

COUNCIL ON GOVERNMENTAL RELATIONS

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MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS

WASHINGTON MARRIOTT HOTEL

June 9 and 10, 2011

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GENERAL DEVELOPMENTS

1. Thursday Morning Session - Commerce/BIS Representative Discuss Export Control Issues

Bernard Kritzer, Director, Office of Exporter Services and Stephen Hall from Commerce/Bureau of Industry and Security (BIS) discussed deemed export compliance obligations and current issues and developments in export controls at a Thursday morning session. Mr. Kritzer indicated that prior to 1994 deemed exports required knowledge that the technology was being exported to a foreign national. However, the rule was changed because industry wanted a bright line for what constituted deemed exports (Note: pending legislation (HR 2004) would reinstate the requirement for knowledge or intent to export or transmit an item for a deemed export to occur). He noted that BIS grants 700-800 deemed exports licenses annually. There is only a 1% denial rate, and BIS acts on license applications with complete information in about 40 days. He reviewed various terms in the Commerce EAR regulations, noting the difference between Commerce and State on “nationality” (Commerce looks to a foreign person’s most recent country of citizenship; State to the history of the nationality of the person). He mentioned compliance issues that have arisen with universities e.g. use of controlled data and startups.

Regarding the I-129 certification (see COGR Winter 2010 Update and February 2011 Meeting Report), Mr. Kritzer indicated that the form was developed by the Department of Homeland Security with input from Commerce based on GAO criticisms of the low number of deemed export licenses granted to H1B visitors. Mr. Kritzer reiterated Kevin Wolf’s statement at the COGR panel in February that H1B petitions do not need to be amended if circumstances change subsequent to submission of the form (Note: the USCIS website includes a set of FAQ’s on the I129 deemed export certification requirement. While there is not an FAQ that addresses this point, it is included in Mr. Kritzer’s PPT presentation which we have posted to the COGR website). Mr. Kritzer discussed best practices for campuses, and indicated that a short questionnaire would be helpful for institutions to develop to comply with this requirement. Many COGR institutions have developed such a questionnaire.

Mr. Kritzer also reviewed the status of the Administration’s export control reform initiative that was discussed by panelists at the February 2011 COGR meeting. He discussed in particular the proposed Strategic Trade Authorization (STA) license exception that was proposed last December (discussed in the COGR Winter Update—15B). He indicated that it will be issued shortly. It covers approximately 30—35 countries and essentially moves the licensing boundary to the foreign consignee. While also applicable to deemed exports, it probably will not be highly used by universities.

In the Q & A there was further discussion of the STA exception and the I-129. In response to a question on what use is being made of the I-129 certification Mr. Kritzer indicated that the data is being collected by USCIS. Problems with consular officers demanding export certifications from other than H1B visitors (i.e. J1’s) also were mentioned. It was suggested the BIS should

consult with State if the problem persists. Mr. Kritzer called attention to the 2100 BIS Update Conference on Export Controls and Policy to be held July 19—21 in Washington (see www.bis.doc.gov/ for more information).

2. Thursday Morning Session – Grant Reimbursement and Cash Drawdowns: University Practices and Proposed Changes at the National Science Foundation

The Thursday morning session presented by the Costing Policies Committee was a panel presentation covering Grant Reimbursement and Cash Drawdowns. Two of the panelists included Jim Fortner, the Director of Grants and Contracts Accounting from the Georgia Institute of Technology, and Jim Barbret, the Associate Vice President for Finance and Controller from Wayne State University and a member of the COGR Board. The unique NSF portfolios of Georgia Tech (700+ active awards, average monthly NSF drawdown, ~ \$5 million) and Wayne State (35 active awards, average monthly NSF drawdown, ~ \$750k) provided a necessary contrast of two NSF award recipients, and importantly, established the fact that the new cash payment system being proposed by NSF must take into consideration the differences and diversity of all NSF award recipients.

After the presentation by Fortner and Barbret, Marty Rubenstein, the Director of Budget, Finance & Administration and the Chief Financial Officer for NSF, shared a short overview of why NSF is planning to implement a new cash payment system. While “Accountability and Transparency” have become generic reasons used for any change related to reporting and accounting practices, Rubenstein was more specific – Congress, the Office of Management and Budget, and other stakeholders are demanding more up-to-date information on how tax dollars are being spent, as well as the status of unobligated balances and spending rates at a program-specific level. Furthermore, since NSF’s current cash payment application is premised on an older technology platform, developing a new cash payment system is a timely endeavour for NSF.

Rick Noll, the Branch Chief of the Cash Management Branch, Division of Financial Management, provided a detailed overview of the proposed NSF cash payment system. NSF currently is in the preliminary stages of planning and system development, **but it is important to note that NSF is targeting the new system to be implemented during FY2013.** NSF will work conscientiously with the grantee community to develop a timeline that will not interfere with the fiscal year end dates of our institutions, which suggests the transition to the new system will take place in late 2012 / early 2013. NSF will provide regular updates to stakeholders as the timeline is developed.

Noll covered a wide range of topics and a number of questions and concerns were raised by those in the audience. Some of the issues raised by Noll and/or those in the audience included:

- The new system will be based on awardees providing award level detail at the time of the payment request – the pooled cash drawdown mechanism will no longer be available.
- NSF will no longer require submission of the quarterly Federal Financial Report (FFR) – essentially, the new system is premised on award-by-award reporting and reconciliations are made in real-time rather than being made on a quarterly FFR.

- PI transfers may be facilitated due to availability of real-time financial status of awards.
- The new system will accommodate award-by-award Manual data entry, Excel spreadsheet upload/download capability, and bulk XML data file upload capability.
- Unlike ARRA reporting, the new system will collect only financial data.
- Three user-application / interface screens are expected – Payment Request Form, Adjustments Form, and a Certification (i.e., summary of the payment request).
- The three screens displayed by Noll during the session were preliminary designs – several in the audience suggested “must haves” (e.g., sorting capabilities of selected data fields and a data element definition sheet), as well as concerns (e.g., the NSF adjustment process may be incompatible with institutional accounting systems and practices). NSF is very interested in user input.
- A “Reconciliation Process” that insures award-by-award grantee balances are in alignment with NSF balances will be necessary to initiate the transition to the new system. NSF then anticipates that the institution will be advanced cash to cover needs for thirty to ninety days – this step will be necessary as grantee-initiated cash requests will be shut down for a period of time as the new system is brought on-line. Noll also noted that NSF would suspend the excess cash interest remittance requirement during the transition period.
- NSF affirmed that the new system will not be viewable by the public. However, how institutional data (e.g., spending rates) is extracted and used from any federal system is not always controlled by the agency. Implementation of new laws or policies, requests by Members of Congress, and other variables will affect what data is made public.

Implementation of a new system will be a challenge for both NSF and for the grantee community. One audience participant raised the point that when NASA implemented a similar system, the award-by-award “Reconciliation Process” (see above) between the grantee and NASA was very problematic.

NSF already has initiated site visits to a number of university campuses, and expects to continue these. NSF also will present at a number of forums, including NSF Regional Conferences, NCURA, FDP, SRA, and other venues such as Town Halls. They will utilize Webinars and email communications, as well. Pilots will be initiated at anywhere from 15 to 30 institutions. Over 2/3rds of the NSF grant recipients have 15 or less NSF awards, so NSF must capture that cohort in their pilots. However, medium-sized and high-volume NSF recipients will be well-represented in the pilots. In summary, NSF is committed to developing a first-class application, while minimizing disruptions to the research and grantee community.

COGR will be engaged with NSF as the process unfolds. We encourage you to contact COGR with your perspectives and concerns. Also note, as NSF moves further along the system development cycle and we learn more about potential technology and staff burdens at our

institutions, we will raise the point about the appropriateness for NSF to issue “planning grants” to help institutions make the transition to the new system.

For those of you interested in the PPT slides from this Thursday morning session, they can be found under the “Meetings” tab at www.cogr.edu.

