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October 2012 COGR Meeting Report

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COUNCIL ON GOVERNMENTAL RELATIONS

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November 16, 2012

MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS WASHINGTON MARRIOTT HOTEL October 25 and 26, 2012

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COSTING POLICIES

<u>Committee</u>: Susan Camber, Chair, University of Washington; James Barbret, Wayne State University; Cynthia Hope, University of Alabama; James Luther, Duke University; James R. Maples, University of Tennessee; Kim Moreland, University of Wisconsin – Madison; John Shipley, University of Miami; Eric Vermillion, University of California, San Francisco; Mary Lee Brown, University of Pennsylvania, ACUA Liaison; Dan Evon, Michigan State University; Terry Johnson, University of Iowa; Cathy Snyder, Vanderbilt University; Pamela Webb, University of Minnesota

Grants Reform and OMB Circular A-21 Update

COGR continues to communicate with the Office of Management and Budget (OMB) on a regular basis as we try to get a sense of when/if the proposed new Circular will be released. In our most recent communication on November 13th, we were informed that the release still is "on track", though there are several clearances that require approval. We expect to receive another update from OMB in early December and we will keep the membership posted.

NIH and Costing for Core Facilities – NEW DEVELOPMENT

In September 2010, NIH published Notice Number: NOT-OD-10-138, "*Request for Comment on FAQs to Explain Costing Issues for Core Facilities*." The NIH shared draft FAQs with the research community to get feedback on costing issues associated with Core/Shared Resource Facilities. The original Notice can be found at: <u>http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-138.html</u>

COGR submitted a response (dated December 8, 2010), which incorporated significant input from the COGR membership. Several of your institutions also submitted responses. At the time, our understanding was that NIH would release a final version of the FAQs in the Spring 2011. However, other priorities, including internal reorganizations at NIH, resulted in this effort being put on hold.

NIH has revitalized this initiative and has shared with COGR a revised set of FAQs based on our community's input from almost two years ago. They have asked for comments on the revised set of FAQs, and based on our comments, they hope to finalize the FAQs. NIH has asked for comments by Friday, December 7th, and will provide an extension, as appropriate. COGR and the Costing Policies Committee have begun its review of the revised set of FAQs and we will have a preliminary assessment completed by late November/early December. We may ask for a deadline extension prior to submitting our final comments to NIH. If you would like to participate in a review of the revised set of FAQs, please contact David Kennedy at <u>dkennedy@cogr.edu</u>. COGR will send you a copy of the revised set of FAQs and provide other logistical details.

Grant Reporting Information Project (GRIP)

At the Wednesday afternoon Costing Committee meeting, we met with Sandy Swab from the Recovery Accountability and Transparency Board (RATB) to learn more about the vision for GRIP and how it could impact COGR member institutions.

First, in previous COGR reports, we incorrectly described GRIP as an "OMB initiative." While OMB is paying attention to GRIP developments, in fact, the GRIP initiative is being led by the RATB. The RATB has primary responsibility for oversight of ARRA reporting and is in a unique position to comment on the value of developing a similar reporting model for all federal grants (note, contracts are not included in the GRIP initiative).

Second, we learned from Ms. Swab that GRIP is in a proof-of-concept/pre-pilot stage. As the RATB works with several federal agencies and 11 grant recipients (8 of whom are COGR members, a community college, a State, and a local municipality), the pre-pilot has been focused on designing data reporting models, evaluating data standardization, and asking broad questions such as: "Can central reporting be done? Could GRIP lessen reporting burden? What federal reports could be eliminated, specifically, the FFR/OMB SF-425?"

The RATB is working with the federal lead agency (the EPA), other participating agencies, and the 11 grant recipients in the proof-of-concept/pre-pilot stage – this includes reporting on quarterly data thru September 30, 2012. The FDP committed to engage with the RATB to facilitate access to the university community. Also, 10 federal agencies have agreed to participate (though note, due to concerns with how "progress reporting" is being treated, NIH has elected not to participate in the proof-of-concept/pre-pilot stage). The results of the pre-pilot will help determine if GRIP should be expanded to a full pilot. Ms. Swab indicated there would be a report based on the results of the pre-pilot and that she would engage COGR, as appropriate, to comment on the report.

Finally, we learned in our meeting with Ms. Swab that the final outcomes of the GRIP initiative will be subject to critical review by many stakeholders and that final outcomes cannot be fully predicted at this time. The RATB, which was established under the ARRA of 2009, will sunset on September 30, 2013 – consequently, another federal agency will have to take over leadership of GRIP. While final outcomes associated with GRIP cannot be predicted at this point, Ms. Swab indicated implementation of a "Universal Award ID" initiative was promising and that the RATB also has addressed the ongoing concern of multiple federal payment systems and if it would someday be feasible to consolidate them into a single payment system.

COGR's primary concern with GRIP is that it could become a new reporting system layered on top of already existing systems, and effectively, create new reporting burdens without eliminating existing reporting requirements. Ms. Swab echoed this concern and we were encouraged that recommendations from the RATB based on the pre-pilot would center on the goal of reducing reporting burden. COGR will pay close attention to and update the membership on all developments associated with GRIP, as well as the "Universal Award ID" initiative and any issues associated with federal payment systems.

Thursday Afternoon Session: The NRC Report on Research Universities

Dr. Teresa Sullivan, President of the University of Virginia, Dr. James Duderstadt, President Emeritus from the University of Michigan, and Dr. Ron Ehrenberg, the Director of CHERI at Cornell University, represented the National Research Council (NRC) Committee on Research Universities in a panel discussion in the late Thursday afternoon session at the COGR Meeting. Dr. Brad Fenwick, formerly from the University of Tennessee, and now at Elsevier as a Senior Vice President for Global Strategic Alliances, also participated on the panel.

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

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

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

Of the NRC's ten recommendations, the four that resonate most for COGR and the COGR membership are:

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

The panel talked to Recommendations 4 and 6 in the most detail, but also engaged in a diverse range of topics related to the future of the research university. The session concluded with a robust Q&A exchange with the audience. A sampling of several comments (as understood and paraphrased by COGR) made by the panelists included:

- Duderstadt: State budget support will not return for public universities; and regarding the full federal funding of research, "this is a serious political problem and needs to be dealt with."
- Sullivan: regarding improving university productivity, there is a "deeply entrenched" view that universities have no incentive to be productive. We need to better communicate how we are efficient and productive, or others will define this for us.
- Fenwick: We need to bring researchers "into the tent" when we talk about research productivity metrics.

- Ehrenberg: concerning the work he has conducted and the impact at universities when research does not receive full federal funding 1) student/faculty ratios increased at public and private universities, 2) lecturers are substituted for professional rank faculty at public and private universities, and 3) undergraduate tuitions at private universities increased more than would have been expected.
- Sullivan: also regarding the topic on improving productivity we must publicize our best administrative practices; anecdotes are helpful and where we can use data, we should; some data is not helpful (e.g., \$s spent per student) and we need to qualify it; our Public Affairs departments should promote our positive stories during the times of year when the press is paying attention (i.e., Admissions and Back-to-School seasons).

