and technology-related services needed by manufacturers and other customers, providing critical support to U.S. economic growth. Phillip Singerman has been appointed to the new Associate Director position. During the Clinton Administration, Mr. Singerman served as Assistant Secretary for Economic Development at the U.S. Commerce Department. He has 30 years of experience leading nationally recognized, regional technology development and transfer organizations, including the Maryland Technology Development Corporation (TEDCO) and Philadelphia's Ben Franklin Technology Partners. Mr. Singerman has expressed a willingness to meet with COGR after "settling in" at NIST.

- **NIST Director Now Undersecretary of Commerce.** Mr. Wixon informed us that in addition, the Director of NIST has been elevated to the level of Commerce Undersecretary, which among other things gives him regulatory authority. NIST plans to renew its commitment to Bayh-Dole and Stevenson-Wydler Act oversight responsibilities (although NIST does not have a "hammer" over other agencies). The implication was that Mr. Singerman may play an active role in this area. NIST plans to issue conforming regulations to Bayh-Dole shortly. The initial focus, however will be on Stevenson-Wydler and improving the tech transfer effectiveness of the federal labs. The Science and Technology Policy Institute has been evaluating their commercialization activities and a report is expected next quarter. Mr. Wixon noted that the Commerce Office of Innovation and Entrepreneurship has been reassigned to EDA, and has less of a focus on tech transfer.

- **Metrics.** Mr. Wixon also noted that as part of the Administration's focus on enhancing commercialization, NIST will be expected to help develop improved metrics and a lexicon to describe them, which are areas in which they might look to COGR for help. In discussion we noted that an effort to develop a common lexicon would be helpful, and that NIST could play a convenor role. There appears to be a belief with regard to commercialization that universities need to do it better, but no one really has defined the "it." We also mentioned the StarMetrics activity to Mr. Wixon.

- **Issues Identified in RFI Responses.** Mr. Wixon indicated that Commerce still is digesting the responses to the OSTP/NEC RFI (see COGR Update) and last year's regional meetings. One idea that was identified in many of the responses was the possibility of implementing a SBIR "Phase O" program. We expressed guarded enthusiasm for this idea, with the understanding that the funds must come from the existing SBIR set-aside (and probably would be opposed by the SBA). We also noted that Bayh-Dole was an unfunded mandate, and that thought should be given to providing universities with more resources for this purpose. We

expressed concerns about proposals such as basing research grants to universities on their success in commercialization, which has been suggested in some of the Commerce discussions. Mr. Wixon appeared to share our concerns about these matters.

10. Commerce Proceeding with Plans for University Commercialization Commitments

We understand that the Commerce National Advisory Council on Innovation and Entrepreneurship (NACIE) is planning to issue a followup to its December message to university presidents (see Update). Universities may be asked for commitments to promote activities such as student and faculty entrepreneurship, actively supporting the university tech transfer function, facilitating university-industry collaboration, engaging with regional economic development efforts, and provide greater recognition to economically engaged universities. Efforts to foster continued dialogue in this area and to implement the recommendations of the October 2010 NAS report on *Managing University Intellectual Property in the Public Interest* (see COGR Fall 2010 Update) may also be part of this effort. As we previously noted, the higher ed. associations have been concerned about the level of specific commitments sought by Commerce. We will continue to closely monitor these activities, in collaboration with the other associations.

11. Commerce Issues New RFI on Innovation

On February 4 Commerce published another RFI seeking input on the Administration's Innovation Strategy (76*FedReg*6395). The RFI implements the Competes Act 2010 Reauthorization Act directive to Commerce to deliver a study by next January on U.S. innovative capacity and international competitiveness. The Strategy has three parts: 1) investing in the foundations of American innovation; 2) promoting market-based innovation; and 3) catalyzing strategic breakthroughs in national priority areas. The RFI lists a series of questions for help in developing comments. Some of these are directed to specific industry sectors. The RFI notes that Commerce and the Administration have issued other recent RFI's on innovation-related topics, and states that commenters are "welcome to submit materials generated for these other matters in order to build the record for our January 2012 report to Congress."

We are not certain that we have much to add to the joint association response last May to the OSTP/NEC RFI. One possibility might be to resubmit that response with a cover letter. However, we have not come to a final decision with the other associations whether or how we will respond to this RFI. Comments are due April 1.

