

COUNCIL ON GOVERNMENTAL RELATIONS

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MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS

WASHINGTON MARRIOTT HOTEL

February 18 and 19, 2010

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COSTING POLICIES

Committee: John Shipley, Chair, University of Miami; James Barbret, Wayne State University; Susan Camber, University of Washington; Natalie Krawitz, University of Missouri; James R. Maples, University of Tennessee; Lynette Arias, Columbia University; Dan Evon, Michigan State University; Mary Lee Brown, University of Pennsylvania, ACUA Liaison; James Luther, Duke University; Casey Murray, University of Chicago

1. The State of Research Infrastructure at U.S. Universities

COGR Board Chair, Al Horvath, testified as part of a panel at a hearing held by the Subcommittee on Research and Science Education, House Committee on Science and Technology on Tuesday, February 23, 2010. Dan Lipinski (D-IL) is the Subcommittee Chair and Vern Ehlers (R-MI) is the Ranking Republican Member. Both Mr. Lipinski and Dr. Ehlers share science backgrounds (note, Dr. Ehlers earned his PhD as a Physicist) and both are advocates of the role that science and research play in the United States.

In addition to serving as Chair of the COGR Board, Al is the Senior Vice President for Finance and Business at Pennsylvania State University. The three others who joined Al to provide testimony were: Dr. Leslie Tolbert, Vice President for Research, Graduate Studies and Economic Development, University of Arizona, Dr. John R. Raymond, Vice President for Academic Affairs and Provost, Medical University of South Carolina, and Chair for the State of South Carolina EPSCoR Committee, and Dr. Thom Dunning, Director of the National Center for Supercomputing Applications, University of Illinois at Urbana-Champaign.

The Subcommittee on Research and Science Education has a web page that includes the “Witness Statements” and the “Hearing Charter” (i.e., a summary of the issues, questions, and concerns of the Subcommittee) from the February 23rd hearing. This page can be found at: http://science.house.gov/publications/hearings_markups_details.aspx?NewsID=2743

COGR Staff attended the hearing. At a high level, part of the Subcommittee’s interest was related to future deliberations on the reauthorization of the National Science Foundation (NSF) and the America Competes Act of 2007. However, of immediate concern was to learn more about the state of research infrastructure at our institutions. NSF was active in research facilities and infrastructure investment in the 1990s via funding provided in the Academic Research Infrastructure (ARI) program. However, ARI and similar programs at other funding agencies have disappeared over the past decade. While there has been a revival of these programs under ARRA, there currently is no plan for funding these types of programs beyond ARRA.

Dr. Tolbert stated that the University of Arizona has estimated its deferred maintenance on buildings and infrastructure to be \$200 million. Al echoed the same by defining the Penn State tab to be close to \$1 billion, of which 40 to 50-percent is applicable to research facilities. Dr. Raymond, as South Carolina’s Chair for EPSCoR, focused on the infrastructure needs of institutions in EPSCoR states where research funding historically has been deficient. Dr.

Dunning's perspective was on Cyberinfrastructure and Supercomputing facilities – despite significant investments by NSF, disparities between states and underlying infrastructure and user-capability concerns are a potential long-term risk area in the area of cyberinfrastructure and supercomputing.

Subcommittee members followed the four witness testimonies with questions. During these questions, references to “deferred maintenance” were relabeled as “infrastructure deficits” and the subcommittee members shared the same anxiety about these deficits. As a corollary, U.S. competitiveness was raised in the context of foreign students and foreign faculty remaining in the U.S. – whereas U.S. universities have been the envy of the world for many years, countries like China have made significant investments in research facilities and infrastructure, resulting in a growing trend where Chinese nationals are more eagerly returning to China to be trained and to conduct research.

There appears to be a willingness by staffers from the Subcommittee on Research and Science Education to continue this discussion. While we need to be careful in advocating for infrastructure funding at the expense of funding for direct research activities, the Subcommittee may be interested if we frame our positions in the context of U.S. competitiveness, enhancing student readiness, and promoting effective partnerships between Universities / Community Colleges / K-12 / State-Local Government / Federal Government / Private Industry. Focusing on improving resource availability to low-interest capital and more fair F&A reimbursement is important – however, we need to be more prepared to address research productivity metrics and how increasing available resources will improve the quality of education and research. Several of our association partners, including AAU and APLU, are actively engaged in this issue, and we will work with them to further advance this discussion.

2. Thursday Afternoon University Forum – Managing ARRA: One-Year Later

Pamela Caudill, Associate Vice President for Research Services from the University of Pennsylvania and Jordan L. Cohen, Ph.D., Interim Vice President for Research and Economic Development from the University of Iowa provided University perspectives on how ARRA was managed at Penn and Iowa, as well as present and future challenges in an era of unpredictable research funding. Some of the specific topics addressed included:

- **A “New Game”.** Both Pam and Jordan shared this theme – ARRA required Central administrators, Research administrators, Departmental administrators, and Faculty to work in a highly coordinated and collegial manner. ARRA compliance was easier to “sell” across each campus, which could have been the result of focused administrative planning and communication, plus the constant message from Washington about the importance of accountability and transparency. Regardless of the cause, Pam and Jordan expressed enthusiasm about the “New Game” – however, the challenge going forward is to maintain the environment of respect and collegiality.
- **Stress on Resources.** While both pointed to some resource increases at their respective campuses (e.g., increased staffing, salary bonuses), staff were pushed hard. ARRA funding opportunities, for the most part have expired. However, Section 1512 reporting continues to be an ongoing challenge, and the corresponding ARRA compliance,

oversight, and audit scrutiny will remain significant. In addition, accountability and transparency applicable to ARRA and non-ARRA funding most likely will be an ongoing emphasis at the Federal level, which could result in further strains on institutional resources.

- **Good Proposal Development Practices Pay Dividends.** Pam focused on the Penn ERA system and the important role it played during the proposal development process. The status of each proposal was easily tracked, which contributed to successful proposal submissions. At Iowa, Jordan shared the success of using Cayuse during proposal development and also recognized that junior faculty was nurtured throughout the proposal development process. Even when ARRA funding was not secured for junior faculty, the experience was positive and the proposals developed could be reframed for future submissions.
- **Other Influences: State Government and the Media.** State Government demands in the form of centralized Section 1512 reporting and oversight of the ARRA State Fiscal Stabilization Funds have presented (and continue to present) management challenges. While Jordan described some of the dynamics unique to Iowa, similar challenges exist for almost every State research university in the country. Media scrutiny also has created a new source of institutional risk. For example, reconciling PI perspectives on job creation with the actual OMB jobs reporting requirements has resulted in the need to closely manage the media relations function of the institution.
- **Unpredictable Research Budgets and Future Challenges.** Despite the Administration's relatively favorable FY2011 budget proposals for research (NIH - \$32.1B, 3.2% increase; NSF - \$7.4B, 8.0% increase; DOE Office of Science - \$5.1B, 4.6% increase), the dire state of the federal deficit, possible discretionary spending freezes, and the eventual wind-down of ARRA all contribute to an unpredictable research funding environment. This leads to institutional uncertainty from both a revenue projection and a research building/lab space planning standpoint. The poor status of State budgets and Endowments further contribute to the uncertainty. Research universities will need to be proactive in cultivating alternative funding sources, managing expectations of university Presidents and Boards, responding to growing compliance and accountability demands, and promoting the benefits of research at the Federal, State, and local levels.