3. Thursday Afternoon Session - Panel Discusses University Role in Economic Development

A panel on Thursday afternoon discussed the commitments made by universities to expand their efforts to achieve economic growth, in response to the Commerce Secretary’s National Advisory Council on Innovation and Entrepreneurship (NACIE). Marvin Parnes, former COGR Board Chair, moderated the panel, which included Philip Singerman, Associate Director for Innovation and Industry Services, NIST; Tim Franklin, Director, Office of Public Partnerships and Engagement, Penn State; and Charles Louis, Vice Chancellor for Research, UC Riverside.

Dr. Singerman discussed trends in federal policies including the Administration’s innovation initiative, the emerging role of manufacturing, and the measurement of impacts. He noted that there is a striking level of interagency cooperation in this area. Since no new funding will be available, pots of existing money must be brought together, such as the i6 Challenge grants. Establishment of the NACIE was recognition of the importance of the university role. On manufacturing Dr. Singerman cited several developments: a NIST manufacturing subgroup, PCAST report on advanced manufacturing, expansion of the manufacturing extension program. On measurement Dr. Singerman mentioned the need to measure the impact of the \$50B federal investment in the federal labs as well as public sector R&D.

Dr. Franklin discussed the need for institutions as a whole to engage in advancing the commitments made in the NACIE letter. There is a high level of community concern throughout the U.S. about economic growth. Universities need to respond to this concern more effectively. Universities create inputs for innovation but measurement of outputs is difficult. Dr. Franklin’s presentation including a striking comparison of average per capita personal income as a percentage of average U.S. per capita personal income between the states of Kentucky and North Carolina. While starting at the same place a half century ago, North Carolina now is substantially higher, due to its greater investment in technology industries. He discussed the necessary elements for a tech-based economy, and the elements provided by universities. However, these assets are not distributed evenly around the country, causing political friction.

Dr. Louis discussed the various stakeholders for university tech transfer offices. He noted the competition for resources on campuses, and the need to balance among the competing priorities. He discussed a recent UC study committee which sought to define success criteria for tech transfer. They identified five goals: creation of public benefit, service to the academic community, establishment of research partnerships with industry, economic development, and receiving fair compensation for university technologies.

In the Q & A questions were raised about measurement, the implications of the shift of higher education from a public to private good, the need for intermediaries such as proof of concept centers, the impact of tax policies, implications of changing the SBIR threshold, and how

institutions can move forward in this area given the expected large budget cuts. Copies of Drs. Franklin's and Louis' presentations have been posted on the COGR website.

4. No Increase in COGR Dues; Meeting Registration Fee to Increase

As announced by the Board Chair, COGR membership dues for FY 2011-2012 will not increase. This is the sixth consecutive year with no increase, which may be a record for Association management. We appreciate your continued support for COGR activities and will continue to strive to make the most effective use of your membership dollars.

Beginning with the October 2011 COGR meeting, the meeting registration fee will increase from \$250 to \$300. This increase is necessary to maintain our goal of covering actual meeting expenses with the fee charged for attendance.

COSTING POLICIES

Committee: John Shipley, Chair, University of Miami; James Barbret, Wayne State University; Susan Camber, University of Washington; James Luther, Duke University; James R. Maples, University of Tennessee; Kim Moreland, University of Wisconsin – Madison; Eric Vermillion, University of California, San Francisco; Mary Lee Brown, University of Pennsylvania, ACUA Liaison; Dan Evon, Michigan State University; Cynthia Hope, University of Alabama; Terry Johnson, University of Iowa; Casey Murray, University of Chicago

5. HRSA Letter of Credit Accounts – “Subaccounting” Practices Suspended

The Health Resources and Service Administration (HRSA) is an operating division under the Department of Health and Human Services (HHS). While its reach to the university community is not as extensive as other research funding agencies, many COGR members have HRSA funding. Recently, HRSA implemented a change in its reimbursement practice – selected HRSA awards were “subaccounted” into the HHS Payment Management System, effectively requiring that cash drawdowns be executed on a grant-by-grant basis using the same interface that was used for cash drawdowns for ARRA awards.

COGR has discussed this issue with personnel from the HHS Policy Office over the past several months. In a positive development, the HHS Policy Office issued a directive to HRSA to cease from moving additional programs into “subaccounting” practices. Unfortunately, according to the HHS Policy Office, those awards that were issued under the “subaccounting” practice cannot be reversed. However, HRSA has agreed not to convert additional programs to “subaccounting” unless an official policy change is made by the HHS Policy Office.

Some of the same pressures applicable to NSF, as described in the previous section, also are applicable to HHS and all the operating divisions under HHS. This includes NIH. The fact that the HRSA practice has been reversed is a positive development, but we need to pay attention to future developments related to this issue. The HHS Policy Office is committed to working with the research community as it reviews the functionality of the Payment Management System. COGR will continue to engage the HHS Policy Office and will keep the membership updated on all developments.

6. NIH and Genomic Arrays: The Costing and the Science

In the Spring 2011 Update (dated May 27, 2011), we included a narrative that addressed Genomic Arrays using “The Costing and the Science” as the context. Using this approach was necessary in order to provide NIH with a costing analysis to support either the elimination or an increase in the Genomic Array (GA) threshold (i.e., under the current policy, on an annual basis, F&A is allowed on the first \$75,000 of GA expenditures).

We have shared this analysis with NIH. COGR's position remains that the policy issued on May 13, 2010 should be retracted (see link to the NIH policy below):

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-097.html>

It is not likely that NIH will retract the policy. However, COGR has recommended to NIH that the threshold be raised on selected types of research and be eliminated on other types of research. In the Spring 2011 Update, we defined the two types of research in detail. In summary, COGR recommended that in regard to Chip-based Genotyping ("high-throughput", type 1), the annual threshold be increased from \$75,000 to \$250,000. This still would achieve the NIH goal of limiting the amount of F&A that can be recovered on an NIH project requiring the use of type 1 GAs, but at the same time, would better recognize that the GA life cycle encompasses a continuum rather than an event isolated to the vendor-purchase. Furthermore, COGR recommended that in regard to Next Generation Sequencing (type 2), the NIH policy should be clarified to state that it is not applicable to type 2 GAs – the NIH Policy is directed to "high-throughput", type 1 GA processing only.

Revision of the NIH Policy as recommended by COGR would not fully eliminate the need for institutions to subsidize some stages of Genomic Research, but it would soften the institutional subsidy. More importantly, revision of the policy would avert the risk where some institutions choose not to participate in certain types of NIH sponsored Genomic Research due to the prohibitive cost.

As we correspond further with NIH, we will update the membership on developments.

7. OMB-lead "A-21 Task Force" is Established – Circular A-21 is the Focus

In the past two COGR Updates (April 26 and May 27, 2011), we reported on COGR engagement with the Office of Management and Budget (OMB). OMB is central to reform initiatives that would be helpful to the research community. Because OMB is the gatekeeper to the *Cost Principles for Educational Institutions* (Circular A-21, codified in 2 CFR, Part 220), as well as the cost principles for Non-Profit Organizations and Hospitals (Circular A-122, codified in 2 CFR, Part 230; and Appendix E to 45 CFR, Part 74; respectively), active engagement with OMB is important.

The Costing Policies and Research Compliance and Administration (RCA) Committees and several staff members from our AAU and APLU association partners met with the A-21 Task Force during our Wednesday, June 8th committee meeting. The A-21 Task Force is co-chaired by three representatives – one each from OMB, NIH, and DOD. In total, the Task Force has over ten members and represents all the major research funding agencies. Our agenda is their agenda – in other words, many of the recommendations COGR, AAU, and APLU have made over the past six months are items that the Task Force will address. The only item that has been specified as not open for discussion is the 26-percent administrative cap. Some of the issues that the Task Force plans to address include:

- Reduce the Burden of Effort Reporting
- Allow Direct Charging of Research Administrative and Compliance Support (i.e., F6b)
- Consistent Application of the 1.3% Utility Cost Adjustment

- Improve the F&A Rate-Setting Process
- Consistent Implementation of Circular A-21 Across Agencies (e.g., Reimbursement of the negotiated F&A rate)
- Reduce the Burden of Subrecipient Monitoring

A “Request for Information” (RFI) has been issued by the Task Force (under the auspices of an NIH RFI). Responses to the RFI are due on Thursday, July 28, 2011. We understand that the Task Force plans to sponsor a “Town Hall” meeting prior to the RFI due date. This will provide the broad community with an opportunity to engage the Task Force in an open forum. The RFI can be accessed at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-091.html>

A COGR workgroup including members from Costing Policies and RCA are preparing responses. Our plan is to share a final draft with the membership several days before the RFI due date. While our responses will emphasize issues related to Circular A-21, we will call attention to those topics that cross-cut with OMB Circular A-122 for Non-profit Organizations and the Hospital Cost Principles. COGR members are encouraged to provide institution-specific responses, and of course, your institution is always welcome to endorse the COGR response. Also, we will be strategizing with AAU and APLU to ensure we provide the most comprehensive and robust responses possible.

