COUNCIL ON GOVERNMENTAL RELATIONS
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November 18, 2011

MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS
WASHINGTON MARRIOTT HOTEL
October 27 and 28, 2011

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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

A-21 Task Force Update

Members from the A-21 Task Force presented an abbreviated version of their "Phase I Recommendations" during the late Thursday afternoon session at the October 27-28 COGR Meeting. The three Task Force Co-Chairs (Gil Tran-OMB, Sally Rockey-NIH, and Mark Herbst-DOD) provided the update to the COGR membership. While the promise that members from the Task Force would be able to discuss the Phase I recommendations in detail did not come to full fruition, we did gain insight into the issues that the Task Force is most focused on, as well as what we might be able to expect in the very near term:

- The "Areas of Review" being covered by the Task Force include many of the COGR Recommendations from the July 28, 2011 COGR letter (see www.cogr.edu, Latest News, July 28, 2011 link on the COGR home page). Included are: Effort Reporting, F&A Rate Setting Process, Subrecipient Monitoring, Agency Limitations on F&A Reimbursement, Cost Sharing, and Direct Charging of Administrative and Communication Costs. The PPT presented by the Task Force that shows their areas of review is available at www.cogr.edu (see the Meetings / October 2011 Meeting Presentations tab).

- At one point, we believed that there would be a formal Phase I and Phase II series of recommendations by the Task Force. Now, it appears there will be a single set of recommendations and the Task Force will have these completed before the end of the calendar year. All recommendations by the Task Force will be reviewed and subject to approval by senior leadership at the Office of Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP).

- A final public report of policy changes specific to A-21 and related areas most likely will be tied to a parallel report applicable to OMB Circular A-87, *Cost Principles for State, Local and Indian Tribal Governments*. The timing of both reports appears likely to be made public in late January, 2012.

The plan for implementing any policy changes will be of great interest to our community. Soon after a final public report is made available, COGR hopes to have access to those responsible for policy implementation and to be able to contribute to the policy implementation process. The Task Force has thoughtfully considered many of the recommendations that COGR and your

institutions have made, and we are cautiously optimistic that that there will be significant and positive outcomes as this process continues to unfold.

What About Effort Reporting?

Elimination of the Effort Reporting requirement appears to have gravitated to the top priority on the A-21 Task Force list. This is driven by a number of factors, including: the COGR recommendation in the July 28th letter to the Task Force, the letters from your institutions to the Task Force, reiteration by AAU, APLU, and other higher education associations, and a sense that faculty and PIs would welcome this outcome. In addition, the concurrent initiative specific to OMB Circular A-87, *Cost Principles for State, Local and Indian Tribal Governments*, has uncovered the same theme of eliminating the effort reporting requirement. In fact, the Department of Education currently is sponsoring a blog (see link below) entitled: "Granting Administrative Flexibility for Better Measures of Success" and one of the discussions is to waive the time and effort reporting requirement in exchange for grantees providing strong performance-based reporting and auditing. See http://www.ed.gov/blog/2011/10/granting-administrative-flexibility-for-better-measures-of-success/

In a meeting with members from the Task Force on October 26th, COGR was asked to further refine the recommendation to eliminate the effort reporting requirement, which was first developed in the July 28th letter to the Task Force. Based on a wide range of input from the COGR Costing and RCA Committees and a number of others from the COGR membership, we submitted a refined solution. A copy of the letter to the Task Force is available at www.cogr.edu (see Latest News, November 9, on the home page).

We describe a "Model Framework" that is predicated on demonstrating that Preventive Controls, Ongoing Monitoring and Review, and Detective Controls are in place. Each institution that adopts the model framework would implement it in a fashion that is appropriate to the business practices and philosophies of the institution. Demonstrating effective implementation of the model to internal and external auditors will provide assurance that the institution maintains a strong compliance infrastructure and that salary and wage charges to federal projects are appropriate. In support of the model framework are "common characteristics" of the payroll distribution system employed by the institution. Each institution through its internal policies and procedures should be able to describe how its business practices address ten common characteristics that normally are present in the payroll distribution system.

By formalizing this approach, we propose that an institution would no longer require an effort reporting system to be layered on top of its existing payroll distribution system. The remainder of the letter includes proposed changes to Section J10, Circular A-21, which would be consistent with the proposed model framework.

The Task Force has indicated a keen interest in including the elimination of the effort reporting requirement as one of its recommendations. However, they also have been clear that it will be important to get buy-in from the audit and federal Inspectors General (IG) community. The COGR proposal is designed to appeal to the audit and IG community – however, we state in the letter that if effort reporting is replaced with another mandated system, then the result simply will

be a new version of an inefficient, expensive, and burdensome process. We also indicated that COGR does not advocate for a narrowly defined pilot. However, as a compromise we could be supportive of a phased approach where at least ten, and as many as fifty institutions, are given clearance to transition away from effort reporting immediately, and all other institutions can transition in a second phase to follow soon after.

Will the Effort Reporting requirement be eliminated? It is too early to tell, but the momentum is real. The diversity of those interested in this issue is wide – through the efforts of Federal Relations staff from several of your institutions, Senators Saxby Chambliss (R-GA) and Johnny Isakson (R-GA) have sent letters to Dr. Francis Collins, Director of NIH, and Jack Lew, Director of OMB, indicating that they are concerned about the cost and administrative burden associated with effort reporting and that NIH and OMB should seriously consider the recommendations described in the November 9th COGR letter to the Task Force. This is a fluid process and we will keep the membership posted on all developments.

Accelerating Spending on ARRA Programs

The Office of Management and Budget (OMB) issued OMB Memorandum M-11-34 on September 15, 2011. M-11-34 can be accessed at the following link and some of the important points of M-11-34 are shown below:
http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-34.pdf

> "Nearly 85 percent of Recovery funds have now been paid out and the vast majority of remaining funds have already been obligated … Despite the rapid pace of spending of Recovery Act funds over the past 30 months., there remain billions in discretionary Recovery Act funds that … have not yet been outlayed. In light of the current economic situation and the need for further economic stimulus, it is critical that agencies spend these remaining funds as quickly and efficiently as possible.
>
> Accordingly, subject to the exceptions described below, Federal agencies are hereby directed to accelerate the spending of remaining Recovery Act funds in discretionary grant programs ... consistent with existing laws and regulations and programmatic objectives. If those funds have not been spent by September 30, 2013, agencies shall reclaim them to the extent permitted by law …
>
> Federal agencies may request waivers from the September 30, 2013 deadline for discretionary grant funds where contractual commitments by the grantee with vendors or sub-recipients prevent adjusting the timeline for spending, where a project must undergo a complex environmental review that cannot be completed within this timeframe, where programs are long-term by design (such as the majority of the High Speed Rail program) and therefore acceleration would compromise core programmatic goals, or where other special circumstances exist. Agencies should request such waivers sparingly, and they will be granted only due to compelling legal, policy, or operational challenges. Agencies must submit all proposed waivers to OMB for review and approval by September 30, 2012. Any waiver requests must be made directly by the head of the agency.

> Agencies should clearly communicate the requirements of this memorandum to grant recipients through adding these requirements to new grant agreements, modifying terms and conditions of existing grant agreements, or other appropriate written means consistent with law ..."

OMB M-11-34 is of particular significance to the National Science Foundation (NSF), and consequently, recipients of NSF ARRA funding. Many NSF ARRA awards were established as multi-year awards with the program period extending beyond September 30, 2013. The Faculty Early Career Development (CAREER) program comprised over half of the ARRA awards with expiration dates beyond September 30, 2013. The Integrative Graduate Education and Research Traineeship (IGERT) program is another example of a program funded by ARRA monies – it is a student-oriented program with expiration dates beyond September 30, 2013.