Over the course of then next year, NRC Committee members will be meeting with stakeholders across the country to seek further input and advocate for implementation of the recommendations. We will share periodic updates with the COGR membership as we learn more about the activities and advocacy efforts of the NRC Committee.

Audit Update: 2013 Workplans for Office of Inspectors General (OIG); HHS and NSF

COGR staff had the opportunity to meet with OIG staff from the Department of Health and Human Services (HHS) and the National Science Foundation (NSF) prior to the October COGR Meeting. We schedule these two separate meetings on an annual basis to discuss their respective workplans. During the Friday Committee Reports, we provided a brief update, 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 Workplan for FY2013 is available at the link below. Part V – Public Health and Appendix B – Recovery Act include audit initiatives specific to NIH. While the published Workplan is a helpful overview of possible high-risk areas, it is important to note that it is a general blueprint only. The Workplan expands and contracts as the HHS OIG does ongoing risk assessment, reacts to Congress, and determines where best to direct its limited resources. https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf

COGR discussions with HHS OIG staff piggybacked on their published Workplan and provided additional depth to a number of the items. Some of the topics covered in our meeting included the following (a cross-reference to the HHS OIG Workplan is shown):

NIH – **College and University Indirect Costs Claimed as Direct Costs (Appendix B, page 121).** First, note that this item is shown under Appendix B – Recovery Act, even though our observation has been that this audit work transcends ARRA activity. The past two COGR Updates have summarized a July 19, 2012 audit report where the HHS OIG recommended that a University "*refund \$2,977,548 to the Federal Government*" and "*enhance oversight of charges to Federal awards to ensure consistent compliance with Federal regulations.*" The HHS OIG audit report is available at: https://oig.hhs.gov/oas/reports/region4/41101095.asp

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

During the meeting with HHS OIG staff, we raised our concern that the significant cost disallowances and recommended refunds throughout the history of this HHS OIG initiative primarily have been associated with HHS Region 4 – this region covers Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. Staff from the HHS OIG indicated that audit staff expertise resides in Region 4, and consequently, Region 4 institutions are targeted under this audit initiative. For now, this is an area that the HHS OIG will continue to focus on, as evidenced by two new audit start-ups in Region 4.

NIH – **Extramural Construction Grants at NIH Grantees (Part V, page 86).** This is listed as a "New" item in the Workplan and is applicable to construction awards made under ARRA. To date, audits of ARRA awards funded by NIH have been limited to standard research projects. As COGR has reported throughout the past year, the audit reports posted for ARRA awards to colleges and universities have indicated no findings or cost disallowances. Though note, the most recent posting indicated several minor findings and disallowances. That report can be found at:

https://oig.hhs.gov/oas/reports/region7/71202778.asp

NIH – Equipment Claims by Grantees (Part V, page 87). This is listed as a "New" item in the Workplan, though this audit initiative was undertaken in FY2012. Two audit reports have been published to-date, both in late September, and are available at the links below: <u>https://oig.hhs.gov/oas/reports/region5/51200074.asp</u> <u>https://oig.hhs.gov/oas/reports/region5/51100102.asp</u>

The first audit report indicated that there were no findings associated with direct charging of equipment purchases. The second audit report included an initial finding that the grantee claimed costs associated with equipment purchases that were "significantly rebudgeted between budget categories and did not receive prior approval for equipment with a purchase price exceeding \$25,000." However, after objections by both the institution and the NIH, the HHS OIG rescinded this finding.

And similar to the Region 4 audit staff expertise discussion from above, HHS OIG staff indicated that in the area of equipment reviews, the expertise resides in HHS Region 5 – this region covers Illinois, Indiana, Ohio, Michigan, Minnesota, and Wisconsin. Also according to HHS OIG staff, four institutions in total have been selected for audit from Region 5.

NIH – **Colleges' and Universities' Compliance with Cost Principles (Part V, page 87).** This is a regular "placeholder" item that provides the HHS OIG with flexibility to embark on related audit issues that may become a hot-button issue during the fiscal year. At this time, there are no specific audit agenda items related to this topic.

NIH – Extra Service Compensation Payments Made by Educational Institutions (Part V, page 87). We are aware of the ongoing audit at an institution in Region 4, and according to HHS OIG staff, there is an audit applicable to HHS Region 2 (New York, New Jersey). This audit initiative is considered a "pilot" by the HHS OIG and it is to be determined if these audits will be expanded.

NIH – Inappropriate Salary Draws from Multiple Universities (Part V, page 88). In our discussion with the HHS OIG staff, they indicated that the audit referenced to in their Workplan appeared to be an isolated case and that this audit area would not be further pursued. We are unaware of an audit posting related to this case, and instead, the resolution may have been completed via a settlement between the affected parties.

NIH – **Cost Sharing Claimed by Universities (Part V, page 89).** The HHS OIG staff indicated to us that these audits have been conducted under the auspices of "Green Cover" audits – i.e., "sensitive, but not released." This terminology is new to COGR and we questioned what would elevate audits of cost sharing to this level. While we did not get a clear answer to this question, we will try to learn more about this audit initiative.

Most of our discussion with staff from the HHS OIG centered on Workplan items related to the OAS (Office of Audit Services). Each Workplan item references either OAS or OEI (Office of Evaluation and Investigations) as the responsible entity. 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.

Finally, we briefly addressed the topic of "Select Agents" in our meeting. The Workplan included two references to Select Agent activity (see pages 90 and 92 of the Workplan). As this activity could relate to universities, the HHS OIG staff indicated that work in this area would be targeted in HHS Region 2 (New York, New Jersey).

Again, the HHS OIG Workplan will evolve as priorities change during the fiscal year. We were told in our meeting that audit work associated with the Affordable Care Act could ramp up, significantly, and that this could divert audit resources away from other areas. We will keep the membership posted as we learn of new developments, and we encourage you to keep us posted on developments at your institution.

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 FY2013 is not available at the time of this writing (note, last year their 2012 Workplan was dated December 12, 2011). Reports and Publications from the NSF OIG are posted at the following website and we expect the 2013 Workplan to be available shortly. 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 FY2013. In addition, a recent posting of an NSF OIG audit report provides additional insight to the priorities of the NSF OIG. Below are COGR perspectives on NSF OIG activity:

NSF OIG and Data Analytics. This was the most significant topic of discussion in our meeting with staff from the NSF OIG. The use of Data Analytics over the past year marks a significant shift in audit approach by the NSF OIG. We are aware of several COGR member institutions that are currently engaged in audits premised on Data Analytics. Under this model, the NSF OIG asks institutions for an electronic version of the General Ledger, specifically, NSF funds and accounts. Based on various analytical techniques, auditors look for indicators that suggest audit risk or need for additional information.

