COUNCIL ON GOVERNMENTAL RELATIONS
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June 24, 2010

MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS
WASHINGTON MARRIOTT HOTEL
June 3 and 4, 2010

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GENERAL DEVELOPMENTS

1. New COGR Board Members, Board Chair Selected

The COGR Nominating Committee recommended, and the Board approved the selection of the following individuals for COGR Board membership, beginning August 1, 2010:

Anne Hannigan, Associate Vice President for Research Administration, Stanford University; Michael Ludwig, Director of Sponsored Program Services, Purdue University; James Luther, Assistant Vice President for Financial Services and Research Costing Compliance Officer, Duke University; Denise McCartney, Associate Vice Chancellor for Research Administration, Washington University-St. Louis; Kim Moreland, Associate Vice Chancellor for Research Administration, University of Wisconsin-Madison; and Eric Vermillion, Associate Vice Chancellor for Finance and Treasurer, University of California-San Francisco

As stated by Jane Youngers, Chair of the Nominating Committee in her report to the Board, "We had an excellent slate of candidates, nearly all of whom would have made excellent Board members, and believe this is a reflection of the strength of COGR, its stellar reputation, and its service to its members." The Board also unanimously agreed with the Executive Committee's recommendation to appoint David Wynes, Vice President, Research Administration, Emory University, to be the COGR Board Chair, effective August 1, 2010. We look forward to the contributions of these extremely well-qualified colleagues. Finally, we must say goodbye to those good friends and colleagues whose Board terms will expire July 31, 2010. Al Horvath, Pennsylvania State University and current Board Chair, Nikki Krawitz, University of Missouri, Jamie Lewis Keith, University of Florida, and Ara Tahmassian, Boston University. Their outstanding contributions during the past six years cannot be overstated, and we thank them for their dedication and service.

2. Guest Speaker – Dr. Robin Stafin, Director for Basic Research, DOD

We were most fortunate to have Dr. Robin Stafin address the COGR meeting attendees. As Director for Basic Research, Dr Stafin determines policy and exercises oversight for science and technology programs of the military services and defense agencies. He ensures that the long-term strategic direction of the Department's basic research program develops the fundamental science that underpins continued technological superiority of U.S. Forces. Dr Stafin explained areas of interest he sees as priorities during his tenure.

> **Determining the right balance of use-inspired research versus curiosity driven research -** He is concerned that DOD may have drifted too far towards use-inspired.
>
> **Developing closer connections between the Office of the Secretary of Defense and universities**. Scientific leadership is needed at DOD and Dr. Stafin is looking for at least five scientists interested in working in OSD under Intergovernmental Personnel Agreements.

Maximizing discovery potential, partly by eliminating or reducing regulatory burdens.

Related to the last point above, Dr Stafin talked about the May 24 memorandum on Fundamental Research issued by the DOD Undersecretary for Acquisition. The memo reinforces an earlier (6/26/08) memorandum on Contracted Fundamental Research and provides additional clarifying guidance. The intention is to assure that DOD fundamental research awards are "fully compliant with National Security Decision Directive (NSDD) 189." As also stated in the CIP section of this meeting report, the memorandum reiterates earlier guidance 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." Exceptions require high level DOD component management approval.

As Dr Stafin described it, an important clarification in the memo is that research performed with funds other than budget category 6.1 or 6.2 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…".

With respect to funding, Dr Stafin said that for FY 2011 the President's budget proposed an 11% increase for Basic Research funding, which would bring the total to $2.0 billion.

3. Panelists Discuss STAR METRICS Project

This project - Science and Technology in America's Reinvestment Measuring the Effect of Research on Innovation, Competitiveness and Science – was discussed in detail by the project leaders, Dr Julia Lane, Program Director from the National Science Foundation's Science of Science and Innovation Policy, and Dr Stefano Bertuzzi from the NIH Office of Science Policy. Also on the panel was Dr Susan Sedwick, Associate Vice President, Research, at the University of Texas-Austin, and a COGR Board member, to describe the UT participation in the pilot testing of the project. The PowerPoint presentations are available on the COGR web site.

As described by Drs. Lane and Bertuzzi, STAR METRICS has two phases – the first will create a reliable and consistent inter-agency mechanism to account for the number of scientists and support staff that are on research institution payrolls supported by federal funds. STAR METRICS will build on this information in the second phase to allow for measurement of science impact on economic outcomes, such as job creation, on scientific outcomes, such as the generation and adoption of new science, often measured by citations and patents, as well as on social outcomes such as public health.

At each stage, according to Dr Lane, stakeholders will assess the effectiveness of the previous work in reaching goals and moving the project forward, and modify the approach as needed. Three sets of "products" are involved:

- Standardized measures of the impact of science investments on job creation and retention;
- Systematized, standardized and validated ongoing measurement of long-term impact of science investments: economic, scientific, social;
- Enabling a community of researchers in science of science policy.

A critical element of STAR METRICS was to work with a group of volunteer PIs and universities to participate in the initial tests.

Pilot Project - The pilot drew on the existing administrative records/systems of academic institutions and other new and existing data on the economic, social and scientific outcomes of federal science investments.

The Federal Demonstration Partnership was a key test community for the pilot. To minimize the impact on the overall membership, the FDP involvement began with a few representative institutions selected to give the pilot team the best chance to uncover the nuances of how large and small, private and public, broad coverage and specialty institutions receive, manage, disburse and report on their use of Federal funding.

Initial Participants: University of Texas at Austin; University of Delaware; George Mason University; California Institute of Technology; University of Alabama; University of Massachusetts, Dartmouth.

Susan Sedwick talked about the University of Texas' experience in the pilot, and emphasized the minimal amount to effort needed to provide the requested information. Susan's slides are also available on the COGR web site.

STAR METRICS is now looking to expand participation, and has another 60-70 institutions expressing interest. If your institution is interested, please contact Julia Lane at jlane@nsf.gov.

COSTING POLICIES

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

1. F&A/Compliance Reform and the Financial Viability of the Research Enterprise

The COGR June Meeting had a strong emphasis on F&A related topics, including F&A/Compliance Reform and the Financial Viability of the Research Enterprise. The timing of these sessions was designed to update the COGR membership on policy initiatives currently taking place in Washington and to utilize the expertise of the COGR membership. By introducing the policy options being discussed, COGR was able to get feedback from the membership to be used to further fine-tune potential policy recommendations.

The Thursday morning session, "Making a Case for F&A Reform", was a panel discussion lead by members of the COGR Costing Policies Committee: Sue Camber from the University of Washington, Jim Barbret from Wayne State University, and Dan Evon from Michigan State University. The discussion covered a full hour of drilling down into some of the most nuanced and detailed areas related to F&A. After that discussion, we were joined by Darryl Mayes, National Director for the Division of Cost Allocation (DCA), Steve Zuraf, Branch Chief for Colleges and Universities (DCA, Mid-Atlantic Field Office), and Debbie Rafi, Director – Indirect Cost Branch of the Office of Naval Research (ONR).

Notable comments by the DCA and ONR included backlog issues and policies toward rate and submission extensions. In the case of the DCA, the Mid-Atlantic office is the most backlogged and it may take up to one year to negotiate rates after an F&A proposal has been submitted. As to rate extensions (e.g., two additional years at the institution's current rate), Darryl Mayes indicated that he would like to see a "halt" to this practice, though if there is a legitimate reason, the DCA will still consider rate extensions. Also, a proposal submission date extension (e.g., 90 days) should routinely be granted. From ONR's perspective, Debbie Rafi indicated her office will not allow for rate extensions or for proposal submission date extensions. In the case of proposal submission date extensions, the DCAA audit backlog has become significant, and in order to establish rates in a timely manner, an institution must submit by December 31 (or the designated submission date).