12. Supreme Court Hears Oral Arguments in *Stanford v. Roche*

On February 28 the U.S. Supreme Court heard oral arguments in the *Stanford v. Roche* case, in which COGR had joined with other higher ed. associations and many universities as an *amicus.* Stanford shared its oral argument time with the U.S. Solicitor General, who had filed a brief supporting Stanford's position.

Many accounts have appeared in various sources including the Chronicle of Higher Education and the SCOTUSblog (www.scotusblog.com/) describing the oral arguments and the justices' questions. These accounts differ quite markedly in emphasis and perceptions as to the justices'

likely positions, and some of the press coverage appears misleading. From their questions the justices seemed quite well-versed on the issues. We have been advised, however that in any event the questions in oral argument tend to be poor predictors of the final outcome.

The most gratifying moment for us occurred when Justice Breyer singled out the *amicus* brief of the university community as "very, very interesting." Justice Breyer specifically noted our argument that the Bayh-Dole Act should be construed consistently with the Executive Order governing the inventions of federal employees. Many of the questions of Stanford's counsel were focused on why Bayh-Dole did not have explicit vesting language if the statute was intended to depart from the traditional rule that an inventor is free to assign his or her invention to a third party. Justice Scalia emphasized this point. Justices Kennedy and Ginsburg questioned the Federal Circuit's decision that the "hereby assigns" language of the Visitor Confidentiality Agreement signed by the researcher should trump Stanford's earlier contract with its researcher in which he "agreed to assign" future inventions to Stanford. They wondered whether the case couldn't be disposed of on those grounds (i.e. by reference to contract law). Justice Alito asked why universities had been obtaining assignments for the past 30 years if they didn't need assignments. The Chief Justice asked whether universities ever differentiated between their arrangements with different researchers, with well-known researchers extracting better deals. If a different patent ownership deal could help attract a star researcher, the Chief Justice asked if Stanford would "be willing to sell the interests of the United States down the river," by colluding with the researcher to bypass Bayh-Dole.

The Deputy Solicitor General stressed that, under Roche's theory, the federal government could have its rights cut off entirely by an individual inventor (and reinforced the Chief Justice's concern about the potential for "deals" to undercut the government's interests). He pointed out that the absence in the statute or implementing regulation of anything requiring an assignment from the inventor to the contractor would be a gaping hole if the inventor were free to assign the federally funded invention to a third party. When asked by Justices Kagan and Scalia whether the government couldn't simply remedy the problem by requiring universities to confirm that they had in place agreements by which they obtain assignments from their researchers, the Deputy SG pointed out that such an agreement should not be necessary. However, if the entire premise of the statute were presumed to be that universities and researchers should be free to make their own agreements, a regulation requiring assignment by the inventor could be challenged as inconsistent with the statute. Roche's counsel adopted Justice Scalia's suggestion that the federal government could protect itself by requiring contractors to obtain assignments from their employees. Justices Sotomayor and Kagan were very active in questioning Roche's counsel and pressed him on why Congress would have adopted Bayh-Dole, with the intent of protecting the government's interests, but then left it up to the choice of individual inventors whether to assign their government funded inventions to the university, which triggers the government's rights under Bayh-Dole.

As the above demonstrates, several of the justices were quite troubled by the consequences of Roche's arguments. At the same time, several questioned whether the seemingly problematic consequences of the Federal Circuit's decision couldn't be addressed by the government adopting a regulatory requirement to obtain assignments and/or by universities changing their employment agreements to utilize "hereby assigns" language. As a consequence, it is difficult to predict with any confidence what the Court will conclude in its opinion. Some observers think

that the likeliest outcome may be a remand given that the fact situation appears somewhat muddled. The implications of such a remand for the Bayh-Dole issues are unclear. The decision is likely to be announced in the May—June timeframe.

13. Senate Passes Patent Reform

On March 8 the Senate passed S. 23, the patent reform legislation (now called the "America Invents" Act) by a vote of 95—5. Perhaps the most important change in the legislation is to change the U.S. patent application system from a "first to invent" to a "first inventor to file" standard. COGR and other higher ed. associations supported this change, which helps harmonize the U.S. patent system with practices followed elsewhere in the world. Many small companies and independent inventors opposed the change. The bill also gives the U.S. Patent and Trademark Office (PTO) the ability to set its own application fees and importantly, prohibits Congress from diverting the funds for other purposes. In addition, it provides authority for PTO to establish an expedited review procedure for a higher fee (PTO already had announced plans to pilot such a program). The Senate bill also provides for a post grant review system which we favored (see COGR February Update for more information).