The A-21 Task Force has proposed an aggressive schedule for reviewing and responding to the RFI responses. Concurrent with the activities of the Task Force, a similar initiative is being conducted specific to OMB Circular A-87, “*Cost Principles for State, Local and Indian Tribal Governments.*” Our understanding is that the A-21 Task Force will provide recommendations to senior leadership at OMB by the end of August.

COGR is viewing this process as a realistic opportunity to develop new solutions and models applicable to a wide-range of vexing research financial and costing issues. We will provide regular updates to the membership as this process unfolds. If you have comments or input or an issue that you feel should be raised to the A-21 Task Force, please contact David Kennedy at dkennedy@cogr.edu.

8. Recent COGR Publications: Improving the F&A Rate-Setting Process

In the past eight months, COGR has released two policy papers and collaborated on a third paper with AAU and APLU. These papers have been instrumental in informing the A-21 Task Force.

Federal Funding Agency Limitations on Cost Reimbursement: A Request for Consistency in the Application of Federal Guidelines, November 2010. There are two documents – the first is the policy paper and the second is the appendix. The Appendix to the paper includes a sampling of Federal agencies and/or programs where arbitrary agency policy results in financial burden for research institutions.

Regulatory and Financial Reform of Federal Research Policy – Recommendations to the NRC Committee on Research Universities, January 2011. This paper includes the

COGR/AAU/APLU recommendations to the National Research Council, National Academies to inform the NRC's "Study on Research Universities."

Improving the F&A Rate-Setting Process with the Federal Government, May 2011. This paper includes the COGR Recommendations in response to the September 2010 GAO Study, "University Research: Policies for the Reimbursement of Indirect Costs Need to be Updated" (GAO-10-937).

Each paper can be accessed at www.cogr.edu under "Educational Materials / Financial Management." If a paper is password protected, you will need to enter your user name (normally, this is your email address) and password information. If you cannot gain access or do not remember your password, you will need to click on the "Log-In | Register" tab in the upper right-hand corner of the home page and follow the directions for access.

9. 2011 COGR Survey of F&A Rates: SEND UPDATES AS RATES ARE NEGOTIATED

The 2011 COGR Survey of F&A Rates was sent to the COGR ListServe on February 9th. It is a 2-page survey that should be relatively easy to complete. To date, we have received over 115 completed surveys. However, at the time of completion, it is understood that your institution may have been awaiting the negotiation of your F&A rates. We request that if this is the case, please send updates to the survey upon the negotiation of your F&A rates. If you have questions or want to confirm the status of your survey, contact David Kennedy at dkennedy@cogr.edu.

10. ARRA Update

The eighth cycle of ARRA Section 1512 reporting will be initiated on July 1, 2011. COGR is in regular contact with the OMB staff that is responsible for implementing ARRA reporting, and we continue to follow up on issues that the membership brings to our attention. Below are several items to note:

Reporting Deadline Extended to July 14th. As we reported to the COGR ListServe on June 13th, OMB shared the following message with COGR: "The Recovery Accountability and Transparency Board (RATB) has made the decision to extend the initial submission reporting timeline for July through Thursday, July 14th. This is the same length [of time] extension that we had last quarter. As with last quarter, this isn't a "late" reporting window but rather just an extended reporting window, meaning that reports submitted from the 11th to the 14th will be treated the exact same by OMB and the RATB as reports submitted from the 1st to the 10th (i.e. there will be no "late" flag), though recipients are obviously encouraged to submit reports as quickly as possible. The updated timeline has been posted on FederalReporting.gov and Recovery.gov."

"Best Available Data" for Section 1512 ARRA Reporting. In the April 26, 2011 COGR Update, we included a detailed description on this topic. Based on some input from COGR, OMB provided a clarification on how "best available data" should be interpreted. The OMB clarification is included in the 2011 A-133 Compliance Supplement (see Part 3, pages 3-L-6, 3-L-7, and 3-L-15). A link to the Compliance Supplement is included in the next section.

ARRA and Audit Developments. The NSF OIG has conducted ongoing audits related to ARRA. The most recent that has been posted stated: “*Specifically, our review disclosed that the University needs to improve its processes and oversight for the reporting of project status and jobs created/retained for subrecipients and vendors.*” All NSF OIG audit reports can be found at: <http://www.nsf.gov/oig/auditpubs.jsp>. As we have reported for almost two years, the HHS OIG did not plan to focus on NIH programs until other more “high-risk” programs and recipients were targeted. However, now that almost two years has passed, NIH programs could be selected for an ARRA-related audit at any time.

NSF Update to ARRA Reporting Guidance. On June 13, 2011, NSF made available an update to the guidance document entitled: “NSF Guidance for Common Recipient Reporting Issues.” It includes updated reporting guidance applicable to the Amount of Award, Total Federal Amount, and the Number of Jobs (including guidance on reporting trainees and fellows). The updated NSF guidance can be found at: <http://www.nsf.gov/recovery/ARRA-NSFCommonReporting%20ErrorsGuidance.pdf>

COGR is interested to learn of situations where your institution has been contacted by an agency or the agency’s OIG to conduct an ARRA-related audit or review. We keep all correspondences confidential, but in situations where we can match you with other institutions that have experienced or are experiencing a similar situation, we can do so at your request.

11. Audit Landscape: 2011 A-133 Compliance Supplement Available

The 2011 A-133 Compliance Supplement is available. Audit guidance specific to research programs is described in the Research & Development (R&D) Cluster section (see Part 5). The most significant update applicable to research institutions is specific to the discussion on “Best Available Data” for Section 1512 ARRA Reporting (see summary in the previous section, ARRA Update). The 2011 version also includes new guidance to A-133 auditors specific to FFATA compliance. The 2011 A-133 Compliance Supplement can be found at: http://www.whitehouse.gov/omb/circulars/a133_compliance_supplement_2011

12. Other Costing Developments and Discussions

Below are topics that are either new developments or items we have reported on in the past and/or continue to follow. If there are cost-related or financial topics that you would like to discuss with COGR, please contact David Kennedy at dkennedy@cogr.edu.

DOD 35-percent F&A Limitation is Eliminated / DOD Guidance Available. As was reported in prior COGR Updates, the FY2011 final budget bill (Department of Defense and Full-Year Continuing Appropriations Act of 2011 – P.L. 112-10) did not include language that addressed the DOD limitation – by virtue of that language not being in the legislation, the DOD limitation effectively has been eliminated for new awards issued by DOD. Guidance was issued in a June 3, 2011 DOD Memorandum for Secretary of the Army. Effectively, all FY2011 funds (including those appropriated under Continuing Resolutions prior to the final budget bill) are not subject to the 35-percent limitation. Still, institutions should contact their DOD awarding officer to confirm the “color of the money” – i.e., in

some cases, FY2010 appropriations could be funding FY2011 activities, in which case, the limitation would be applicable to the FY2011 activity. We have posted the DOD Memorandum on www.cogr.edu (see “Latest News!”, June 3 link on the COGR home page).

HHS OIG Administrative & Clerical Audit Initiative (i.e., “College and University Indirect Costs Claimed as Direct Costs”). COGR is aware of 7 of the 8 institutions that have been selected by the HHS OIG. At least several of these audits are proceeding at a good pace. Some variations in the experience level of the audit teams have been reported, though how this will impact a given audit is difficult to determine at this point in time.