The Thursday afternoon session, "The Financial Viability of Research Universities and the Research Enterprise", was a panel discussion led by Nikki Krawitz, the Chief Financial Officer for the University of Missouri System, John Shipley, the Chief Financial Officer for the University of Miami, Matt Owens from the Association of American Universities (AAU), and Howard Gobstein from the Association of Public and Land-grant Universities (APLU). This

session began with presentations by Nikki Krawitz and John Shipley that covered case studies of the unmistakable and severe financial stress that is being experienced by research universities. Both panelists emphasized that the infrastructure and cost required to run a research university is much more extensive than what is required to operate a traditional undergraduate institution. Matt Owens and Howard Gobstein followed with the AAU and APLU perspectives on the advocacy strategies and policy recommendations that currently are unfolding.

The overlap between the material discussed during the two sessions at the COGR meeting, developments since the COGR meeting, and the fluid nature of ongoing events is significant. In order to update the COGR membership on all activities, the remainder of this section of the June Meeting Report is presented as a series of Important Questions & Answers (IQAs). The IQAs address policy logistics, key players, the policy recommendations being considered, and strategic presentation of policy recommendations.

Why the Current Focus on F&A/Compliance Reform? - The deteriorating economic conditions over the past several years have highlighted the fragile state of university finances. The significant extent to which research universities subsidize F&A costs has been magnified during the economic crisis. Consequently, University Presidents and Senior Administrators have been moved to address this issue. This dynamic, coupled with how the Obama Administration views research, science and technology as a critical factor toward long-term economic well-being, has resulted in the right convergence of events to address F&A/Compliance Reform.

What Is the Goal of F&A/Compliance Reform? - While concerns such as the 26% cap and suffocating compliance burden are rallying points, the core issue is about reaffirming the Government-University Research Partnership. The observation of many leaders in the research community is that the research partnership is no longer a partnership and has descended into a one-sided, contract-for-services relationship. If the partnership can be reaffirmed, it is possible that a number of concerns related to cost reimbursement and compliance burden can be effectively addressed.

Which Organizations are Engaged in the Reform Initiatives? - The APLU sponsored five regional workshops in April with University Presidents as the primary invitees. F&A/Compliance Reform was a major topic of discussion. Also, AAU has developed an internal discussion document to address F&A/Compliance Reform. Both APLU and AAU addressed F&A/Compliance Reform during their June President's meetings. The Federal Demonstration Project (FDP) also has engaged in this issue and has targeted several areas on which to focus.

What is the Status on the National Academies Study on Research Universities? - In a letter to the National Academies dated June 22, 2009, Congress asked the National Academies to complete a study on the top ten actions that will assure that American research universities maintain the excellence in research and doctoral education required for the United States to compete in the global economy. One year and one day later (June 23, 2010), the National Research Council announced the launch of the Study on Research Universities.

The study will provide an authoritative, independent voice that addresses a wide breadth of issues – F&A/Compliance Reform could be an important part of the study. The 21-member panel to be chaired by Chad Holliday, Chairman of the Board, Bank of America, and Chairman and CEO, E.I. du Pont de Nemours and Company (DuPont) (retired), includes current and former University Presidents, as well as corporate leaders. A final report should be completed within one year. A summary of the initiative can be found at: http://sites.nationalacademies.org/PGA/bhew/researchuniversities/index.htm

What Federal Agencies are the Primary Players? - The Office of Science and Technology Policy (OSTP) is an Executive Office of the President and advocates for effective and productive Science policy. OSTP officials have engaged actively with COGR, as well as with APLU, AAU, and the FDP over the past year. The Office of Management and Budget (OMB), also an Executive Office of the President, will play a central role in any reform efforts. How to approach OMB will be determined based on strategic discussions between COGR, APLU and AAU.

What is the Role of the Rate Negotiating Agencies in this Process? - The Division of Cost Allocation (DCA) and the Office of Naval Research (ONR) undoubtedly will be consulted by OSTP and OMB if any of the proposed reform initiatives gain traction. While the DCA and ONR are not policy making entities, their expertise in cost reimbursement issues is respected throughout the Federal community.

What is the Role of the COGR Membership in this Process? - The COGR Membership has always been responsive and available to calls for survey data or anecdotal information. We may need to call on the membership on selected occasions for help. Providing education and information, as well as dispelling rumors, across your campuses also is helpful. Note there is no single, predictable path to engaging Federal officials, so there could be "stops" and "starts" along the way. And finally note, our colleagues at APLU and AAU strongly suggest that the productive path is through OSTP and OMB, rather than engaging Congress. While Members of Congress and Congressional Staff often are very supportive and friendly to the research community, many of the nuanced issues related to F&A/Compliance Reform are best addressed through OSTP and OMB.

What is COGR's Role in the Reform Initiatives? - COGR works closely with APLU, AAU and the FDP on a number of issues. As both APLU and AAU are President's organizations, COGR often complements them with the "front-line" expertise on all costing and compliance issues, and this is the case as we move forward on F&A/Compliance Reform. COGR is well-respected by Federal officials and agencies, which allows us to gain instant credibility on all analysis and technical points for consideration. Furthermore, we are poised to provide input to the National Academies Study on Research Universities.

What Specific Tasks and Policy Reform Ideas are Being Considered by the COGR Costing Policies Committee? - The Thursday sessions at the June Meeting were incredibly helpful in terms of getting input from the COGR membership. Active engagement with APLU and AAU during the past four months, as well as participating in several meetings with Federal officials, also have helped shape our perspective on the most effective policy areas on which to focus. Over the next six months, COGR and the Costing Policies

Committee may target a series of short, policy-based white papers that serve as advocacy and educational material. Some of the areas COGR may focus on include:

1. **Compilation of "Rogue" Agencies and Programs**, with an emphasis on documenting examples of caps and cost-sharing that carry the most financial burden.
2. **Implementation of a New Compliance Cost Pool**, assuming efforts to address the 26% cap are unsuccessful.
3. **Feasibility of Direct Charging Research Specialists** and how this can be reconciled with current practices on direct charging administrative support.
4. **Documenting Administrative Efficiencies** – can demonstration of cost savings and administrative efficiencies enhance our advocacy efforts?
5. **"De-coupling" F&A Application to Awards from the Recovery Mechanism/Use of F&A Reimbursement** – is there value in developing a user-friendly explanation describing how these two processes should be viewed as separate processes?
6. **Advocacy for Extension of the 1.3% Utility Cost Adjustment (UCA)** to all Institutions, with an understanding that excluding institutions is inherently unfair.
7. **Improving the Rate-Setting Process with DCA and ONR** – is there an opportunity to engage DCA and ONR on better models for establishing F&A rates?
8. **New Financial Research Models** – if it is true that the "research partnership" has disintegrated into a "contractual" relationship, does this suggest the need to advocate for new financial models?

We encourage feedback, especially as it relates to these Tasks and Policy Reform Ideas being considered by the COGR Costing Policies Committee. If you have unique insights on any of the topics addressed above, please contact COGR staff.

Is there a Timeframe and How Realistic are the Prospects for Reform? - The next twelve months are important. The Obama Administration and OSTP are engaged now, though one year from now many at the Administration level will turn their attention to "re-election" mode. Peter Orszag, the Director of OMB, announced that he will be leaving the Administration – this is a slight set-back in that Mr. Orszag was knowledgeable about our concerns and his departure could create some uncertainty at OMB. However, this slight set-back clearly does not derail our initiatives. The timing on the National Academies Study on Research Universities is ideal and should help maintain momentum. While it is difficult to predict how realistic the prospects for reform are, there is consensus among many leaders in the research community that now is the best opportunity we have had in many years to address F&A/Compliance Reform.