The future challenges are significant and these discussions need to be continued in various forums. COGR will advance those issues that are consistent with the COGR mission. For those that are interested, the presentations from this session are available at:

http://www.cogr.edu/meetings/Meeting_February2010.htm

3. ARRA Reporting and General Update

While Section 1512 reporting remains a resource challenge at most of our institutions, many of the difficult and confusing reporting issues (e.g., jobs reporting, vendor reporting) have stabilized. However, there are several new reporting issues that have arisen and new challenges that are being presented. Below are the ARRA-related issues that COGR is most focused upon:

- **Construction Grants.** NIH, NSF, and NIST have awarded construction grants. Compliance requirements specific to Buy American and Davis-Bacon wage rate provisions are applicable. Jobs reporting is required and corresponding reporting expectations at the general contractor and subcontractor level is relevant to how your institution reports required data elements. COGR contacted OMB to inquire if there would be more guidance on any of these issues. In the case of jobs reporting, there will not be additional guidance. However, institutions should make a reasonable effort to account for jobs charged to ARRA awards by contractors and subcontractors. According to OMB, the Davis-Bacon wage sheets have been utilized by State and Local government recipients to assist in supporting jobs reporting. In the case of Buy American, this is a “hot topic” that has political overtones – institutions must have practices in place to assure compliance with the Buy American provisions, and it is possible that OMB will release additional guidance related to Buy American provisions in the near future.
- **Status on Guidance.** There will be updated OMB guidance prior to the opening of the April 1-10 reporting cycle. However, we have been assured that the guidance is directed more to agencies rather than recipients. One issue that may not appear in the updated guidance, but that is being reviewed is the “Continuous QA Process” where FederalReporting.gov remains open for a defined period of time (e.g., for the most recent reporting cycle, the continuous open period is February 2 - March 15). For the agencies, this has created a problem where recipients make corrections, but there is not an effective process for the agencies to monitor the corrections. One solution being discussed is for reports to remain “locked” during the continuous open period, and reports are “unlocked” by the agencies only when recipients ask permission to do so.
- **Congressional Districts (CD).** Several of you have shared situations where your institution is aligned with a single CCR registration, and hence a single zip code. FederalReporting.gov utilizes the zip code to automatically populate the CD. However, there are situations where a different CD is applicable (e.g., activity taking place in a remote location, a sister campus, etc.). FederalReporting.gov does not allow for CD “overrides”. Initially, we conveyed this to the Recovery Accountability and Transparency Board (note, the RATB is responsible for technical management of FederalReporting.gov). We now have elevated this issue to OMB and they are reviewing specific examples that we have shared with them. Since this seems to be a situation that could create misleading data to the public, OMB is going to further evaluate this issue.
- **Agency Requirements Exceeding OMB Requirements.** The OMB Implementing Guidance for ARRA includes approval guidelines that agencies must follow before imposing new requirements on grantees. Several of your institutions have shared situations, most notably concerning the Department of Energy, where the agency is requiring “above and beyond” reporting and/or administrative requirements to be met. COGR raised this concern to OMB. Unfortunately, because certain high profile DOE ARRA programs (e.g., weatherization) were cited by the DOE IG and the GAO to require more thorough oversight, additional reporting requirements proposed by DOE were approved by OMB and became universal to all DOE programs. However, there are several other DOE requirements (e.g., use of payment systems) that OMB has agreed to look at and they will follow up with us shortly.

- **State Fiscal Stabilization Funds (SFSF) and OMB Circular Applicability.** Both in COGR messages to the COGR ListServe and through the COGR-FDP FAQs, we have shared the guidance we received from OMB that indicated “effort reporting” is not required for SFSF monies. In addition, the Governmental Audit Quality Center (sponsored by the AICPA and with some collaboration from OMB) is a reliable resource for audit compliance. The document referenced below is dated December 24, 2009 and provides audit guidance on the SFSF. Page 8 confirms that “effort reporting” is not required for SFSF monies, and states:

Because of the unique characteristics of this program ... while the specific requirements in the OMB Circulars that apply cost principles ... do not apply to SFSF funds, expenditures attributed to the SFSF program must still be ‘reasonable and necessary,’ and consistent with applicable State and local requirements. This document can be found at: <http://www2.ed.gov/programs/statestabilization/auditor-guidance.pdf>

- **Payroll Transfers to Prior Periods.** The OMB Guidance on Jobs Reporting, dated December 18, 2009, specified that FTEs charged to ARRA awards will be calculated on a quarterly basis only (i.e., no cumulative reporting). In addition, after a specific date (e.g., for the January reporting cycle, March 15th is the last day to correct data), corrections can no longer be made. Therefore, if a payroll transfer is made after March 15, there is no way to update the FTEs reported on an ARRA report from a previous quarter. There is no specific guidance, to-date, on how to handle this situation. Preliminary discussions with some Federal officials suggest that the impact on the FTEs charged should be carried forward to the next ARRA reporting cycle. COGR will be in contact with Federal officials to get more clarification.

We will keep the membership updated on the issues listed above. We encourage the COGR membership to continue sharing questions, insights, and experiences related to ARRA reporting and administration. We will utilize the COGR ListServe and selected updating of the COGR-FDP FAQs to communicate new information. Also contact David Kennedy at dkennedy@cogr.edu if you want to discuss specific topics of concern.

4. Auditing ARRA and Other Audit Updates

The COGR Costing Committee met with representatives from Inspectors General (IG) offices for the Department of Health and Human Services (HHS) and the National Science Foundation (NSF) during the Wednesday, February 17th Costing Committee Meeting.

Lori Pilcher, Assistant Inspector General - Grants, Internal Activities & IT Audits, represented the HHS IG office and was joined by her colleague Lisa Martz. Tim Cross - Deputy Inspector General represented the NSF IG office and was joined by two colleagues, Laura Hansen-Rainey (A-133 specialist) and Kristen Cutforth (ARRA Reporting specialist). Some of the points raised by our guests included:

- The initial approach by both IG offices was to review HHS and NSF internal ARRA management capability. Some of these internal reviews will continue.