Action now shifts to the House. While House Judiciary Committee Chair Lamar Smith introduced the original version of the patent reform legislation (H.R. 2795) in 2005, many features have evolved. Although we expect the House version to support first inventor to file, we understand the House may have concerns about the post grant expanded *inter partes* review procedures (one of the failed Senate amendments would have stripped this process from the bill, and it is opposed particularly by large IT companies), and that the House version may also expand "prior user" rights, which has been a major concern for universities. It is not clear when Chairman Smith may introduce his version of the bill.

We have reported frequently to the COGR membership on the status of proposed patent reform legislation since Congressional action began in 2005. COGR has been collaborating with other higher ed. associations on patent reform since then. For the correspondence and position papers developed by the higher ed. associations over this time, see http://www.aau.edu/policy/article.aspx?id=9602 . We frequently have reported to the membership on the status of the proposed legislation, and will continue to keep the membership informed. While understanding that the Senate bill is not perfect, the associations strongly support it, and believe we have been mostly successful in having our concerns addressed. In a March 8 editorial the New York Times also strongly supported the America Invents Act.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Michelle Christy, Chair, Massachusetts Institute of Technology; Michael Amey, The Johns Hopkins University; Kelvin Droegemeier, University of Oklahoma; Michael Ludwig, Purdue University; Denise McCartney; Washington University in St. Louis; James Tracy,. University of Kentucky; Pamela Caudill, University of Pennsylvania; Carpantato Myles, University of Alabama; Carol Zuiches, University of Chicago

14. NSB Reviews NSF Merit Review Criteria

The National Science Board (NSB), the governing body of the National Science Foundation (NSF), has initiated a review of the merit criteria used to select proposals for funding. As a part of that review, the NSB has asked the research community to weigh-in on the strengths and weaknesses of the current criteria – intellectual merit and broader impacts. They seek ideas for how to change the criteria, if appropriate, the role of the institution in assisting investigators in meeting their goals and if the criteria help shape the design of the research programs. Comments are due March 15, 2011 and can be posted to the NSB website at: http://www.nsf.gov/funding/meritreviewform.cfm

As a part of the February COGR meeting, Joanne Tornow, Executive Secretary to the NSB Task Force on merit Review, described the initiative and, along with her colleague Jean Feldman, Head of the NSF Policy Office, engaged in a spirited discussion with the attendees about the merit review criteria. One of the goals of the Thursday morning session was to help COGR frame its comments to the NSB. Because of the additional task facing NSF to develop and implement a policy reflecting the Congressional goals outlined in the America COMPETES Act Reauthorization of 2010(PL 111-358) Section 526, much of the discussion focused on the broader impacts review criteria and will frame the COGR response.

As a number of individuals noted investigators find it difficult to state with certainty what the broader impacts of their basic research will be at the time of application arguing that meeting the broader impacts with each separate proposal is inappropriate. Goals that link individual scientists and their projects to economic competitiveness, partnerships with private industry, scientific literacy, national security or general public benefit draw responses that are, by the nature of the question, speculative or ill-defined. Other goals linking individual scientists to broadening the participation of women and underrepresented minorities in science, improving K-12 education or developing a globally competitive workforce are daunting for the individual. Some investigators fear that emphasizing the broader impacts of the activities may diminish the value and appreciation of the intellectual merit of the proposed activities.

Most participants know that NSF recognizes that not all science and engineering activities supported by the Foundation will have an easily defined broader impact beyond enhancing scientific knowledge through the broad dissemination of the research results. In considering

changes, NSF might consider the broader impacts criterion as multi-faceted with some aspects easily associated with a specific research activity and appropriately addressed in the application phase and other aspects more suited to description in a final or outcomes report. Taking this approach, NSF may get a more complete picture of the broader impacts of its support of science.