2. NIH Policy on F&A Reimbursement for Genomic Array Purchased Services

On May 13, 2010, the NIH policy announced a new policy for F&A reimbursement on Genomic Array (GA) purchased services. The new policy appeared to originate from concerns at several NIH Institutes and Centers that GA activity comprised a significant portion of NIH award budgets, and after the full F&A rate was applied to GA activity, the financial impact on the award budget was unacceptable.

The new policy, to be applied prospectively to new commitments established by competing awards and by administrative supplements, states that GA purchased services are to be treated more like a subcontract where essentially only the first $75,000 (on an annual basis) of GA purchased services are eligible for F&A recovery. The new NIH policy can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-097.html

COGR strongly opposed the new policy in a letter to NIH. We objected on a number of levels, including: 1) the inconsistency of the new policy with standard Circular A-21 cost principles, and 2) the poor precedent this action would set for how policy is made by Federal agencies. The NIH notice references section G2 of Circular A-21 that states: "*Other items may only be excluded where necessary to avoid a serious inequity in the distribution of F&A costs*." While COGR understands that certain cost items disproportionately generate F&A, the entire F&A rate calculation process is premised on an "averaging concept" designed to normalize the variations across different programs and cost items. If unchecked, this language from section G2 could be used (and abused) regularly by an agency to circumvent paying F&A costs.

The COGR letter is posted on the COGR home page at www.cogr.edu, and can be found under the link titled: "May 27, 2010 - Letter to NIH on Genomic Arrays Policy. A number of you have shared with COGR the letters your institutions have sent to NIH. We encourage you to email or fax letters to Sally Rockey at NIH: Sally Rockey, Acting Deputy Director for Extramural Research (sally.rockey@nih.gov or fax to 301-402-3469). Any references of support from faculty members may also be helpful.

COGR staff is scheduled to meet with NIH representatives concerning this topic in mid-July. We will keep the COGR membership posted on important developments.

3. Department of Energy (DOE) and ARRA Reporting Requirements

In the COGR April Update (dated April 23, 2010), we reported on the status of the DOE Proposed ARRA Emergency Information Collection Activities. Between late March and early April, DOE posted at least four almost-identical requests in the Federal Register. Each DOE notice came from a different DOE administrative or program office and had a consistent theme: DOE requests for approval from OMB to formally expand ARRA data collection. Each notice sought approval for monthly reporting in addition to the quarterly reporting already required in the ARRA legislation.

COGR, as well as many of your institutions, responded to one or more of the Federal Register notices. Some of the points we made were that the proposed emergency collection of information by DOE would create additional administrative burdens for Research Universities; inappropriately label programs managed by research universities as "high risk" programs; and due to the non-specific nature of exactly what the emergency collection of information entailed, create an open-ended "blank check" for DOE to ask for unlimited information. A copy of the first letter sent to DOE can be found on the COGR home page at www.cogr.edu (see the link for "Latest News, April 9, 2010 – DOE ARRA Funded Programs").

COGR contacts at OMB, including the lead for the OMB Recovery Team and the DOE Desk Officer from the OMB Office of Information and Regulatory Affairs (OIRA), have verified that

there are only several DOE programs where OMB has approved emergency data requests, including: CFDA 81.041 – State Energy Program, CFDA 81.042 – Weatherization, and CFDA 81.128 – Energy Efficiency Block Grants. Beyond the selected programs where there has been approval, additional reporting or monthly reporting is not required and OMB representatives confirmed that your institution should "push back". In the specific case of ARPA-E requests for additional reporting or monthly reporting, we were told by our contact at OIRA that ARPA-E would be providing a clarification notice that may be helpful. However, we were also told ARPA-E may post a new Federal Register Notice for emergency collection of information, which again may necessitate comment letters from COGR and your institutions. Unfortunately, this issue refuses to die.

Also, some DOE programs are sending automated messages that reporting for the next ARRA reporting cycle is due on July 7th, rather than the FederalReporting.gov extended deadline of July 14th. COGR's contact from the OMB Recovery Team suggested that these actions are in response to OMB's Memorandum M-10-17 (dated May 4, 2010) that instructed Federal agencies to me more aggressive in addressing recipient non-compliance. In the case of reporting by July 7th, this appears to be an example of a program/agency over-reacting to the OMB memorandum, and consequently disregarding the official guidance on FederalReporting.gov. While we realize the conflict in messages puts the institution in an awkward position, COGR's discussion with OMB representatives confirm that the reporting deadlines posted on FederalReporting.gov represent the official reporting deadlines.

If there are situations that arise related to DOE ARRA reporting that you believe require OMB intervention, contact COGR staff and we can provide you with OMB and/or OIRA contact information.

4. ARRA Reporting and Audit Updates

The fourth cycle of ARRA Section 1512 reporting begins on July 1st – the announced reporting deadline extension is described below. There are several other topics we continue to follow, including audit-related issues.

Reporting Deadline Extended to July 14th. The reporting deadline for the July reporting cycle has been extended to July 14th. ARRA reports can be submitted as late as July 20th, but will be flagged as "late" reports after July 14th. The "Reporting Timeline" for the July reporting cycle can be found on FederalReporting.gov.

Best Available Data. With a June 30 fiscal year end date for many of your institutions, the July reporting cycle may prove to be the most challenging. While "best available data" has been discussed in several different contexts over the past year, one clear benchmark is to provide data that is accurate on the reporting date and serves the accountability and transparency statutory requirements of ARRA. Institutions should continue to follow their documented and internal practices that have been used in the prior ARRA reporting cycles.

Construction Grants. NIH, NSF, and NIST have awarded construction grants. Compliance requirements specific to Buy American and Davis-Bacon wage rate provisions are applicable. Jobs reporting is required and corresponding reporting expectations at the

general contractor and subcontractor level is relevant to how your institution reports required data elements. If there are concerns related to construction grants, please contact COGR staff.

Continuous QA Period and Agency Request. We are tracking any potential Agency guidance that concerns the "Continuous QA Period". Our understanding is that the Continuous QA Period creates challenges for the agencies when recipients make corrections – i.e., there is not an effective process in FederalReporting.gov to notify the agencies of what data has changed and agencies have to perform multiple checks on recipient data each quarter to monitor the corrections. Consequently, some agencies are requesting that grantees make changes only in regard to significant errors that have been communicated to grantees by the agencies.

FederalReportng.gov Functionality – Congressional District (CD) Data Entry. In a discussion with a representative from the Recovery Accountability and Transparency Board (note, the RATB is responsible for technical management of FederalReporting.gov), it was explained to COGR that "address" and "place of performance" can be differentiated and that the correct CD can be accommodated in FederalReporting.gov. If there are concerns related to CD data entry, please contact COGR staff.

Submitting Final Reports. OMB Updated Guidance from March 22, 2010 (M-10-14) addressed when a recipient should indicate it is submitting a "Final Report" (item 5. per M-10-14). In addition to OMB's responses in M-10-14 (i.e., award period has ended, and all ARRA funds have been received, and the project status is complete, or the award has been terminated / cancelled), OMB (and the RATB) have provided additional guidance to the agencies to help determine if a report is final. A Federal official shared the following: *The RATB has indicated that they want those reports to be closed out properly on FederalReporting.gov meaning – Recovery funds have been received with Award Amount equal to received/expended, Project Status is 100% complete, Final Flag is marked as Yes. The RATB will not allow agencies to change data on the reports but would prefer that recipients change the data on their submissions to reflect accurate reporting status.*

Auditing ARRA: NSF, Education, Energy, NIH. The most active audit activity from the University perspective is coming from the NSF Inspector General (IG). The February Meeting Report contained a detailed update on the NSF IG audit approach taken to-date, and it appears that many of those areas described in that report are still applicable. The Department of Education IG has initiated audits of State Fiscal Stabilization Funds in all 50 states; half of those audits are on-site and the other half are desk audits. The Department of Energy IG also has initiated audits at several universities, while the Department of Energy, Office of Science has conducted an ARRA program review at one institution. The Department of Health and Human Services IG, responsible for auditing NIH programs, has not yet focused on NIH award recipients. Their focus has been on Head Start and Community Health Center programs, and we expect NIH-related audits to begin later this year or early next year.