- **NSF IG recipient capability reviews are underway.** There are 10 institutions that have been selected, to-date. One focus will be on internal controls established to manage ARRA funds, with a closer look at specific compliance areas (see next section, NSF IG Compliance Focus Areas for ARRA Reviews). COGR's interpretation is that the NSF IG will use lessons learned from these first 10 institutions to further refine their audit approach.
- **HHS IG audits have started at "high-risk" recipients** – specifically, less-established institutions that are receiving HRSA (i.e., community health center funding) and Head Start program funding. Universities are considered lower risk due to HHS IG recognition of more established controls and experience managing Federal funds. However, recipients of NIH ARRA funding still will be scrutinized, and most likely we can expect to see HHS IG audit activity beginning in 2011.
- **Salary charging of Administrative and Clerical personnel** is a concern of the HHS IG. In addition to an audit last year that cited over \$1 million of cost disallowances, another ongoing audit also may reveal significant cost disallowances. In effect, this suggests that when auditors are on-site, ARRA as well as non-ARRA funding is subject to review, and that auditors are free to look at multiple compliance areas.
- **Section 1512 reporting, including jobs reporting,** does not appear as though it will be a major IG audit focus. However, audit focus can change at the direction of Congress – and if jobs reporting continues to be a hot political topic, it could become a higher profile item in IG audits.
- **The HHS IG has hired approximately 50 new people** and the NSF IG has taken the approach of expanding the use of outsourcing audit work to CPA firms. This may create situations where inexperienced auditors are involved in an audit project. The IG offices take quality control seriously, and in situations where auditors are too inexperienced, the IG offices may be interested in being notified about these situations.
- **The Recovery Accountability and Transparency Board (RATB)** is responsible for audit oversight of ARRA and the RATB includes IGs from selected agencies. To date, the RATB has not established centralized agency-wide audit direction, and it appears that audit direction will continue at the agency-specific level.
- **The 2010 Circular A-133 Compliance Supplement** should be available soon and will include ARRA audit guidance to A-133 auditors. ARRA awards will be considered "high-risk" and the A-133 audit will be skewed to ARRA programs. Section 1512 reporting will be reviewed, though according to our guests, A-133 auditors will not be expected to look closely at jobs reporting. However, compliance areas covering A-21 allowability, Davis-Bacon wage rate compliance, Buy American, Subrecipient monitoring, appropriate ARRA documentation on the SEFA, and Special Provisions on awards will be emphasized. COGR has suggested in several recent updates that ARRA is new and unprecedented and the A-133 audit landscape presents many unknowns. Consequently, there could be auditor interpretations that require further discussion. It will

behoove your institution to engage senior audit partners, senior audit professionals and other experts in these situations with the understanding that everyone is doing their best to make judgments that are consistent with the ARRA legislation and Federal guidance.

- One other note on the **Circular A-133 audit** front is that there is a push by some entities at the Federal level to reduce the due date for the A-133 audit report from 9 months after the fiscal year end to 6 months. This may be phased in over a three to four year time period. We would expect that there would be some form of public comment opportunity, and COGR will stay engaged as we learn more.
- **The Labor and Effort audit program conducted by the NSF IG** over the past five years appears to be over. Sixteen audits were completed. The NSF IG plans to release a “Capstone” report that will summarize findings and recommended practices. We believe that report may be available later in the spring or summer.
- Some of your institutions have been contacted by the Investigation unit of an IG office at various times. It was explained to the Costing Committee that Investigation units operate separately from the Audit division. Sometimes the Investigation unit will approach your institution and ask for data and information, which you disclose, but then you never hear back. Essentially, the “investigation” disappears into a black hole. This appears to be a normal process and suggests that the Investigation unit was operating on some tip, but in the course of their review, they found nothing irregular.

5. NSF IG Compliance Focus Areas for ARRA Reviews

In the Friday morning Committee report, Mike Laskofski, Director of Sponsored Programs at George Mason University, provided an update on the compliance areas selected by the NSF IG during their initial two-week review (note, the review has now extended to six weeks). As we suggested in the previous section, we believe that the NSF IG will use lessons learned from their initial reviews to further refine their audit approach. The items on the NSF IG’s list included:

- FCTR/FFR Reconciliation
- Fringe Benefits
- Indirect Costs
- Participant Support
- Subaward and Subrecipient Monitoring
- Special Terms and Conditions
- Effort Reporting
- Cost Sharing
- Procurement
- Property and Equipment
- Travel
- Consultants
- Annual and Final Project Reports
- General Management
- Accounting and Financial System Review

- Program or Award Related Income
- ARRA

According to Mike, the NSF auditors will want to talk to an expert that can explain the administrative and financial controls for each audit area that are used to record, process and report in accordance with Federal requirements and NSF award terms and conditions. Ideally, an auditor would meet with the George Mason subject area expert to discuss the process and controls in place. Next, the auditor would test a sample of transactions and discuss the results with the subject area expert.

While this approach might not be followed in an identical manner at each institution, it provides initial insight on the NSF IG approach to auditing ARRA. We will continue to pay attention to audit developments and share updates with the membership.

6. Thursday Morning Costing Session – Revisiting Effort Reporting

Kim Moreland, Associate Vice Chancellor for Research Administration and Director - Research and Sponsored Programs from the University of Wisconsin, Jim Luther, Assistant Vice President and Research Costing Compliance Officer from Duke University, and Michael J. Vernick, Partner at Hogan & Hartson, LLP, each presented during this Thursday morning session. Jim presented first and emphasized many of the proactive risk assessment and monitoring activities that have been introduced at Duke. Kim presented second and raised some of the frontline issues at UW, with a backdrop being that the NSF IG Labor and Effort audit report for UW was recently released. Mike presented last and provided a broad overview of effort reporting risk areas, while also discussing Federal recent enforcement actions in the area of effort reporting. Some of the specific issues addressed included:

- **NSF salary policy.** UW discussed this issue with NSF IG auditors during their labor and effort audit. While the auditors initially attempted to impose an unusual interpretation to calculate the summer salary rate of pay, this was resolved in a fair and rational manner. The 2-month rule also was addressed with the NSF IG auditors, though more thorough interpretations were made by NSF Audit Resolution personnel. NSF Audit Resolution has stated that additional months beyond 2 months may be allowable if there is no change in scope of work – this approach by NSF Audit Resolution is consistent with institutional rebudgeting authority. Still, the best course is for an institution to justify the time exceeding 2 months during the proposal stage. *COGR is pursuing additional clarification with NSF.*
- **Total Professional Effort and Other Entities.** This is an ongoing challenge for institutions and PIs in the context of supporting available effort and commitments. In the case of NIH K-awards where effort commitments are significant, an even stronger microscope is put on this issue. Jim discussed how entities such as the VA and the Practice Plan require close consideration when determining available effort, while also pointing out the challenges of accounting for “hours worked” as is required for the Medicare Cost Report. Duke, as well as UW, each shared how they actively monitor proposals submitted, Medicare responsibilities, and other commitments to help ensure that over-commitment is effectively managed.

- **Federal Enforcement.** Audit reports can be useful to the research community by describing specific instances of non-compliance. However, as Mike specified, cases are often resolved through a settlement between the institution and the Department of Justice. In two recent settlements, the treatment of base workload/base pay and supplemental compensation was at issue. While the details of these cases are not in the public domain, the treatment of supplemental compensation appears to be a risk area. Mike also provided additional insights on some of the “hot topics” addressed by Jim and Kim, such as cost transfers, 100% research faculty, K-awards, effort commitments, and summer salary.

