June 2013 Meeting Report

Author: COGR Staff

Published Date: 06/21/2013

COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 750, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)

June 21, 2013

June 6 and 7, Meeting Report

COSTING POLICIES

- **NIH Update: Meeting with NIH Representatives**
- **COGR Submits Comments on the proposed OMB Guidance**
- **OMB Controller Danny Werfel Moves to the IRS**
- **Important Contributions from the COGR Workgroups and Membership**
- **Administration of Service Centers and Federal Guidance**
- **Audit Update: Tracking the Audit Resolution Process**
- **Other Costing Developments and Discussions**

CONTRACTS AND INTELLECTUAL PROPERTY

- **Supreme Court Invalidates Certain of Myriad's Human Gene Patents**
- **Patent Reform 2.0 Under Discussion**
- **White House Addresses Patent Troll Issues**
- **White House Convenes Lab to Market Summit**
- **Export Controls: Rules Proposed for Transition of Satellites from ITAR to EAR**
- **DOD Proposes Export Control Compliance Clause for Contracts**

RESEARCH COMPLIANCE AND ADMINISTRATION

- **NASA China Restrictions**
- **Restrictions on IT Purchases**
- **NSB Investigates Investigator Burden**
- **NSF Revising PAPPG and Seeking Comments**
- **PCORI Agreements**
- **NIH Review of Financial Conflict of Interest Policies**
- **Prostitution Policy Provisions Unconstitutional**

COSTING POLICIES

Committee: 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

NIH Update: COGR Costing Committee Meets with NIH Representatives

The COGR Costing Committee met with representatives from NIH during the Wednesday, June 5th, Costing Committee meeting. Michelle Bulls, Director for the Office of Policy for Extramural Research Administration (OPERA) and Joe Ellis, Special Advisor, joined the Costing Committee for a one-hour roundtable discussion. Michelle was named the Director of OPERA in October 2012 and Joe held that position prior to his retirement last June. Several of the topics that we addressed are summarized below:

- **NIH Fiscal Policy.** On May 8th, NIH published their fiscal policy for grant awards for the remainder of FY2013 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-064.html). In addition to a summary of broad NIH fiscal policies, the Notice also states that the NIH awarding Institutes/Centers will develop and post their fiscal policies consistent with overall NIH goals and available FY2013 funds. Sequestration has presented unique challenges for NIH and its awardees. We shared with Michelle and Joe that our community appreciates frequent updates on the status of Sequestration and the NIH budget, even when those updates simply indicate that future updates will be forthcoming as NIH learns more.

- **"Subaccounting" for Cash Payment Requests is Imminent.** Cash payment requests will be transitioned from the "pooling" method to grant-by-grant requests, i.e., to the "subaccounting" methodology. This methodology follows the recently implemented NSF Award Cash Management $ystem (ACM$), also a grant-by-grant premised system, and is being directed by the Department of Health and Human Services (HHS) Grants Policy Office. As an operating division under HHS, the NIH will be one of the final operating divisions under HHS to convert to this methodology. According to Michelle and Joe, the Payment Management System (PMS) will be able to accommodate the "subaccounting" methodology. We shared with them that we are concerned about this transition. At this stage, the timing is uncertain; however, Michelle and Joe encouraged COGR to engage with HHS and highlight all concerns related to this change.

- **New Grant Close-out Requirements.** Also at the direction of the HHS Grants Policy Office is the implementation of new grant close-out requirements. This change is in response to ongoing pressure by Congress, on the federal agencies, to better account for expired grant funds. For example, in a recent GAO report (http://www.gao.gov/products/GAO-12-360), the GAO found that: "*At the end of fiscal year 2011, GAO identified more than $794 million in funding remaining in expired grant accounts—accounts that were more than 3 months past the grant end date and had no activity for 9 months or more—in the Payment Management System (PMS).*" The NIH implementation date is to be determined.

- **Linking Performance and Financial Reporting.** This appears to be an initiative being led by OMB. The "*Proposed OMB Uniform Guidance: Cost Principles, Audit, and Administrative Requirements for Federal Awards*" included problematic language, which COGR addressed in its response to OMB. In the case of NIH, reporting that links performance and financial indicators is evident in recent Hurricane Sandy Funding Opportunities from NIH. The linkage is a trend that is gaining popularity throughout the HHS operating divisions and may be appropriate in the service areas where, for example, head counts and funding have a more direct correlation. Research, on the other hand, is not conducive to a model where a certain funding level can be correlated to a research breakthrough or discovery. Michelle and Joe encouraged COGR to be active in engaging with OMB, HHS, and NIH to articulate our concern with this trend.

The themes of "Accountability" and "Transparency" were obvious in almost every topic addressed during our roundtable discussion. Michelle and Joe, as well as NIH, are advocates for our community. However, varying degrees of pressure from Congress, OMB, and HHS are real and will impact how NIH is required to manage their budget appropriations, going forward. COGR will work with NIH and the COGR membership, as well as other key federal entities, to address those areas where new requirements can be facilitated and do not translate to excessive faculty and administrative burden.

COGR Submits Comments on the Proposed OMB Guidance

COGR submitted its comments on May 31st in response to the "*Proposed OMB Uniform Guidance: Cost Principles, Audit, and Administrative Requirements for Federal Awards.*" A copy of the COGR Response is available on the COGR website home page at www.cogr.edu (see Latest News, May 31, 2013 link).

The COGR Response is a 104-page comment letter that addresses the Proposed OMB Guidance on a section-by-section basis. Eight workgroups including over 35 individuals (see subsequent section for recognition of these individuals) from the COGR Costing and RCA Committees, plus at-large volunteers, crafted the COGR Response. The COGR comments were designed to categorize specific sections of the proposed guidance, as follows: "Major Concern", "Concern", "Recommendation", and/or "Thank You." In many cases we provided OMB and the COFAR with suggested changes to their proposed language.

There are 319 "results" posted on the OMB website. Many of the comment letters came from COGR member institutions, though other stakeholders also responded. One way to review

comment letters is to access www.regulations.gov and in the Search box, enter "OMB-2013-0001". All comment letters are displayed. As an alternative (310 "results" are shown here), the link below provides access to each comment letter. However, this link shows the "Organization" and "Submitter Name" and seems to be a better interface to select those comment letters that may be of interest to review.
http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=OMB-2013-0001;refD=OMB-2013-0001-0001

COGR plans to review selected comment letters. It is important that COGR has a good sense of comments made by entities beyond COGR member institutions. We expect to engage OMB and the COFAR later this summer on those issues that are most important to our community. If there are other stakeholders that have comments that are opposed to (or consistent with) our comments, we need to be prepared to propose compromise solutions (or rally support around the popular solutions). If you would like to help review several letters and summarize comments, please contact David Kennedy. Also, we'd like to see those comments that your institution made that are: 1) opposed to COGR's position, 2) especially important to your institution, and/or 3) unique to your institution. While it will be nearly impossible for COGR staff to read every letter in detail, we are very interested if 1), 2), and/or 3) are applicable to your institution. Please send those summaries to David Kennedy at dkennedy@cogr.edu.