The current criterion asks how the proposed activity enhances the infrastructure for research and education, such as facilities, instrumentation, networks, and partnerships and how results will be disseminated or made broadly available. Most scientists can address these types of questions if reframed to encourage investigators to describe how novel techniques, unique instrumentation and other innovations might be demonstrated and/or disseminated to other investigators or, as appropriate, with other research sponsors. These types of broader impacts are appropriate for an application.

Asking investigators to link their specific research activity to more global goals – national security, US economic competitiveness, and public scientific literacy – may not be productive. Those facets linked to STEM education, teacher training, workforce development and enhancing diversity may be best addressed by the investigator in partnership with their institution and after the research activities have been completed. It may be appropriate for NSF to raise these aspects of broader impacts as a goal and ask the investigator at the conclusion of the project period to describe activities that occurred to address those goals.

In line with the objective proposed in the America COMPETES Act Sec. 526, institutions could be encouraged to offer programs in partnership with NSF that acquaint investigators with those broader impact goals including the critical importance of enhancing the participation of women and underrepresented minorities in their labs, engaging elementary or secondary teachers in their research, and/or partnering with private industry to bring promising ideas to the marketplace.

With resources made available by NSF, institutions can link investigators with opportunities available through local community institutional partnerships and programs. NSF could offer workshops at professional scientific meetings or regularly available teleconferences and provide support to institutions to implement proven activities that link basic scientists with teacher training programs and/or public literacy programs, etc.

15. Retrospective Regulatory Review

As reported at the meeting, President Barack Obama issued Executive Order 13563 (EO 13563), Improving Regulations and Regulatory Review on January 18, 2011. The EO reaffirmed the current regulatory review process and expanded and added elements that reflect the Presidents emphasis on transparency, accountability and scientific integrity. The most immediate impact of the Order was its call for a retrospective review of current regulations , triggering an on-going round of requests by Federal agencies for public comment on current regulations. Agencies have been charged with identifying those regulations that may be “outmoded, ineffective, insufficient or excessively burdensome” and consider how “to modify, streamline, expand, or repeal them.” Each agency is required to develop and submit within 120 dates of the EO a preliminary plan for the periodic review of its existing “significant” regulations with a goal of an agency regulatory program that is more effective and less burdensome.

In addition to the retrospective review and consistent with the Obama Administration's focus on transparency, EO 13563 adds an important emphasis in the review of regulations under the current system (EO 12866 reviews) on public participation in the rule making process calling for a more "meaningful opportunity to comment" on proposed rules and regulations by the public, in general, and those who would benefit and those potentially subject to the rule, specifically. Adding to the current system, agencies must consider ways to promote greater coordination and harmonization of regulations across agencies in addition to the combined or cumulative effect of their regulations and those of other agencies on the regulated community. Agencies are urged to be more flexible and explore alternatives to direct regulation and/or mandates or prohibitions to achieve the same regulatory goal. EO 13563 returns to the President's theme of scientific integrity by requiring agencies to ensure objectivity through the use of science and technical information that is free from inappropriate influences. Finally, agencies are asked to identify, as appropriate, approaches to regulations that promote innovation.

To guide the Federal agencies in meeting the challenges posed by EO 13563, Cass Sunstein, Administrator of the US Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs – the OMB office that reviews new regulations – issued a memorandum to the agencies providing guidance on the new principles and requirements incorporated in EO 13563. Michael Fitzpatrick, Deputy Administrator, emphasized the OMB/OIRA role in the review of regulations during his presentation at the COGR meeting.

COGR will respond to the various research-related agencies as appropriate. The US Department of Energy issued the first such request for information from the public establishing a special link on its web page for submission of ideas. Comments to the Department of Energy are due March 20, 2011. Our goal is to develop a standard template which includes the association's recommendations to the National Research Council's on-going review. On January 28, 2011, COGR joined with the Association of American Universities (AAU) and Association of Public and Land-grant Universities (APLU) to submit recommendations to the National Research Council's (NRC) on-going Committee on Research Universities' examination of actions that can be taken by all stakeholders to assure the ability of the American research university to maintain excellence in research and doctoral education. (The recommendations are available on the COGR website at: www.cogr.edu.)