The March 2007 COGR paper on Compensation, Commitments, and Certification remains a timely document and addresses many of the same topics from the session. Glossy-version copies are available for a minimal shipping fee. In addition, the presentations from this session are available at: http://www.cogr.edu/meetings/Meeting_February2010.htm

7. Other Costing Committee Updates

Some of the items below were listed in the February 4, 2010 Update and several are new. If you have comments or input to any of these items, or of there is an issue not listed that you would like to discuss, contact David Kennedy at dkennedy@cogr.edu.

Status of DOD 35-percent F&A Limitation and the GAO Study. As reported in the February 4, 2010 Update, this statutory requirement remains in effect under the FY2010 DOD Appropriations Act. In addition, the GAO continues to work on their study of F&A costs and reimbursement – we expect they will finalize their report this year. The primary champion of the DOD cap was Representative John Murtha (D-PA) from Johnstown, PA. He passed away on February 8th after a long and distinguished career in public service. Mr. Murtha was a former Marine Corps officer and a Vietnam veteran, Chairman of the House Appropriations Defense Subcommittee, and he served in the House since 1974.

Furlough Programs and Implications for Financial Research Compliance. Many of you requested this paper after the February 4, 2010 Update was released. It is now available on www.cogr.edu under the Educational Materials / Financial Management tabs.

Faculty Appointments at Academic Medical Centers; A Focus on VA-University Joint Appointments. An updated version, dated February 12, 2010, is now available. We believe this reflects the final version of the paper. However, due to the sensitivity of some of the discussions, we are being cautious before announcing an official and final release. If you are interested in the updated version, contact David Kennedy.

F&A Rate Negotiation Summaries. We continue to collect information from the membership concerning recent F&A rate negotiations. Several of your institutions have provided information including: Results of your recent negotiation, Primary concerns raised by the Federal negotiators, and ARRA-related issues that were addressed. We are compiling this information and will have updated reports this Spring.

Sensitive Compartmented Information Facility (SCIF). One of our members inquired if anyone from an institution that housed a SCIF would be willing to discuss operational issues and topics related to recovering operations and maintenance costs. If so, please contact David Kennedy.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Ara Tahmassian, Chair, Boston University; Michael Amey, The Johns Hopkins University; Michelle Christy, Massachusetts Institute of Technology; Kelvin Droegeheimer, University of Oklahoma; Jamie Lewis Keith, University of Florida; James Tracy, University of Kentucky; David Wynes, Emory University; Allen DiPalma, University of Pittsburgh; Regina White, Brown University

1. National Science Foundation Issues FAQs on Responsible Conduct of Research

The National Science Foundation (NSF) has posted Frequently Asked Questions (FAQs) concerning its the responsible conduct of research (RCR) requirement as implemented in the NSF *Proposal and Award Policies and Procedures Guide* effective January 2010. The FAQs are available on the NSF Policy Office website at http://www.nsf.gov/publications/pub_summ.jsp?ods_key=rcrfaq. Jean Feldman, head of the NSF Policy Office, joined the COGR membership during a Thursday morning discussion at the February meeting about the NSF and National Institutes of Health RCR requirements. Feldman promised that FAQs to assist the community were forthcoming.

One issue raised during the discussion in February was who must receive training? The FAQs state that “NSF expects institutions to be able to verify that those students (undergraduates and graduates) and postdoctoral researchers who receive NSF funds (support from salary and/or stipends to conduct research on NSF grants) will obtain RCR training.” Thus, institutions must be able to document the training of any student or postdoctoral fellow that receives salary or stipend support to conduct research. The training requirement applies to all proposals submitted to NSF to conduct research. It does not apply to non-research proposals like conference, symposium, workshop or travel proposals.

There is a difference between what is required and what an institution may elect to do for its students and fellows. The important distinction outlined in the NSF FAQ is that the institution must be able to document the training of only those students and fellows who receive support to conduct research. Similarly, NSF makes clear that the content, frequency, and method for training are the responsibility of the institution. Additional FAQs describe and provide links to a variety of resources available to assist institutions in developing programs. The FAQs address questions concerning flowdown to subawardees (yes), applicability to scholarships and stipends through programs like NSF S-STEM (yes), direct costing (read the FAQ!), etc.

Send questions concerning the implementation of RCR and the FAQs to NSF (policy@nsf.gov) and your questions may serve as the basis for additional FAQs.

2. National Institutes of Health and Responsible Conduct of Research

Rodney Ulane, the National Institutes of Health (NIH) Training Officer and Director of the Division of Scientific Programs in the Office of Extramural Research, joined the Thursday morning session to discuss the November 24, 2009 *Update on the NIH Requirement for Instruction in the Responsible Conduct of Research* (NOT-OD-10-019). Ulane described the Update as a clarification to the then-current policy based on experiences gained since the policy first went into effect in 1989.

The discussion highlighted the marked difference between the NIH and NSF policies in terms of applicability, submission of the plan, and how it is reviewed and, finally, reported on by the awardee. NIH's training requirement applies only to trainees (broadly defined) and applicants submit the plan as a part of the application. The peer reviewers discuss the plan and rate it as either "acceptable" or "unacceptable." The rating of the plan is not a factor in determination of the priority score but unacceptable plans will need to be revised before NIH makes an award.

The issue in the Update that raised the greatest concern for the research community and was the focus of the discussion at the February COGR meeting is the fear that the description of "best practices" throughout the Update will become default standards when reviewed by agency auditors or the inspector general's staff. Notwithstanding the language that "encourages" the incorporation of specific elements or "best practices," research institutions know that identified best practices are used as minimum standards in the compliance review.

It is likely that auditors will expect institutions to demonstrate that the university provided instruction in all topics outlined as acceptable subject matter and to document faculty participation and the achievement of eight non-online instructional contact hours between the trainees and the faculty. It would not be unusual for an auditor or inspector to ask the institution to provide documentation of the trainee's completion of training "no less than once every four years" during appropriate career stages.

The meeting participants assured Ulane that in most cases institutions endorse the principles articulated by NIH and in many cases have RCR instruction programs that easily meet and in some cases clearly exceed NIH's expectations. Research universities understand the strengths and weaknesses of a variety of instructional formats and the value of faculty participation as instructors and mentors. Faculty know that in-depth interactions have an important instructional role and that the reiteration and reinforcement of principles and ideas throughout a trainee's career are important for understanding.

COGR will continue to discuss the Update with Dr. Ulane and his colleagues at NIH. He proposed preparing Frequently Asked Questions to address some of the research community's concerns. Unfortunately, auditors and inspectors rely on the policy statements and Updates and infrequently visit FAQs. Our goal will be a clarification or update of the Update.