COGR member institutions have been contacted by NSF program staff to discuss strategies for accelerating spending on ARRA programs that are scheduled to extend beyond September 30, 2013. NSF policy staff currently is coordinating with policy staff from NIH on implementation of M-11-34 and plans to issue guidance to the community as soon as possible.

2011 COGR Survey of F&A Rates and Rate Negotiations Update

One of the Thursday morning sessions at the COGR Meeting covered "The COGR Survey of F&A Rates, Current Trends, Future Surveys, and an Update on Recent Negotiations." The session had two themes: 1) A General Discussion of F&A Rate Trends based on the 2011 COGR Survey of F&A Rates, and 2) A Negotiation Update by Gary Talesnik (Special Consultant, Attain Consulting, LLC), with an emphasis on tying recent negotiation experiences to the recommendations COGR has made to the A-21 Task Force.

2011 COGR Survey of F&A Rates and Future Surveys

F&A rate trends by various cohorts (e.g., MTDC volume, Public/Private, DCA Region and ONR) were summarized. The basis for analysis is the recent COGR survey, which includes data from over 150 COGR institutions. There are two data tables, both in XLS format, that are available to the membership: Historical Rates and Components. The Historical Rates is a 10 page table and the Components 15 pages. The Components table has more columns and may be trickier to follow, but we tried to make it as user-friendly as possible for both review and printing.

The data in the tables is "Confidential and for Internal Institutional Purposes Only." This was a discussion covered during both the Thursday morning session and during the COGR Costing Committee and Board meetings. Copies of the two data tables can be sent to your institution by contacting David Kennedy at dkennedy@cogr.edu. We encourage you to double-check your data for accuracy. As you review the tables, some may be disappointed that their institution is not included. Our intent is for the survey to have a "real-time" element and to regularly update the tables, so we will always accept your institutional data. When there are changes to your data, please update COGR on a real-time basis. We will periodically notify the membership of updated versions of the tables.

We also discussed what data elements that the COGR membership was most interested in for future surveys (above and beyond the two XLS data tables). For example, items such as fringe benefit rates, effective F&A recovery, use of consultants and software, development of special studies, just to name several, were raised. COGR hopes to formulate a survey later in 2012 and we are interested in accumulating your ideas. Again, contact David Kennedy with your input.

F&A Rate Negotiations and the A-21 Task Force

Gary Talesnik provided an overview of the organizational status at the Division of Cost Allocation (DCA) and addressed the issues of substance that are being raised in F&A rate negotiations. The discussion that followed was designed to connect the issues being raised during recent negotiations, as well as the process for negotiation, to one of COGR's recommendations to the A-21 Task Force: *Formalize an F&A Rate Negotiation Model that is transparent, unambiguous, consistent and collaborative between the Federal government and Research Universities and Institutions.*

We understand that the Task Force is considering taking action on this recommendation, and if they do, it will be important for COGR to be prepared to help inform specific actions that could be taken by the Task Force. While one message from the session was recognition that there is a subjective element to every F&A rate negotiation, there are some areas where uniformity and consistency are necessary. Our proposed actions to the Task Force, as paraphrased from the July 28th letter, were:

- Transparent documentation related to: a) the proposed F&A rate, and b) the potential F&A rate adjustments, should be provided,
- Rate increases should not be artificially limited,
- Rate should be negotiated within six-months after the submission of the F&A rate proposal,
- A Central office and/or OMB-designee should be available to resolve exceptional situations – if not settled, an appeals process should be clearly defined and understood by all parties, and
- OMB should convene an annual meeting between representatives from DCA, ONR, OMB, other applicable Federal entities, and Research Universities and institutions to review current trends, rate development methodologies, and other issues specific to F&A rate negotiations.

Consequently, it is helpful to COGR if you can share your most recent experience with your F&A rate negotiation. Specifically:

- Did DCA/ONR provide documentation on rate adjustments?
- Was there "low-balling" related to rate offers?
- Was there a rate ceiling? e.g., 2-point increase?
- Were you "empowered", or was it "take-it-or-leave-it"?
- Overall, would you characterize the negotiation as fair/transparent/acceptable/etc.?
- Other Comments?

As mentioned previously, the work of the A-21 Task Force is a fluid process. Your input is important and contact David Kennedy at dkennedy@cogr.edu to share your perspectives on the F&A rate negotiation process at your institution.

Audit Update: Inspectors General (IG) 2012 Workplans for HHS and NSF

COGR staff had the opportunity to meet with IG staff from the Department of Health and Human Services (HHS) and the National Science Foundation (NSF). In two separate meetings in October, we met with IG staff to learn more about the workplans and audit activity scheduled for fiscal year 2012 (FY2012), as well as insights on recent audit activity and areas of risk. During the Friday Committee Reports, we provided a brief update on those meetings, and in the sections that follow we have provided additional detail.

Department of Health and Human Services, Office of Inspector General (HHS OIG)

The HHS OIG is responsible for auditing NIH programs. The HHS OIG Workplan for FY2012 is available at: http://oig.hhs.gov/reports-and-publications/workplan/index.asp#current

The HHS OIG Workplan for FY2012 highlights several initiatives, shown below. These items are described in more detail in Part V: Public Health Reviews, Part VII: Other HHS-Related Reviews, and Appendix B: Recovery Act Reviews. Several of the initiatives are carry-overs from last year and the others listed in the Workplan are indicted as "New" initiatives.

While the published Workplan is a helpful overview of the areas in which the HHS OIG considers could be high-risk, it is important to note that it is a general blueprint only. The Workplan will expand and contract as the HHS OIG does ongoing risk assessment and determines where to best direct its limited resources. Other events, such as auditor intuition, congressional directives, recent settlements and/or significant findings, and other unpredicted influences can determine where the HHS OIG focuses its resources. COGR will follow the status, accordingly. The published Workplan includes the following items (note, the numerical listing is based on those items COGR extracted from the Workplan and does not reflect HHS OIG priorities or their numbering schema):

1) Colleges' and Universities' Compliance With Cost Principles-OAS, page V-9
2) Review of Extra Service Compensation Payments Made by Educational Institutions-OAS, page V-9
3) Recharge Centers at Colleges and Universities-OAS, page V-10
4) Informed Consent and Privacy Protection Procedures for NIH Grantees Conducting Genetic Research-OEI (New), page V-10
5) Inappropriate Salary Draws From Multiple Universities-OAS (New), page V-11
6) Cost Sharing Claimed by Universities-OAS (New), page V-11
7) Awardee Eligibility for Small Business Innovation Research Awards-OEI (New), page V-11
8) Classifications of Federal Pass-Through Funding Recipients-OAS, page VII-7

9) College and University Indirect Costs Claimed as Direct Costs-OAS , page B-7

Note that each item falls under OAS (Office of Audit Services) or OEI (Office of Evaluation and Investigations). OAS-indicated activities represent more traditional financial audits based on accounting and cost allowability standards. OEI-indicated activities represent those that require more exploratory probes where the criteria for findings are not as clearly defined. OAS and OEI are separate offices of the HHS OIG and each will pursue their audit plans based on risk assessment, resource availability, and other events.

ARRA Audits

The HHS OIG has been engaged in ARRA audits throughout the past year and will continue this initiative in FY2012. After initially focusing their ARRA audits on higher risk programs from other agencies (e.g., HRSA and ACF), they are now looking more closely at NIH-sponsored programs.

Generally, the ARRA audits of NIH programs have been grant-specific with a focus on the financial aspects of the grant (i.e., cost allowability, internal controls of financial processes, etc.), and have included lengthy information requests – though jobs reporting has not been emphasized. The HHS OIG is comprised of 8 regional audit offices in the country, and our understanding is that 2 institutions are being (to be) audited in each of the 8 HHS OIG audit regions.