We are not certain on the OMB/COFAR gameplan for reviewing comment letters, nor are we certain of their timeframe. We will reach out to OMB and the COFAR later this month and try to learn more on their next steps. We will keep the membership posted on all significant developments.

OMB Controller Danny Werfel Moves to the IRS

COGR has worked closely and productively with OMB on Grants Reform for over two years. Danny Werfel, as the OMB Controller, has been a leading force behind this initiative and has been a trustworthy and available partner throughout the process. Danny was appointed as the OMB Controller in October 2009, and soon after, COGR worked closely with him during the implementation of ARRA. Danny is a strong supporter of the higher education community and has helped to ensure that the interests of research universities have not been lost amidst the loud voices of the States and other constituencies. Effective May 22nd, at the appointment of President Obama, Danny moved into the role as Acting Commissioner of the IRS. We are not sure if Danny will remain at the IRS in a permanent role, or if he could return to OMB. Regardless, COGR will continue working closely with OMB and the COFAR over the next year as final guidance is prepared and grants reform is implemented.

Important Contributions from the COGR Workgroups and Membership

Seven "original" workgroups, an eighth workgroup that was created to do a final cold review/edit, and in total, over 35 individuals from the COGR Costing and RCA Committees, plus at-large volunteers, formally were involved in developing the COGR Response. This is a major effort and those individuals from each of the eight workgroups are recognized below (first name listed represents the workgroup chair).

As we shared in the past two COGR Updates, a special recognition to Wally Chan who unexpectedly passed away on March 29th. Wally was a great friend of the higher education and research community, serving as a higher education consultant in private industry and in the San Francisco office of the Division of Cost Allocation (DCA) for over thirty years. After his retirement from the DCA at the end of 2011, he joined the University of California, San Francisco (UCSF) in 2012 and served as a special advisor to the UCSF Vice Chancellor of Finance. He was an important contributor to the Costing Principles workgroup and helped us begin to formulate several key responses to the proposed guidance.

Administrative Requirements:
Mike Ludwig (Purdue)
Pam Caudill (Harvard Medical)
Michelle Christy (MIT)
Patricia Greer (MIT)

Costing Principles:
Dan Evon (Michigan State)
Sue Camber (U of Washington)
Wally Chan (UCSF)
Nilo Mia (UCSF)
Eric Vermillion (UCSF)
Pamela Webb (Minnesota)

Audit Requirements:
Mary Lee Brown (Penn)
Pam Caudill (Harvard Medical)
Charlene Hart (Nevada, Reno)
Ron Maples (UT, Knoxville)
Michael Miller (NYU)

F&A:
Cindy Hope (Alabama)
Mike Anthony (U of Washington)
Cathy Snyder (Vanderbilt)

Definitions Review:
Susie Sedwick (Texas, Austin)
John Shipley (Miami)

Subrecipient Monitoring:
Pamela Webb (Minnesota)
Jim Barbret (Wayne State)
Rick Inglis (Johns Hopkins)
Maggie Gillean Schamber (Texas, Austin)
Susie Sedwick (Texas, Austin)

Effort Reporting/Payroll:
Jim Luther (Duke)
Dan Evon (Michigan State)
Joe Gindhart (Washington U)
Terry Johnson (Iowa)
Kim Moreland (Wisconsin)

Cold Review/Edit:
Sara Bible (Stanford)
Ginger Baker (CalTech)
John Chinn (East Carolina)
Mike Daniels (Northwestern)
Jill Ferguson (Missouri)
Marcia Landen (Southern Mississippi)
Dara Little (Northern Illinois)
Polly Knutson (Idaho)
Rebecca Puig (South Florida)
Ryan Rapp (Missouri, System)
Mary Beth Rudofski (Chicago)
Naomi Shrag (Columbia)

Many of you, in addition to the individuals shown above, contributed insights either through channeling your comments through the leadership at your institution, or by directly contacting COGR staff. We appreciate all the input that you have provided; thank you!

Thursday Morning Session at June 6th COGR Meeting: Administration of Service Centers and Federal Guidance

The Thursday morning Costing Policies session at the June 6th COGR Meeting focused on managing institutional service centers. Three panelists presented institutional perspectives on those issues that they view as most challenging. The three panelists for this session were:

Sara Bible, Associate Vice Provost for Research – Stanford University

Terry Johnson, Associate Vice President & Controller – University of Iowa

Lynn McGinley, Assistant Vice President for Sponsored Projects, Accounting and Compliance – University of Maryland at Baltimore

The timing for this session was driven by several recent developments. First, the April release of the FAQs for Costing of NIH-Funded Core Facilities (NIH Notice Number: NOT-OD-13-053; http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-053.html) has provided an opportunity to assess how our institutions manage core facilities. Second, COGR's response to the Proposed OMB Guidance allowed the research community to propose recommendations specific to service center activities (e.g., working capital reserves, equipment replacement when equipment is purchased with federal funds). And third, the Research Business Models (RBM) subcommittee at OSTP has reached out to COGR to document challenges associated with federal instrumentation programs, and this affords another opportunity to raise issues such as equipment replacement at core facilities.

After several introductory comments that recapped the NIH FAQs, the COGR response to the Proposed OMB Guidance, and the RBM outreach to COGR, the three panelists presented their case studies. Some of the highlights and key points of the presentations are summarized below.

- **"Known" Service Centers on Campus.** Each presenter had an excellent grasp of the service centers operating on campus. However, there was a sense that there could be some activities that were not "known" by central administration. Most likely, the "unknown" would be relatively small volume departmental recharge centers and would not pose significant audit risk. Still, the fact that many institutions are challenged to inventory every service center and recharge center on campus demonstrates one of the challenges of managing this enterprise.

- **Terminology and Thresholds.** The terminology to describe these activities includes Service Centers, Recharge Centers, Specialized Service Facilities, Core Facilities, and variations on each of these. Each presenter shared the terminology and volume of activity thresholds used at their institutions, and a lesson learned is that there are not uniform terminologies and threshold levels across institutions.