3. OMB Issues Guidance on Integrity and Performance Reporting for Grants

On February 18, 2010, the Office of Management and Budget (OMB) Office of Federal Financial Management offered for comment proposed guidance for federal agencies concerning

the *Reporting and Use of Information Concerning Recipient Integrity and Performance* (75FR7316). Comments on the proposed Guidance are due April 19, 2010.

This proposed Guidance is the grants reporting companion to the rule proposed by the Federal Acquisition Regulations (FAR) Councils in September 2009 (74FR45579). The proposed rule and this proposed Guidance (rule/guidance) implement Section 872 of the Duncan Hunter National Defense Authorization Act for 2009 (the Authorization Act, PL 110-417). The Authorization Act and implementing FAR rule and OMB guidance establish requirements for recipients of federal awards (contracts and grants) in excess of \$500,000 and holding a cumulative value of federal awards greater than \$10 million. These recipients are required to provide information relating to criminal, civil and administrative proceedings that reached final disposition in the most recent 5-year period and involved the award or performance of a federal or state award. The \$10 million+ recipients must report at least semiannually to maintain the currency of the information. The rule/guidance flows down to a recipient's direct (i.e., first-tier) subrecipients.

The agencies are required to report in the information system: terminations due to material failures; administrative agreements to resolve suspensions and debarments; and any finding made by the agency that the entity was not qualified to receive an award. The recipients have the ability to submit comments on any information in the system about the entity. Before making an award "in excess of the simplified acquisition threshold [\$100,000]," all federal contract/grant officials are required to determine whether the entity is qualified to receive the award.

COGR commented on the proposed FAR rule in November 2009 (a copy of the letter is posted to the COGR website, www.cogr.edu, under What's New). The FAR proposed rule has not yet been finalized but, on March 1, 2010, the FAR Councils requested comment on its submission to OMB of an information clearance related to the rule (75FR9217). The FAR Councils propose a new FAR clause that requires offerors to check a box indicating whether, or not it currently has contracts/grants in excess of \$10 million (the information collection under review). If the offeror answers in the affirmative (it has contracts/grants in excess of \$10 million), the offeror will need to enter or update the integrity/performance information collected in the Central Contractor Registration (CCR) database. In its letter on the FAR, COGR sought additional information on how/where the information would be collected; this request for clearance answers that question. The database/system for the FAR and the OMB guidance is called the Federal Awardee Performance and Integrity Information System (FAPIIS).

COGR's comment on the OMB proposed Guidance will echo, as appropriate, the questions and issues raised in its response to the proposed FAR rule. It is important to note, however, that the proposed guidance announcement includes a number of modifications and amendments throughout Chapter 1 of Title 2 of the Code of Federal Regulations (2CFR), the CFR title where OMB is consolidating the requirements that apply to federal financial assistance agreements, including the OMB Circulars. These amendments are necessary to better organize 2CFR, implement the Section 872 requirements, and, in a way, bring 2CFR up-to-date with current policies and requirements that have been issued over time as OMB memoranda to the agencies. Included in these amendments is the requirement for prime and first tier subrecipients to have DUNS numbers and register in the CCR (see related Update below), and OMB policies

implemented by memorandum as a part of other actions like implementation of the FFATA and ARRA reporting requirements.

In COGR's comment, we will continue to encourage uniformity between contract and grant in the design of the actual reporting process through the CCR. We welcome your comments and observations on the proposed Guidance (cblum@cogr.edu).

4. Use of DUNS and CCR

One of the amendments incorporated into the proposed OMB Guidance *Reporting and Use of Information Concerning Recipient Integrity and Performance* (75FR7316) is the requirement for recipients and any first-tier subrecipients to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number and maintain current registration in the federal government's Central Contractor Registration (CCR) system.

As reporting wonks will note, the issue of requiring DUNS numbers and CCR registration has been pending since a June 2008 OMB notice of proposed guidance to agencies linked to the implementation of the Federal Funding Accountability and Transparency Act of 2006 (FFATA). In the 2008 proposed guidance, OMB outlined the requirements for recipients and subrecipients to report federal funding obligations as required by FFATA. Part of the proposed 2008 guidance included the requirements for recipients and all subrecipients to have a DUNS number and register. The subrecipient receives a subaward, defined in the 2008 guidance as an agreement to provide support for the performance of any portion of the substantive project or program. Subaward explicitly excluded procurements of property and services needed to carry out the project. This requirement flowed down to all subrecipients that received a subaward of \$25,000 or more through the life of the project.

The response to the DUNS/CCR requirement is resolved in the proposed Guidance on Reporting Integrity and Performance; and resolved with a narrower requirement. OMB proposes now to require a DUNS number and current CCR registration for the recipient and first-tier subrecipients. Thus, subrecipients need not flow the requirement down to their subs. OMB includes its response to comments received in 2008 in the Supplemental Information associated with this new guidance and notes that this proposed guidance supersedes the DUNS/CCR elements in the June 2008 proposed guidance. Reporting wonks will note, as well, the very brief observation that if "future" implementation of FFATA or other statute requires DUNS/CCR to lower tiers, OMB will propose an amendment to 2CFR part 25 and request comments.

5. FDA Proposed Rule on Reporting Falsification of Data

The Food and Drug Administration (FDA) proposes to amend its regulations "to require sponsors to report information indicating that any person has, or may have, engaged in the falsification of data in the course of reporting study results or in the course of proposing, designing, performing, recording, supervising or reviewing studies that involved human subjects or animal subjects conducted by or on behalf of a sponsor or relied on by a sponsor." The proposed rule appeared in the February 19, 2010 *Federal Register* (75FR7412) and comments are due May 20, 2010.

FDA is proposing the rule to resolve what an internal working group described as ambiguities in the current regulations concerning the extent of reporting to the FDA, the content of sponsors' reports, the timing of reports, and whose actions are reportable. FDA's goal is to protect the integrity of the data used by the sponsor and FDA and ensure the protection of human subjects. The proposed rule requires the sponsor to report within 45 days after the sponsor becomes aware of the information and the responsibility to report is on-going. FDA will use the information to identify patterns, potential signals or other indications of misconduct to conduct investigations.

The FDA defines falsification as "creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred." Errors in data reporting are excluded from the requirements. Sponsors will be required to report any confirmed or possible falsification of data by anyone involved.

In issuing the rule, FDA notes that Department of Health and Human Services (HHS)' Public Health Service (PHS) has regulations addressing research misconduct. FDA considers the PHS research misconduct regulations as insufficient in scope to encompass the research evaluated by the FDA. FDA has chosen to define falsification differently than PHS to embrace the kinds of falsification that the agency actually encounters. With similar logic, the FDA does not deem it necessary to include plagiarism in its definition as it is an area generally outside the scope of FDA compliance oversight.

COGR will be commenting on this proposed rule. Our comment will likely focus on the absence of a compelling rationale for taking an approach that departs from the HHS/PHS research misconduct policy; the definition FDA uses for falsification; and the required immediate notification that may make it difficult for institutions to comply with the HHS/PHS research misconduct policies. We welcome your observations and comments (cblum@co.gr.edu).