The HHS OIG 2012 Workplan includes ARRA audit work in Appendix B: Recovery Act Reviews, though five of the six items listed are specific to NIH internal controls. The only item specific to external grantees is the familiar, *College and University Indirect Costs Claimed as Direct Costs* audit initiative (discussed in more detail in the next section). This is a somewhat confusing description of ARRA audit activity – our understanding is that the ARRA audits are not focused on administrative and clerical expenses. As described above, the scope of the ARRA audits as described to us in our meeting is on the more general financial aspects of the grant.

Other Workplan Items

The October meeting with staff from the HHS OIG informed additional insights to the published Workplan. Item 1), Compliance with Cost Principles, is a standard HHS OIG "placeholder" item – in other words, if there is occasion to initiate audits specific on topics not listed in the Workplan, that particular initiative could be categorized under the generic header of "Compliance with Cost Principles." Items 2) and 3), Extra Compensation and Recharge Centers, both included in the FY2011 Workplan, were described in our meeting with the HHS OIG as "ongoing pilots" and only would be escalated if the pilots uncover issues that the HHS OIG considers serious. At this point, there is no indication either way if Extra Compensation or Recharge Centers will be escalated. Item 8), Classifications of Federal Pass-Through Funding Recipients, also was included in the FY2011 Workplan and also is preliminary and not clear if it will be escalated.

Items 5) and 6), Inappropriate Salary Draws From Multiple Universities and Cost Sharing, are new items in the Workplan that have not been initiated. If resources allow the HHS OIG to commence either or both of these items, they will start as pilots. Items 4) and 7), Informed Consent and Awardee Eligibility for SBIR are associated with OEI – if and when they are initiated is to be determined.

Item 9), College and University Indirect Costs Claimed as Direct Costs, while listed in Appendix B: Recovery Act Reviews is a stand-alone, separate initiative from the ARRA audits. An update on this audit item is summarized below.

HHS OIG Administrative and Clerical Audits

The eight schools that were selected for this audit work (officially entitled, *College and University Indirect Costs Claimed as Direct Costs*) are at different stages of completion, and each is assigned to one of the eight HHS OIG regional audit offices. There are indications that each HHS regional audit office has employed a unique approach to its audit work. Consequently, the audit experience for each school has varied from region to region.

To date, two audits reports (August 2011 and October 2011) have been released:
http://oig.hhs.gov/oas/reports/region10/11101500.pdf
http://oig.hhs.gov/oas/reports/region2/21102000.pdf

The first audit report included no cost disallowances and concluded that the institution complied with Federal regulations. The second audit report stated that the institution "generally claimed Federal reimbursement for administrative, clerical, and extra service compensation expenditures in accordance with Federal regulations." However, $82,922 of cost disallowances were identified. Upon providing additional documentation, the total disallowance amount was reduced to $48,651. The institution also agreed to implement corrective actions to further tighten its controls for charging administrative, clerical and extra service compensation expenditures to sponsored agreements.

COGR is following the developments related to the Administrative & Clerical audits as well as any broader repercussions that could ensue. We will keep the membership posted.

National Science Foundation, Office of Inspector General (NSF OIG)

The NSF OIG is responsible for auditing all NSF programs. The NSF OIG Audit Workplan for FY2012 is not available at the time of this writing (note, last year the 2012 Workplan was dated November 23, 2011). Reports and Publications from the NSF OIG are posted at the following address and we expect the 2012 Workplan to be available shortly. See http://www.nsf.gov/oig/pubs.jsp

While the published Workplan is not available at the time of this writing, the October meeting with staff from the NSF OIG was helpful in understanding some of their priorities for FY2012.

1) The NSF OIG is transitioning to a new audit approach that emphasizes data and statistical analysis, rather than the more traditional approach of topic oriented audit initiatives (e.g., labor and effort audits). One staff person from the NSF OIG described this approach as allowing them to be "more nimble."
2) The data and statistical approach manifests itself in a new methodology where the NSF OIG will ask institutions for an electronic version of the General Ledger, specifically, NSF funds and accounts. Based on various analysis techniques (not shared with COGR), NSF OIG staff will look for indicators that suggest audit risk or need for additional information. Our understanding is that between 10 and 20 institutions will be audited in FY2012 using the new methodology.
3) ARRA audits will continue to be conducted – like the HHS OIG approach described previously, they are grant-specific with a focus on the financial aspects of the grant (i.e., cost allowability, internal controls of financial processes, etc.). However, unlike the HHS OIG approach, jobs reporting has been more of a factor in the NSF OIG ARRA audits.
4) We have reported a number of times over the past year that the Effort Reporting "capstone report" should be released shortly – the report was to be a summary of findings from the labor and effort audits between 2006 and 2010. However, it now appears this report will not be released. While the NSF OIG has some strong sentiments on the (in)effectiveness of effort reporting, they most likely will address their concerns through other forums to be determined later.
5) As we reported last year, the NSF OIG continues to shift away from the "outsource" audit model to one where more NSF OIG audits are done in-house by NSF OIG personnel. While they expressed that it is difficult to hire due to a competitive labor market for auditors, the data and statistical analysis approach may allow them to be more productive and conduct more of their work in-house.
6) Oversight of NSF operations continues to be a focus of the NSF OIG, and this often trickles down to grant recipients via additional monitoring and reviews by NSF.
7) The Audit Resolution process, which is the responsibility of the NSF's Cost Analysis and Audit Resolution Branch (i.e., it is not the formal responsibility of the OIG), has been "tightened" to allow more communication between the OIG and the Cost Analysis and Audit Resolution Branch.
8) Compliance with Responsible Conduct of Research regulations and how institutions manage Financial Conflict of Interest remain on the NSF OIG radar.

We do not expect the official release of the NSF OIG Audit Workplan for FY2012 to impact the summary from above. If there are significant updates in the Workplan, we will share them with the membership.

As always, COGR is interested in audit experiences at your institution so that we can update the general landscape for the membership. Please contact David Kennedy at dkennedy@cogr.edu if your institution has been contacted by any agency to conduct an audit or review. We will keep all correspondences confidential.

Other Costing Developments and Discussions

Below are topics that are either new developments or items we have reported on in the past and/or 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.

NSF Cash Payment System and COGR's View. As COGR wrote in the June Meeting Report (June 29, 2011), NSF plans to roll-out a new Cash Payment System. Since then, NSF has presented at various forums across the country and recently at the NCURA 53rd Annual Meeting in Washington D.C. Also, the September/October 2011 edition of NCURA Magazine includes a related article written by NSF staff. COGR recommends that the community be diligent in voicing its concerns and trepidations. The scheduled roll-out is January, 2013. COGR suggests that NSF instructions for the "cash reconciliation" between the "old" NSF system and the "new" NSF system be clear and user-friendly in order to minimize any potential cash flow problems. The new NSF rules for requesting cash must be understood so that institutions can plan cash requests, accordingly. And transitory and/or new administrative burdens must be anticipated as accurately as possible so institutions understand any additional costs of doing business that could be incurred. It is unknown at this point how NSF will address Public Comments through a Federal Register Notice – however, COGR is following all developments closely.

NIH under a Continuing Resolution (CR). As of this writing, the current CR that funds government agencies is applicable through November 18, 2011. The Congress will have to approve a new measure, which may be in the form of a new CR. NIH funding under a new measure, most likely, will be dictated by the October 7, 2011 NIH Notice Number: NOT-OD-12-004. This Notice states: *Until FY 2012 appropriations are enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). This is consistent with our practice during the CRs of FY 2006 - 2011. Upward adjustments to awarded levels will be considered after our FY 2012 appropriations are enacted but NIH expects institutions to monitor their expenditures carefully during this period.*

If there are changes to the NIH policy, COGR will contact the membership. The October 7, 2011 NIH Notice is available at:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-004.html

Workplace Flexibility ("Family-Friendly") Science Policy. In late September, the White House Office of Science and Technology Policy (OSTP) and the National Science Foundation (NSF) announced a series of new NSF policies allowing for new flexibilities related to child and dependent care leave, including flexible award deferral and no-cost extension policies, award supplements to pay for staff to maintain a lab while the PI is on leave, and "virtual" peer review for those who cannot travel. Links to the White House press release, the NSF Notice, and NSF FAQs Related to Dependent Care are shown below.