The NRC recommendations address some of the principles that are articulated in Executive Order (EO) 13563 notably the need for coordination and harmonization, as appropriate; the burden of cumulative, prescriptive regulations; and the need for a balance between regulation and flexibility in the performance of work under a Federal grant or contract. The recommendations address financial reforms as well because of the unique challenges faced by research universities under the severe limitations imposed by a cap on the recovery of our facilities and administrative (F&A) costs when conducting research for Federal agencies. This cap results in a situation where every new regulation is an unfunded mandate placed on the university.

In addition to the Department of Energy (due March 21), calls for comments and regulations for consideration have been issued by the Environmental Protection Agency (due March 20), and Departments of Interior (March 28), Justice (March 31), Transportation (April 1), Economic Development Commission (Commerce, April 11) and Housing and Urban Development (May

2). A search of the *Federal Register* using "EO 13563" as the key word will provide further information.

16. NIH Adopting NAS/ILAR *Guide for the Care and Use of Laboratory Animals: Eighth Edition*

The National Institutes of Health (NIH) has requested comment from the research community on its planned adoption National Academy of Sciences' Institute for Laboratory Animal Resources (ILAR) *Guide for the Care and Use of Animals: Eighth Edition*. Comments are due March 25, 2011 (See NIH Guide notice NOT-OD-11-042 for information on submitting comments.) As you know, NIH uses this Guide, as the basis for its policy on the care and use of animals in research supported by NIH. The Eighth Edition was published in June 2010; NIH has completed its review and proposes implementation of this edition no later than March 31, 2012. Institutions will be required to complete at least one semiannual program and facility evaluation under the new Guide by March 31, 2012. For NIH, this is a policy (guidelines) revision not a regulatory change however the Health Research Extension Act of 1985 requires notice and comment.

There are substantive changes to the Guide. In describing the changes in the 8th edition, ILAR highlights: the inclusion of the first discussion of animal biosecurity practices; measures taken to contain, prevent, and eradicate infections that may cause disease or otherwise make laboratory animals unsuitable for research; expanded information on topics such as transportation, pain and distress, euthanasia, and veterinary medicine; and, notably, the addition of information on the care and use of fish and other aquatic species. The new edition reaffirms the use of performance standards in managing animal care and use.

COGR's comment will focus on the costs of implementing the Eighth Edition of the Guide. We welcome comments and suggestions from the membership. Please provide any comments ASAP but no later than March 21, 2011 (cblum@cogr.edu).

17. Bioethics Commission to Review Human Subjects Protections

The Presidential Commission for the Study of Bioethical Issues has requested comment on the Federal protections for human subjects to assess the adequacy of those protections domestically and internationally; how "global research" using human subjects works in practice; and the ethical and social justice issues emerging from that research. The Commission has outlined a series of specific issues – differences across global norms and standards; trial design; challenges faced by US investigators working internationally, etc. Comments are due May 2, 2011. The request appears in the *Federal Register* on March 2, 2011 (76FR11482).

The Commission, as currently constituted, advises the President on bioethical issues that may emerge from advances in biomedicine and related areas of science and technology by identifying and promoting policies and practices that ensure research is conducted in an ethically responsible manner. As you will recall, there has been a long and varied history of bioethics commissions dating to 1974 and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, author of the Belmont Report in 1979. More recently, the National Bioethics Advisory Commission (NBAC; 1996-2001) and the President's Council on Bioethics (PCBE; 2001-2009) have addressed topics in addition to protections of human subjects

including cloning and stem cell research. The current Commission recently reported to the President on the need for Federal oversight of synthetic biology.
The review of human subjects' protections is being conducted at the request of the President. As we reported in the Winter Update to the membership, following the revelation in October 2010 concerning the U.S. Public Health Service supported research about sexually transmitted diseases in Guatemala from 1946 to 1948, President Obama asked the Bioethics Commission to assure him that current rules for research participants protect people from harm or unethical treatment, domestically as well as internationally. This request for comments and the creation of an International Research Panel reflect the start of the Commission's fact finding. The request, information on the panel and general information concerning the Commission is available at: http://www.bioethics.gov/

COGR is considering a comment that describes the general effectiveness of the current federal regulations for research conducted in the US, highlights the need for harmonization across Federal agencies and indentifies areas for streamlining the regulations for non-biomedical research. We welcome comments and suggestions from the membership ASAP but no later than April 15, 2011 (cblum@cogr.edu).