NIH Request, Costing on Core Facilities – ON HOLD. COGR submitted a response letter to NIH concerning the NIH request for comments on “*FAQs to Explain Costing Issues for Core Facilities.*” A copy of the COGR letter can be found on www.cogr.edu (see the home page, “Latest News!”, December 8, 2010). Our latest update from NIH on this topic is that any action is on-hold, partly due to reorganization that is taking place at the National Center for Research Resources (NCRR). We will keep the membership updated on developments.

NSF Survey of R&D Expenditures and Treatment of Departmental Research. Several COGR members have contacted us regarding site visits related to the NSF Survey of R&D Expenditures. The question being pursued by NSF’s National Center for Science and Engineering Statistics (NCSES) is whether or not it is viable to quantify research expenditures associated with “departmental research” – more specifically, university research activities that are not separately budgeted and accounted for. According to the NCSES, they have no intention of updating the survey format, but rather decided to look at this issue from an “exploratory” standpoint. If there is more information to be shared, we will do so.

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; Catherine Innes, University of North Carolina, Chapel Hill; Alexandra McKeown, The Johns Hopkins University; Jennifer Murphy, George Mason University; John Ritter, Princeton University; Kevin Wozniak, Georgia Institute of Technology

13. Supreme Court Decides Against Stanford in Stanford v. Roche Patent Case

We have extensively reported on this case, in which COGR jointed with other higher ed. associations in submitting an *amicus* brief supporting Stanford, in previous COGR Updates and Meeting Reports (e.g. see Winter 2010 Update).

On June 6 the Supreme Court in a 7 - 2 opinion by Chief Justice Roberts decided against Stanford. His majority opinion held that the Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors (e.g., universities). The opinion held that the Bayh-Dole Act addresses only the respective rights of the federal government and federal contractor in federally funded inventions, and does not affect the rights of the inventor. For Bayh -Dole to apply there has to have been an effective assignment from the (faculty) inventor to the institution. In the Court's view, "subject inventions" under Bayh-Dole means inventions owned by the contractor (the statute reads "...inventions of the contractor..."). Given the basic principle that inventors own rights to their inventions, it can't be an invention of the contractor unless and until there is an effective assignment to the institution.

The dissent by Justice Breyer adopted a view of the Bayh-Dole Act and background principles relating to federally funded inventions much more in line with that of the universities. Justice Breyer expressed concern regarding the principles adopted in the Federal Circuit's FilmTec Corp. v. Allied-Signal, Inc., 939 F.2d 1568 (Fed. Cir. 1991), under which the Federal Circuit had concluded that an agreement to "hereby assign" a future invention has priority over a previously executed "agree[ment] to assign" the same future invention. He argued that the question presented—in the proper context—had not been fully addressed by the parties and so the case should have been returned to the Federal Circuit. Justice Breyer referred six times to our *amicus* brief. Justice Sotomayor concurred in the majority opinion, but wrote separately to note that she shared Justice Breyer's concern with respect to the Federal Circuit's holding in FilmTec. The majority opinion specifically stated that it was not addressing the question whether the Federal Circuit was correct in its holding regarding the priority of the competing assignment clauses because it did not view that issue as encompassed within the Court's grant of *certiorari*. Given that the majority did not challenge the Federal Circuit doctrine, the result means that "hereby assigns" language is necessary for assignments of federally funded inventions to be effective.

The decision raises a number of serious compliance issues for COGR institutions. One is the need to change policies and agreements with faculty and researchers to incorporate the “hereby assign” or equivalent language. There is a great variety of existing institutional policies and practices with regard to assignment language. For those institutions that previously have followed an approach of using other assignment language, obtaining such assignments may be relatively straightforward with new faculty. However, we understand that universities already are receiving pushback from existing faculty who came aboard under other assignment language. Also, while changing the assignment language is highly advised, this will not fully resolve the issue of potentially dualing assignment agreements in the future (e.g. an employee who executes two or more “hereby assign” agreements with different employers over time).

While such changes will help prospectively, another issue which may be difficult if not impossible to resolve is previous assignments to third parties that a faculty member may have made. The effect may be to cloud title to inventions, and inability to warrant clear title, as most licensees require. Institutions may want to seek more conditional warranty language (e.g. “no knowledge of” other ownership claims), which may complicate license negotiations. A high degree of due diligence will be necessary to try to obtain clear assurance that there are no potentially conflicting assignments. In fact, institutions may want to consider performing such due diligence even with existing licenses. No amount of due diligence can fully solve the problem, however or avoid the possibility of people coming out of the woodwork claiming invention rights, based on something a faculty member signed years ago. We expect that companies may push for more robust warranties, and that “hereby assign” language may start to show up in sponsored research, materials transfer, and other types of agreements. COGR plans to include a discussion of these issues in the pending updated COGR [Tech Transfer Tutorial](#).

Another implication is that universities may need to review faculty consulting agreements or any other agreements with IP terms that faculty enter into with third parties, to assure they do not inadvertently assign invention rights. In fact, companies may seek greater protection and ask for assurances from universities that faculty can fulfill obligations with regard to invention rights in consulting and other agreements. Obviously greater institutional involvement in faculty consulting agreements may raise sensitivities, and increase burden.

Some of the legal commentary on the decision has suggested that the practical effect of the case is likely to be trivial or transitory. However, we fear that the effect of the decision may be to increase tensions between institutions and faculty. In an editorial criticizing the majority opinion, the New York Times stated “Although the decision is based on a literal reading of a poorly drafted initial agreement between Stanford and the researcher, it is likely to have a broader effect. It could change the culture of research universities by requiring them to be far more vigilant in obtaining ironclad assignments from faculty members and monitoring any contracts between researchers and private companies. Relationships between the university and its faculty are likely to become more legalistic and more mercantile. By stressing ‘the general rule that rights in an invention belong to the inventor,’ the majority opinion ... romanticizes the role of the solo inventor. It fails to acknowledge the Bayh-Dole Act’s importance in fostering collaborative enterprises and its substantial benefit to the American economy.”

On the day the decision was announced, COGR joined other higher ed. associations and BIO in a joint statement. The statement noted that “the U.S. system of public-private technology transfer

that was established under the 1980 Bayh-Dole Act has been extraordinarily successful in moving university discoveries from experimental laboratories to the marketplace through collaborations with private industry...Although BIO and the undersigned higher education associations held different views on the *Stanford v. Roche* case, the organizations are united in the desire to ensure that the U.S. technology transfer system continues to generate these public benefits through the robust provisions of the Bayh-Dole statute. We are committed to working together in light of the Supreme Court's decision to ensure the continued vibrancy of public-private partnerships and success of our shared objectives." A copy of the full statement may be found on the AAU website.

14. Supreme Court Affirms Presumption of Patent Validity

In a decision handed down the same week as *Stanford v. Roche* (and the COGR meeting), the Supreme Court affirmed that patents are presumed to be valid, in the case of *Microsoft v. i4i*. We reported on this case in the COGR February 2011 Update. It involved Microsoft's appeal of a \$240M jury verdict for i4i for infringement by a version of Microsoft Word of i4i's patent on a method for editing documents containing markup languages like XML. The Federal Circuit affirmed the verdict (the largest patent infringement award ever affirmed on appeal) and also affirmed a permanent injunction against the sale of certain versions of Microsoft Word containing an XML editing function.

The basic issue in the appeal was whether the Federal Circuit's clear-and-convincing-evidence standard for challenges to patent validity is appropriate, even when the challenge is based on prior-art evidence not considered by the patent examiner. Microsoft requested the Supreme Court to lower the evidentiary standard to "preponderance of the evidence" when a patent invalidity defense is asserted based on the existence of prior art that was not considered by the U.S. Patent and Trademark Office (USPTO) in issuing the patent.

In a unanimous decision, the Court rejected Microsoft's appeal, holding that invalidity defenses require clear and convincing evidence. The Court based its decision on a 1934 case involving the Radio Corp. of America (RCA). The Court also rejected Microsoft's proposal that the presumption of validity should be changed for challenges based on prior art not considered by USPTO, noting however that if USPTO did not have all the facts before it, it may be easier to sustain a clear and convincing evidence defense to infringement. The Court acknowledged policy arguments that had been raised in various *amicus* briefs, but said that it was bound to follow precedent, given no evidence that Congress intended to change the RCA holding in the 1952 Patent Act.