Circular A-133 Compliance Supplement – Draft Version Available. Normally, the Circular A-133 Compliance Supplement is available in March or early April. We are still

awaiting its official release, which will include ARRA audit guidance to A-133 auditors. However, a "draft version" is available through the AICPA web site. It can be found at: http://www.aicpa.org/InterestAreas/GovernmentalAuditQuality/Resources/Pages/Draft2010ComplianceSupplement.aspx

If there are situations that arise during the ARRA July reporting cycle that you believe require OMB intervention, COGR can provide you with OMB contact information. Furthermore, some situations may be more appropriate to address through the Recovery Accountability and Transparency Board (RATB). In these situations, COGR can provide you with RATB contact information.

5. Other Costing Developments and Discussions

There are several other items that are either ongoing issues that we are following or that represent more recent issues that have been raised by the membership.

DOD 35-percent F&A Limitation. This statutory requirement remains in effect under the FY2010 DOD Appropriations Act. As it relates to the FY2011 appropriations legislation, there is an interest on several levels to eliminate the DOD 35-percent F&A limitation. As this process unfolds, we will keep the membership posted.

GAO Study on F&A Costs and Cost Reimbursement. The GAO is close to finalizing their study of F&A costs and reimbursement – the study initially was called for by the House Armed Services Committee in response to the DOD 35-percent F&A limitation. One area that the GAO was asked to review, but most likely will not be addressed in the final report, is a comparative study of Private Industry rates. We will update the membership upon release of the final report.

NSF Survey of R&D Expenditures. COGR responded to the March 26, 2010 Federal Register (Volume 75, FR14633) request for comments on the redesign of the NSF Survey of R&D Expenditures (to be renamed the Higher Education R&D Survey). Beginning with the FY2010 survey cycle, the redesigned survey will be in effect. A copy of that letter is available upon request.

NSF Salary Policy. We included a summary of COGR concerns with the NSF Salary policy in the COGR April Update (dated April 23, 2010). In the April Update, we concluded that the long history behind the NSF salary policy is wrought with confusions and inconsistencies. The "old" 2/9ths summer rule and the revised 2-month rule both suggest an artificial "cap" that is administratively cumbersome, is out-of-line with other agency salary policies, and serves little purpose from a scientific standpoint. While the policy revision in January 2009 was helpful on some fronts, many of the same confusions still exist. How best to address this issue with NSF and/or the National Science Board (NSB) is under consideration, and we will keep the membership update on any developments.

RESEARCH COMPLIANCE AND ADMINISTRATION

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

1. NIH Proposed Financial Conflict of Interest Policy

The discussion of the Department of Health and Human Services' (HHS) Public Health Service (PHS) proposed amendments to the regulations outlining the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contracts – also known as the National Institutes of Health (NIH) Financial Conflicts of Interest policy – offered a rich reservoir of ideas for the comment COGR will prepare. Comments on the proposed rule (published in the Federal Register on May 21, 2010 – 75FR28688) are due by July 20, 2010. Throughout this discussion we will refer to the proposed amendments as the "rule." We recognize these are amendments to regulations and are considered by the community as a policy. It is important to recognize that this is a Public Health Service (PHS) regulation as opposed to a NIH policy. We will reference actions by the PHS in this discussion as appropriate.

As highlighted during the discussion, COGR will focus on those elements of the proposed rule that will make fundamental changes to the operation of institutional efforts to identify and manage financial conflicts of interests. Based on discussions with NIH since the release of the Advanced Notice of Proposed Rulemaking in May 2009, some of the changes are considered critical for successful oversight and monitoring and are likely to be retained in the final rule. For example, we expect the proposed new thresholds for identifying significant financial interests (SFI - $5,000 in remuneration and equity holdings in a publicly traded company; $0 equity in a non-publicly traded company) will be a part of the final rule. We are grateful there is a threshold given other proposed changes. The shifting of responsibility from the investigator to the institution for making a determination of whether the SFI is related to the PHS-funded research addresses concerns about our ability to manage financial conflicts raised by the public, Congress and the Government Accountability Office (GAO) and will remain in a final rule.

While we are relatively confident some components will not change in the final rule, we are equally confident we can have an impact on the shape of other parts of the proposed rule and will raise some critical questions that we believe should be addressed before PHS implements the new rule. Among the general questions or comments COGR will raise is how some of the proposed revisions address the basic goal of the rule to ensure objectivity in research and will remind PHS that the changes proposed should be viewed through the lens of objectivity.

We will suggest that the proposed stipulation of more stringent institutional standards as the prevailing standards for disclosure, reporting and management may have the unfortunate effect of forcing institutions to modify their policies to match the proposed PHS standards. Institutions that may want to identify and evaluate financial interests and relationships with a risk-based approach to allow a sharper focus on higher risk research like clinical trials may feel constrained to implement that approach.

We will ask PHS to describe how the submitted reports will be assessed. We understand that the current practice is a review by the NIH Institute/Center (I/C) program officer. Will the process of review under the new policy change? If the I/C program officers will retain the responsibility, how will they be trained to ensure consistent reviews across the agency? Will NIH prepare guidelines consistent with the proposed rule and provide the affected communities an opportunity to comment on those guidelines?

We will challenge PHS's Regulatory Impact Analysis, a required part of any proposed amendments or new rules under the Unfunded Mandates Reform Act of 1995. Agencies must assess whether the proposed action will result in expenditures of more than $142 million in any one year for the affected entities. Admittedly, the threshold for financial impact is high but we believe the costs of some of the changes far exceed any benefit to objectivity in research and must be reassessed. PHS builds on an estimate that 40,500 investigators at 5,000 institutions will have SFI that may fall under the policy. This approach ignores the total burden of the policy. To identify those investigators with SFI related to research, the new rule will require disclosures from all investigators. As the proposed rule shifts to disclosures related to institutional responsibilities as opposed to research exclusively, institutions will likely see a greater number of disclosures. The costs associated with this review and other parts of the proposed policy – notably the $35 per institution, per year to implement and maintain the web postings – do not reflect the real costs.

In terms of the operational requirements and associated definitions, COGR will request changes and/or clarification on a number of issues. There is general concern about the prime awardee's responsibilities with regard to sub awards particularly those to foreign entities. An institution's ability to assess and monitor compliance to a US standard will be difficult; equally difficult will be requiring the investigators at that foreign entity to fall under the US institution's policies. The seemingly simple shift in the rule from disclosures based on anticipated income in the next 12 months to disclosure based on the preceding 12 months as a baseline is a problem. It requires disclosure of SFI that may no longer exist but, under one reading of the proposed rule, may need to be managed and posted to the web site for five years.

The required posting "via a publicly accessible web site" of financial conflicts of interest information and maintaining those posting for five years from the last update of that information is certainly one of the most significant and unanticipated proposed changes. PHS asks for alternatives to the approach outlined in the proposed rule. COGR will question the value of such a posting in terms of ensuring objectivity in research but welcomes from the membership any alternatives that can be proposed to PHS in the comment letter.