- **Local versus Central Administration, and Staffing.** There was consistency across the three presentations: the local role is to look closely at the science and the service being provided, and that the local/departmental/faculty expertise informs the service center rate

development and other day-to-day management activities. The central role is to focus on oversight and compliance with federal costing requirements. Each presenter also shared that service centers are reviewed on either an annual or biennial basis, with the frequency for each center dependent on risk assessment. Staffing at the central administration level varies between 1 and 3 FTEs, though that variation seems to be explained by the size of each institution.

- **Rate Development Policies**. There are many considerations in service center rate development. While each presenter emphasized that institutional policies establish the parameters, variation both across institutions and within the same institution are inevitable due to unique needs and situations. Key considerations include:
  - acceptable level of an institutional subsidy (most service centers receive an institutional subsidy, but exactly what is the right amount?);
  - competition (is the service available off campus, and if so, how does this impact rate development?);
  - longevity of the service center (a brand new service center could require special considerations, and in some situations, there may be reasons for central administration to discourage the establishment of a service center);
  - composition of external users (e.g., if private industry uses the center, whether or not tax-exempt bonds have been used for the building in which the center is located becomes a consideration); and
  - other factors (e.g., what should/should not be included, such as equipment charges and F&A, in the rate; should some external users, such as local high schools or community colleges, receive "free" or discounted rates; and how best to manage faculty acceptance and their occasional advocacy that their use of a service should be "free"?). The presenters stressed their policies of non-discriminatory rates. If rates are discounted, a subsidy needs to be provided to cover the discount.

- **Equipment Acquisition/Replacement.** When expensive equipment is necessary for a service center and funding is uncertain, several solutions were discussed. Making available internal loan funds at low interest rates is one option. A second option is a "pass the hat" approach where contributions from the Dean, the VP of Research, and other entities at the institution help to fund the necessary equipment.

- **Future Issues for Advocacy.** Several issues that were addressed included: 1) formal recognition of allowable working capital reserves, 2) equipment replacement when equipment is purchased with federal funds, and 3) the use of administrative service centers (e.g., IRB, Information Technology, and even traditional administrative functions). Each of these also was addressed in the COGR Response to the Proposed OMB Guidance, and we will pursue each of these, accordingly.

COGR hopes to use ideas from this session to continue our advocacy as it relates to the NIH FAQs, the COGR response to the Proposed OMB Guidance, the RBM engagement, and other venues where issues related to service centers unfold. In addition, we will use input from this session to determine if good practices can be documented in a manner that would be beneficial to research institutions. The PPT presentations are available at www.cogr.edu (see Meetings | June 2013 Meeting Presentations tab).

Audit Update: Tracking the Audit Resolution Process

COGR regularly checks the HHS (NIH) and NSF Office of Inspectors General (OIG) websites (see links below). We also rely on updates from COGR member institutions on the status of new and ongoing audits.

https://oig.hhs.gov/reports-and-publications/oas/nih.asp
http://www.nsf.gov/oig/auditpubs.jsp

A review of the HHS (NIH) website shows a consistent posting of audit reports related to ARRA over the past year, most of which documented minimal findings and cost disallowances. However, the most recent posting (June 7, 2013) includes a recommendation that the university refund over $1.4 million to the federal government. The university disagreed with some of the findings. In the case of NSF, while several audit reports with more significant findings have been posted over the past year, the current breadth of ongoing audits is not reflected on the website.

In fact, the NSF OIG audit program emphasizing Data Analytics is robust and being implemented widely. At least ten institutions are amidst an NSF OIG Data Analytics audit. Under this model, the NSF OIG asks institutions for an electronic version of the General Ledger, specifically, NSF funds and accounts. Other data, electronic and organizational, are included in the NSF OIG data requests. Based on various analytical techniques, auditors look for indicators that suggest audit risk or need for additional information.

The first audit report using the Data Analytics model was posted on the NSF OIG website last Fall. In COGR Updates late last year (November 16th and December 20th), we reported on this first audit (*Audit of Incurred Costs for National Science Foundation Awards for the Period January 1, 2008 to December 31, 2010*). As stated in the audit report: *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*.

There were major concerns raised by the institution, and effectively, all of the NSF OIG findings were disputed. COGR summarized these concerns in the aforementioned COGR Updates.

COGR is closely tracking the audit resolution process. After a 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/CAAR, with the expectation that NSF/CAAR take responsibility for agreeing to a final resolution with the affected institution.

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 encourage you to share with COGR the status of active OIG audits, including details relevant to the audit resolution process. We will continue to advocate for a clear and certain audit process so that institutions are sufficiently empowered to respond to audit findings, and further are able to access an audit resolution process that is functional and fair.

We are interested in audit experiences at your institution so that we can update the general landscape for the membership – do not hesitate to contact us. We have the most access to HHS OIG and NSF OIG initiatives, but also are interested in activity related to the OIGs at other agencies, as well as other internal and external audit activities.

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

GAO Study on Indirect Costs. As we have reported in the past several COGR Updates, the U.S. Government Accountability Office (GAO) – an independent, nonpartisan agency that works for Congress to investigate how the federal government spends taxpayer dollars – is in the middle of a study on the indirect costs for National Institutes of Health (NIH) funded extramural research. COGR has met with the GAO team conducting the study, and we know of six COGR schools that have met with the GAO staff.

The study is in response to a request from Senator Jeff Sessions on the Senate Committee on the Budget. The GAO study will examine: a) the protocol for setting policies for covering indirect costs paid to universities, b) the amounts in indirect costs paid out to the largest universities by NIH, and c) how indirect costs vary across NIH grantees. You may recall the GAO study completed a study in 2010 (see http://www.gao.gov/products/GAO-10-937), which was conducted in response to the 2007 DOD indirect cost cap on basic research awards. While the new study appears to be unrelated to the 2010 study, some of the same issues are being covered. We will continue to report on this development and will update the membership as we learn more.

Department of Justice (DOJ) – Restriction on Cost Reimbursement. The DOJ, Office of Justice Programs recently released clarifying guidance, *Policy and Guidance for Conference Approval, Planning, and Reporting*, on the application of F&A rates to subcontracts/subawards and to participant support costs. The clarifying guidance broadens the definitions of the $25,000 Subcontract/Subaward Limitation and Participant Support Costs, and effectively, restricts application of the F&A rate on costs related to conferences, trainings and meetings. COGR staff has conferenced with staff from the DOJ policy office and legal counsel and has raised objections to the DOJ policy clarification. Their position is that the $25,000 threshold is applicable not only to subrecipient agreements, but to third-party vendor contracts, as well. COGR is pursuing this issue and raised this topic in our response to the Proposed OMB Guidance.