The NSF FAQs include one FAQ (FAQ #4) that is inconsistent with how many institutions account for sick leave, vacation time, and other leave time. While supportive of family-friendly policies, COGR is in contact with NSF in regard to FAQ #4.

http://www.whitehouse.gov/the-press-office/2011/09/26/white-house-and-national-science-foundation-announce-new-workplace-flexi

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=balance

http://www.nsf.gov/pubs/2010/nsf10032/nsf10032.jsp?org=EHR

NIH and Genomic Arrays. In the Spring 2011 Update (dated May 27, 2011), we included a narrative that addressed Genomic Arrays using "The Costing and the Science" as the context. We have shared this analysis with NIH and COGR's position remains that this NIH policy should be retracted. We highlighted this specific concern in the response to the A-21 Task Force (Recommendation B2). We continue to correspond with NIH on this topic and we will update the membership on developments.

NIH Grant Policy Statement Update. The NIH announced the publication of the revised NIH Grants Policy Statement (GPS), to be applicable to NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2011. The revised GPS includes new and modified requirements and other changes that have taken place since the significantly modified GPS was made effective on October 1, 2010. The NIH Notice that announced the release of the revised GPS is shown below and includes links to the revised GPS and a summary of significant changes. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-003.html

NIH Request, Costing on Core Facilities – On Hold, but plans to address in near future. 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 Latest News, December 8, 2010 link on the COGR home page). Our latest update from NIH on this topic is that any action is on-hold, partly due to reorganization that is taking place at the National Center for Research Resources (NCRR), but that NIH plans to revisit soon.

Policy Paper: Reforming Regulation of Research Universities. In the Summer 2011 issue of the quarterly journal, *Issues in Science and Technology Policy*, COGR staff co-authored with staff from the Association of American Universities (AAU) a paper entitled: *Reforming Regulation of Research Universities*. The paper proposes regulatory reform solutions that will help restore some balance to the current regulatory and financial burdens being faced by all research institutions. Several of the themes addressed in the recommendations to the A-21 Task Force are addressed in the policy paper. A copy of the article can be found at www.cogr.edu (see Latest News, September 1, 2011 link on the COGR home page).

Maintaining Momentum on "Arbitrary Agency Policies." The November 2010 paper, *Federal Funding Agency Limitations on Cost Reimbursement: A Request for Consistency in the Application of Federal Guidelines*, was one of the formal initiatives by COGR designed to address the broad topic of "Financial Reform." The paper (and Appendix with examples) can be accessed at www.cogr.edu under the Educational Materials / Financial Management tab. In the COGR Recommendations to the A-21 Task Force, we reiterated our concern with

arbitrary agency policies (e.g., limitations on F&A reimbursement, vague cost sharing requirements, etc.) and our understanding is that the Task Force is earnestly addressing this topic. Over the past year, you have provided examples and we continue to document these. In a letter to OMB dated September 8, 2011, COGR provided 11 recent examples of arbitrary agency policies. A copy of the letter can be found at www.cogr.edu (see Latest News, September 8, 2011 link on the COGR home page).

NRC "Study on Research Universities" Update. It's been almost one-year since COGR began reporting on the study to be completed by The National Academies, National Research Council (NRC) to address the top ten actions that research university stakeholders and the nation can take to ensure U.S. global competiveness. We initially reported that the study would be completed in the Summer – however, completion of the study has been delayed. Our understanding is that the NRC is close to finalizing their report and that it should be available by the end of this year or in early 2012.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Charles Louis, University of California, Riverside, Chair; Elaine Brock, University of Michigan; 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; Wendy Streitz, University of California; Kevin Wozniak, Georgia Institute of Technology

Patent Reform; PTO Patent Reform Coordinator Meets with CIP Committee

Janet Gongola, Patent Reform Coordinator at the U.S. Patent and Trademark Office (PTO), met with the CIP committee for an intensive discussion of the planned PTO implementation of the American Invents Act (AIA). The October Update included links to a number of references for discussion of the AIA, as well as to PTO's helpful implementation website: (http://www.uspto.gov/patents/init_events/aia_implementation.jsp).

PTO Implementation

Ms. Gongola indicated that PTO has divided implementation into 3 groups: changes that are effective as of the date of enactment (9/16/11) or within 60 days thereafter (Group 1); those that are effective within 12 mos. (9/16/12) of enactment (Group 2); and those that are effective in 18 mos. (3/16/13; Group 3). PTO is planning rulemakings within each group; a total of 21 in all. University input will be sought in each rulemaking. The Act also requires a number of studies: seven with PTO as the lead; and two with PTO as a consultant to other agencies.

Much of the discussion with Ms. Gongola focused on technical issues associated with patent reform that will not be of interest to most of our members. A very important concept is that the **most significant change resulting from the AIA—the change in the U.S. patent system from first to invent to first inventor to file—is in the Group 3 category of changes that will not be effective for 18 mos. (3/16/13). In the meantime the existing first to invent system will continue**. PTO plans to issue a rulemaking, as well as guidance to patent examiners once the change is effective.

Studies

The initial two studies have been announced: International Patent Protection for Small Businesses, and Prior User Rights. Ms. Gongola indicated that PTO Director Kappos specifically requested her to ask us for university input to these studies, which are due in 4 mos. It is not clear that the university community has much to say on the small business study. On prior user rights, we informed Ms. Gongola that universities typically have not asserted them. While we did not favor expansion, the way prior user rights were

expanded in the AIA carved out universities from having the defense asserted against university-owned inventions so that our interests are protected. She said a statement to this effect would be helpful. (There are some concerns about the exception to the carve out for inventions that could not be federally-funded; see below).

On November 8 the six higher ed. associations that have been working on patent reform submitted a joint statement to PTO. The statement reiterated our longstanding concerns about prior user rights, but expressed understanding that for private companies engaged in complex products and manufacturing processes, such products or processes can become vulnerable to a charge of infringement from a patent acquisition company which could threaten an entire product based on a single unpatented component. An appropriately structured prior user rights scheme could provide legitimate protection against such threats. We noted that the AIA protects university patents, but urged PTO to examine in its study the effect of prior user rights in other countries. A copy of the full statement is on the AAU website.

GAO Study

While not discussed with Ms. Gongola, the AIA requires GAO to conduct a study of the consequences of patent litigation by non-practicing or patent assertion entities, and to report within one year with recommendations for any changes to laws and regulations that will minimize any negative impact of such patent litigation. There are six specific elements: 1) annual volume of litigation of this type over 20 years; 2) those found "without merit" after judicial review; 3) impacts on time to resolve claims; 4) estimated costs for patent holders, licensors and licensees, inventors and users; 5) economic impact on the U.S. economy; and 6) benefit if any of such entities.

This study is aimed at patent "trolls." Our concern is that the study raises definitional issues. COGR member institutions fall within the "non-practicing" entity status, but as institutions that create knowledge they are not trolls. However, there are hybrid institutions that aggressively assert patent rights but claim also to do independent research, and large corporations that aggressively enforce huge portfolios of patents that they do not practice. Also the elements of the study raise additional definitional and scope issues; e.g. what does "found to be without merit after judicial review" mean?
Our concern is these nuances will not be familiar to GAO, or easy to explain or understand. Also our understanding is that GAO does not intend to commence the study until after the first of the year. This will provide very little time to deal with the nuances or define the scope of the 6 required elements. A "quick and dirty" study by GAO could lead to unfortunate outcomes for COGR member institutions. We plan to coordinate with GAO once their study plan is announced, and to try to focus their attention on the differences between our members and those entities that the study requirement is seeking to address.