A number of definitional changes deserve attention. The lifting of the exemption from disclosures of remunerations from non-profits is a problem because it sweeps all non-profit

sector service (and health-related research) under the rule. This change is particularly problematic as travel reimbursement is no longer exempted from disclosure. Those investigators who serve on advisory or review panels for professional organizations and/or journals who are reimbursed for travel and related costs by the organization will need to report the reimbursement if the value exceeds $5,000. While most of this service is unlikely to be related to the PHS-funded research but may be linked by institutional responsibilities, institutions will have to review the disclosure for significance. The use of phrases like "reasonably appear" (in assessing whether SFI is related to institutional responsibilities) introduces a level of ambiguity that is not necessary. Such a phrase can be reworded to state "is related" and serve the same purpose. These and other questions will be raised in a comprehensive comment letter from COGR.

At the Thursday morning session we invited the membership to offer a timeline for implementation. NIH does not propose an effective date. If we were to propose a timeline, what would be the date for full compliance assuming the final rule (issued by September) is as proposed (all requirements intact)? Should the timeline be staggered? For example, can the annual disclosures and enhanced reporting to NIH be implemented first (within one year of final rule) and the investigator training and database within two/three years?

Our goal is to provide the membership with a draft comment letter early in July. We believe that institutions should consider sending a letter that highlights concerns from the institution's perspective and includes estimates of the number of disclosures that will require review and the costs of implementing the rule as proposed.

As noted, we welcome your suggestions on alternatives to the prescribed web posting and a reasonable timeline for implementation of the rule (cblum@cogr.edu).

2. NIH Review of Financial Conflict of Interest Policies

Some COGR member institutions have reported receiving a very recent letter from NIH noting that the institution has been selected for a review of compliance with the **CURRENT** *Responsibility of Applicants for Promoting Objectivity in Research* – the financial conflicts of interest policy (FCOI). NIH is required to provide oversight of the extramural community and this request for policies is one mechanism NIH uses in the oversight process.

The letter from Diane Dean, Director of the NIH Division of Grants Compliance and Oversight in the Office of Extramural Research, requests a copy of the institution's FCOI policy "and other related documents that demonstrate full implementation" of the NIH policy. If your institution's policy relies on a separate procedures document to fully implement the NIH policy – if your institution's policy is general in nature and commits to meeting the unique requirements of a particular Federal agency's policy – you may have a procedures document that outlines how you meet the specific requirements of the NIH policy. The letter asks for information on "how your institution has managed any instances of investigator non-compliance." The **CURRENT** NIH policy requires you to have "adequate enforcement mechanisms and provide for sanctions where appropriate."

If you have had such an instance of non-compliance, answer in the affirmative. An institution may rely on general policies for addressing faculty/staff failures to perform their duties or comply with all institutional policies – including the institution's FCOI policy. If that is the case, you should describe that process (not the particulars of the incident). If you have had no instances of non-compliance with the NIH FCOI policy, you should note that in your response.

Finally, NIH asks if you'd like to share your institutional (as opposed to individual) FCOI policy, if you have developed such a policy. Share; don't share – that's your decision. There is no Federal requirement for an institutional financial conflicts of interest policy. If you are in the process of developing a policy that remains in draft form, you may not want to share the draft to avoid any confusion at a later date concerning what materials may be available for review by interested parties.

3. NIH Vertebrate Animal Section Review

We continued our discussion with NIH concerning the review of the Vertebrate Animal Section (VAS) as a follow-up to a letter COGR sent to NIH in March asking for clarification on the roles of the Scientific Review Groups (SRG) and the institutional IACUC. The meeting preceding the June COGR with the Research Compliance and Administration (RCA) Committee followed a smaller meeting with the NIH Office of Extramural Research, Office of Laboratory Animal Welfare and Center for Scientific Review staff member. The focus of the COGR letter and discussion is the role and added value of the SRG review. We expressed our concern that investigator could receive conflicting reviews from the SRG and IACUC and resolving those conflicting reviews may lead to undermining the investigator's confidence in the IACUC. We suggested that the vaguely worded assertion that the SRG review "may affect the priority score" would push conscientious investigators to submit their animal protocols before submitting the application thus undermining just-in-time efficiencies implemented by NIH.

NIH is attempting to address two related issues: incomplete or missing VAS sections in applications and inconsistent review of the VAS by the SRG. We urged them to be more precise in the description of the roles of the IACUC and SRG– the former reviews and approves Animal Welfare issues (veterinary care, etc.); the latter, scientific questions. We urged them to indicate clearly and unambiguously those situations that would affect the priority score – missing or incomplete sections – and move comments or questions from the SRG to a discussion that follows the scoring and are included as an administrative note to be resolved before funding – just-in-time. We will continue this discussion with NIH and expect further clarification to be issued by NIH.

4. USDA's Age of Enforcement

The US Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) recently announced a new **Age of Enforcement**. In what is described as an effort to provide more fair and consistent inspections across the country and to change the perception that the USDA is lax in its enforcement of the Animal Welfare Act, APHIS has revised the Inspectors Requirements with a series of attachments that include instruction for citing entities for non-compliant items. Institutions will want to review the new Inspection Guidance. Institutions will likely see more citations and, because APHIS tiers the facility according to "repeat violations"

more enforcement actions that will require more time in preparing responses. In addition to reviewing the Inspection Guidance, institution will want to review again the guidelines for responding to citations. Our colleagues in NABR (the National Association for Biomedical Research) will be monitoring the implementation of this new age and we encourage NABR member institutions to report to NABR any patterns of citation, changed interactions with inspectors, etc.

As part of the effort to "move more swiftly and consistently to take enforcement action in response to animal welfare violations, and to make its actions transparent and accessible to the public," the USDA/APHIS is issuing monthly press releases that highlight enforcement actions taken in response to violations of the Animal Welfare Act (AWA) and Horse Protection Act (HPA). The posting of enforcement actions follows the posting of Inspection Reports for research facilities beginning in November 2009. Copies of the Inspection Guidance, related attachments, press releases on enforcement, etc., can be found on the USDA/APHIS Animal Welfare website at: http://www.aphis.usda.gov/animal_welfare/index.shtml . The Inspection Reports are available from the USDA/APHIS homepage at http://www.aphis.usda.gov/ and click on FOIA Reading Room.

5. Clinicaltrials.gov

It's all about timing. You will recall that the Food and Drug Administration Amendments Act (FDAAA) of 2007 expanded the NIH's National Library of Medicine (NLM) clinical trials registry and results database known as ClinicalTrials.gov and set new requirements for trials supported in whole or in part by NIH funds. The NIH implementation requires: 1) the registration of "applicable clinical trials" in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; 2) the reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA; and, 3) for an "applicable clinical trial" funded in whole or in part by an NIH grant or cooperative agreement, grant and progress report forms shall include a certification that the responsible party has made all required submissions. This simple description of the requirements is incomplete and any one conducting a trial with NIH support should review the information available on the NIH web site at: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm .

Investigators who hold Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) or have been designated the "responsible party" by the sponsor of a trial that began on/after September 27, 2007 (please review information on applicable trials – there are numerous caveats to this date) were required to register the trial at Clinicaltrials.gov and, one year after completion of the trial, provide the required report. Some of those reports are coming due.

Some investigators have found that they did not collect the information needed in a manner that facilitates the completion of the report. Others have found that the completion of the report takes more time than they anticipated. We urge institutions to remind their investigators of their

responsibilities for reporting in Clinicaltrials.gov and to review the reporting instructions before they begin to ease the process of reporting.