Some institutions have raised concerns to COGR on the new audit approach, both in terms of substance (e.g., relevance of the issues raised by the auditors) and process (e.g., unclear protocols for providing responses to findings). In addition, Data Analytics is not necessarily accepted as the "gold standard" by the audit community. An individual from another federal entity suggested to COGR that there is no replacement for "boots on the ground" – i.e., overreliance on Data Analytics can lead to false conclusions if the appropriate follow-up is not included in the audit plan.

At the time of the COGR meeting with NSF OIG staff, there were no published audit reports available and we were not able to discuss the experience-to-date with the new NSF OIG approach to audit. However, an audit report made public on the NSF OIG website on October 25th provides a first look, and below we have provided some insights.

Audit of Incurred Costs for National Science Foundation Awards for the Period January 1, 2008 to December 31, 2010. This recent audit report, dated September 28, 2012 (but made public on October 25th), stated: "Our audit questioned \$6,325,483 of the costs claimed [by the university] because [the university] did not comply with Federal and NSF award requirements. Specifically, we found \$1,913,474 of overcharged summer salaries; \$2,821,676 of excess Federal Cash disbursements resulting from [the university] not fulfilling its grant cost share requirements; \$496,466 of inappropriate cost transfers into NSF awards; \$473,465 of indirect cost overcharges to NSF grants; \$440,148 of unallowable costs charged to NSF grants; and the utilization of \$180,255 of remaining fellowship funds for non-award purposes." The audit report is available at: http://www.nsf.gov/oig/UCSB_12-1-005.pdf

The recommendations in the audit report included: "*Repay to NSF the \$6,325,483 of questioned costs in this report*" and "*Strengthen the administrative and management controls and processes over its federal awards*." The university raised serious concerns with all of the findings, as well as the audit process (see next section, below).

University Concerns with the Audit of Incurred Costs and Understanding the Audit Process. The University response to the Audit of Incurred Costs was critical, especially in the area of audit process. One issue was timing of the release of the final audit report (dated September 28, 2012). In their response, the University stated: "... eight days is insufficient time to respond fully to all of the issues NSF/OIG has raised in this draft report."

At issue may be misunderstanding of how the release of a "Final Audit Report" should be linked to a "Notice of Findings", to an "Exit Conference", and to a "Draft Audit Report." At issue also may be the appropriate cycle for providing initial documentation, additional documentation, and other information that can help to resolve differences, prior to the release of a "Final Audit Report." A "Notice of Findings" is provided to an institution much earlier in the audit process – weeks or months before issuance of a "Draft Audit Report." As an audit always will be a sensitive topic for the affected institution, COGR suggests the audit process and timing must be clear and certain for all parties. Because the release of a final report could create significant damage to an institution's reputation, it would behoove all parties to work constructively to resolve differences prior to the release of the final audit report.

After the final audit report is released, OMB Circular A-50 – Audit Follow-up, specifies that the audit findings be resolved and a corrective action plan be established within six months of the final audit report. This audit resolution process for an NSF OIG audit is the responsibility of NSF's Cost Analysis and Audit Resolution Branch (CAAR), which is independent of the NSF OIG. In effect, a final audit report is a recommendation from the NSF OIG to NSF, with the expectation that NSF/CAAR take responsibility for agreeing to a final resolution with the affected institution.

NSF/CAAR and the institution will work together to resolve disagreements. Some findings may be supported, others may not be. While the audit resolution provides an institution a formal process to resolve disagreements, COGR believes a sound audit process prior to the release of a final audit report is crucial. If reputational damage already has been done, even a favorable result in audit resolution cannot repair the initial damage. While COGR is not in the position to engage actively in the substance of audit findings, we are in a position to engage in policy issues related to audit protocol. We have shared our perspectives on audit process with several federal officials – we will continue to advocate for a clear and certain audit process so that institutions are sufficiently empowered to work with the OIG and feel as though all issues have been addressed adequately prior to release of a final audit report.

Outsource Audit Model versus In-house NSF OIG Staffing. Over the past few years, the NSF OIG has tried to shift away from the "outsource" audit model to one where more NSF OIG audits are done in-house by NSF OIG personnel. Possibly due to the challenges of hiring in a competitive labor market for auditors, they have continued to rely on the outsource model, at least in some situations. This seems to have been a point of contention in the audit described above – as stated by the University in their response: "… this audit may have taken much longer than ordinary due to the many auditor staffing changes that occurred at NSF over the course of this two-year audit."

Improving the A-133 Single Audit Process? The NSF Inspector General, Allison Lerner, has actively reached out to COGR since she assumed the role of the NSF IG in 2009. One topic where there could be mutual ground for constructive engagement is "improving the A-133 single audit process." Duplication of audit activities across federal agencies, and the

burden this creates, is a concern for our community. As these discussions can be advanced within the audit community, we will reach out to the COGR membership for your ideas.

We do not expect the official release of the NSF OIG Audit Workplan for FY2013 to impact the summary from above. If there are significant updates in their 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 <u>dkennedy@cogr.edu</u> 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 continue to follow. If there are cost-related or financial topics that you would like to discuss with COGR, please contact David Kennedy at <u>dkennedy@cogr.edu</u>.

Superstorm Sandy and Disruptions to Research. We know of at least one institution that was severely affected. In this case, the NIH Office of Policy for Extramural Research Administration (OPERA) is working with the institution to facilitate a wide-range of issues and provide uniformity across all NIH ICs. In the case of Hurricane Katrina in 2005, OMB was active in providing guidance and central coordination across all federal agencies, though this may not be the case for Superstorm Sandy. If your institution experienced dramatic disruptions of research due to Superstorm Sandy, please contact COGR and we can share additional information.

NIH Funding Policy Under the Continuing Resolution (CR). The Federal Government now is operating under a CR, which became effective October 1st and funds the Federal Government through March 27, 2013. NIH posted its funding policy under the CR, and in an October 11, 2012 Notice (NOT-OD-13-002), NIH announced: "… *NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). This is consistent with our practice during the CRs of FY 2006 - 2012. Upward adjustments to awarded levels will be considered after our FY 2013 appropriations are enacted but NIH expects institutions to monitor their expenditures carefully during this period …". The NIH Notice (NOT-OD-13-002) is available at:*

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

The Federal Budget and Sequestration. As we expanded on in the prior COGR Update (October 12, 2012), the possibility of Sequestration (large, automatic cuts in federal spending established in the Budget Control Act of 2011) and how COGR institutions should prepare, is on the minds of many. While guidance should come from the Administration (via the Office of Management and Budget) or from the federal agencies themselves (e.g., HHS-NIH, NSF, etc.), federal officials most likely will not provide any guidance until Sequestration appears to be unavoidable. In order for Sequestration to be averted, Congress

and the President will need to agree on a solution, prior to the trigger date of January 2, 2013. If Sequestration becomes imminent, we will share information as we learn it.