First Inventor to File

While there has been much controversy about this change, in our view it is unlikely to have a substantial adverse effect on COGR member institutions. Most institutions today

want to protect foreign patent rights, and for that it is necessary to preserve absolute novelty so that no public disclosure or publication of an invention is made before a patent application is filed. Also the new personal U.S. grace period provided by the AIA protects faculty inventors. The date of any public disclosure or publication by the inventor becomes the priority date for purposes of a later patent filing, and essentially gives them and their institution up to a year to file a patent application (for U.S. rights). Once the public disclosure is made they are safeguarded against any subsequent claims by others during this period. There may be an increase in provisional patent applications by universities. These are streamlined applications that require only a description of the invention and do not require formal patent claims or other supporting materials required for regular patent applications. However, any subsequent claims must be supported ("enabled") by the description in the provisional application. The filing date of the provisional application is considered the filing date for any subsequent patent application that claims the invention disclosed in the provisional. While many universities have made use of provisional applications, some have been reluctant to do so in the past because of the enablement requirement. This may change.

Micro-Entity Status

We had assumed that the new micro-entity status would apply to COGR member institutions once PTO publishes its new schedule of patent fees (see October Update). This provides for a 75% reduction in standard patent filing fees. Under the AIA, micro-entity status applies to small entities (individuals, small business or nonprofit organizations including institutions of higher education) who have not been named as an inventor on more than 4 previous patent applications, do not have gross income exceeding 3x the median household income in the preceding calendar year, and have not assigned a license or ownership interest in the patent to an entity that exceeds the gross income limit. However, we had understood that institutions of higher education were separately included as micro-entities in the AIA (Sec. 123(d)). PTO evidently is reading the micro-entity status requirements conjunctively as applied to institutions of higher education, which would rule out all COGR member institutions. Ms. Gongola promised to provide clarification on this point. (Micro-entity status will be the subject of a Group 1 rulemaking even though not immediately effective).

Other Concerns - Human Organism Prohibition

The AIA prohibits patents for claims "directed to or encompassing a human organism." PTO long has held that inventions that encompass a human being are not patentable (MPEP-2105). PTO reads the PTO prohibition as stating the same policy. However, some commentators have expressed the view that the statutory prohibition conceivably is broader, and could affect gene patents, stem cells, etc. In that regard, the European Court of Justice recently prohibited European Union patents involving human embryonic stem cell research if an embryo was destroyed during the derivation process. The interpretation of the AIA provision is likely to play out in the courts.

Other Concerns - Exception to University Exception for Prior User Rights Defense

As noted above, the prior commercial use defense to patent infringement cannot be asserted against inventions owned by institutions of higher education. However, this exception does not apply if any of the activities required to reduce the subject matter of the invention to practice could not have been undertaken using federal funds (Sec. 273(e)(5)(B)). Presumably this exception to the exception is aimed at inventions resulting from research for which federal funding is prohibited by law or policy (e.g. patents resulting from research that involves the destruction of human embryos). However, as with the human organism prohibition, the language is ambiguous and may need clarification through further court or regulatory action.

President's Jobs Council Report Recommends Faculty Free Agency

The Interim Report of the President's Council on Jobs and Competiveness issued on October 12 2011 included a recommendation (p. 22) that university faculty be allowed "to shop discoveries to any technology transfer office, other than solely to their own university's technology office." The report discussion stated that:

> "The Council recommends allowing research that is funded with federal dollars to be presented to *any* university technology transfer office (not just the ones in which the research has taken place). Additionally we recommend adding successful entrepreneurs to university academic staffs on 25 campuses nationwide; incentivizing the creation of 15 additional entrepreneurship centers like the University of Michigan's Center for Entrepreneurial Studies; and winning commitments from 25 universities in the next 12 months to use an "open-source" approach for researchers with government funding."

The problems with the proposed faculty "free agency" approach were extensively discussed in a panel session at the February 2010 COGR meeting. The discussion is summarized in the Meeting Report. For a more recent summary by one of the panel participants of the issues raised, see http://goforthandinnovate.blogspot.com/2011/11/free-agency-its-bad-idea.html

COGR, AAU and APLU representatives subsequently met with the Executive Director and Deputy of the Jobs Council to express concerns about the recommendation. An OSTP representative also participated in the meeting. From the discussion it appeared that the Council staff had not fully considered the implications, nor understood the concerns of the university community with the recommendation. We are hopeful that the recommendation may be deleted from the final version of the Report, which is due at the end of the year.

While not the focus of discussion, we also pointed out that the recommendation to add entrepreneurs to academic staffs raises personnel and resource issues for universities, and that the Michigan center is an academic unit located in the business school. The Jobs Council members may not have understood the nature of this center.

Informal discussions with White House and Commerce Department staff indicate that the Administration is not interested in pursuing this recommendation. Nevertheless, the fact that the

free agency proposal keeps coming up in a variety of forums remains of concern. We agreed to provide suggestions to the Jobs Council staff of more acceptable recommendations for university actions.

Patent Cases Involving Natural Phenomena Continue to Raise Concerns

The October Update discussed the case involving patents held by Myriad Genetics on certain genes linked to breast and ovarian cancers which had been invalidated as "products of nature" by the federal district court but then upheld by the Federal Circuit. We noted that the Federal Circuit did uphold the district court's finding that Myriad's diagnostic patent claims that involved comparing and analyzing the BRCA genes and "normal" gene sequences were abstract ideas ineligible for patents. The plaintiffs (ACLU and others) now have announced their intention to appeal the decision to the Supreme Court.

Meantime another case involving somewhat similar issues will be heard by the Supreme Court this term. This case, *Mayo v. Promotheus*, involves claimed infringement of a patent on a blood test that individually calibrates drug prescriptions for patients with autoimmune diseases such as Crohn's disease. The test analyzes a patient's reaction to a specific dosage and immediately determines whether that dosage was too high or too low. The case has attracted wide interest and a number of *amicus* briefs have been filed on both sides, due to the implications for personalized medicine and physicians' diagnostic practices.

AAMC has filed a brief supporting the defendant, arguing that correlations between metabolite levels and therapeutic toxicity which undergird the patented test are unpatentable natural phenomena. AUTM has filed a brief supporting the plaintiff's position that the application of natural phenomena is and should be patentable, and that process improvements in the medical field (as in any other) often combine known physical steps with novel observations and discoveries.

COGR has not been asked to participate, but we have been asked for our views by other higher ed. associations. One of the COGR criteria for considering participation in *amicus* briefs is a high degree of consensus within the COGR membership, which is demonstrably not present in this case. However, in our discussions with the other associations we have agreed that more cases that pose these types of issues are likely, and development of a generalized joint approach to guide our consideration would be helpful. We will continue to discuss this matter.

iEdison Invention Reporting System Issues Discussed Again

We discussed issues related to iEdison in both the COGR Late Summer 2010 Update and the October 2010 Meeting Report. In previous discussions with COGR representatives, NIH expressed the view that the level of compliance with Bayh-Dole disclosure and invention reporting is lower than it should be. Random reviews of university invention reporting by several federal agencies including NIH suggested there may be a substantial compliance problem. NIH representatives also noted that NIH is not receiving the required invention utilization reports from the majority of awardee institutions. Last year's NAS report on University IP Management (see COGR Fall 2010 Update) included a recommendation (#15) to reinvigorate iEdison and make the data available for analysis by researchers. We did not support

this latter recommendation because of concerns about the accuracy and completeness of the i-Edison data. Last October's Meeting Report also noted concerns about technical issues, resource issues, and "ownership" issues with iEdison. From a user standpoint, lack of consistent implementation by funding agencies also is a problem.