NIH National Institute of Allergy and Infectious Diseases (NIAID) – Restriction on Cost Reimbursement. In an almost identical situation to the DOJ position described above, in a contract issued by the NIAID to a COGR (recipient) institution, the NIAID has indicated they will not reimburse F&A for the amount over $25,000 on a third-party vendor contract issued by the recipient institution.

Department of Energy (DOE), Golden Field Office, Office of Energy Efficiency and Renewable Energy – Restriction on Cost Reimbursement. Again, in an almost identical situation to the DOJ and NIAID positions, the Golden Field Office has interpreted that a vendor contract is subject to F&A recovery only on the first $25,000 of the contract. The Golden Field Office has taken this position with at least two COGR institutions; in one case, the Golden Field Office reversed its position and allowed for the full cost reimbursement.

NASA – Restriction on F&A Reimbursement for IPAs. At least one COGR institution has encountered a new NASA policy related to F&A reimbursement on Intergovernmental Personnel Agreements (IPAs). According to an excerpt from the NASA Procedural Requirements (NPR 3300.1B), section 6.5.2.1 states: *NASA shall no longer reimburse non-Federal entities for indirect/administrative costs associated with IPA assignments*. COGR is pursuing this issue with NASA personnel.

Accelerating Spending on ARRA Programs: NSF and NIH. In early March, NSF notified all awardees of the status of their ARRA awards and reminded them to responsibly accelerate spending. On March 20th, NSF sent a follow up email to only those awardees with ARRA awards included on NSF's waiver list to notify them that NSF had received verbal approval from OMB to inform awardees that NSF's requested waivers would be granted. Therefore, ARRA awards included in the NSF's waiver request may continue as necessary beyond September 30, 2013, in accordance with the award terms and conditions. In the case of NIH, the ICs have made contact with the impacted grantees, and in the specific case of construction waivers, these waivers were approved by OMB.

Grant Reporting Information Project (GRIP): REPORT AVAILABLE. COGR has provided updates on GRIP since last October. GRIP is an initiative currently being led by the Recovery Accountability and Transparency Board (RATB) to explore implementing an ARRA-type reporting model for all federal grants (note, contracts are not part of GRIP). The initiative is in a proof-of-concept/pre-pilot stage and should be considered preliminary. The results of the pre-pilot will help determine if GRIP should be expanded to a full pilot. The RATB released a report on June 20th (see link below). COGR will review the report and provide an assessment at a later date.
http://www.recovery.gov/About/board/Documents/Grant%20Reporting%20Information%20Project%20Report_June%202013.pdf

A-133 Compliance Supplement for 2013. We continue to check with OMB and the OMB Circulars website (http://www.whitehouse.gov/omb/circulars_default/) for the status on releasing the A-133 Compliance Supplement for 2013. We expect it will be released soon.

HHS Memorandum to HHS Grantee Community – Grants Policy Statement. HHS has notified the grantee community that HHS has completed a revised draft version of its Grant

Policy Statement. They anticipate publication in the Summer of 2013 and implementation in the Fall of 2013. They have indicated that they will keep the grantee community posted and that all appropriate documentation will be posted at: http://www.hhs.gov/grants/

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: David Winwood, Chair, University of Alabama at Birmingham; 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;

Supreme Court Invalidates Certain of Myriad's Human Gene Patents

For some time we have followed and reported on the *Association for Molecular Pathology et.al. v. Myriad Genetics* case, involving the validity of Myriad's patents on the BRCA1 and BRACA2 genes (see COGR Summer 2011 and Fall 2012 Updates). Mutations of these genes are associated with greatly increased risks of breast and ovarian cancer. Myriad's patents cover diagnostic tests to detect these mutations. They include patents covering both isolated DNA gene sequences and synthetic DNA sequences or complementary DNA (cDNA).

In a (nearly) unanimous decision issued on June 13, the Supreme Court invalidated the isolated genomic DNA patent claims but upheld the cDNA claims. The Court in an opinion by Justice Thomas held that the isolated DNA claims fell within the law of nature exception to patentability in Section 101 of the Patent Act. Discovering the exact location and sequence of the BRCA1 and BRCA2 genes and separating them from other genetic material was not an act of invention. The Court stated that "Groundbreaking, innovative or even brilliant discovery does not by itself satisfy the 101 inquiry." The Court found that the gene sequences occurred naturally and were not new compositions of matter with different characteristics eligible for patent protection. There also were no new applications of knowledge involved, since the processes used by Myriad for isolating DNA were well understood and widely used (and not included in the patent claims considered by the Supreme Court). On the other hand, the cDNA does not occur naturally. It is not a product of nature but is created in a lab. Removing certain extraneous non-coding sequences ("introns") makes it new and therefore patentable even though mirroring natural DNA sequences.

The Federal Circuit had upheld the patent eligibility of both the isolated and cDNA claims, but in a split decision where the judges cited different rationales for upholding the isolated DNA claims. One judge found that isolating strands of DNA created a non-naturally occurring molecule while another cited the Patent and Trademark Office (PTO) practice of granting such patents and the reliance of patent holders on that practice. The Supreme Court in its opinion explicitly refused to give deference to PTO's determination. (The Department of Justice (DOJ)

had filed a brief in the case supporting the plaintiffs with regard to the isolated DNA claims. The Supreme Court basically adopted the DOJ position).

AUTM, BIO and other groups had filed *amicus* briefs in the case supporting Myriad, but COGR did not take a position. Many had anticipated that the Supreme Court would rule in the way it did. Justice Scalia concurred in the judgment, but refused to affirm the lengthy discussion in the opinion of the molecular biology underlying the patent claims.

Reaction to the decision has been mostly positive. Both the New York Times and Washington Post carried front page articles, and editorials supporting the decision. Myriad claims that 75% of its BRCA screening analysis business still is protected, and that it is planning to phase out its BRCA gene tests by 2015 anyway in favor of more sophisticated tests. Other companies and universities already have announced plans to offer BRCA gene tests. NIH issued a statement strongly supporting the decision as encouraging development of more individualized gene-based tests and treatments for the rapidly emerging field of personalized medicine.

(http://www.nih.gov/about/director/06132013_statement_genepatent.htm).