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

NSF Survey on R&D Expenditures – FY2010 Results and Changes for the FY2012 Survey. The National Science Foundation, National Center for Science and Engineering Statistics (NCSES), released results from the FY2010 Higher Education Research and Development (HERD) Survey. The FY2010 report represents the first year of the new survey format and includes new data points such as expenditures funded by Nonprofit organizations and a more detailed breakdown on Institutional Funded expenditures (i.e., unrecovered indirect costs, cost sharing, and internal research projects). The report can be found at: http://www.nsf.gov/statistics/infbrief/nsf12313/

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

Reducing Regulatory Burden and a Request for a New GAO Review. As we reported in the prior COGR Update (October 12, 2012), Rep. Mo Brooks (R-AL), chairman of the House Research and Science Education Subcommittee, asked the U.S. Government Accountability Office (GAO) to review regulatory actions that hinder our nation's research universities. COGR has worked with our colleagues at AAU and APLU to share information with Rep. Brooks' staff and to provide materials addressing regulatory burdens. Specifically, we have discussed effort reporting, subrecipient monitoring of entities already subject to the A-133 audit, and paperwork retention requirements under FAR 4.703. Each of these was addressed in the letter to the GAO. We expect at some point, as in past GAO reviews, the GAO staff will contact COGR for further information and discussion. Rep. Brooks' letter to the GAO is available at:

http://science.house.gov/sites/republicans.science.house.gov/files/documents/Letters/100312 brooks_GAO.pdf

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

CONTRACTS AND INTELLECTUAL PROPERTY

<u>Committee</u>: David Winwood, Chair, University of Alabama at Birmingham; Elaine Brock, University of Michigan; Alexandra McKeown, The Johns Hopkins University; Cordell Overby, University of Delaware; Marianne Woods, University of Texas at San Antonio; Kevin Wozniak, Georgia Institute of Technology; Mark Crowell, University of Virginia; Valerie McDevitt, University of South Florida; Fred Reinhart, University of Massachusetts; John Ritter, Princeton University; Wendy Streitz, University of California;

<u>COGR Members Urged to Endorse Association Comments on Proposed Implementation of</u> <u>"First Inventor to File"</u>

The October <u>Update</u> included a discussion of the joint higher ed. association comments on the proposed implementing rules published by the U.S. Patent and Trademark Office (PTO) for the conversion of the U.S. patent system from "first to invent" to "first inventor to file." We noted that the proposed rules raise serious issues for universities with regard to the grace period for scientific publications and treatment of patent applications where a prior art publication has more authors than inventors named in a subsequent patent application.

We do not know the reason for PTO's extremely narrow interpretation of the grace period. It is possible that it may have arisen partly from an intent to help build the record for future legislative action to amend the America Invents Act to clarify the grace period provisions (see COGR February and Spring 2012 <u>Updates</u> and February 2012 <u>Meeting Report</u>). If so, obviously a strong response to the proposed rules from the university community would be helpful. At the October meeting COGR members were encouraged to consider writing letters to PTO to endorse the joint association comments. AUTM issued a similar request to Technology Transfer Office Directors. We understand that a number of letters were submitted to PTO by the (extended) comment deadline (November 5).

GAO Meets with University Officials to Discuss Non-Practicing Patent Entities

One of the mandates included in the American Invents Act (Section 34) was for the Government Accountability Office (GAO) to conduct a study of the consequences of litigation by non-practicing patent entities (often referred to as "patent trolls"). The study is to include the annual volume of litigation of this type over a 20-year period, volume of cases found to be without

merit, impacts on time required to resolve patent claims, estimated costs for all parties associated with such litigation, the economic impact on the U.S. economy, and any benefits supplied by such entities. A report was due Congress within one year (although GAO appears to be well behind in meeting this deadline).

We have been concerned that GAO understands the distinction between universities that create knowledge and innovation and other types of non-practicing patent entities. We have been informed that GAO representatives met with officials at a COGR member institution last month to obtain background information for the study. From the discussion GAO appeared to understand this distinction. Reform efforts in the federal courts and International Trade Commission to limit discovery in patent infringement cases also were discussed. The institution observed that management of specific cases by judges has the advantage of tailoring discovery to particular cases as opposed to a general legislative solution. It was noted that universities increasingly have been involved in patent litigation partly in response to standing to sue issues on the part of licensees. However, it was pointed out that litigated university patents typically do not involve minimal incremental advances in technology, which has been the focus of concern of the IT industry with what they regard as abusive litigation practices by non-practicing entities. Also universities typically do not sell patents to such entities.

To date the higher ed. associations have not been contacted by GAO. We will seek to follow and report on the progress of the GAO study.

<u>Higher Ed. Associations Urge FDA to Impose a Patent Certification Requirement for</u> <u>Biosimilar Applicants</u>

COGR has joined the 5 other higher ed. associations (including AUTM) with whom we have worked closely on patent reform in urging the Food and Drug Administration (FDA) to require applicants for biosimilar approvals to certify their compliance with the notification provisions of the 2010 Biologic Price and Innovation Act.

By way of background, the Act established a detailed pathway for the resolution of patent disputes prior to launching biosimilar products. Applicants must notify the sponsor of the product that might be infringed by the biosimilar. The referenced product sponsor then must identify all patent rights to be litigated under the pathway (including those in-licensed from universities). The biosimilar applicant designates patents to be litigated pre-launch, and those deferred for later litigation (and notifies the sponsor by providing confidential access to the information and subsequently a copy of its FDA application for review). The statute does not address the rights of the actual patent owners to participate in the litigation. Failure by the reference product sponsor to list a patent can render it unenforceable. Owner-licensors such as universities and product sponsor-licensees also may not necessarily have the same interest in designating patents for initial litigation. Early litigation (180 days prior to the commercial launch of the biosimilar product) applies to listed patents not designated for early litigation. In the event the applicant does not wish to follow the pathway and provide a copy of the application to the sponsor, immediate litigation may ensue.

These events are non-public. If the application is not shared by the biosimilar applicant, the pathway cannot be followed and neither "early" nor "late" litigation is possible. And lack of

notice to the sponsor and/or licensor means immediate litigation also is not possible, undermining the entire statutory scheme. Failure to follow the pathway also means that ownerslicensors and sponsors-licensees cannot work together to make joint decisions about the litigation process. FDA needs to manage the biosimilar application process to ensure the necessary notifications are provided and the statutory scheme followed. To date, however it has not required that biosimilar applicants certify they have met their information sharing obligations under the Act.