Recently NIST informally asked COGR for our views on iEdison. We mentioned some of the concerns that have been raised. One possibility is for Commerce/NIST to take ownership of iEdison as part of its oversight responsibilities for Bayh-Dole. There also is a question of the interface between iEdison and subsequent phases of STAR METRICS. The CIP Committee plans to continue to focus attention on iEdison. At some point the issues will need to be addressed by policymakers. Our hope is that this will not come at the expense of universities because of GAO or IG findings.

New Coulter Foundation/NSF Commercialization Prize Raises Questions

We noted in the Update that at the America Invents Act signing a new university commercialization prize was announced that is to be jointly funded by NSF and the Coulter Foundation with AAAS designing and implementing the prize competition in partnership with other agencies and organizations. The White House Press Release stated "This prize competition will be used to identify and promote incentives to adopt best practices that improve university commercialization efforts. Supported by $400,000 in funding from the Wallace H. Coulter Foundation ($300k) and NSF ($100k), AAAS will lead the design and implementation of the prize in coordination with a diverse array of partner agencies, foundations, and organizations."
Little information about this prize is available beyond the quoted information in the Press Release. The eligibility requirements and the nature of the prize competition are unclear. We understand that AAAS is considering focusing the award at the dean level (i.e. schools or departments) and avoiding both the university presidents' level and tech transfer offices (based in part on advice from the Kauffman Foundation). Funding is available only for the first year, but the hope is that funding will be found to make the award on an annual basis. NSF plans to use peer review for the prize competition.

COGR, AAU, and APLU plan to meet with AAAS for further discussions. AAAS has been influenced by the NAS University IP Management report which noted a number of mechanisms exist for university technology transfer in addition to those provided by tech transfer offices. We do not necessarily object to this approach, although it may raise issues as to the direct linkage with commercialization.

COGR/AAU Comment on Proposed Changes to DOE Nuclear Export Regulations

The Update discussed the proposed changes to the DOE regulations (10 CFR 810) on providing assistance to foreign atomic energy activities. On November 7 COGR and AAU jointly submitted comments on the proposed changes. Our comments expressed support for moving from a specific authorization to general authorization approach. We also expressed support for the clarification that Part 810 does not apply to public information or basic scientific research.
However, we expressed the view that the goal of federal policy should be to align export control regulations as closely as possible across all federal agencies and departments. In that regard, we questioned certain terms and definitions in the proposed DOE regulations, particularly "Basic

Scientific Research." We pointed out that the proposed 810 revision departs significantly from the term and definition of "Fundamental Research" used in the EAR and ITAR based on NSDD 189. We urged DOE to change "Basic Scientific Research" to "Fundamental Research" and to define it consistent with the NSDD 189 definition. We also pointed out that the definition of "U.S. person" in the proposed 810 revision is inconsistent with the counterpart definition in the ITAR and EAR. It would exclude U.S. permanent residents who are treated the same as U.S. persons in the ITAR and EAR. The definitions should be consistent.
A copy of the comment letter has been posted on the COGR website.

New Privacy Act Training Requirements Proposed for Contractors

On October 14 the FAR councils proposed amending the Federal Acquisition Regulations to require contractors to complete training in the Privacy Act of 1974 protections and the safeguarding of personally identifiable information (76*FedReg*63896). The proposed FAR rule includes seven mandatory training elements (including agency-specific training), and requires that contractors maintain training records that must be made available to the government on request. It includes two alternate contract clauses: one for which the contractors conducts the training using its own materials (under the standard clause the government will provide the training materials), and the other (Alternate II) if the agency elects to provide the training itself.

While the Federal Register notice states that the training requirements and burden on contractors are minimal, in COGR's view the proposed rule raises many questions and issues. The Privacy Act has been in existence for over 35 years and the notice provides no explanation as to why these training requirements now are viewed as necessary. More importantly, the proposed rule does not supersede other applicable laws or regulations requiring instruction of contractor personnel on compliance requirements with regard to handling and safeguarding personally identifiable information (e.g. contracts subject to Federal Information Security Management Act (FISMA)/OMB Circular A-1-130 controls still will require security awareness training). It appears unnecessarily duplicative with no clear value added, and raises obvious burden issues which seems counter to the Administration's regulatory reform initiative. In addition, the agency-specific training requirements could necessitate separate specific employee training tailored to each different federal agency. Also if the agencies provide such training, it is unclear how contractors can comply with the record keeping requirement (although Alternate II is preferable from a burden standpoint). Finally, the scope of contractor employees subject to the requirement also is not clear. The proposed language leaves open the question whether the requirement applies to all contractor employees with access to personally identifiable information, or only to those who are paid under the particular contract containing the clause.

In summary, the proposed rule does not appear well thought out or to respond to a demonstrated need. It will lead to increased burdens on contractors, including COGR member institutions who receive contracts requiring access to personally identifiable information or to a government system of records fairly frequently. We plan to raise these issues in a comment letter, and to urge that the proposed rule be withdrawn. Comments are due by December 13.

SBA Proposes New Small Business Subcontracting Requirements

On October 5 the Small Business Administration (SBA) proposed changes in its regulations for contracts for which small business subcontracting plans are required (federal contracts in excess of $650,000 or in excess of $1.5M for construction of public facilities). The proposed changes (76*FedReg*61626) mostly implement provisions of the Small Business Jobs Act of 2010 (P.L. 111-240), and also respond to a 2005 GAO Report (No. 05-459). SBA held 13 public meetings at locations around the country to discuss implementation of the Jobs Act provisions.

The principal changes are to require contractors: 1) to notify the government contracting officer: when the contractor does not utilize a subcontractor used in preparing the bid or proposal during the contract performance (utilization includes referencing the subcontractor in the proposal or the subcontractor's participation in drafting any portion of the proposal); 2) provide notification when payment to a subcontractor is reduced or is 90 or more days past due for goods or services provided by the subcontractor; and 3) update subcontracting plans whenever an option is exercised or when a modification causes a contract to exceed the subcontracting plan thresholds. A number of changes in reporting requirements also are proposed. These include reporting small business subcontracting as a percentage of total subcontracting dollars rather than a percentage of total contract dollars (although contracting officers can establish small business subcontracting goals as a percentage of total contract dollars); including indirect costs in individual subcontract reports rather than only in summary reports where indirect costs are included in the contractor's subcontracting base; and where GSA schedule contracts are used, requiring small business subcontracts to be reported on an order-by-order basis.

The proposed changes also clarify that contracting officers are responsible for evaluating compliance with subcontracting plans. They must do so within 60 days of report ending dates. Where reports are rejected, contractors must make corrections and resubmit the report within 30 days. Contracting officers also must record the identities of contractors with bad subcontractor payment histories (defined as 3 incidents within a 12 month period) in the Federal Awardee Performance and Integrity System, and may consider requiring such contractors to enter into funds control agreements with neutral third parties.

We currently are evaluating the effect of the proposed changes on COGR member institutions. While they will lead to increased burdens, the changes mandated by the Jobs Act do not appear to leave SBA with much discretion. Comments are due December 5.

COGR Co-Sponsors NACUA Virtual Seminar on *Stanford v. Roche*

COGR is co-sponsoring with the National Association of College and University Attorneys (NACUA) a virtual seminar on December 1 on issues and options in the aftermath of the Supreme Court decision in *Stanford v. Roche.* The decision and its implications were extensively discussed in the June 2011 COGR Meeting Report. The seminar will focus on the impact and changes in policies and procedures that universities may want to consider. For information and registration information see www.nacua.org/meetings/virtualseminars/december2011/home.html.