However, there are questions about the implications for patents on non-human genes isolated from other natural products e.g. bacterial genes. U.S. policy now also is very different from that followed in Europe and other countries (e.g. Australia) regarding patentability of isolated naturally-occurring biological material. PTO already has advised patent examiners that they should reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not (www.uspto.gov/patents/law/exam/myriad_20130613.pdf).

(For good analyses of the potential implications of the Myriad decision see http://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html?nl=todaysheadlines&emc=edit_th_20130614 and http://m.nbcnews.com/business/supreme-court-ruling-genes-could-boost-biotech-6C10314979).

Patent Reform 2.0 Under Discussion

As noted in the COGR May 2013 Update, a number of patent-related legislative initiatives are pending. They are aimed primarily at discouraging patent litigation and increasing the costs of filing infringement suits as well as promoting more transparency in the process. On the whole the effect appears positive for small business and university startups.

The most comprehensive of these is a 38-page discussion draft being circulated by Rep. Goodlatte (R-VA), House Judiciary Committee Chair. The bill would seek to incentivize settlements in patent litigation through requiring payment of costs and attorney fees to a settlement offeror if the final judgment is not more favorable to the offeree than the offer; require disclosure of financial interests and ownership in patents; protect downstream customers and retailers in patent infringement suits by allowing manufacturers of the infringing products to intervene and stay cases; limit discovery burdens in patent-related lawsuits; provide for development of early case management practices in patent cases in federal district courts; and provide for educational resources and outreach to small business related to patent infringement. It also provides for studies of secondary market oversight for patent transactions and of patents

owned by the U.S. government. Finally it makes some technical corrections to the America Invents Act (AIA) and provides clarifications to claim construction in AIA post grant and *inter partes* proceedings.

The current draft does not address university concerns about the narrow AIA grace period nor issues about micro entity filing status eligibility that have been discussed in recent COGR Updates and Meeting Reports. COGR and the other higher ed. associations that have worked together on patent reform plan to develop and propose additional legislative language to address these concerns. At its June meeting the COGR CIP Committee also met with the senior IP counsel at BIO to discuss the issues raised by the Goodlatte draft and other pending legislation. We will follow and report on further developments in the legislative process.

White House Addresses Patent Troll Issues

The COGR April and May Updates mentioned recent legislative initiatives aimed at the patent troll problem. On June 4 the White House announced five executive actions and seven legislative recommendations to address troll issues. The legislative measures would require disclosure of the real party in interest in patents and patent applications, similar to the Goodlatte draft and Deutsch bill (H.R. 2024) discussed in last month's Update; provide more discretion to district courts in awarding attorney's fees in patent cases; expand the Patent and Trademark Office (PTO) transitional program for covered business methods to permit more challenges to issued computer-enabled patents similar to the Schumer bill (S. 866); protect downstream customers from infringement suits in a manner similar to the Goodlatte draft; align the International Trade Commission (ITC) standards for obtaining injunctions against infringement with the eBay four-factor test followed by the federal district courts; allow the ITC to hire more administrative law judges; and incentivize public filing of demand letters. The five executive actions involve a PTO rulemaking requiring regular updating of patent ownership information designating the "ultimate parent entity;" more training of patent examiners to reduce overbroad patent claims; new PTO education and outreach materials for consumers and retailers threatened by patent trolls; greater outreach to stakeholders by PTO including expansion of the PTO Edison Scholars program; and review of the scope of ITC exclusion orders.

Accompanying the announcement was a report prepared by the President's Council of Economic Advisors, the National Economic Council and OSTP on patent assertion entities (PAEs). The report discussed PAE tactics, the explosive growth in litigation brought by PAEs (now 62% of all enforcement suits), the increasing targeting of end users, particularly small business, by PAEs, the costs of PAE activities, and particular problems with the scope and validity of software patents ("function" vs. "means" issues). The report noted similar problems had occurred in the past with agricultural and railroad equipment in the 19th century (citing an 1878 quote from Sen. Christiancy (R-MI) on blackmail of inventors by "patent sharks" in the legal profession). The report noted that in the past when the underlying conditions changed the "patent shark" business model no longer became profitable. It called for three main areas of change today: clearer patents with higher standards of novelty and non-obviousness; reduced disparity of litigation costs between patent owners and technology users; and greater adaptability of the innovation system to new technologies and business models.

The report conceded that patent intermediaries may provide specialized knowledge and effective brokering of patents. They also may increase incentives to innovate by protecting patents from infringement. However, the clear inference in the report is that PAEs do considerably more harm than good.

The report does not mention universities. Previous reports (e.g. FTC/DOJ—see COGR December 2012 Update) have carefully distinguished non-practicing entities such as universities from patent assertion entities. COGR and the other higher ed. associations have consistently sought to focus policymakers on that distinction, and we will continue to do so.

In his remarks accompanying the White House announcement President Obama stated that the AIA patent reform efforts "only went about halfway to where we need to go. What we need to do is pull together additional stakeholders and see if we can build some additional consensus on smarter patent laws." Given all this activity, obviously we may expect further developments.

White House Convenes Lab to Market Summit

On May 20, 2013, OSTP and NIH/NHLBI convened a Lab to Market Summit. They gathered a panel of 19 national external experts to examine selected innovative commercialization programs in five agencies (DOE/ARPA-E, NIH National Centers for Accelerated Innovation (NCAI), NSF/I-Corps, DOC/ I-6 Challenge, and DOD Telemedicine and Advanced Technology Research Center (TATRC)) with the aim of identifying possible synergies as well as underlying challenges to these and other federal commercialization programs. Several Federal agency representatives also were involved both to discuss their respective programs and to share their views on these matters.

The premise was that commercialization of discoveries from federally-funded research is basically an afterthought in the federal R&D system. The external Expert Panel was asked to address common barriers and approaches to lab-to-market models; agency end market or technology-specific barriers; resources that can be leveraged across agencies and programs; mechanisms to inventory and share best practices; policies that enhance cross-agency program cooperation and public-private partnerships; cross-agency initiative development; current/potential linkages with the private sector, and related local and state programs; and metrics of success.

Discussion centered around the relatively low priority for technology transfer in the fragmented federal R&D system and the lack of effective oversight of technology commercialization. While there have been successful innovative agency programs, there is little coordination or incentives on a government wide level.

The panel currently is preparing recommendations. While given the constrained resource environment there seems little possibility of additional funding being made available for these purposes, the growth in SBIR/STTR (3.2% of agency extramural research budgets by 2017) may present opportunities (COGR has been informally discussing with other higher ed. associations some similar initiatives for SBIR/STTR). We also have long been concerned about the lack of effective oversight of agency implementation of the Bayh-Dole Act, which is related to these issues. We will report on the panel recommendations in the future.