6. National Institutes of Health Vertebrate Animal Section Review

COGR members have expressed concerns about the increased emphasis by NIH scientific review groups (SRG) on the review of the Vertebrate Animal Section (VAS) of applications. With the issuing of a new checklist, the responsibilities for the scientific review groups (SRGs) seems significantly more detailed than in the past. Like the enhanced review of the human subjects protocol section of the application, this review and subsequent requests for changes may undermine the institutional animal care and use committee (IACUC) and institutional responsibilities for the review and management of the care and use of vertebrate animals in research.

As with its concerns with the human subjects review, COGR believes it is appropriate for the SRG to assess the justification of the use of animals including the choice of species and numbers to determine if the use is appropriate relative to the scientific work proposed. However, we believe it is inappropriate for the SRGs to serve as an IACUC for the proposed research. SRG members may or may not be appropriately trained to serve as a member of an IACUC. The SRG may or may not have the necessary experience and expertise to meet the requirements for an IACUC as defined in regulation. The enhanced application submission and review undermines the use of just-in-time mechanisms at the institution. What happens if the SRG proposes modification to the VAS before the IACUC has the opportunity to review a protocol? If the

SRG's requirements may not coincide with those of the IACUC, whose determination will prevail? If not the IACUC, will NIH become responsible for the conduct of the activity?

COGR will begin discussions with NIH to seek clarification and, if appropriate, modification of this role for the SRGs.

7. Letters Submitted and Available: RPPR, FDA on Continuing Review

As described in the February Update, COGR has submitted comments on the FDA draft Guidance for IRBs, Clinical Investigators and Sponsors concerning IRB *Continuing Review after Clinical Investigation Approval*; and the Office of Science and Technology Policy's (OSTP) Research Business Models (RBM) Subcommittee uniform format for *Research Performance Progress Reports* (RPPR) for federally funded research projects. These comment letters are available on the COGR website: www.cogr.edu under "What's New".

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; Denise Clark, University of Maryland; Catherine Innes, University of North Carolina, Chapel Hill; Alexandra McKeown, The Johns Hopkins University; Jennifer Murphy, George Mason University; John Ritter, Princeton University

1. COGR Joins AUTM Leadership for Meetings with Commerce Officials

COGR representatives participated with the President, Public Policy Committee Chair, and Executive Director of the Association of University Technology Managers (AUTM) in meetings with officials of the Department of Commerce. We met with Esther Lee, Director of the new Commerce Office of Innovation and Entrepreneurship Policy, and Robert Sienkiewicz, Senior Advisor. Another meeting was with NIST officials, including Director Patrick Gallagher, Acting Deputy Director Mark Stanley, and Chief Counsel Henry Wixon.

In these meetings the Commerce officials indicated that they are keenly interested in mechanisms to enhance commercialization of university research and are committed to continued discussion and input from stakeholders. They also stated that Commerce is not endorsing any particular course of action at this time with regard to federal policies on university technology transfer or the Bayh-Dole Act, including the Kauffman Foundation proposal for faculty “free choice” in invention management. We noted concerns about conflicts of interest that might arise from increased commercialization, and related inconsistencies in federal policies. The establishment of a new interagency council on innovation chaired by Commerce was mentioned by the Commerce representatives at both meetings. The NIST representatives indicated that there was considerable ferment at the federal level in these areas, and that the “barriers are down” between the agencies both within Commerce and elsewhere. NIST, who currently has oversight of Bayh-Dole, is in a listening mode, but is interested in playing a greater role with regard to universities, innovation and economic development. Our impression overall was that while NIST is more knowledgeable, the role of academic technology transfer within university missions is not well understood by Commerce. Also there seems to be considerable jostling among the agencies over their roles and responsibilities in this area.

2. Commerce Holds Forum on the Commercialization of Academic Research

As reported in the COGR February 2010 Update, on February 24 Commerce Secretary Locke hosted an invitational forum with around 30 university leaders and key stakeholders on the role of universities in innovation, economic development, job creation and commercialization of federally funded research. While as noted in the Update some of the pre-meeting discussion of the forum focused on criticism of university technology transfer, reports indicate that this was

not the focus of discussion during the forum itself. Rather, possible ways to speed commercialization without shifting the federal emphasis on funding fundamental research at universities were discussed. These could include increased collaboration to promote national and regional innovation ecosystems, regional tech transfer centers, greater sharing of best practices, and improved metrics for measuring “success” in commercialization. (Both the Chronicle of Higher Education (2/24) and Inside Higher Ed (2/25) carried accounts of the forum).

The discussion was positive and there appears to be strong interest on the part of some government officials to encourage other agencies to adopt programs designed to promote greater innovation such as the NSF centers. There also is interest in exploring the possibility of including some form of tax or set aside for economic development purposes in certain Federal research programs such as the NIH Clinical and Translational Science Awards. Other issues such as whether all universities realistically can be expected to be successful in this area and the effect on basic university purposes and missions may need to be further considered. During the discussion it was mentioned that the major role of universities in job creation and economic development remains the training of people, which means other federal policies such as visa policies also should be part of the focus. It is unclear what kind of follow-up will result from the forum. As noted in the Update, AAU and APLU were involved in the forum planning. We will continue to discuss these issues and possible follow-up activities with these associations.

3. Kauffman Proposal Provokes Lively Discussion at COGR Meeting

The COGR February Update also described a recent proposal of the Kauffman Foundation that faculty inventors should be free to choose their agent to license the technology, whether affiliated with their university or not. A panel session at the COGR meeting discussed the advantages/disadvantages and potential implications of the Kauffman proposal. Panel participants were Lesa Mitchell, Vice President for Advancing Innovation at the Kauffman Foundation; John Tyler, Kauffman General Counsel; Keith McDowell, Vice Chancellor for Research and Technology Transfer at the University of Texas System, and Emanuel Petricoin, co-director of the George Mason University Center for Applied Proteomics and Molecular Medicine. COGR Board member Charles Louis, Vice Chancellor for Research at University of California Riverside, served as moderator.

In her presentation Ms. Mitchell indicated that the goal of the Kauffman Foundation was to promote discussion of ways to encourage greater university contribution to economic growth. Rather than focus on the recent proposal, Ms. Mitchell discussed the need to explore alternative approaches to commercialization of university technologies, repeatedly stating that there are necessarily multiple pathways. She also suggested that faculty deans (rather than individual faculty) should be able to choose the most appropriate pathway for inventions, which could include outsourcing the technology to another organization for management. Mr. Tyler noted that Kauffman’s basic concern is whether existing systems are doing enough to advance innovation and maximize the commercial potential of taxpayer-funded research. Both he and Ms. Mitchell stressed that Kauffman is not seeking to change Bayh-Dole. However, Mr. Tyler pointed out that a basic federal policy embodied in Bayh-Dole is to promote the use of publicly-funded inventions and protect the public against non-use. He questioned whether university leadership

is sufficiently focused on the appropriate goals for technology transfer, rather than revenue maximization. Both he and Ms. Mitchell pointed to the need for better metrics.