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

NIH Financial Conflicts of Interest Policy – Implementation

During the COGR meeting, attendees had several opportunities to discuss the recently enacted changes to the Public Health Service/National Institutes of Health (PHS/NIH) financial conflicts of interest (FCOI) regulations – formally titled *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors* (42 CFR Part 50 and 45 CFR Part 94). The Thursday morning discussion examined the major changes in the regulations focusing on how institutions will address those changes in policy and/or procedures.

Reimbursed or Sponsored Travel

The single most troubling new requirement is the reimbursed or sponsored travel disclosure by investigators and resulting review, relatedness and conflict determinations and, if appropriate, management by the institution. Institutions are struggling with how to capture reimbursed or sponsored travel as it is "acquired," within 30 days of the trip. Without a dollar threshold or limits on the types of sponsoring entities – business or non-profit organization, etc. – investigators will be required to update their financial disclosures on an on-going basis. This requirement is the single most contentious aspect of the new regulations. During the afternoon presentation and discussion with Sally Rockey, Deputy Director of NIH and Director of the Office of Extramural Research, members expressed their frustration to Dr. Rockey and other members of the NIH staff including Joe Ellis, Director of the NIH Office of Policy for Extramural Research Administration (OPERA), Diane Dean, Director of the OPERA's Division of Grants Compliance and Oversight, and Kathy Hancock, Assistant Grants Compliance Officer in the Division.

During the Friday morning committee reports, the attendees asked the COGR Board to consider challenging these requirements. The most obvious avenue is to petition to have the rule re-opened to solicit comments concerning this aspect of the rule. When cautioned that opening the rule could result in other changes as well, the attendees assured the Board that they were willing to take that risk.

Since the October meeting, the COGR staff have been researching the process to file a proper objection to the final rule – a petition for rulemaking. The Board will take this up

this recommendation in the very near future. At the same time, we are investigating whether or not there are other mechanisms to provide relief on the strict, narrow interpretation of the travel provisions of the regulation as presented at COGR. The outcome of any request for revisions is uncertain, so institutions should proceed with implementation accordingly. We will keep the COGR membership informed as we move through this process.

Other Issues in Implementation of the PHS/NIH FCOI: Training and Determinations

During the Thursday morning discussion, several institutions asked how their colleagues will meet the training requirement. Capturing each and every individual that is involved in the design, conduct and reporting of research will be a challenge particularly with the more fluid engagement in research activities of undergraduate and graduate students. Most institutions reported looking for opportunities in current training programs, e.g., new faculty and graduate student orientations; using a combination of online training (either locally developed or as a part of a vendor relationship, e.g., the CITI program) and in-person training for NIH-supported investigators, etc. The regulations do not require but most institutions recognize that they need to develop some process for documenting or tracking the training to ensure that investigators can be re-trained within four years. Absent changes in the PHS/NIH regulations or institutional policies and procedures or non-compliance by the investigator (which require immediate re-training), NIH recognizes that the 4 year training is more a reminder or refresher rather than a complete re-education process.

During the discussion on how institutions will make the various determinations required by the regulation – related to institutional responsibilities and PHS-supported research; a conflict with the PHS-supported research, etc. – Andy Rudczynski, Yale University, talked about developing questions as opposed to criteria for making the determination. As a part of its process, Yale introduces the general "factors that may be taken into consideration in this determination" including the role of the individual in the project and the opportunity for that individual to bias the results, etc. "Other factors" are offered in the form of questions: whether the research is of a basic or fundamental nature or whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; whether the project is a comparative evaluation of a technology in which an investigator has a SFI or to validate a particular approach or methodology that could affect the value of the SFI; or involves human subjects, etc.

Some COGR institutions and Yale are interested in continuing discussions with other COGR members to develop and refine such questions to assist in meeting these institutional responsibilities. Institutions/individuals interested in participating in a focused exploration of such questions should contact COGR (cblum@cogr.edu). We'll organize a discussion with the goal of providing ideas to the membership at the February COGR meeting.

Discussions about the regulations are being held across the research community at meetings of associations, compliance professionals groups, etc., in an effort to identify and share information and strategies for implementing the new regulations. We encourage participation in those discussions. NIH continues to collect questions and will post response to the NIH website Frequently Asked Questions (FAQs) at http://grants.nih.gov/grants/policy/coi/. We encourage

you to ask a question of NIH because we suspect that you are not the only institution that may need clarity on a provision within the regulations.

COGR Access to and Sharing and Retention of Data Revised

Under the guidance of the Research Compliance and Administration Committee and the leadership of Mike Amey, Johns Hopkins University, we have completed a revision of the *Access to, Sharing and Retention of Research Data: Rights and Responsibilities (Access and Retention Guide)* document. Designed as a companion guide to COGR's *Rights In and Responsibilities for Technical Data and Computer Software Under Federal Awards*, (October 2009), the Access and Retention Guide examines the broader context of data stewardship and the institution's obligations irrespective of the outside funding source and regardless of the type of funding mechanism selected. The Guide begins with general guidelines for retention and access and then examines unique Federal agency policies or regulations and special circumstances that affect the access to and sharing and retention of data. It includes case scenarios to illustrate various data management questions and offers suggestions for addressing these questions.

What's new in this edition is a brief paper in Appendix A discussing the conundrum of defining research "data" and research "materials;" updates to include Federal policies on data sharing and other relevant regulations and policies; and a general re-grouping of information and editing for clarity. We've added a "sidebar" format that highlights areas for consideration by the institution in developing policies and investigators in establishing effective practices concerning data management. The highlights or "checks" for institutions are replicated in an institutional checklist (to be available online only) that can be used within the institution and be improved with references to institutional policies and procedures. The Case Scenarios have been reviewed and edited as appropriate and we've added a new misconduct case.

It is our goal to have an electronic version including all attachments as a single document by early December 2011 and will notify the membership when it is available. We will print a limited number of the booklet and send copies to the COGR Primary Representative in early in 2012.

We want to thank the COGR members that assisted Mike Amey in this revision: Elaine Brock, University of Michigan, Kelvin Droegemeier, University of Oklahoma, Sheila Garrity, Johns Hopkins University, Victoria Hamilton, Columbia University, Michael Ludwig, Purdue University and Carol Zuiches, University of Chicago.

OSTP Seeks Information on Public Access to Publications and Data

Following the COGR meeting, the Office of Science and Technology Policy (OSTP) published two separate but related requests for information (RFI) in the *Federal Register* on November 4, 2011. Both RFIs seek information to meet requirements of the America COMPETES Reauthorization Act of 2010 (Sec. 103. Interagency Public Access Committee. ACRA, PL 111-358). ACRA directs OSTP to establish a working group to coordinate Federal policies concerning dissemination and long-term stewardship of the results of research including digital data and publications. OSTP is charged with the development or designation of standards for both data and publications; coordination of agency programs and activities to support this

stewardship; establishment of priorities for the development of Federal policies; notably, consideration of the distinction between publications and data; and, finally, the views and roles of stakeholders including scientific publishers.

OSTP approached this task by forming two working groups. The first, the multi-agency Task Force on Public Access to Scholarly Publications, requested information on ***Public Access to Peer-Reviewed Scholarly Publications Resulting from Federally Funded Research*** (76FR68518) on November 4, 2011. Acknowledging earlier public meetings and consultations on access to publications, the Task Force poses a series of questions in the RFI. The questions focus on a variety of related issues including: growing "existing and new markets" for the use of publications including how archiving strategies affect access and potential use of information for economic and scientific growth; protecting intellectual property rights; the virtues of centralized versus decentralized management; and, the question that has plagued these discussions for several years, the appropriate embargo period for access.