Export Controls: Rules Proposed for Transition of Satellites from ITAR to EAR

On May 24 proposed rules were issued by the Departments of Commerce and State for the transition of spacecraft systems and satellites from the US Munitions List (USML) to the Commerce Control List (CCL). The COGR December 2012 Update discussed the FY 2013 National Defense Act Authorization Act (NDAA) authorization for the President to transfer satellites from USML controls under the ITAR to the CCL controlled by the EAR. This overturned the provision in the FY '99 NDAA which transferred export jurisdiction for satellites to the ITAR list. The October 2012 and June 2012 Meeting Reports discussed the recommendations in the April 2012 report pursuant to Section 1248 of the FY '10 NDAA (Section 1248 report) that most satellite technologies be transferred to the CCL.

a) Proposed EAR Rule

The proposed rule (78FR31431) implements the President's authority and the Section 1248 report recommendations. The EAR rule proposes to establish a new "500 series" of Export Control Classification Numbers (ECCN) for spacecraft systems and related items removed from the USML. More specifically, it establishes a new 9x515 ECCN series for spacecraft including satellites ((9A515); ground control systems and training simulators specially designed for tracking and control of spacecraft (9A515b); radiation hardened microelectronic circuits for 9A515 items that meet certain characteristics (9A515d); test, inspection and production equipment specially designed for 9A515 commodities (9B515); and specially designed software for the development, production, operation, installation, maintenance, repair, overhaul, or refurbishing of 9A515 and 9B515 items (9D515). Similarly, technology required for 9A515, 9B515, or 9D515, would be controlled (9E515). All 9x515 controlled items would be controlled for National Security, Regional Stability and Antiterrorism controls, and some would be subject to Missile Technology controls. All 500 series item exports to countries that were subject to U.S. arms embargo policies when listed in the USML would continue to be subject to such policies under the EAR (EAR Country Group D:5). Items destined for state sponsors of terrorism would continue to be subject to a policy of denial. The definition of "specially designed" for 500 series controls would be equivalent to the definition of "space-qualified" in the multilateral Wassenaar Arrangement. Except for arms embargo destinations, the same *de minimus* percentage (up to 25%) of controlled U.S.-origin content would apply to 500 series items as apply to 600 series items (which covers other items transferred from the USML to the CCL; currently limited to military aircraft and gas turbine engines—see COGR April 2013 Update).

As noted in previous Updates and Reports, the U.S. space science community generally has strongly supported the transfer of satellites and related items from the ITAR to the EAR. COGR joined AAU and APLU in a letter supporting the NDAA provision that gives this authority back to the executive branch. However, one aspect of the proposed EAR rule is of concern. The definition of "software" and "technology" for the new 9D515 and 9E515 ECCNs is specially designed (software) or required (technology) "for the development, production, operation, installation, maintenance, repair, overhaul, or (emphasis added) refurbishing of spacecraft and related commodities." Especially for 9E515 technology, this raises the issue of the "and/or" debate that was the subject of

intense controversy 9 years ago with regard to use technology controlled under the EAR. COGR members will recall that the Commerce IG had recommended that "or" replace the conjunctive "and" in the EAR. The university community strongly and successfully resisted this recommendation. Informal discussions with Commerce representatives indicate no intention to revisit the IG recommendation with regard to other EAR-controlled technologies. However, we understand that the current proposed language was strongly supported in the executive branch deliberations over the transfer of items from the USML to the CCL, although it is not discussed in either the proposed 500 series rule or the final rule (78FR22660) that established the 600 series control structure. (Similar terminology is used in the ECCNs for military aircraft (ECCN 9E610) and gas turbine engines (9E619)).

We plan to raise this issue in our comments to Commerce on the proposed 500 series rule. The effect is to create a discrepancy in the CCL between 500 and 600 series technologies and other technologies controlled under the EAR. Access to 500 or 600 series technologies for any one of the enumerated purposes is controlled. We believe at the least Commerce should explain the rationale for this different treatment, especially since we may expect to see similar language as additional ITAR items are transferred to the CCL 600 series (we understand at least four more transfers are in process). Comments on the proposed 500 series rule are due July 8.

b) <u>Proposed ITAR Rule</u>

The proposed counterpart ITAR rule (78FR31444) revises Category XV of the USML to limit the scope and more specifically describe the Category XV items remaining on the USML (e.g. launch vehicles, military satellites). It asks for specific examples of satellites and related items, if any, that would be controlled by the revised Category XV that are now in normal commercial use. It also adds a new provision that allows ITAR licensing for EAR commodities, software and technical date that are used in or with defense articles controlled in Category XV.

Importantly for universities, the proposed rule also included a proposed new definition of "defense services." The revised definition proposed (ITAR 120.9(a)(1)) is "the furnishing of assistance (including training) **using other than public domain information** (emphasis added) …to a foreign person…whether in the United States or abroad, in the design, development, engineering, manufacture, production, assembly, testing, intermediate- or depot-level maintenance…., modification, demilitarization, destruction or processing of defense articles…"

A second component of the revised definition (ITAR 120.9(a)(2)) is "The furnishing of assistance to a foreign person, whether in the United States or abroad, for the integration of any item controlled on the (USML)…. or items subject to the EAR….into an end item …or component….that is controlled as a defense article on the USML, regardless of the origin." A definition of "integration" also is provided: "Integration" means the systems engineering design process of uniting two or more items in order to form, coordinate, or blend into a functioning or unified whole, including introduction of software to enable

proper operation of the article…."Integration" is distinct from "installation"… (which does not require any changes or modifications to the item in which it is being installed)."

A third component of the revised definition indicates "defense services" includes the furnishing of assistance including training to a foreign person regardless of whether technical data is transferred including informal instruction in the U.S. or abroad by any means in the tactical employment but not basic operation of a defense article. There also are provisions specific to satellites. Several other activities also are enumerated that are not defense services (120.9(b)), including training in organizational-level (base-level) maintenance of an approved defense article export and servicing of an EAR controlled item that has been integrated or installed into a defense article.

Two years ago the State Department proposed a revised definition of defense services that COGR commented on (see COGR May 2011 Update). That proposed revision also excluded furnishing assistance including training using data solely in the public domain from being considered to be a defense service. Currently a license is required for a U.S. person to work with a foreign person on defense articles even if all the information conveyed is in the public domain. Excluding such situations from defense services long has been a goal of the university community. There also was a broad scope proposed for training in the employment of defense articles, which we expressed concern about and which is not included in the proposed definition (which now distinguishes "tactical employment" from "basic operation").