6. NSF to Change Data Sharing Policy

In a May 10 press release following the May 2010 National Science Board meeting, National Science Foundation officials "announced a change in the implementation of the existing policy on sharing research data. In particular, on or around October, 2010, NSF is planning to require that all proposals include a data management plan in the form of a two-page supplementary document. The research community will be informed of the specifics of the anticipated changes and the agency's expectations for the data management plans." The release goes on to note that "the changes are designed to address trends and needs in the modern era of data-driven science. "

COGR will look for and alert the membership to changes in policy on sharing research data. The current NSF Award & Administration Guide (as part of the PAPP) requires investigators "to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections and other supporting materials created or gathered in the course of work under NSF grants." The NSF Grant Proposal Guide identifies data management and sharing – the "development and/or refinement of research tools; computation methodologies, and algorithms for problem-solving; development of databases to support research and education" – as examples of the broader impacts of proposed research.

7. ILAR Updates Guide for Laboratory Animals

The National Academies' Institutes for Laboratory Animal Research (ILAR) made available in early June a pre-publication edition of the 8th edition of the National Research Council's *Guide for the Care and Use of Laboratory Animals*. Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals requires that institutions base their programs of animal care and use on the Guide. NIH published a notice on June 4 (NOT-OD-10-102) acknowledging the pre-publication edition clarifies that "until the 8th Edition of the Guide is published in its final form, the 1996 Edition will remain the official Guide for the purposes of implementation of the PHS Policy." NIH's Office of Laboratory Animal Welfare (OLAW) "will issue guidance on implementation of the 8th Edition of the Guide after it is published."

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

We will notify the membership when the NIH OLAW guidance is available.

CONTRACTS AND INTELLECTUAL PROPERTY

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

1. Commercialization of University Research Receives Much Attention

A) Administration Activities and Responses of the Higher Education Associations

The Administration is focusing much attention on programs and initiatives to increase commercialization of university research. We sent the COGR membership the Joint Higher Education Association Response to the Office of Science and Technology Policy (OSTP)/National Economic Council (NEC) Request for Information on Commercialization of University Research (it was sent along with the May 2010 Recent Developments report and also is available on the COGR website).

At its June meeting the CIP Committee met with Robert Samors, Associate VP for Research, Innovation and STEM Education of the Association of Public and Land-Grant Universities (APLU). He described the activities of the APLU Commission on Innovation, Competitiveness and Economic Prosperity (CICEP). CICEP is seeking to develop new approaches for measuring and describing university contributions to regional innovation and a self-assessment tool for use by institutions to gauge their policies and practices in this area. Currently 12 campuses are participating in piloting the institutional assessment tool and more are welcome. APLU also has developed recommendations for federal programs to accelerate innovation and economic growth by creating additional linkages between universities, entrepreneurs and companies (regional university centers, business engagement centers); accelerating innovation/commercialization (innovation grants, gap funding, innovation networks, entrepreneur-in-residence programs, etc.); accessing human capital; and funding innovation infrastructure for "hollowed out" communities. (For more information see http://www.aplu.org/NetCommunity/Page.aspx?pid=265).

Mr. Samors noted that the issue of appropriate metrics to assess university contributions to regional economic development continues to receive much focus. A survey of participants in an NSF-funded metrics workshop last year identified a number of potential new measures: progress over time of companies started with university IP; faculty/staff consulting with industry; alumni employment paths/progress; university investments in technology transfer/commercialization; and impacts on industry of university research or

technical assistance. NSF is interested in further exploring such measures but has backed off plans to duplicate collection of certain AUTM survey data. AUTM also has a New Metrics project closely linked to the APLU activities, and the OSTP STAR Metrics project also plans to collect certain related data (see General COGR Meeting Report Discussion).

The Commerce Department is planning to host a series of regional campus-based forums this summer with a similar theme to the invitational forum held in Washington last February on the role of universities in innovation, economic development, job creation and commercialization of federally funded research (see COGR February 2010 Meeting Report). AAU and APLU are assisting Commerce in planning for the regional forums, as they did with the February forum. The product of these forums will be recommendations to the Commerce Secretary as to actions that the government might take to improve university commercialization of federally funded research. It appears that planning for these regional forums to date has been somewhat haphazard (as it was for the February forum).

In discussion with Mr. Samors CIP members expressed concern about the coordination of these various activities. Apparently Commerce is participating in a review team to review the hundreds of pages of responses to the OSTP/NEC RFI, so there does appear to be some coordination. The Administration is intensely interested in this area and there appears to be common engagement across agency lines. However, university representatives need to continue to stress to government officials that these commercialization activities must not come at the expense of the federal government's priority role in supporting university fundamental research.

B) Congressional Hearings

Two hearings are being held on university technology transfer by subcommittees of the House Science Committee. The first was a hearing held on June 10 by the Subcommittee on Research & Science Education on "From the Lab Bench to the Marketplace: Improving Technology Transfer." See http://science.house.gov/Publications/hearings_markups_details.aspx?NewsID=2855

The panel of witnesses consisted of Dr. Thomas Peterson, Assistant Director of the Directorate of Engineering at the National Science Foundation, Lesa Mitchell, Vice-President of Advancing Innovation at the Ewing Marion Kauffman Foundation (and a panelist at our February COGR meeting), Wayne Watkins, Associate Vice President for research at the University of Akron, Keith Crandell, co-founder and managing partner of ARCH Venture Partners, Mark Crowell, Executive Director and Associate Vice President for Innovation, Partnerships and Commercialization at the University of Virginia, and Neil Kane, President and Co-founder of Advanced Diamond Technologies, Inc. Committee members present were Committee Chair Bart Gordon (D-TN), Subcommittee Chair Daniel Lipinski (D-IL), Representative Marcia Fudge (D-OH), Representative Brian Baird (D-WA), and Subcommittee Ranking Member Vernon Ehlers (R-MI).

The purpose of the hearing was to look at the effectiveness of the transfer of research innovation and technology from universities to the commercial market. The panel of witnesses agreed that more comprehensive measures than the traditional AUTM data were necessary to more accurately gauge the effectiveness of technology transfer. The panel also recommended urging universities to be supportive of faculty and graduate students in their entrepreneurial endeavors and establishing a stronger support structure for teaching business related skills.

Questions focused on the role of American workers in innovation; international competitive challenges; whether the internal reward structures within the academic community properly incentivize discovery and innovation; what universities and organizations like the ones represented on the panel can do to facilitate a better environment for entrepreneurs and start-up businesses; the role of education; and what makes for an effective university tech transfer office. Rep. Fudge asked the panel for views on the Kauffman faculty ownership proposal (skepticism was expressed by one panel member) and whether the Kauffman recommendations are data-driven (Ms. Mitchell responded that Kauffman has collected many stories from faculty members about problems).

Rep. Gordon expressed some skepticism about Star Metrics and a fear that such a manner of reporting progress and results might provide a disincentive for basic research. He also asked if there was a time frame for testing and further evaluation. A member of the panel acknowledged that it was easier to make evaluations when looking at applied research because there are usually more tangible results. An evaluation report is expected later this summer.

Rep. Baird stated that he felt much research done at universities leads to “so what” reactions that the academic community often answers with rationalization and excuses rather than legitimate explanations. He asked if there had been an analysis of the criteria for promotion and tenure at major universities. The panel said that it would be dangerous to tie patents to a professor’s ability to get tenure, as that would likely result in over-patenting. Rep. Baird asked the panel what their thoughts were on an amendment that was recently voted down that would restrict NSF funding to citizens of the United States. The panel unanimously agreed that this would be a poor decision.

The second hearing will be held by the Subcommittee on Technology and Innovation with a focus on the Bayh-Dole and Stevenson-Wydler Acts. Our information is that the purpose is primarily member education with no particular agenda. As of this date the hearing has not yet been scheduled. We will keep the COGR membership informed.