COGR did not join in an *amicus* brief in this case, as discussed in the previous Update. However, many consider it to be an extremely important decision. A contrary decision would have significantly weakened patent validity, with possibly significant implications for university tech transfer.

15. House Passes Patent Reform Legislation

The long-running patent reform saga may be almost at an end. On June 23 the House passed H.R. 1249, the Leahy/Smith America Invents Act of 2011, by a vote of 304 to 117. Six

substantive amendments were offered on the House floor; all were defeated. COGR joined the other higher ed. associations in a press release applauding passage of the Act.

We have extensively reported on the six-year Congressional effort to reform U.S. patent law. A summary of the benefits was included in the May 18 message to the COGR membership, and also can be found on the AAU website (www.aau.edu/). COGR joined the other five higher ed. associations with whom we have been working in a June 22 letter to all House members reaffirming our support for H.R. 1249. The associations believe the legislation will benefit universities and strengthen the U.S. patent system overall, enhancing the capacity of the system to promote invention, innovation, and U.S. economic competitiveness in the increasingly competitive global environment.

There were two contentious issues that held up the vote on the final bill. One was the proposed expansion of prior user rights (PUR) as discussed in the COGR May 2011 Update. While we continue to believe that any expansion of prior user rights is bad public policy, the final version of H.R. 1249 restricts them to processes, or machines, manufactures or composition of matter used in a manufacturing or other commercial process that was in commercial use in the U.S. at least one year before filing of the application on the patent against which the PUR defense is asserted (or commencement of the grace period for filing of the patent application). There also is a carveout for all university-owned inventions, unless they result from research that could not have been supported with federal funds (e.g. stem cells, assuming the ban on federal funding was reinstated). These provisions should provide adequate protection for university interests.

The other contentious issue involved the diversion of fees charged by the US Patent and Trademark Office (PTO) to users (i.e. patent applicants) for other purposes. The bill as reported out by the Judiciary Committee (Section 22) would have prevented such diversion, by creating a mandatory revolving fund in the U.S. Treasury to consistently capture all user fees collected by PTO, and allowing for their expenditure for no other purpose than funding the USPTO. While strongly supported by the associations, Congressional appropriators objected to this loss of control over use of the funds. A compromise was reached in the final version of the legislation that creates a Treasury Reserve Fund into which fees in excess of funds appropriated to PTO will be deposited for use only for PTO operations. According to a letter of understanding, procedures will be implemented in annual appropriations acts to assure PTO access to the Reserve Fund and prevention of diversion of the funds for other purposes.

While we have reservations about the jerry-built nature of this approach and the potential for further Congressional interference in future years, we and other groups supporting patent reform as well as the Administration concluded that supporting the compromise was necessary to avoid undoing the six-year patent reform effort at the last minute. Hopefully the Congressional commitment letter and other assurances will provide sufficient protection against fee diversion.

We understand that there are concerns in the Senate about the PTO funding provisions in H.R. 1249. This could complicate the expected action by the Senate to adopt the House bill in an expedited procedure. We will continue to report on the status.

16. CIP Committee Discusses Subcontracting Issues with DOD Representative

The CIP Committee met with Erin Fitzgerald, from the Office of the Assistant Secretary for Defense for Research and Engineering (ASD(R&E); formerly DDR&E)—Basic Sciences. Our primary focus of discussion was the subcontracting issue. The latest FDP Troublesome Clauses monitoring report indicates that troublesome flowdown clauses to universities from DOD contractors remains a significant issue (over an approximately 8-month period from May – December, 2010 there were 61 issues reported involving award terms in corporate subcontracts to universities).

Erin indicated that few such cases have been reported to her office. She also indicated that the latest DOD memo on fundamental research in May 2010 (see COGR June 2010 Meeting Report; the memo is available on the DOD/ASD(R&E) website; click on “Resources”) emphasizes that restrictions should not be placed on projects scoped as fundamental research, even if funded by other than DOD 6.1 or 6.2 funding. However, despite this broadening, her office cannot act if they do not hear of problems. She noted that her office does not “own” the programs where troublesome clauses clause may be used, which complicates their ability to address the issue.

She also discussed training modules for contracting officers that have been developed by DARPA. Senior contracting officers have completed the modules, but they have not necessarily trickled down to lower level contracting officers. One issue is the need also to educate industry contractors. Erin spoke at the DARPA industry conference last year, but more outreach would be helpful (The UIDP has a new flowdown project in which industry is directly participating; this might be a mechanism to help educate industry).

In the discussion we noted that DOD contracting officers typically consult only the DFARS; the fundamental research carveout from the DOD 7000 publication approval requirement has not been incorporated into the DFARS. (In the COGR Meeting Report a year ago we noted that “it is essential that the essence of the (May 2010) memorandum be incorporated into the DOD Acquisition Regulations (DFARS), ...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 “). At one time DOD used an alternate version of the 7000 clause with universities for fundamental research (there also were alternate DOD agency-specific versions of the clause). However, this did not necessarily address the subcontract issue. Erin invited us to suggest DFARS language that would incorporate the fundamental research carveout, either in the prescription or in the form of an alternate clause (or both). Subsequently, we provided her office with proposed language that incorporates the carveout directly into the 7000 clause, and the “review and comment” concept that was in the old 7000 clause deviation.

We also discussed the possibility of direct participation by her office in a working group to address the issues, which also would include DOD contracting officers. FDP is the logical mechanism to form such a group, under the auspices of the Contracts Task Force. We will further pursue this with FDP. Another troublesome clauses update will be developed based on the FDP data next month, which may help provide additional information and momentum.

17. Revised FAR Coverage on Organizational Conflicts of Interest Proposed

On April 26 a proposed Federal Acquisition Regulation (FAR) rule (76FR23236) was published that provides revised coverage on Organizational Conflicts of Interest (OCI). The proposed rule provides a different approach from that proposed in a DFARS rule last year (see COGR April 2010 Update; some of the material describing the proposed DFARS rule was inadvertently included in the discussion of the new proposed FAR rule in the COGR May 2011 Update).

The existing FAR coverage regarding OCIs is addressed in FAR 9.5 and relies primarily on providing examples of OCIs, which according to the Federal Register notice some in the contracting community incorrectly thought were inclusive of all OCIs. The proposed FAR rule responds to a requirement in the '09 Defense Authorization Act as well as report recommendations and developments such as increased outsourcing of services by government agencies and increased use of multiple task and delivery order contracts. It provides a new OCI definition, splits out access to nonpublic information from OCI, and provides new guidance to contracting officers and new FAR clauses for their use. The approach suggested in the Proposed Rule identifies two risks posed by OCIs and the two types of harm that can come from them and prescribes how each risk must be addressed.

- Risk to the Integrity of the Competitive Acquisition – such risk must be substantially reduced or eliminated to the maximum extent possible; and
- Risk to the Government's Business Interests – it may be appropriate to accept this potential harm as a performance risk.

The proposed rule also sets forth 8 questions on which it solicits public views.

We did not comment on the proposed DFARS rule, or an earlier FAR ANPR on this subject, because situations where OCI considerations would apply appeared of somewhat narrow applicability to COGR member institutions. To the extent the proposed FAR rule addresses OCIs this remains the case. OCIs are fairly narrowly defined to apply to situations where the contractor is exercising judgment to assist the government in a task (e.g., preparing specifications, assessing another contractor's proposal or performance) and the contractor performing this task and/or its affiliates have an interest (financial or other) at stake, which could lead to improper influence or unfair competitive advantage from previous work. Part VII of the proposed rule indicates that circumstances that lead to OCIs as defined are most likely to occur in large businesses that have diverse capacity to provide both upfront advice and also a capacity for production. These circumstances do not apply in the case of COGR member institutions, and the impact of this part of the proposed rule for our members is likely to be limited. We will urge the FAR Councils to make clear that the approach to OCIs in the proposed rule is for specific purposes and should not be used as a model for agencies to address OCI for other purposes.