In his presentation, Dr. McDowell challenged the evidence for the claims underlying the Kauffman proposal to Commerce. He characterized the alleged underperformance of university technology transfer offices (TTOs) as an “urban myth.” He noted an ongoing transformational cultural change in university technology commercialization, citing examples from Texas. He then outlined a series of problems with the Kauffman free choice proposal, concluding that “the Kauffman Free Choice proposal is an evolutionary dead end and we should stop spending time on it,” and suggesting that we “move on to new ideas that have buy-in from all the players and a chance to actually accelerate technology commercialization.” Dr. Petricoin discussed his positive experiences as a faculty entrepreneur working with his institution’s TTO. He noted the need for a team approach within the institution, and the role of the TTO in helping to manage his Center’s large grant portfolio with its inherent complexities. He also pointed out that institutions make a tremendous investment in a researcher and his/her lab, which should not be overlooked. Finally he acknowledged that in discussions with colleagues at other institutions there were occasional anecdotal “horror stories,” but for the most part faculty inventors appeared happy with the performance of their TTOs.

Issues raised after the discussion included the lack of a matrix for demonstrating suboptimal performance by TTOs as asserted by Kauffman, the inappropriateness of linking FDA data showing declining drug approvals with university research, the absence of industry views, the need to address the lack of adequate resources for TTOs, the complexities of multiple inventors, whether TTOs should be painted with a “broad brush” as implied by the Kauffman proposal, and the changing language and culture of university technology transfer. The Kauffman representatives were asked if the free choice proposal actually was still “on the table.” The response was that there is no attempt by Kauffman to impose it across the board, but that it was among the models that should be considered.

The discussion at the COGR session implied some backing away by Kauffman of the free choice proposal they previously have advocated. From our discussions with Commerce it also appears that the proposal is not under serious consideration by Commerce at this time. However, Kauffman may be continuing to advocate the proposal in other forums. Copies of Ms. Mitchell’s and Dr. McDowell’s presentations will be posted to the COGR website.

4. SACGHS Releases Report to HHS Secretary

The February Update discussed the report of the HHS Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS) on “Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests.” The final version of the report was approved by the SACGHS on February 5, 2010 and was unanimously recommended to be forwarded to HHS Secretary Sebelius upon the addition of an Executive Summary and other editing.

The final version of the report is somewhat toned down and more tightly focused than the previous draft on which COGR and AAU commented last May (see COGR Spring 2009 Update). The Conclusions and Recommendations now are better supported by the report discussion. However, some of the report recommendations remain problematic. These include

creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes as well as an exemption for those who use patent-protected genes in the pursuit of research. Our concern is that statutory infringement exemptions for particular classes of patents and/or particular uses are not sound either as a matter of policy or law, and may impact industry interest in developing therapeutic treatments using the same patents. Similarly, while we might support a broad statutory research exemption, a narrow exemption for a particular class of patents is likely to lead to confusion and disputes over the scope of the exemption.

Another recommendation suggests that the HHS Secretary promulgate regulations to limit the ability of grantees to exclusively license federally funded inventions when licensed for the genetic diagnostic field of use. In our view this would undermine the Bayh-Dole Act, which leaves licensing decisions to federal funding recipients. It could lead to a slippery slope resulting in government control of licensing decisions for other technologies and/or fields of use. The specific recommendation is for HHS to promote adherence to a variety of guidelines developed by NIH and other groups that lean toward non-exclusive licensing of diagnostic genomic technologies. The problem with this recommendation is that promoting adherence easily could devolve into rigid compliance requirements or regulations. We discussed our concerns with this approach in our comment letter on the draft SACGHS report last May.

While the SACGHS unanimously endorsed transmitting the report to the Secretary, three members dissented from the conclusions and recommendations. In their dissent, included in the report, they expressed the view that statutorily modifying the gene patents system through creating infringement exemptions would be more harmful than helpful to patient access and the quality of new genetic diagnostics. In their view gene patents have not been demonstrated to have a direct negative impact on patient access as asserted in the report. They believe that other factors such as the payment policies of public and private health plans are a more significant factor, and that HHS should focus on these issues. Finally, the dissent states that determinations of patentable subject matter and its protections should be left to the Patent and Trademark Office, Congress and the courts.

COGR and AAU jointly wrote to the HHS Secretary on February 1 citing the importance of a careful objective review of the SACGHS recommendations and a full analysis of their impact in the highly complex area of gene patenting and licensing. The Biotechnology Industry Association (BIO), in a letter to Sec. Sebelius on Feb. 4, noted that restrictive patenting and licensing practices with regard to federally funded inventions such as those advocated by the SACGHS were the norm prior to Bayh-Dole, with well documented negative effects. The BIO letter noted the need for flexibility in licensing and that by undermining the value of gene-based patents, the recommendations would chill future investment and innovation in this area.

We previously had expressed concern to Dr. Francis Collins, Director of NIH about the SACGHS recommendations. In a response to COGR dated Dec. 7, 2009 Dr. Collins stated "An assessment of the public policy implications of the SACGHS recommendations, which are advisory in nature, would be part of any Department consideration of the final SACGHS report." We plan to stay in close contact with NIH with regard to HHS actions on the SACGHS recommendations or possible implementation. There also are potential legal developments such

as the pending ACLU lawsuit vs. Myriad Genetics (see COGR Holiday 2009 [Update](#)) that could have a direct impact on the recommendations. We will keep the COGR membership informed.

5. Concerns Continue Over Federal Circuit Decision in *Stanford v. Roche*

We have discussed the *Stanford v. Roche* decision in recent COGR meeting updates and reports. In this case the Federal Circuit ruled that Stanford had no standing to bring a patent infringement lawsuit where a faculty inventor had “hereby assigned” his invention rights to an outside company in a “Visitor’s Confidentiality Agreement” (VCA) even though in an earlier Copyright and Patent Agreement he had “agreed to assign” to Stanford rights to inventions arising from third party contracts and grants. The Federal Circuit held that the Stanford agreement was a mere promise to assign rights in the future whereas under the VCA the outside company immediately gained title to the inventions.

Our primary concern has been the implications for the Bayh-Dole Act. The inventions at issue in this case were developed at Stanford with NIH funding, and thus were “subject inventions” under the Bayh-Dole Act. Stanford had disclosed the inventions and provided the confirmatory licenses to the government as required by Bayh-Dole. Despite this, the Federal Circuit held that Bayh-Dole did not automatically void the inventor’s rights or his contractual transfer of those rights to the outside company. The court held that Bayh-Dole “provided the Government with, at most, a discretionary option to (the inventor’s) rights,” and that Stanford could claim “whatever rights were still available after the government declined to exercise its option.” As discussed in the COGR October [Meeting Report](#), we believe this reflects a misunderstanding of the Bayh-Dole Act. The Bayh-Dole Act gives federal funding recipients the right to elect to retain title to subject inventions. It is only when the contracting organization (i.e., Stanford) elects not to retain title that title may then pass to the government upon request by the federal funding agency.