The associations submitted a letter to the FDA on November 5. The letter notes that currently biosimilar applicants can effectively circumvent the patent litigation provisions of the statute simply by failing to provide timely notice and access to the reference product sponsor without meaningful consequences, despite the statutory requirement for such notification. As universities are commonly licensors of biological products, numerous university patents may be affected by biosimilar applications. It urges FDA to take immediate action to impose a certification requirement, which would serve to clarify and enforce the obligations of biosimilar applicants in this regard. The letter notes that the Biotechnology Industry Organization (BIO) previously has raised these concerns and also has suggested this proposed response from FDA. It expresses strong support for this course of action. (BIO originally had invited the associations to sign on to its letter to the FDA, but we believed the interests of the university community were better served by a separate letter).

A copy of the letter can be found on the COGR website.

New March-In Request Filed with NIH

On October 25, 2012, the American Medical Students Association (AMSA), Knowledge Ecology International (KEI), U.S. Public Interest Research Group (PIRG) and the Universities Allied for Essential Medicines (UAEM) filed a petition with HHS requesting that the National Institutes of Health (NIH) grant Bayh-Dole Act march-in rights for six patents held by Abbott Laboratories relevant to the manufacture and sale of ritonavir, a federally funded invention that the petition alleges is five to nine times more expensive in the United States than in Canada, Europe or other high-income countries. It includes a survey of 14 NIH-funded drugs, which found that 13 of the 14 were priced higher in the U.S. than elsewhere. It also alleges that Abbott has refused to license the patents to other drug makers for use in co-formulated fixed dose combination drugs used for the treatment of HIV/AIDS. The petition asks NIH to grant open licenses on patents held by Abbott for the manufacture and sale of ritonavir.

The petition also requests the NIH adopt two rules that will create standards for future march-in requests. One is to set a ceiling on prices to U.S. residents. According to the petition, the ceiling should be based on the high, mean and median prices charged in the ten largest foreign economies as determined by the World Bank. If U.S. prices are higher than seven of the comparison countries, or 10% higher than the median price of the referenced countries, NIH should grant licenses to competitors to supply the product to U.S. consumers. A licensee can rebut the premise of unreasonable pricing by providing evidence that its actual risk adjusted R&D costs would not be recovered but for charging higher prices in the U.S. market, or other evidence of risk adjusted costs.

The second would require PHS/NIH to grant licenses to third parties to use patented inventions that have benefited from federal funding, subject to the payment of a reasonable royalty and an appropriate field of use, if a product based on those patented inventions:

(a) is a drug, drug formulation, delivery mechanism, medical device, diagnostic or similar invention, and

(b) is used or is potentially useful to prevent, treat or diagnose medical conditions or diseases involving humans, and

(c) its co-formulation, co-administration or concomitant use with a second product is necessary to effect significant health benefits from the second product, and

(d) the patent holder has refused a reasonable offer for a license.

A previous request for march-in involving the same drug was submitted and rejected by NIH in 2004 (see COGR June 2004 <u>Meeting Report</u>). COGR had sent a letter to NIH at the time emphasizing the importance of proper understanding of the Bayh-Dole Act march-in rights. We had expressed concern that a substantial reinterpretation of the Bayh-Dole Act's march-in provisions could undermine the ability of universities to make their federally funded technologies available for public use. COGR noted that march-in rights accrue to the government <u>only</u> for the purpose of ensuring prompt commercialization of federally funded inventions and to avoid the possibility of companies stifling the development of new products. Following a public hearing, NIH determined that march-in is not an appropriate means of controlling prices, and that the issue of pricing of drugs made using federal funds should be addressed legislatively.

The petition expresses the view that NIH and other federal agencies have broad discretion when considering march-in requests. It alleges that the 2004 NIH decision did not hold that NIH had no authority to address cases of excessive or discriminatory pricing, but that NIH chose not to exercise it. The petition states that a march-in could be justified under the failure to achieve practical application grounds in the Bayh-Dole Act (35USC203(a)(1)) since benefits are not available to the public on reasonable terms, or failure to reasonably satisfy health or safety needs (203(a)(2)), or requirements for public use (203(a)(3)) based on the Americans with Disabilities Act or the Patient Protection and Affordable Care Act. It also notes that high health care costs contribute to lack of global competitiveness by U.S. corporations.

This petition is more sophisticated than the previous petition and of broader scope. While the concerns we expressed previously continue to apply, we have not yet fully assessed the new petition or considered an appropriate COGR position. It appears that the considerations that led NIH to reject the previous petition might continue to apply, but we have not discussed the issues with NIH nor do we know their views. We will keep the membership informed of developments.

Recent FDP Troublesome Clauses Data Show Same Trends as Before

Most COGR member institutions are familiar with the two COGR/AAU "Troublesome Clauses" surveys conducted in the past decade. The second survey (available at

<u>http://www.aau.edu/policy/export_controls.aspx?id=7314</u>) was conducted with the assistance of the Federal Demonstration Partnership (FDP), which has continued to collect data from institutions on troublesome clause issues.

Recently we have analyzed the latest FDP data. While the sample of institutions and the time frames differ from the previous COGR/AAU reports, the same problems we previously identified continue to exist. The vast majority of troublesome clauses reported were from DOD flowdowns, with the "notorious" DFARS 252.204-7000 "Disclosure of Information" clause continuing to predominate. However, the more recent data showed a sharp uptick in export control flowdown clauses from DOD. Of 194 total instances reported, 109 were DOD flowdowns with 84 of these involving either the 7000 clause (50) or export controls (34).

In May of 2012 DOD issued clarifying guidance on "Contracted Fundamental Research" (see COGR June 2010 Meeting Report). The guidance reinforces an earlier DOD memorandum (6/26/08) and reiterates that DOD awards for contracted fundamental research should not involve classified items or be subject to export controls. It states that "The performance of contracted fundamental research also should not be managed in a way that it becomes subject to restrictions on the involvement of foreign researchers or publication restrictions." This normally applies to activities funded with budget category 6.1 or 6.2 (now Research, Development, Test and Evaluation Budget Activity 1 and 2). Exceptions require high level DOD component management approval. Importantly the memo also recognizes that research performed with funds other than 6.1 or 2 might still be fundamental research, and that "the DOD must not place restrictions on subcontracted unclassified research that has been scoped, negotiated, and determined to be fundamental research within the definition of NSDD 189 according to the prime contractor and research performer and certified by the contracting component..." Responsibility for monitoring compliance was assigned to the DOD Director for Basic Science.

We have encouraged institutions to push back when receiving the DOD 7000 (or equivalent DOD agency) clause using the May 2010 memorandum. Institutions have reported some success, either through bringing the memo to the attention of the prime contractor and/or DOD program manager or contracting officer, or through reporting the situation to the DOD Director for Basic Science. However, the data suggest that the DOD guidance is not being completely followed by DOD contracting components.

The May 2010 memorandum also indicated that training modules on contracted fundamental research would be developed for research program and acquisition personnel. Recently COGR was informed by DOD that progress has been made on training modules that include guidance on contracted fundamental research, and that such modules would be integrated into Defense Acquisition University courses (we also were informed that a final draft revision of the 7000 clause was under review). Hopefully these developments will help address the situation.