C) House Democratic Caucus Task Force on Competitiveness Holds Forum

On June 15 the House Democratic Caucus Task Force on Competitiveness held a Congressional Forum on U.S. Economic Competitiveness. There were three panels: Transitioning from R&D to Commercialization; Reinvigorating Manufacturing; and Supporting Emerging Industries.

The leadoff presentation for the first panel was by John Ritter, Director of the Office of Technology Licensing and Intellectual Property at Princeton University and a member of the COGR CIP Committee. Mr. Ritter provided background on university tech transfer; discussed the challenges associated with the early stage nature of university inventions; provided data on the success of university tech transfer and the Bayh-Dole Act; and reviewed several of the suggestions in the joint association response to the OSTP/NEC RFI on Commercialization noted in 1.a. above. Other panelists discussed the role of venture capital and related university programs. The second panel featured a discussion by Deborah Wince-Smith, President of the Council on Competitiveness (CoC) of the new CoC Manufacturing Initiative which is to be rolled out on June 23. (We did not sit in on the third panel).

The session was well-attended by Caucus members, with at least six present for most of first and second panel discussions. Member questions centered around the proper role of the federal government and responsibilities at the federal level for programs related to fostering and encouraging innovation. Clearly there is keen Congressional interest in this topic.

D) NAS Committee on University IP Management

We have reported a number of times on the activities of this committee in COGR Updates and Meeting Reports. We understand that the final report now is undergoing NAS peer review. It is expected to be released sometime in the late summer. The report is likely to receive more visibility than it might have had it been released on the original schedule last year, given the current Administration and Congressional focus on this area.

2. Supreme Court Action Awaited in Stanford *v.* Roche Appeal

As discussed in the April COGR Update, COGR has joined other higher education associations and forty universities in an amicus brief urging the Supreme Court to grant cert on Stanford's appeal of the Federal Circuit decision. The brief emphasizes the government's interest in the case, since the Federal Circuit decision seems to threaten the government's rights under Bayh-Dole and calls into question universities' ability to achieve successful commercialization of federally-funded inventions, a key government policy objective. Two other university amicus briefs were also filed in support of Stanford's appeal. In its response brief, Roche asserted that the case involves an atypical factual situation which "is unlikely to recur, notwithstanding the insistence of Stanford and its chorus of *amici.***"** Roche also asserted that there is no issue of Stanford losing rights to the invention because of the assignment of rights to it by the other co-inventors, and that the case presents no issue of government patent rights.

We expect the Court to announce its response to the appeal by the end of the month. While it is considered unlikely that the Court will agree to hear the case, the hope is that the emphasis on the government's interests may cause it to ask the U.S. Solicitor General for her views.

3. COGR/NIH IP Roundtable Initiatives Proceed

The COGR June 2009 Meeting Report discussed an IP Roundtable established between COGR and NIH to discuss issues and concerns related to IP and tech transfer between NIH and research institutions. As an outgrowth of that activity, a working subgroup on Materials Transfer Agreements (MTAs) has been established. One initial focus of that group was to revisit the Uniform Biological Materials Transfer Agreement (UBMTA). However, 30 new institutions have signed on to the UBMTA in the past year, suggesting that it still is a viable document. As the working group continued discussions, it has begun to focus on a "suite" approach, consisting of the UBMTA, the Simple Letter Agreement (SLA), and a new self-contained letter not requiring recipient countersignature for transfer of low risk biological materials, somewhat analogous to a self-contained "shrink wrap" type of mechanism. We currently are discussing with the NIH representatives the minimum number of concepts that NIH feels should be reflected in such a document. NIH ultimately wants to move to an electronic system for materials transfers. The workgroup considered some other recent MTA streamlining initiatives, including the "treaty" approach developed by the "Little Eleven" institutions. One concern is the inability to track transfers made under the "treaty." NIH and at least some institutions feel that it is important to continue to track transfers, even in low risk situations, particularly when there are obligations or expectations associated with the transfer. The new approach under discussion would provide that capability. We hope to have a model available for discussion at the COGR October meeting.

As another outgrowth of the IP Roundtable, we had planned to have a session with NIH at this COGR meeting on data sharing, and the issues and obligations for institutions posed by NIH requirements for data sharing and data management plans. However, because of the strong interest in the proposed NIH conflicts of interest requirements being discussed at the same time, we decided to postpone the data sharing session until October, and also possibly broaden it to include the pending NSF requirements.

On one other matter related to the IP Roundtable, while COGR participated in the policy development process for the revised IP policy for the NIH Cancer Therapy Evaluation Program (CTEP), "Intellectual Property Option to Collaborator", we continue to have concerns about the revised policy announced by NIH in April. A copy of the COGR comment letter to NIH on the revised policy was attached to the May 2010 Recent Developments report sent to the COGR membership.

4. FDP Establishes Troublesome Clauses Website

The Federal Demonstration Partnership (FDP) recently opened a new phase of data collection on burdensome provisions appearing in federal awards, including those which would be considered Troublesome Clauses within the COGR/AAU definition, where agreements contain restrictions on publications and/or participation in research by foreign nationals. The initial phase, begun in July 2007, allowed members to (1) determine the frequency with which research institutions receive clauses in government contracts that require lengthy negotiation for acceptance or which are so burdensome that the contract cannot be accepted; and (2) enabled the FDP membership to more effectively and efficiently negotiate and execute contracts. As

previously reported, this initial phase included collaboration with COGR and AAU, where FDP gathered the data used for the COGR/AAU report entitled "Restrictions on Research Awards: Troublesome Clauses 2007/2008." The report documented that restrictions in research agreements persist, and that universities most often find publication restrictions and restrictions on the participation of foreign nationals. The report also revealed that Federal agencies have expanded the type of controls imposed in award terms and conditions, and are now including such terms in grants and cooperative agreements in addition to contracts.

As an extension to the data collection initiatives undertaken to write the COGR/AAU Troublesome Clauses report, FDP recently announced the launching of a new website (http://nrc59.nas.edu/clauses2/login.cfm) that will serve as a resource to the FDP membership (both research institutions and federal agencies) for improving grant and contract negotiations. The improved reporting functionality will also allow COGR/AAU to continually monitor the occurrence of troublesome clauses in university agreements.

All COGR members who are also members of FDP are encouraged to participate. (COGR will seek to assure the participation of the original 20 institutions whose experiences were the basis for the "Troublesome Clauses" reports). Members who participate will gain access to information regarding what a troublesome clause is and how to negotiate changes. It is expected that data collected will enable agencies to help research institutions troubleshoot issues as they are occurring. In addition, reports will be developed on topics such as types of restrictions faced, average completion times for specific issues, sponsors, and types of agreements.

The issue of whether a particular clause is "troublesome" sometimes may be situation-specific. We will continue to discuss with FDP the reporting of such situations. For example, it may be helpful to include all instances where institutions receive the DFARS 7000 clause (see below), even where the work performed is not considered fundamental research.

5. DOD Issues New Memo on Fundamental Research

On May 24 the DOD Undersecretary for Acquisition issued a new memorandum on Fundamental Research. The memo reinforces an earlier (6/26/08) memorandum on Contracted Fundamental Research and provides additional clarifying guidance. The intention is to assure that DOD fundamental research awards are "fully compliant with National Security Decision Directive (NSDD) 189."

The memorandum reiterates earlier guidance 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." Exceptions require high level DOD component management approval. Importantly the memo also recognizes that research performed with funds other than budget category 6.1 or 6.2 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…" Training and reporting requirements for DOD personnel also are included in the memorandum.