Because of the importance of this issue to federal policies with regard to federally funded inventions, COGR joined with three other higher ed. associations including AUTM and a number of universities in an *amicus* brief requesting an *en banc* rehearing of the case by the Federal Circuit. The brief emphasized that under Bayh-Dole title to federally funded inventions must vest with the contracting research institution. Clarifying who owns and can license federally-funded inventions was a central purpose of Bayh-Dole, which the Federal Circuit decision threatens to undermine. Unfortunately the request was denied.

We understand Stanford now is planning to appeal the Federal Circuit decision to the Supreme Court. COGR and a number of other associations and institutions have been approached about joining another *amicus* brief in support of Stanford. Any decision to participate will be made by COGR based on the [Criteria Developed for COGR Participation in Amicus Briefs](#).

In addition to the Bayh-Dole issues, concerns also have been raised about the implications of the decision for overall university patenting and licensing practices. As it stands the decision clouds the ability of universities to warrant title in license agreements, including executed agreements, since they are likely to be unaware of other agreements that faculty may have signed. We previously had suggested that institutions may need to review the language of their policies and employment agreements with regard to invention rights in light of this ruling. We understand that some institutions are conducting such reviews and may be revising their current policies

and/or employment agreements. Discussions with COGR members indicate that some additional guidance to the membership on these issues and examples of revised polices would be of use. While COGR cannot provide legal advice, we will explore what types of materials might be helpful.

6. New Developments on Export Controls

A) GAO Again Reviews Deemed Exports

The Government Accountability Office (GAO) is conducting another review of awareness and compliance with requirements for protection of deemed export controlled information. We understand the new review is being conducted at the request of the ranking members of the House Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations.

GAO previously reviewed the Department of Commerce's controls on deemed exports in 2002 (GAO 02-972), primarily focusing on foreign national access to technologies at U.S. high tech firms. In subsequent report dated December 2006 (GAO 07-70), GAO recommended that the Commerce and State Departments strategically assess potential vulnerabilities in the conduct and publication of academic research and improve interagency coordination and outreach. In this new review, GAO will focus on the extent to which Commerce has implemented and changed the deemed export system to protect U.S. national security and economic interests; the extent of information sharing between Commerce and other agencies regarding deemed exports; and how Commerce monitors and enforces deemed export licensing requirements.

COGR and AAU representatives met with the GAO representatives late last year. We called their attention to recent recommendations made by other groups including the 2008 NAS "Fortress America" report, the 2007 Deemed Export Advisory Committee report, and reports by various other groups and provided some suggestions. We noted that Commerce has improved its outreach efforts to universities in recent years, and expected that GAO again would focus its review in this area as in the 2006 report.

However we understand GAO subsequently contacted one COGR member institution with a list of questions. While some involved overall deemed export compliance procedures and the effectiveness of the U.S. government's (principally Commerce but also State and US ICE) outreach efforts to universities and coordination among them, others included trends with respect to nationalities of deemed export applicants; number of foreign nationals working on research exempted by the fundamental research exclusion; technologies involved in deemed export license applications; and information about research involving select agencies and toxins at the university. We would appreciate hearing from other COGR members if they are similarly contacted by GAO.

COGR also has been contacted by GAO for help in setting up roundtable discussions with universities in the Boston area and California to discuss deemed export controls in biotechnology. We currently are working with GAO and COGR member institutions in these areas to help arrange for these discussions.

B) USCIS Proposes Adding Deemed Export Acknowledgement to Form I-129

On February 8 the U.S. Citizenship and Immigration Services (USCIS) proposed adding a deemed export acknowledgement requirement to the Form I-129 required for certain H-1B visitors and others (75*FedReg* p. 6212). The acknowledgement would require petitioning organizations to submit evidence that a review of the deemed export license requirements required by the EAR has been completed and indicate whether or not a deemed export license is required. If not, whether or not the technology is subject to the EAR must be indicated and if so, the ECCN must be provided. If so, a copy of the approved license must be provided. (For a copy of the draft form see <http://www.nafsa.org/resource/library/default.aspx?id=18506>).

We understand from USCIS that the proposed addition implements the 2004 recommendation of the Department of Homeland Security (DHS) Inspector General (OIG 04-23) that “DHS strengthen current DHS change of status adjudication procedures to include additional controls, such as obtaining a Security Advisory Opinion (SAO) from State for preventing the inappropriate release of protected technologies to foreign nationals from countries of concern. USCIS should also assess the feasibility of modifying Interagency Border Inspection Services (IBIS) to interface with those federal agencies currently responsible for issuing SAOs to the State Department and for advising Commerce on the protection of controlled dual-use technologies.” USCIS also cites the finding in the 2002 GAO report noted above that vulnerabilities in the deemed export licensing system could allow technology transfers to countries of concern and that the Department of Commerce was not sufficiently coordinating its efforts with those of INS (now USCIS) to identify and follow-up on foreign nationals changing their immigration status to obtain jobs that could involve dual-use technology controlled under the Export Administration Act.

Obviously implementation of this requirement will add a significant compliance burden to institutions submitting petitions for H-1B visitors. Also in many if not most cases the specific technologies the visitor will have access to may not be known in advance, and the requirement ignores the fundamental research exclusion from export controls. The timing also seems curious given the ongoing high level Administration review of export controls discussed in last month’s COGR Update. Finally USCIS does not have responsibility for enforcement of export controls.

We expect to submit a comment letter jointly with AAU making the above points. The Federal Register notice asks for comments on four points to which we will also respond. Comments are due April 9. We hope to have a draft available by mid-March to assist COGR members who may be considering submitting their own comments. The Federal Register docket no. is 2010-2662; OMB Control No. 1615—0009.

7. COGR/NIH MTA Working Group Plans to Move Forward with Initiative

The February Update discussed the establishment of a joint COGR/NIH working group on Materials Transfer Agreements (MTAs). The Update noted that the group planned initially to

review the current Uniform Biological Materials Agreement (UBMTA), Simple Letter Agreement (SLA), and other materials from individual universities and institutions. Assuming agreement on terms, the next step would be discussion of possible streamlining and electronic implementation.

The group has met twice by conference call. Given that a significant number of institutions continue to sign on to the UBMTA (30 last year), it was agreed that the UBMTA terms appear to continue to be relevant and appropriate. After reviewing other current initiatives, the group tentatively has decided to explore the concept of a suite of agreements. These would include the existing UBMTA and SLA, and a third mechanism to transfer non-hazardous, non-human materials between NIH and non-profit researchers, or between researchers at different institutions. The goal would be to develop this third tool as an electronic mechanism, perhaps in the form of a simple letter from providers to investigators. It would be used when the materials do not involve any restrictions, obligations to sponsors or licensees, or commercial uses. We also may consider possible electronic implementation of the SLA.

Once the group has made some further progress, we plan to explore this approach with AUTM and possibly schedule a session for further discussion at the June COGR meeting.