However, we are concerned about the potential impact of the proposed rule that deals with access to nonpublic information. The proposed rule indicates that typical contracts that may provide such access include services contracts such as professional, administrative or management support or special studies and analyses. Universities do not typically engage in the former types of services but often do perform special studies and analyses for government agencies. The new

definition of “nonpublic information” is very broad. According to the proposed rule it is defined as any Government or third-party information that is exempt from disclosure under the FOIA or other authority or has not been disseminated to the general public and the Government has not yet determined whether it will be made available. Universities generally require information that is furnished to them to be identified as confidential, or will not treat it as such. There is no requirement in the proposed for marking the nonpublic information, and there is no exception for having received the information from the government without restriction. It is not clear whether the expectation in the proposed rule is that anything furnished by the government must be protected and limited for dissemination. This could become an issue for our members with Federal contracts for research or certain types of studies that could provide access to such nonpublic information.

The proposed rule includes a clause on Access to Nonpublic Information (52.204—XX) that mandates signed nondisclosure agreements from employees as well as provides for indemnification and a right for third party owners of the nonpublic information to seek damages from contractors for any violation of the clause. These provisions will not be acceptable to most universities. This clause also is a mandatory flowdown, so institutions could receive it as subcontractors. It is likely that this clause will be included in the majority of solicitations and contracts given that the proposed rule vests great discretion in the contracting officer. Faculty also often may gain access to such information through consulting or visiting scientist agreements without their home institution’s knowledge. This may readily lead to situations where they have access to nonpublic information but the institution would not have the necessary knowledge to comply with another new clause (52.204—YZ) requiring offerors to report on whether they possess any nonpublic information, which will be required for virtually all solicitations.

We provided comments on the proposed rule on June 27. The COGR comments expressed general support for the proposed framework, but indicated that greater guidance and clarification needs to be provided to contracting officers. The comments urged the FAR Councils to make clear that this approach to OCI is for limited purposes and should not be used as a model for agencies to use elsewhere. We also pointed out that the proposed Access clause is unacceptable to most universities and that the reporting clause will cause compliance problems. We urged the FAR councils to consider including a carveout for universities from remedies that might disqualify the entire organization and from the indemnification and liability provisions as well as the mandatory flowdown in the Access clause, and to limit the applicability of the required nondisclosure agreements to those who will have access to the information (the proposed rule provides “may have access”). The comment letter is posed to the COGR website.

18. Data License Requirements for National Children’s Study Raise Concerns

The National Children’s Study is a longstanding longitudinal study funded by NIH/NICHD with multiple sites. Recently a number of COGR institutional participants were requested by NICHD to complete a Data Use Agreement which includes restrictions on the publication of the research results. The base contract includes the general FAR data rights clause (FAR 52.227-14) with Alternate IV, giving the institutions the right to publish and copyright data first produced in the performance of the contract. Several institutions have refused to sign the data use agreement.

NICHHD based its request on the Privacy Act and FISMA, and the license covers personally and “socially” identifiable data. NICHHD claims that the institutions that have refused to sign the agreement are out of compliance with federal law, and has demanded written position statements as to the rationale for the non-compliance. The institutions also have been threatened with “incident” reports documenting their non-compliance.

This situation is not dissimilar to situations that have arisen in the past few years with other agencies (e.g. AHRQ, BLS). However, the tone of the discussion is of concern. We understand responses have been provided to NICHHD, citing strong institutional policies against acceptance of sponsor restrictions on publication. Discussion at the COGR meeting indicated that not all Children’s Study participating institutions have received (or are aware of) the Data License requirement. However, given the level of concern, we called the situation to the attention of Sally Rockey, NIH Director for Extramural Research, during the COGR meeting. A follow-up letter also was sent to her by the concerned institutions. We will keep the COGR membership informed of further developments.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Michelle Christy, Chair, Massachusetts Institute of Technology; Michael Amey, The Johns Hopkins University; Kelvin Droegemeier, University of Oklahoma; Michael Ludwig, Purdue University; Denise McCartney; Washington University in St. Louis; James Tracy, University of Kentucky; Pamela Caudill, University of Pennsylvania; Carpantato Myles, University of Alabama; Carol Zuiches, University of Chicago

19. The DATA Act

Since the June COGR meeting, the US House of Representatives' Committee on Oversight and Government Reform approved and sent to the full House the *Digital Accountability and Transparency Act of 2011 or DATA Act* on June 22, 2011. Authored by Rep. Darrell E. Issa (R-CA), the DATA Act (HR 2146) supports accountability and transparency in federal spending by enhancing the reporting requirements of Federal agencies and recipients of federal funds. The DATA Act repeals the Federal Funding Accountability and Transparency Act (FFATA). If passed, the Act would be effective October 1, 2011. The Board established by the Act would be required to issue Guidance, establish common data elements and create the required web site within 180 days of the October effective date.

There are two levels of reporting required by the DATA Act: for recipients and for Federal agencies. Recipients would be required to report, not less than quarterly, basic location information, individual Federal awards by agency, the total amount of funds received and the amount of funds expended or obligated for an individual award per quarter, subawardees (or prime awardee depending on status of recipient) and any additional information requested. Agency would be required to report obligations and expenditures as reported in a number of Federal databases including the Federal assistance and procurement data systems. The agency information would identify recipients to enable a comparison between the two reports.

The DATA Act calls for data standardization across agencies and federal funding mechanisms, i.e., financial assistance and contracts, and requires full disclosure of the information reported on a publicly accessible searchable web site. The functions of the website USASPENDING.gov will be transferred to the website developed under the Act. In addition to the public transparency website, the Act calls for a Federal accountability portal to be used by Federal agencies to verify the eligibility of recipients to receive Federal funds and for Federal agencies and inspectors to track awards to detect and prevent waste, fraud and abuse. There are financial penalties for non-compliance or submitting a report with material omissions or misstatements.

The Act establishes a Federal Accountability and Spending Transparency Board to which are transferred the functions and all powers and duties of the Recovery Accountability and Transparency Board, established to manage the reporting under the Recovery Act. The Board, comprised of inspectors general and deputy secretaries and directors from various Federal

departments and chaired by a Senate-confirmed, Presidential appointee, is responsible for the data collections, serving as the authoritative source for information on Federal spending and the coordination of and, as appropriate, conduct of oversight of Federal funds to prevent fraud, waste and abuse.

With the repeal of FFATA and the transfer of USASPENDING.gov, the DATA Act absorbed the FFATA functions and, in a manner, replaces the FFATA reporting except for the notable addition of quarterly expenditure reporting. This expenditure reporting echoes the reporting requirements linked to the Recovery Act. With the absorption of the Recovery Act Board function (and staff) to the newly formed Federal Accountability and Spending Transparency Board the relationship between the DATA Act and Recovery Act reporting is highlighted.

COGR issued a joint statement with the Association of American Universities (AAU) and the Association of Public Land-grant Universities (APLU) opposing the Act when under consideration by the House Committee. With the timely assistance of the Federal Demonstration Partnership's (FDP) preliminary data on the costs of Recovery Act reporting we were able to highlight the costs of reporting under requirements similar to those included in the DATA Act.

Most research institutions have completed subawardee reports under FFATA through the Federal Subaward Reporting System (FSRS.gov). You will recall that many of the reporting fields in FSRS.gov are pre-populated from information included in the Central Contractor Registration (CCR) system. If the DATA Act is passed by the House, adding the quarterly award expenditure element to the FSRS.gov reporting may be a simple transition. If additional information is requested under the DATA Act, the functionality of FSRS.gov will need to be considered.

Companion legislation was introduced on June 16, 2011 in the Senate by Sen. Mark Warner (D-VA) as S 1222 and referred to the Senate Committee on Homeland Security and Governmental Affairs. No further action has been taken in the Senate.

COGR and its Washington-based association colleagues will continue to monitor the progress of this legislation. A copy of the associations' statement is available on the COGR website under Latest News (www.cogr.edu).

20. NSF Implementation of RPPR – Volunteers Needed!

The National Science Foundation (NSF) is preparing to implement the government-wide Research Performance Progress Report (RPPR) format and it needs your help. You'll recall that as a part of the general streamlining efforts initiated in response to PL 106-107 and crafted by the Research Business Models Subcommittee of the National Science and Technology Council's Committee on Science, the Office of Management and Budget and Office of Science and Technology Policy (OMB/OSTP) established a uniform project reporting format to be implemented by agencies that support research and research-related activities. Each agency was directed by OMB/OSTP to post an implementation plan within nine months of the issuance of the policy in January 2001. Those generally very brief agency specific plans are available at: <http://www.nsf.gov/bfa/dias/policy/rppr/>.