While we had been suggesting to DOD that reissuance of the earlier memo would be helpful, we understand that the immediate impetus for the new memorandum was a meeting between a group of AAU Presidents and Secretary Gates in April. However, it is essential that the essence of the memorandum be incorporated into the DOD Acquisition Regulations (DFARS), which did not occur with the earlier memo. We had long urged DOD to address the issue of subcontracted fundamental research, as in the quoted statement above. However, the existing prescription for use of the DFARS 7000 clause on Disclosure of Information is inconsistent with the new guidance in that it mandates flowdown of the 7000 clause restrictions regardless of the nature of the research. We plan to continue to work with DOD to assure that the new guidance is appropriately incorporated into the DFARS. Also, we urge COGR members to contact DOD/DDR&E as indicated in the new memorandum in the event they receive restrictions in fundamental research awards that conflict with the guidance. A copy of the memorandum may be found at http://www.aplu.org/NetCommunity/Page.aspx?pid=1644.

On May 28 DOD/ARO issued a solicitation (W911NF-10-R-0006) "DOD Research and Educational Program for Historically Black Colleges and Universities and Minority-Serving Institutions (HBCU/MSI) FY 2010" (http://www.arl.army.mil/www/default.cfm?Action=6&Page=8)). One of the terms of the solicitation was that "The principal investigator and/or any collaborator must be a U.S. citizen or permanent resident. Also, students selected for scholarships or other financial support must be U.S. citizens or permanent residents." COGR was contacted by a member institution who expressed concern that the restrictions were problematic and appeared to conflict with the new DOD memorandum. Subsequently other institutions contacted COGR with similar concerns. We encouraged the first institution to contact DDR&E directly. They did so and were informed that the restrictions would be removed. Subsequently ARO confirmed the removal based on the DOD memorandum. The amended version of the solicitation now has been posted. This is an encouraging development. It appears to confirm that DOD will require that its components adhere to the policy guidance in the memorandum.

6. Administration Continues Planning for New Export Control System

The COGR April 2010 Update summarized the Administration's plans for a new export control system. The system has four principal elements: a single export control list, a single licensing agency, a single enforcement-coordination agency, and a single information technology system. As noted, the plans would be implemented through a three-phased process over the next year. The first phase would involve the transition to the single list and single licensing agency. The second phase would complete the transition to a single IT structure, implement the new tiered control list, and move towards the single licensing system. These changes could be made through executive action. The third phase would involve legislative action to authorize the single licensing agency and single enforcement agency.

According to recent reports, the responsible federal agencies are getting close to agreement on a decision tree to filter, review and pare down the Commerce Control List (CCL) and the U.S.

Munitions List (USML). They are also close to agreement on a single license application form. Plans are also well under way toward establishing a single information technology (IT) system, which will be the current DOD IT system. The DOD system is the most modern, it already allows users to see both Commerce and State Department data, and Congress already set aside appropriations for this system to be applied to State, Commerce and Treasury. The Administration also is working on the blueprint for eventual legislation to create a single export control agency as part of the third phase of the export control reform effort. As we noted previously, the first two phases will be accomplished by regulatory changes alone, but the blueprint of the eventual phase three legislation is needed in order to structure the first two phases. The first step toward revising the USML is to convert it to a positive list of items, with only the "crown jewels" of U.S. military technology remaining on the list. Work is also being finalized on developing a common list of definitions of important export control terms such as what constitutes a "U.S. person" or an "export."

While these developments appear hopeful, a key question that remains unresolved is the agency home of the proposed new single licensing agency. The draft legislation may clarify that. The higher education community to date has not been directly involved in the reform process. We will seek opportunities to make our views known. Another website relevant to expert controls that was mentioned at the COGR meeting is http://www.securityandcompetitiveness.org/

7. OMB Issues Proposed Policy on Reserving Work for Performance by Government Employees

On March 31, 2010 OMB/Office of Federal Procurement Policy (OFPP) issued a proposed policy notice (75*FedReg*16188) to clarify when outsourcing of services is and is not appropriate. (The FY'09 Defense Authorization Act (Sec. 321) required OMB to create a single definition for "inherently governmental functions" and criteria to identify "critical" functions that should only be performed by federal employees).

The proposed policy notice essentially updates existing definitions based on the "FAIR" Act (Federal Activities Inventory Reform Act—P.L. 105-270) and OMB Circular A-76 guidance. Existing guidance recognizes a category of functions closely associated with inherently governmental functions where greater management attention and oversight of contractor performance is necessary. (Inherently governmental functions are those that involve discretionary exercise of government sovereign powers such as control of prosecutions, command of military forces and conduct of foreign relations). The proposed policy letter adds the concept of "critical" associated functions that are so important to an agency's mission and operations that the agency must retain a core capability to have them performed by federal employees. Examples given include designing the next generation of NASA satellites, analysis of IRS compliance burdens, and performing mediation services. In such instances case-by-case determinations must be made that agencies retain sufficient internal capability with additional outsourcing of such functions based on cost considerations.

In the proposed policy letter OMB asks a series of questions including whether there should be a presumption of performance of closely associated and/or critical functions by federal employees, how to differentiate critical and closely associated functions, and whether these categories should be merged and treated identically. OMB also asks about proper classification

of a number of specific functions including acquisition planning, the use of contractors to manage other contractors, management of federal grantees, and physical and cyber security services.

Comments were due June 1. COGR member institutions may occasionally perform "closely associated" types of services, perhaps on a subcontract basis. However, they do not appear to be heavily impacted by the proposed policy. For this reason we did not provide a response. However, we will follow and report on whatever policy changes ultimately are made.

8. DOD Proposes New Requirements for Organizational Conflicts of Interest

DOD was mandated by the '09 Weapons System Acquisition Reform Act (P.L. 111-23; Sec. 207) to provide uniform guidance and tighten existing requirements for organizational conflicts of interest (OCIs) by contractors in major defense acquisition programs. On April 22, 2010 DOD published its proposed implementation of this requirement (75*FedReg*20954).

The Panel on Contracting Integrity has been considering recommendations for changes in the existing FAR coverage (Section 9.5) on OCIs (ANPR; 73*FedReg*15962; 3/26/08). DOD is proposing to use DFARS 203.12 in lieu of FAR 9.5 to address this issue, but will incorporate the FAR once it is revised. The proposed DFARS provision provides definitions for types of conflicts that have been identified in recent GAO decisions and case law; clarifies the responsibilities of contracting officers; provides specific guidance on identifying OCIs; and on methods of resolution (avoidance, neutralization, and mitigation). It provides specific guidance on OCI concerns raised by task and delivery order contracts, including multiple award task or delivery order contracts (e.g. GSA Schedules). Specific restrictions are included for systems engineering and technical assistance contracts for major systems defense acquisitions, prohibiting contractors from participating in the development or construction of a weapon system under the program (such contractors may receive advice from independent sources such as FFRDC's).

The proposed DFARS OCIs provisions apply to contracts with both profit and nonprofit organizations, including nonprofits created with government funds. Thus they would apply to COGR institutions, particularly those with DOD University Affiliated Research Centers (UARCs) or FFRDCs. However, the types of OCIs identified in the proposed DFARS rule involve evaluations of products or services of competitors, access to non-public information that would provide an unfair competitive advantage in a later competition, or establishing ground rules for other government acquisitions, such as preparing statements of work or source selection criteria. These are not of significant applicability to COGR institutions. Also most of the proposed rule is addressed to the responsibilities of DOD contracting officers in identifying and resolving OCIs. The burden on the institution is one of disclosure of actual and potential conflicts at the time the time a proposal is submitted. The rule does not specifically require institutions to have an OCI policy in place. After consultation with a number of COGR institutions with UARCs, we decided not to provide specific comments.