The second RFI, issued by OSTP's Interagency Working Group on Digital Data, requests comment on ***Public Access to Digital Data Resulting from Federally Funded Scientific Research*** (the RFI was reissued on November 10, 2011 to correct the comment deadline date, 76FR70176). Again, drawing on earlier discussions summarized in a 2009 report, the Interagency Working Group observes that while Federal agencies have policies for managing data, the agencies have not extended their intramural policies for preservation and access to data to the extramural research community with the notable exceptions of NIH's Data Sharing Policy and NSF's reaffirmation of its data management policy requirement. Recognizing that these models may not be applicable across Federal agencies, the Working Group poses questions concerning "preservation, discoverability and access" and "standards for interoperability, reuse and repurposing." Questions address encouraging access to promote economic and scientific growth and protecting intellectual property as posed in the RFI concerning publications. The questions also raise the challenges associated with the costs of long-term preservation and burden of compliance and verification of compliance; and the development of data standards that are effective, coordinated with international efforts, and support links between the data and related publications.

Responses to the RFIs are due January 2, 2012. We encourage institutions to respond directly to OSTP and/or offer comments and suggestions to us to help frame COGR's responses. With the holidays that occur between today and January 2, 2012, comments and suggestions should be forwarded by December 12, 2011 to assist COGR (cblum@cogr.edu or rhardy@cogr.edu).

NSF Revises Grant General Conditions – Open Skies! And Expenditure Reporting

The National Science Foundation (NSF) announced changes to the Grant General Condition (GC-1) that are effective February 1, 2012. The changes will be effective for new NSF grants and funding amendments to existing NSF grants. The complete text of the GC-1 conditions (as well as other NSF grant policy issuances) is available on the NSF website at: http://www.nsf.gov/bfa/dias/policy/.
The changes to Article 10 (Travel) and Article 16 (Expenditure Reports) will be incorporated in the next issuance of the NSF Award and Administration Guide. Any questions should be

directed to the Policy Office, Division of Institution and Award Support, on (703) 292-8243 or by e-mail to policy@nsf.gov.

Travel

One of the significant changes reflects modifications to the travel provisions in the US/European Open Skies Agreement that affect compliance with Fly America policy restrictions. Article 10, Travel, has been updated to incorporate revised circumstances under which the use of a foreign-flag air carrier is permissible. Those of you that have followed the ins and outs of using foreign air carriers for Federally funded travel will recall that the US entered into an Open Skies Agreement with the European Union ("EU") in 2002. The agreement was modified in June 2010 giving EU airlines (airlines of Member States) the right to transport passengers and cargo on flights funded by the US government, when the transportation is between: (1) any two points outside the United States; or (2) a point in the United States and any point outside the United States that the EU airline is authorized to serve under the "Open Skies" Agreement.

As NSF outlines in the GC-1, in 2011 two significant changes have been made to the US/EU Open Skies Agreement. First, EU airlines are now granted the right to transport civilian agency-funded passengers who are NOT eligible to travel on General Services Administration (GSA) Airline City Pair Contract fares (e.g., grantees) between a point in the United States and a point outside the United States even if there is a GSA Airline City Pair Contract fare in effect between the origin and destination points. This provision means that grantees can use EU carriers even if a city-pairs agreement exists – a prior, significant limitation.

The changes also allow EU airlines to transport passengers between points in the United States and points outside the EU if the EU airline is authorized to serve the route under the Agreement. This includes flights that originate, arrive, or stop in the EU. Prior to this change, EU airlines were limited to flying passengers between points in the U.S. and points in the EU.

These changes affect travel **and the tickets purchased** for travel after February 1, 2012. Tickets purchased before that date must meet the (old) current requirements. You should not purchase tickets under these revised provisions in advance of February 1, 2012. When in doubt, check with your grants/contract officer before purchasing tickets.

Expenditure Reporting

The other important change is in Article 16 which now requires that all Federal Financial Reports (FFR) be submitted through Research.gov. There are instructions for using the FFR available on Research.gov under Help by selecting "Federal Financial Report (FFR)." Additional help or advice is available from the Grantee Cash Management Section staff at http://www.nsf.gov/bfa/dfm/cmeab.jsp. You will recall that Research.gov is the Grants Management Line of Business initiative developed by NSF in cooperation with the National Aeronautics and Space Administration (NASA) and the US Department of Agriculture's National Institute of Food and Agriculture. The goal of Research.gov is

to enable organizations and researchers to access research grants management tools, services and other resources for multiple federal agencies in one location. Currently, at Research.gov investigators can prepare and submit the Project Outcomes Report for the General Public required by NSF; check the status of applications, from submission to decision, as they are received and reviewed by NSF, USDA/NIFA, and DoD/ARO and, now, prepare and submit the FFR to NSF using the new government-wide standard form. Research.gov will be the site for investigators to complete and submit the Research Performance Progress Reports (RPPR) using the new standard form.

NIH Changes to Grants Policy Statement and Implementation of FFATA

In a notice posted November 10, *Expanded Transparency Act Subaward and Executive Compensation Reporting Requirements for FY2012 and Beyond* (NOT-OD-12-010), NIH noted that its original implementation of the Federal Funding Accountability and Transparency Act (FFATA, the Transparency Act) applied only to New (Type 1) competing awards issued on or after October 1, 2010 with an expectation that the scope of the requirement would be changed when the Office of Management and Budget (OMB) extended the requirement for agencies. OMB has not changed the agencies requirements so, as a consequence, NIH will retain the original scope of the application of the FFATA reporting requirements – new (Type 1) awards issued on/after October 1, 2010 but extend its applicability to any subsequent award action following an applicable "New" NIH award.

Thus, effective immediately, and unless specifically exempted, NIH awards for competing Type 1 award issued on or after October 1, 2010 will be subject to the Transparency Act subaward and executive compensation reporting requirements. These requirements will now also apply to all subsequent award actions to any such NIH grant or cooperative agreement award; e.g., a Type 5 award issued subsequent to an applicable Type 1 award. NIH will include a specific statement concerning the FFATA status in the Notice of Award (NOA) terms and conditions.

NIH Updates Grants Policy Statement

NIH issued a revised Grants Policy Statement (NIH GPS) on October 1, 2011. The revised NIH GPS is available at: http://grants.nih.gov/grants/policy/policy.htm#gps and becomes the standard term and condition of awards issued on or after October 1, 2011. As in the past, this revision incorporates new or modified requirements issued by NIH as notices since the last revision of the NIH GPS in October 2010. In addition to formal changes in policy or operations, NIH uses these revisions to offer clarification to current policies based on user requests. Revisions include the implementation of the Federal Financial Reporting (FFR) system for reporting expenditures and the new Fly America provisions concerning Open Skies agreements (see discussion above concerning NSF). It is important to note, however, that agencies can/will take different approaches to the implementation of similar national policies like the FFR system and Open Skies provisions and institutions should acquaint themselves with the specific agency requirements.

As a Reminder:

CDC and APHIS Propose Amendments to Select Agent Regulations

On October 3, 2011, the HHS Centers for Disease Control and Prevention (CDC) and the US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) published the biennial request for comment on the list of select agents and toxins regulated jointly by CDC and APHIS as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The CDC and APHIS Federal Register notices were published on October 3, 2011 at 76FR61206 and 76FR61228, respectively. In addition to the biennial review of agents and toxins, CDC/APHIS propose amendments to the regulations including the tiering of select agents to provide for greater security measures for those that cause the most risk; removal of a agents/toxins from the list; and changes in the security risk assessment to better vet foreign nationals.

COGR will be preparing a comment on the CDC/APHIS request (due December 2) and welcomes your comments and observations (cblum@cogr.edu).