However, while the current data includes a different mix of research institutions over a more extended period of time, it indicates that, after nearly a decade and with much attention focused on the burdens associated with troublesome clauses, they remain a source of challenge and frustration for research institutions. We are considering whether it may be time for another structured survey in order to develop further the findings of the previous two surveys. However,

perhaps other approaches may be more appropriate, ones which would more actively engage the federal agencies that hold a stake in ensuring effective contracting of fundamental research over the next decade. Suggestions and inputs from COGR members on these issues are welcome.

COGR Joins Letter of Support for Satellite Act

On November 8 COGR joined with AAU and APLU in a letter to the leadership of the Senate Committee on Armed Forces expressing support for the Safeguarding United States Satellite Leadership and Security Act of 2012 (S. 3211), a bill introduced by Senator Bennet (D—CO) which addresses export control policies for satellites and related items. The letter requested the Committee leadership to consider amending the final FY 2013 National Defense Authorization Act to include language similar to that contained in S. 3211 that would return to the executive branch authority to determine the export control jurisdictional status of satellites and related items.

The letter noted the requested action would be consistent with recommendations made in April 2012 by the Departments of Defense and State in their *Report to Congress on Section 1248 of the National Defense Authorization Act for Fiscal Year 2010 (Public Law 111-84).* That report "identified two satellite types, and related items, that are not purely defense-related and thus should not be designated as defense articles on the US Munitions List (USML) or controlled under the International Traffic in Arms Regulations (ITAR)." It recommended that items such as communications satellites, remote sensing satellites with lower performance parameters, and satellite components with lower performance parameters should be designated as dual-use and controlled under the Department of Commerce's Export Administration Regulations (EAR). Selected satellites and space-related items with critical components and sensitive technologies should remain on the USML.

We discussed the Section 1248 Report in the COGR June <u>Meeting Report</u>. We noted that the 1248 Report includes two appendices. Appendix 1 is a draft revised USML Category XV that sets forth satellites and related items and services that should continue to be protected under the USML. Appendix 2 is a proposed CCL ECCN Category 9X515 for spacecraft and related commodities. Informal feedback from a few COGR institutions with extensive space research indicated that their research does not typically involve most of the technologies included in the draft revised USML Category XV.

The letter expresses agreement with the recommendations in the report on the technologies that should remain on the USML. However, it notes the blanket statutory requirement currently in place which mandates that all satellites and related items be placed on the USML, even those which have legitimate dual-uses and pose minimal national security risks, adversely affects the ability of universities and their faculty to conduct valuable space science research and to train students in related subjects. This has hindered the participation of leading international scholars and students at U.S. universities in many space-related research projects and classes, and has led some campuses to decrease their research efforts in these particular areas. The current export controls rules related to satellites have also impeded U.S. space scientists from participating in legitimate and potentially valuable international scientific collaboration. The specific problems arising from of the current application of ITAR to space science research at universities were outlined in by the National Research Council in a 2008 summary of a workshop it held on *Space*

Science and the International Traffic in Arms Regulations (see: <u>http://www.nap.edu/catalog.php?record_id=12093</u>).

The letter urges the Senate to act on the Section 1248 Report recommendations. A copy may be found on the AAU website.

APLU/CICEP Metrics Project Holds Workshop for Participants and Stakeholders

We discussed the APLU/CICEP metrics project in the COGR February 2012 <u>Meeting Report</u>. This project was launched by APLU's Commission on Innovation, Competitiveness and Economic Prosperity ((CICEP) to develop appropriate tools to better communicate the complete array of higher education contributions to regional economies. The aim is to develop a "template" of potential new measures which institutions can adopt to better communicate their role. The <u>Meeting Report</u> discussed some issues and concerns with regard to the project that were discussed with APLU representatives at the February meeting. We noted that we would keep the COGR membership informed as the project develops.

The CICEP metrics initiative team hosted a workshop in Washington on October 10th to allow project participants and stakeholders to review progress to date and to plan next steps. Approximately 60 people including COGR/CIP representatives attended the workshop.

Currently there is a metrics implementation group made up of two teams-one focused on ongoing development of the list of metrics (which are continued to be researched for feasibility and future testing); and one focused on outreach and support-creating materials/guidelines to go out with metrics, and gathering feedback from participating institutions. The plan is to encourage a cross-functional campus team approach to institutions-much of the value that institutions will get out of the metrics will be in convening conversations among people who need to get together to talk about these kinds of university inputs and outputs. Thought is continued to be given about how to combine and encourage campuses to combine, metrics data with narrative/qualitative information-contextualizing and perhaps visualizing the data. The plan is to look closely at AUTM's Better World report approach and see if this kind of approach might work along with (rather than separate from) the metrics data themselves. There also is a need to assure that the CICEP metrics complement and not replicate or duplicate other metrics efforts (like AUTM, NBIA, etc.). In fact, one goal will be to try to provide guidance in the materials regarding what other metrics initiatives/data are out there and how APLU universities could/should use these to complement the CICEP metrics. APLU has been contracted by both NSF and NIST to provide a report on how the lessons learned can inform their initiatives. They hope to continue to play this kind of advisory role to other organizations/agencies trying to find ways to describe university contributions to the economy.

By way of additional observations, the conversation is still new to many of the stakeholders, including APLU members, so lots of awareness/education is needed. Outcomes are still not part of the CICEP metrics, but everyone acknowledges that it is very difficult (and perhaps dangerous) to connect university contributions to specific outcomes in the economy, in particular the outcomes most politicians are interested in—jobs. Using a "logic model" approach to communicating the contributions (showing the expected path from inputs/outputs to desired outcomes) could help. Including narrative/qualitative information along with data will be

important. It also will be important for requests for collecting these data to come from highest levels of institution administration—top-level buy-in has made the difference between an institution's being able to collect data or not in the pilot phase.

There is continued concern that the data could be used to benchmark institutions' performance inappropriately. The number of data elements continues to fluctuate. 53 were identified for data collection during the pilot phase. Of these, 11 were identified as first priority for the workshop discussion and 23 as second priority requiring further study. Most participants appeared to feel the 11 first priority metrics were too few but as noted above, the list continues to be developed. Overall the CICEP metrics activity continues to be a work in progress.

RESEARCH COMPLIANCE AND ADMINISTRATION

<u>Committee:</u> James Tracy, Chair, University of Kentucky; Pamela Caudill, Harvard University; Michelle Christy, Massachusetts Institute of Technology; Kelvin Droegemeier, University of Oklahoma; Michael Ludwig, Purdue University; Susan Sedwick, University of Texas, Austin;; Michael Amey, The Johns Hopkins University; Kathleen Delehoy, Colorado State University; Suzanne Rivera, Case Western Reserve University

Discussions with NSF Inspector General

Members of the COGR Board's Research Compliance and Administration Committee had the opportunity to meet informally with the National Science Foundation's (NSF) Inspector General, Allison Lerner and members of her staff in the Office of the Inspector General (OIG) before the COGR meeting. The focus of the discussion was on the processes used to review non-financial issues including the range of compliance and integrity policies. In discussing the process used by the OIG if it directly receives an allegation against an NSF-supported institution or project, the OIG described regular meetings of the investigative staff that review the allegations received and, after screening out the obvious crank "calls," assigns the allegation and/if its related to NSF-support.