However, we previously expressed concern about adding "integration" to the definition. As proposed then and now, the definition does not exempt use of public domain information in providing such assistance. While the proposed revision clarifies the definition of "integration," the scope appears very broad, apparently including making any changes or modifications no matter how minor to the defense article in which an item is being installed. The revised definition also omits a helpful provision previously proposed that excluded assistance (including training) in medical, logistical (other than maintenance), or other administrative support services to or for a foreign person from defense services.

Apart from these concerns, the proposed rule also indicates (p. 31446) that revised definitions of "public domain" information and "technical data" will be forthcoming. Those provisions are critical for universities. Any proposed restrictions on the current exemptions for fundamental research or teaching of general scientific, mathematical or engineering principles obviously would be of great concern. As with the proposed EAR rule, comments are due July 8. COGR plans to comment jointly with AAU on both proposed rules.

DOE Proposes Export Control Compliance Clause for Contracts

On June 12 the Department of Energy (DOE) proposed to amend the Department of Energy Acquisition Regulations (DEAR) to add export control compliance requirements (78FR35195). The proposed requirements are in response to two DOE IG reports and a GAO report which identified weaknesses in export control guidance and compliance.

The proposed DEAR amendments cite a series of export control laws and regulations. They also implement DOE requirements for Export Restriction Notices for any transfers, sales, or other offerings of high risk personal property, which includes export controlled items (41 CFR 109.5303(b)(6)). The proposed DEAR policy (48 CFR 925.7101) states the need for contractors to comply with the applicable export control requirements as well as the DOE personal property management requirements. As such it does not establish new requirements.

However, the proposed new DEAR clause (952.225-XX) includes a provision that an Export Restriction Notice be included in all transfers, sales or other offerings of unclassified information, materials, technology, equipment or software pursuant to a DOE contract. Similar requirements are included for DOE management and operating contracts (970.5225—1). Both the 952.225 and the 970.5225—1 requirements flow down to subcontractors.

The scope of this clause is not clear, particularly as it applies to unclassified information. The current DOE property management requirements apply to personal property and do not have as broad a scope. We may ask DOE to clarify that the notice requirements do not apply to information or other products of fundamental research performed under DOE contracts. Comments are due July 12.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: 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

---

NASA China Restrictions

The Research Compliance and Administration Committee met with Max Bernstein, the lead for research in the NASA Science Mission Directorate, concerning NASA's implementation of the China Restriction on NASA (and OSTP) funding. You'll recall that institutions are asked to sign an assurance committing the institution to not use NASA funds to support bilateral activities with China or Chinese companies. Last year, COGR recommended modifying the assurance by amendment or an attached statement to assert the fundamental nature of the research. The problem arose at that time with the instructions provided by NASA through its Grants Information Circular – the GIC 12-01 – linking the statutory restriction to an individual's nationality. In September 2012, NASA modified that GIC – GIC 12-01A – and focused the implementation on bilateral activities with entities not individuals because of their nationality but rather their affiliation with a prohibited entity. As a consequence, NASA considers (as it always did) the amendment or addendum to the assurance unnecessary. Grants officers will not accept such modifications to the assurance. We know the modifications to the GIC 12-01A don't solve

all the questions concerning export controls but those questions aren't necessarily unique to this restriction.

In the discussions with Dr. Bernstein, we were reminded of the challenge of the performance-based flexible standards we advocate. As we described the struggles institutions have determining who is "affiliated" with China or a Chinese entity – and NASA considers Chinese colleges and universities as a whole no matter what their status to be subject to this restriction – Bernstein reminded us to step back and view this from NASA's perspective.

In the statutory framework, NASA must assure Congress that it is restricting its funds. NASA meets this obligation by asking us to assure them we are meeting that restriction. NASA has given us the maximum flexibility. They don't tell us how to do that, just to assure them we are. The Frequently Asked Questions (FAQs) provided by NASA are intended to help us meet our assurance obligations. NASA does not prescribe how we meet our obligation – just that we've made a reasonable effort to assess NASA funded projects and made a determination that in our relationships – formally in collaborations or through the investigators working on the project – NASA funds are appropriately restricted. This process is a model of performance-based standards.

Dr. Bernstein invited the community to continue to pose questions for response and posting to the FAQs. To maintain maximum flexibility the research community should be thoughtful about pushing for greater refinements and granularity from NASA because the result could be a narrowing of our ability to make reasonable decisions on campus. Some parameters are clear. If an institution determines in its assessment that an individual is affiliated with a Chinese entity – receives support – that individual should not receive support from NASA funds to conduct research.

Restrictions on IT Purchases

During the discussion, the recently enacted restriction on the purchase of information systems came up for discussion. Section 516 of the Consolidated and Further Continuing Appropriations Act of 2013(PL 113-6) enacted March 26, 2013, prohibited the use of funds provided to the Departments of Commerce and Justice, NASA and the National Science Foundation (NSF) for the purchase of information technology system unless and until the Department or agency head, in consultation with the Federal Bureau of Investigation, made an assessment of any associated risk of cyber-espionage or sabotage. Any potential purchase of a system produced, manufactured or assembled by one or more entities that are owned, directed or subsidized by the People's Republic of China requires a report to of the determination to Congress. NASA's procurement division issued a Procurement Information Circular 13-04 dealing with these purchases (available at: http://www.hq.nasa.gov/office/procurement/regs/pic13-04.html).

As Dr. Bernstein notes there is no mention of grants or cooperative agreements and PIC 13-04 excludes "systems acquired by a contractor incidental to a contract." He understands that information technology systems purchased through research awards (the primary purpose of which is research, not the purchase of IT systems) are not restricted, even if it's a contract. Thus, any awards from Research Opportunities in Space and Earth Science (ROSES) should be exempt.

As a note on the information technology system restrictions: NSF reads this restriction to apply to purchases being made the Foundation itself for Foundation use. This interpretation seems more in line with the statutory language.

NSB Investigates Investigator Burden

COGR along with Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU) submitted comments in response to the National Science Board's (NSB) request for information on ways to Reduce Investigator Administrative Burden. Because the deadline for comments was extended to June 7, 2013, the COGR membership had a timely opportunity during the June meeting to continue to offer comment to Jeremy Leffler, Executive Secretary to the NSB's Task Force on Administrative Burden and Outreach Specialist in the NSF Policy Office, and Lisa Nichols, National Science Board Office (NSBO) Liaison to the NSB Task Force and NSB Science Policy Analyst. Leffler and Nichols provided an overview of the work of the Taskforce to date and described some of the comments the Taskforce had received through its solicitation and at public roundtables held in late April and early May. The themes are not surprising: Funding Levels, IRBs/IACUCs, Effort Reporting, Reporting, in general, and Biosketches.