NSF needs individuals – investigators and sponsored program staff – to view the “wireframes” it proposes to use for RPPR reporting. A “wireframe” is a blueprint demonstrating the page layouts to give viewers a sense of how the content and features are presented and the system is designed to function. NSF needs individuals to go through the RPPR layout (not the content of the RPPR) and see how it works, how it feels. NSF has crafted some specific questions for investigators (e.g., what do you like/dislike about FastLane’s reporting system; does the organization and flow through these screens make sense?, etc.) and sponsored program staff (e.g., do you want to see awards with overdue reports?, how often do you use the project report search in FastLane?, etc).

You can volunteer to help by sending an email with the subject “RPPR Volunteer” to feedback@research.gov, or jfeldman@nsf.gov, or to COGR at cblum@cogr.edu – we’ll forward your name on to NSF. If you have/are sponsored program staff assigned to NSF or to disciplines that receive primary support from NSF, consider volunteering to assist NSF. And encourage at least one of your investigators to volunteer as well.

As to the RPPR itself, you will recall that COGR has participated in discussions of the RPPR format for a number of years. Gunta Lidars, University of Rochester, provided comments at the March 2007 Grants Policy Committee’s stakeholders’ meeting and COGR submitted formal comments in November 2007 and again in February 2010 in response to the formal requests. As the final format emerged with a single mandatory category – Accomplishments – COGR expressed its hope that the agencies will minimize the number of optional categories selected for required reporting. Nonetheless, we suspect most agencies will approach the RPPR in a manner consistent with NSF’s approach which is implementation of almost all optional categories of reporting. It’s important to note that any separate agency- or program-specific reporting components beyond the mandatory and optional categories must be reviewed and approval by OMB.

NSF has chosen not to include the optional budgetary information category and will utilize the special reporting requirements as needed by a specific program. NIH, on the other hand, will likely include the budgetary information request as it implements the RPPR for its non-competing continuation progress report (PHS 2590) and the fellowship progress report for continuation support (PHS 416-9). NIH implementation is proposed to begin July 2012 applicable to FY 2013 issued awards. NIH plans to rely exclusively on electronic submissions through eRA Commons.

We continue to be concerned with request for the demographic information about the research staff and potential conflicts with official institutional records and violations of state and federal privacy laws. We appreciate the observation in the response to comments in the *Federal Register* that “if an institution has regulations preventing its reporting, the award recipient may choose not to provide such data.” As we argued in the past, state laws and university policies often require this information to be redacted from any archived materials – electronic or paper. We understand this is an optional category and reminded the federal agencies that some institution will be unable to complete this component of the report.

The addition of the Signature of the Submitting Official on the Cover Page is problematic. We understand that the institution, as the grantee, is responsible for the submission of required

reports. However, this requirement may complicate the process for the submission of the reports, particularly if the official is not able to designate the principal investigator or other institutional official to meet that obligation. We have urged all agencies to allow a designee to sign the RPPR. Finally, the request for the identification of any individual who has worked on the project for at least one person month, “regardless of the source of compensation” again will require review by the institution.

21. NSB Proposed Recommendations for Merit Review

As you know, over the past year, the National Science Board (NSB) has been conducting a review of the National Science Foundation's merit review criteria (Intellectual Merit and Broader Impacts). At the February 2011 COGR meeting, Joanne Tornow, Executive Secretary to the NSB Task Force on Merit Review, described the initiative and engaged in a discussion about the merit review criteria. Because of the additional task facing NSF to develop and implement a policy reflecting the Congressional goals outlined in the America COMPETES Act Reauthorization of 2010 (PL 111-358) Section 526, much of the discussion focused on the broader impacts review criteria.

At the NSB's May 2011 meeting, the NSB Task Force on Merit Review proposed a revision of the two merit review criteria with the goal of clarifying the criteria's meaning and how they are to be used in the review process. The Task Force proposed grounding the criteria in a set of underlying principles. The NSB's proposed revisions are available for comment by the public. The information is available on the NSB website at: http://www.nsf.gov/nsb/publications/2011/06_mrtf.jsp and are published as NSB-11-42. Comments are due July 14, 2011.

In presenting its recommendations, the Taskforce described the process of consultation with the internal and external communities, noting the consistency of issues and suggested solution, regardless of the perspective – whether a NSF program director, reviewer or applicant. The Taskforce affirmed that the two criteria – intellectual merit and broader impacts – fit NSF's mission but the link to the mission needed to be highlighted and the meaning or content of the criteria needed clarification. Thus, “in summary, the NSB believes that all NSF projects should be of the highest intellectual merit with the potential to advance the frontiers of knowledge and, collectively, help to advance a broad set of important national goals.”

The NSB echoed and enhanced the national goals included in the reauthorization of the America COMPETES Act: increasing U.S. economic competitiveness including developing a globally competitive science, technology, engineering and mathematics (STEM) workforce; increasing the participation of women, persons with disabilities, and underrepresented minorities and improvements in STEM education from pre-K through post-secondary education building on solid teacher development; increasing partnerships with industry and public literacy in and engagement with science and technology; ensuring national security; and, finally, enhancing the infrastructure for research and education, including facilities, instrumentation, networks and partnerships.

The NSB noted that “Broader impacts may be achieved through the research itself, through activities that are directly related to specific research projects, or through activities that are

supported by the project but ancillary to the research.” Applicants will be asked to address both criteria in their proposals to NSF. The intellectual merit criteria description changes the least; the broader impacts criteria challenges applicants to identify the national goal addressed by the proposal; provide a compelling rationale and a description of how the proposal addresses the criteria; and the quality of the team and resources. You will want to review the complete discussion presented by the NSB before preparing a comment, if appropriate.

In commenting on the initial request for comments, COGR endorsed the current framework for describing and evaluating the intellectual merit criterion. In a discussion of the description and evaluation of a proposal’s broader impacts, COGR noted that investigators find it difficult to state with certainty what the broader impacts of their basic research will be at the time of application and we fear layering a set of national goals for consideration may draw responses that are, by the nature of the question, speculative or ill-defined. We argued in our comment that NSF needed to continue to recognize that not all science and engineering activities supported by the Foundation have an easily defined broader impact beyond enhancing scientific knowledge through the broad dissemination of the research results and each discipline – each NSF directorate – will have different opportunities for having a broader impact. We expressed the fear of some investigators that emphasizing the broader impacts of the activities may diminish the value and appreciation of the intellectual merit of the proposed activities.

COGR will comment on the proposed revisions and welcomes your thoughts and suggestions no later than July 6, 2011 (cblum@cogr.edu).

22. NSF and Tech Transfer and Commercialization

NSF is considering how to implement another section, Section 520, of the America COMPETES Act Reauthorization. This section of the Act requires colleges and universities receiving at least \$25 million in total Federal research grants “to keep, maintain and report annually to [NSF] the universal record locator [URL] for a public website that contains information concerning [an institution’s] general approach to and mechanisms for transfer of technology and the commercialization of research results.” NSF is directed to maintain a website accessible to the public that links to each institutional website.

The institution’s website is expected to contain contact information; information on the institution’s technology licensing and commercialization strategies; success stories, statistics, and examples of how the university supports commercialization of research results; technologies available for licensing; and any other information deemed by the institution to be helpful to companies with the potential to commercialize university inventions. The Act explicitly states that institutions will not be required to reveal confidential, trade secret, or proprietary information on its website.

NSF will provide the research community an opportunity to comment on its planned implementation.

23. FDA Drafts Guidance on Financial Disclosure by Clinical Investigators

The Food and Drug Administration (FDA) has made available draft *Guidance for Clinical Investigators, Industry and FDA Staff: Financial Disclosure by Clinical Investigators* for comment that are due July 25, 2011. A notice inviting comment appeared in the May 24, 2011 Federal Register (76FR30175) and provides information on how to access the draft Guidance.