If there is an allegation of plagiarism, and the majority of the complaints received by the OIG have to do with questions of plagiarism, the OIG contacts the investigator (respondent), reviews the relevant materials with the investigator, and makes a determination. If the alleged plagiarism doesn't rise to a level of a "significant departure from accepted practice," the OIG will close the review and notify the investigator with an admonition, if appropriate. If, in the review, there is evidence of other misconduct (fabrication and falsification), the OIG refers the case to the investigator's home institution. RCA members suggested that the OIG let the home institution know of the plagiarism reviews and determinations because the institution may have related issues/concerns and should be aware of the review by the OIG.

As some institutions know, awardees will occasionally get a request for documents from the OIG that simply states that the request is a part of an investigation without disclosing the nature of the

allegation. In the absence of follow-up requests and site visits, sometimes the only indication to the institution from the OIG of a resolution is the receipt of a letter announcing the case is closed. We suggested that it would be valuable to receive additional information to help the institution conduct self-assessments or evaluations of its programs and procedures to avoid any misunderstandings on the part of staff and students. For example, if a staff member reported a violation of the regulations governing human subjects research and the OIG found the allegation without substance, knowing the area of confusion, e.g., the elements of the informed consent process, etc., could suggest that the human subjects training should cover the informed consent process in greater detail in order to avoid further confusion. The OIG recognized the value of more communications but noted that the OIG posts the elements of closed cases on its website on the NSF OIG website under reports and publications - first link at the top of the page: http://www.nsf.gov/oig/closeouts.jsp. Institutions that receive notification of a closed investigation will find the case report number included in the letter's text. You can search the closeout memorandum by case number, type of case, etc. The files are redacted to remove the institutions name from the public posting.

Finally, we discussed the information collection posted by the OIG concerning a review of NSF's implementation of the requirement to train undergraduate and graduate students and postdoctoral fellows in the responsible conduct of research (comments were due November 15). The information collection is proposed as a series of interviews with three groups of individuals: senior institutional administrators; compliance program administrators; and trainees. The notice described areas for questions for each of these groups of individuals. The OIG proposes to assess institutional commitment to the training program, "including resources and staff," and expectations for the program in interviews with senior administrators. Compliance program administrator interviews will focus on areas that include course structure, content, faculty participation and resource allocation. Students and fellows will be asked to evaluate their training experience and examine the benefits and drawbacks of RCR training, in general.

We suggested in our discussion and in the final letter submitted by COGR (available on the website at: <u>www.cogr.edu</u>) that the limited nature of the policy requirements – that the institution have a plan, make that plan available on request, and be able to verify that the students and fellows received training – made the interviews unnecessary and, as a consequence, burdensome. When the OIG suggested that they just wanted to ensure that institutions had effective training programs, we observed that our programs are not required to be effective. We didn't want to be glib about the responsible conduct of the research and assured the OIG that institutional commitment to ensuring the integrity of the research enterprise is unwavering. However, there is a difference between realizing such a commitment and demonstrating compliance with a policy requirement.

NSF New PAPPG, Cost Sharing and Implementation of the RPPR

Jean Feldman, head of the NSF Policy Office, joined the membership on Thursday morning to provide a wide-ranging up-date on a number of issues with a focus on the changes to the *Proposal and Awards Policies and Procedures Guide* (PAPPG), progress on cost sharing at NSF, and the implementation of the Research Performance Progress Report (RPPR) on Research.gov. The detailed slides that Ms. Feldman used in her presentation are available on COGR's website under the Meetings tab (www.cogr.edu). We provided a general review of the

changes to the PAPPG in the update sent to the membership before the meeting. We've highlighted below additional changes that may assist the membership in meeting the new requirements for the submission of proposals and management of NSF awards.

ARRA Deadline Waivers - Before digging into the PAPPG changes, Feldman outlined NSF's process and expectations concerning requests for waivers from the general ARRA project deadline of September 30, 2013. Agencies could apply to the Office of Management and Budget (OMB) for waivers to the ARRA award end date for individual projects or classes or groups of projects under a specific program. NSF submitted its request for waivers to OMB (due date November 30, 2012) and anticipates notification in late in 2012 or early 2013. Any NSF awardee whose request for a waiver was included in the NSF request received a notification from NSF in September 2012. If an investigator did not receive a notification from NSF, the end date of September 30, 2013 is applicable to the ARRA-funded award. As a group, NSF asked for waivers for the career awards (approximately 300 awards) and various scholarship programs including the Noyce scholarships, approximately 53 awards. NSF will notify awardees as soon as it receives information from OMB.

"Proposals Not Accepted" - With the implementation of the new PAPPG, FastLane will include text boxes that must be completed or "FastLane will not permit submission of the proposal." The Project Summary will have separate text boxes that must be completed that include 1) an Overview, 2) a Statement on Intellectual Merit, and 3) a Statement on Broader Impacts. This change in Fastlane complements the revisions in NSF merit review criteria. In addition to required text in the Project Summary, "FastLane will not permit submission of the proposal" that is missing a data management plan and a postdoctoral mentoring plan.

New Certifications - The Proposal Certifications have been updated to include a new Organizational Support Certification to address Section 526 of the *America COMPETES Reauthorization Act (ACRA) of 2010.* You will recall that the COMPETES Act required "evidence of institutional support" for meeting the broader impacts review criteria. As implemented by NSF in the PAPPG, institutions are asked to certify that the institution supports the proposal including the sections of the proposal that meet all the criteria including the broader impacts. The certifications include statements on tax obligations/liability and felony conviction as required of many/most agencies by the *Commerce, Justice, and Related Agencies Appropriations Act of 2012.*

Removing PI from Budget and Other Cost Sharing Issues - Feldman noted that only 6 NSF programs have been approved to require cost sharing, the newest on that list is the Innovation Corps or I-Corp program. With the changes in the format to the *Facilities, Equipment & Other Resources* section of an NSF proposal, NSF expects that if no person months are requested for senior personnel, they should be removed from the budget section of the proposal. Their names should/could remain on the coversheet and their role should be described in the *Facilities, Equipment and Other Resources* section of the proposal.