The discussion at the COGR meeting was lively. In addition to reiterating some of the comments in the associations' response, COGR members described the reporting burden in its broader context of preparing additional reports in response to audits and investigations and how institutions eventually need to involve the investigators in the preparation of those responses as well. The seemingly endless reports – technical, financial and monitoring/auditing – increase and exacerbate the shared burden. Members highlighted the role of agency guidance and FAQs in extending the regulations and noted that the accrediting bodies – Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) and Association for the Accreditation of Human Research Protection Programs (AAHRPP) – add to the problem by establishing standards that go well beyond the regulations.

The usual regulatory burden suspects emerged – effort reporting, risk-adverse-driven IRB and IACUC implementation, the need for harmonized regulations across agencies, greater use of just-in-time requirements, and modular budgeting for NSF.

The Task Force's next steps will be to review and report recommendations by the end of 2013 or early 2014. Comments specific to NSF will be made available to the NSF Director and a copy of the report and the recommendations will be delivered to the Executive Office of the President and Congress with the goal of initiating discussions with Congressional leaders. The NSB will look for opportunities to promote or advance current or pending work geared to reducing the administrative burdens and open discussions with other Federal agencies and offices.

NSF Revising PAPPG and Seeking Comment

NSF issued a draft of a revised the *Proposal and Award Policies Procedure Guide* (PAPPG) on May 30, 2013 and is accepting comments until June 28. The notice of the information collection is available in the *Federal Register* (78FR32474) and the draft document including a four page

summary of proposed changes is available on the NSF website at: http://www.nsf.gov/bfa/dias/policy/papp/papp14_1/draftpappg_june2013.pdf.

Many of the proposed revisions are consistent with changes in operation that have been announced to the research community through past notices or clarifications. NSF introduces a new process and procedures with regard to environmental impacts that includes a checklist that will be used only if additional information is needed and requested by NSF. NSF has provided useful information and guidance concerning the allowability of visa costs. In its comment, COGR will mention its continuing disagreement with the exclusion of participant costs from the Facilities & Administrative (F&A) calculation.

Unfortunately, NSF continues to make modifications to its financial conflicts of interest policy through an "extension with revision" information collection of the PAPPG. COGR will ask for the proposed additional requirement to provide notification to the NSF Office of General Counsel (OGC) "if the institution finds that research will proceed without the imposition of conditions or restriction when a COI exists" to be struck from the PAPPG. Under the current policy, a determination by the institution to allow a project to proceed without restrictions or conditions is a managed conflict of interest and not reportable to NSF.

During the last PAPPG revision, NSF made a change to the requirements concerning an unmanageable conflict of interest. The current (effective January 2013) PAPPG elaborates the actions to be taken by the OGC when notified by an institution that "it is unable to satisfactorily manage a conflict of interest" including an examination of institutional policies to determine the procedures for addressing unmanageable conflicts be removed in its entirety. As we noted at that time, institutional policies are not required to contain procedures for addressing unmanageable conflicts, per se, beyond notifying NSF.

COGR's comment will focus on the changes under the policy for financial conflicts of interest but we encourage institutions to review the proposed revisions and provide any comments to NSF by the deadline of June 28, 2013.

PCORI Agreements

Representatives from several COGR member institutions and the COGR staff met with staff members of the Patient-Centered Outcomes Research Institute (PCORI) to discuss continuing concerns with the March 13, 2013 version of PCORI Contract for Funded Research Projects. The meeting's tone was collaborative and we believe PCORI heard the institutions' concerns and would take them under consideration for future negotiations and versions of the contract. We understand PCORI continues to insist that the current March 13 contract without modifications be used for the most recent round of awards. Institutions that would like to see the changes proposed should contact Carol Blum (cblum@cogr.edu) for a copy of the COGR proposed revisions.

NIH Review of Financial Conflict of Interest Policies

On September 21, 2012, NIH informed the research community that it would launch a new Proactive Financial Conflict of Interest (FCOI) Compliance Program to assess institutional

implementation and compliance with the 2011 Revised Federal FCOI regulatory requirements (see NIH Notice NOT-OD-12-159). As the first phase of this compliance program, NIH evaluated the publicly accessible FCOI policies on institutional websites for a sample of NIH grantee institutions and pledged to notify institutions if deficient areas are noted for institutions to formally address and resolve. The results of the FCOI Compliance Program review will be shared as results are available with the research community as part of NIH's continuing educational efforts to improve and enhance compliance with FCOI regulatory requirements.

The notifications concerning the results of those reviews are arriving on campuses sampled. It is not entirely surprising that NIH found elements missing from many if not most policies posted online. NIH expected that all procedural detail would be incorporated into an institutional policy and found that, generally, that was not the case. COGR recommends that institutions avoid unnecessary policy revisions by notifying NIH where the procedural information is housed – whether in a standard operating procedure (SOP) or posted as a list of FAQs for the institutional community.

Prostitution Policy Provisions Unconstitutional

You may recall that in implementing the Trafficking Victims Protection Reauthorization Act of 2003 (PL 108-193) and US Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (PL 108-25),Federal agencies, notably the Centers for Disease Control and US Agency for International Development (USAID) required recipients, domestic and foreign, primes and subrecipients, to have organization-wide policies opposing prostitution. Congressional interest resulted in request for copies of institutional policies and international agencies and governments began refusing US assistance.

The first lawsuit was filed in 2005 by DKT International challenging the anti-prostitution policy requirement. While DKT prevailed in the US District Court, it lost on appeal when the US Court of Appeals ruled in February 2007 that the government would allow speech regarding prostitution as long as it is done through an affiliate that doesn't receive federal funding. In September 2005, the Alliance for Open Society International sued USAID and other agencies arguing that the requirement that groups receiving U.S. funds pledge their "opposition to prostitution" forces those groups and their employees to censor even their privately funded speech regarding the most effective ways to engage high-risk groups in HIV prevention. The Alliance was granted a preliminary injunction against implementation of the requirement and the case has been moving through the courts since. The US Supreme Court ruled on June 20, 2013 that it is a violation of the First Amendment of the US Constitution for the Federal government to force organizations to endorse the government's views opposing prostitution in order to receive funds to conduct HIV/AIDS prevention and other related programs overseas. The case was decided 6-2 in Agency for International Development v. Alliance for Open Society International.