The new format of the *Facilities, Equipment and Other Resources*, a required component of the proposal, should assist proposers in complying with NSF cost sharing policy. Applicants are directed to provide an aggregated description of the internal and external resources (both physical and personnel) that the organization and its collaborators will provide to the project without reference to cost, date of acquisition, and whether the resources are currently available or would be provided upon receipt of award. As with the other required "FastLane will not permit submission of the proposal" elements, if there are no resources to describe in the *Facilities, Equipment and Other Resources*, a statement to that effect should be included in this section of the proposal and uploaded into FastLane.

RPPR - Finally, Feldman outlined the staggered implementation strategy for the Research Performance Progress Report (RPPR) on Research.gov. NSF has been piloting the implementation since October with a limited number of institutions. Full implementation is targeted for January 2013. It is important to note that implementation of the RPPR on Research.gov will freeze report submissions through FastLane. If your investigators have outstanding reports due to NSF, you should encourage them to complete those reports as soon as possible but before January 2013 to avoid confusion. Feldman's slides include a detailed timeline and activities (Slide 55) as well as slides with images from Research.gov. You should encourage your investigators to become familiar with the reporting portal at <u>www.research.gov</u>.

NIH Financial Conflict of Interest Implementation

A portion of the Friday morning membership meeting was dedicated to a discussion of how COGR member institutions are implementing various aspects of the Public Health Service/National Institutes of Health (PHS/NIH) Objectivity in Research/Financial Conflicts of Interest regulations. The topics for discussion were driven in large part by questions posed by the membership before the meeting. Summaries of various questions or issues are provided below.

Most institutions have created separate policies or procedures to implement the more stringent PHS/NIH requirements, either through entirely separate policies (a minority) or through separate procedural requirements, e.g., a separate lower \$5,000 threshold, for PHS-funded investigators. Few institutions are requiring all investigators, across a campus, to follow the PHS/NIH regulations. Most institutions have assigned or hired more than one (but less than three) staff members to assist in the management of the conflicts of interest policies and procedures.

Most institutions are using a narrow definition of institutional responsibilities and will rely, in part, on information from the investigator in making a determination of the relatedness of a financial interest or relationship to the PHS-funded research. Most institutions are relying, in part, on online tools to provide training and use the online "certification" as one of the ways of documenting that training has occurred.

Most institutions will require their subawardees to have or create a policy that meets the PHS/NIH regulatory requirements. The Federal Demonstration Partnership (FDP) has created a clearinghouse of institutions "whose authorized official have certified that they are compliant

with the PHS Financial Conflict of Interest rules and regulations." In addition to the institutional certifications of compliance, FDP is compiling a list of agencies and organizations that have implemented the PHS/NIH regulations. These lists rely on information provided by the research community. We encourage you to participate by including your institution in the certification list and by notifying FDP if you identify an agency or organization using the PHS/NIH regulations. The information available on the FDP website is at: http://sites.nationalacademies.org/PGA/fdp/index.htm.

The definition of a subawardee is important for some institutional procedures. In the case of clinical trial sites, the determination of whether a site is independently responsible for aspects of the research will determine whether the site needs to achieve compliance with the regulations. Some institutions do not treat clinical sites that are providing study interventions as responsible; others consider clinical sites that enroll patients in a study by performing the informed consent process as responsible parties to the research.

In the case of independent (not associated with an organization that is or could be compliant with the PHS/NIH regulations) consultants or collaborators, most institutions will have the consultant or collaborator disclose under their policy but will appropriately apply a narrow definition of the "institutional responsibilities" as associated only with the individual PHS-funded project. Many institutions are focused on a very careful consideration of the responsibilities of a consultant or collaborator in the "design, conduct and/or reporting" of the research. Not all consultants have an independent role and would not necessarily fall under the regulations.

As to travel disclosures. The recent NIH determination concerning travel disclosure included in the Frequently Asked Questions (FAQs) and in a notice offering further clarification of the implementation of the Disclosure Requirements for Reimbursed and Sponsored Travel - 42 CFR Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought" (NOT- OD-13-004) confirms NIH expectation that the disclosure, at the time of application, of reimbursed and/or sponsored travel is retrospective – the preceding twelve months – and includes travel by an investigator's spouse and dependent children as related to the investigator's institutional responsibilities. NIH allows institutional discretion in "impose[ing] the \$5,000 de minimis threshold to reimbursed or sponsored travel disclosure in their institutional policies which specify the disclosure details." In subsequent meetings, NIH has confirmed this approach.

Most institutions have indicated that they are not changing their current (as designed to meet the 2011 regulations) policy provisions for the disclosure of reimbursed and sponsored travel, at this time. Institutions have taken a variety of approaches to the implementation of this portion of the disclosure requirements – some request current and prospective information, others, retrospective; most did not have a threshold for disclosure; almost all do not require disclosure of spouse and dependent children travel. There is a measure of risk in not meeting NIH's determination however it is worth noting the significant differences between the regulations and NIH's more stringent determination. Institutions are required to be in compliance with the regulations.

There is a general concern that changing the travel disclosure procedures at this time will add a measure of confusion that will discourage investigator compliance. Some institutions are being

pressured to implement the threshold requirement and may incorporate that provision into their current policies to assist in limiting the disclosure burden on investigators. Others will use the threshold as the first criteria in determining whether a further review is necessary; others will not use the threshold because it would require investigators to gather information that may not be readily available from sponsors.

Institutions may want to document any deliberations made on this question to demonstrate to NIH and others that the institution is aware of the NIH determination and has proceeded in its implementation in light of that awareness.

DATA Act Update

COGR has joined with other associations in reviewing and meeting, as appropriate, with Congressional staff members concerning the recently introduced Senate Bill 3600, a new version of the Digital Accountability and Transparency Act (DATA Act), introduced by Senator Mark Warner (R-VA) and Rob Portman (R-OH). In short, the new Senate version of the DATA Act imposes no new reporting requirements on the recipient community, relies on our subaward reporting under Federal Funding Accountability and Transparency Act of 2006 (FFATA) through the FSRS.gov (Federal Subaward Reporting System), requires OMB to conduct a review of the financial reporting requirements across agencies and reduce duplicative financial reporting and compliance costs for recipients and includes institutions of higher education in the discussions concerning ways to reduce duplicative reporting – we have a seat at the table. The Department of the Treasury in consultation with OMB, the General Services Administration and the other Federal agencies is charged with establishing government-wide financial data standards – we have asked for an opportunity to comment on any new financial data standards recommended for Federal reporting.

The associations are preparing talking points that can be used by the higher education community if asked by Congressional members and/or the media. The questions may be framed as a comparison or expression of preference between the recent Senate version, S. 3600, or the House-passed version of the DATA Act (HR 2461). You'll recall the House version creates a new recipient reporting requirement similar to ARRA reporting for all Federal financial assistance awards. The associations have been reluctant to make such a comparison except to note that the Senate version aligns most closely with our position in the past by relying on the information currently provided agencies through our financial reports and makes a commitment to review and recommend changes to financial reporting that streamlines the processes and avoids duplicative reporting.