As with all FDA clinical research activities, the FDA establishes a relationship between the FDA, sponsor of a clinical trial and/or drug, device or biologic products marketing applicant and the clinical investigator. The role in the management financial interests and relationships that may pose a conflict that we customarily reserve for the investigator's home institution is not recognized by the FDA. As a consequence, the draft Guidance presented here for comment focuses the disclosure of financial interests and arrangements to the sponsor and/or marketing applicant. The reporting thresholds are different than those required under the Public Health Service/National Institutes of Health policies governing financial conflicts of interest and are to be reported in a particular FDA format/form. Thus, institutional investigators participating as clinical investigators on a trial regulated by the FDA will be submitting disclosures in two different formats to (at least) two different entities – the institution and the trial sponsor. This dual reporting is frustrating and sometimes confusing for investigators. The reportable category of “Significant payments of other sorts (SPOOS)” which includes payments to the investigator or their institution during the period of the covered study for other activities involving the investigator is reportable. This requirement may require disclosure by the institution for the investigator.

In offering the Guidance for comment, the FDA asks if it should require public disclosure (on a website) of the financial disclosures made by investigators and the format for that release, e.g., a summary for all investigators related to a marketing application or individually in a de-identified list of investigators.

COGR will comment noting the duplication and resulting burden of multiple disclosures for investigators that are in institutions following the PHS/NIH policies and questioning the value of a public posting of financial disclosures. We will recommend a summary of the financial interests rather than individual data and will note this is yet another list using differing criteria that describes the financial interests and relationships of individuals. Posting information that fails to inform but adds to the confusion of the public is not a useful source. If you have addition comments or suggestions, send them to COGR no later than July 15, 2011 (cblum@cogr.edu).

24. NIH Appendix Limitations

At the February COGR meeting, members expressed concern with how the type and size of materials appended to National Institutes of Health (NIH) applications were evaluated. More specifically, some members reported applications being returned without review because of the appended material. Since the February meeting, we have met with NIH staff members to discuss the meaning of the instructions provided for appending material under the SF 424 (R&R) Application guidelines.

You will recall that the Appendix Guidelines begin by cautioning applicants not to use the appendix to circumvent the page limits on the research strategy section of the application. The guidelines outline the number of PDF attachments and their location in the application, etc. The problem with the appended materials is related to whether or not the list of materials that “may” be included in the appendix is inclusive or descriptive. The list includes publications, accepted manuscripts and online publications; patents; and surveys, questionnaires and other data collection instruments, protocols, etc. Some investigators viewed this list as descriptive and would include other materials related to the project proposed.

NIH sees this list as restrictive meaning that the list of materials are the only items that may be included in the appendix unless an item is specifically requested in a Funding Opportunity Announcement (FOA). NIH is rewriting the Appendix Guidelines to make this restriction clear and updating, as appropriate, FOAs to ensure that the materials to be submitted with an application are accurately described. These revisions may take some time and not be fully incorporated until the next version of the application guide is released.

In the short-term, applicants to NIH using the SF 424 (R&R) format should restrict the appended material to only those items listed in the Appendix guidelines unless explicitly requested in the FOA. Further information concerning this advice is available from COGR (cblum@cogr.edu).

25. NIH Considering Comments on New Animal Care Guide

NIH’s Office of Laboratory Animal Welfare (OLAW) is reviewing the comments submitted on whether and, if so, how NIH should adopt the National Research Council’s Institute for Laboratory Animal Research’s *Guide for the Care and Use of Laboratory Animals: Eighth Edition*. COGR offered comment in a joint letter with AAU and the Association of American Medical Colleges (AAMC). A copy of the May 24, 2011 letter is available on the COGR website under Latest News (www.cogr.edu). In a June 9, 2011 notice (NOT-OD-11-082), OLAW says it will issue position statement(s) for review by the research community and offer a 60 day public comment period.

During this period of review, NIH reminds the research community that the Public Health Service (PHS) *Policy on Humane Care and Use of Laboratory Animals* (Policy) requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals*. As of June 2011, and until notified of a change through the NIH Guide for Grants and Contracts, this guidance for Assured institutions refers to the **seventh edition of the Guide**.

26. OHRP Institutes New Assurance Forms/Terms

On June 21, 2011, the Department of Health and Human Services’ (HHS) Office for Human Research Protections (OHRP) announced the availability of new Federalwide Assurance (FWA) and Terms of Assurance reflecting important changes to the management of the assurance process. The forms and terms are available on the OHRP website at: <http://www.hhs.gov/ohrp/>

When OHRP proposed the changes to the assurance process, COGR endorsed those changes in October 2010 and is pleased to see them incorporated into the assurance process. Notably, only internal IRBs are to be listed on an institution's FWA unless the institution relies on an external IRB for a significant portion of its covered research. The submission process is entirely electronic including the signature of the institutional official and the approval period is now five (5) years. There are of course provisions for reporting charges in the parameters of the assurance, e.g., changes in the designated IRB, more frequently and OHRP expects institutions to document arrangements for relying on another, external IRB with a written agreement but the whole process has been streamlined.

27. NSABB Draft Guidance on Personnel Reliability

During its June 23 meeting, the National Science Advisory Board for Biosecurity (NSABB) reviewed and approved *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility*. You will recall that the NSABB has been examining the question of ensuring personnel reliability and issued an earlier report in May 2009 (Enhancing Personnel Reliability Among Individuals with Access to Select Agents [NIH, May 2009]). The NSABB was asked to develop specific strategies in consultation with experts and community. The NSABB has conducted those consultations including a public consultation in January, 2011.

In this new Guidance, the NSABB recommends a number of effective practices that build on simple good management practices as a foundation. From the NSABB's perspective, good management includes strong institutional and laboratory leadership, a clear articulation of priorities and expectations, and an institutional framework that provides relevant education, training, performance review, and employee support. The Guidance continues by offering suggestions in a number of areas. Recommendation for hiring and employee management practices include a willingness on the part of employers to provide candid references; a thorough checking of references; and a rigorous, biosecurity-minded review of credentials and professional status of prospective employees including check of any possible criminal history. The NSABB promotes periodic performance review for all laboratory personnel that build on a clear articulation and documentation of conditions of employment and expectations regarding trust, integrity, and reliability; and notice that all information regarding the employee's reliability or suitability with respect to biosafety and biosecurity can be shared with potential employers.

Leadership, both at the institution and laboratory levels, is a key element in enhancing a culture of trust, integrity, and responsibility and fostering biosecurity. Leaders must convey the importance of biosecurity and provide individuals with the information and tools needed including formal and informal training and education. The NSABB advocates a clear code of conduct as a critical tool for strengthening the culture of responsibility. Institutional leadership should also ensure that all employees are educated about their responsibility to and the processes for reporting behaviors or activities that raise biosecurity concerns.

The NSABB also briefly discusses other potential practices to ensure the security of the facilities and the reliability of employees. The community is likely to have an opportunity to discuss the NSABB recommendations either as a part of future rulemaking or under Guidance issued as a part of the select agent programs. We recommend institutions consider this NSABB report and

prepare for contributing comments and suggestions. The Guidance is available on the NSABB website in the May meeting materials at: <http://oba.od.nih.gov/biosecurity/biosecurity.html>.

28. FESAP Recommends Changes to the Select Agent Program

As the NSABB prepared to meet, the Federal Experts Security Advisory Panel (FESAP) publicly released its Recommendations Concerning the Select Agent Program (November 2010-June 2011). The report is available on the HHS Public Health Emergency website at: <http://www.phe.gov/Preparedness/legal/boards/fesap/Pages/default.aspx>.

The Federal Experts Security Advisory Panel (FESAP) was established by Executive Order 13546 on July 2, 2010 to provide recommendations related to the security of biological select agents and toxins (BSAT) to the Secretaries of HHS and Agriculture and the Attorney General. As our colleagues in AAU note, while these do not themselves constitute policy changes, the EO requires the FESAP recommendations to be considered in the next round of revisions to the select agent regulations.

FESAP released the recommendations in order to give the community time to consider the impact of the recommendations so that they can be prepared to comment in the fall, which is when the rulemaking process is expected to begin. Among the recommendations offered: tiering of select agents to provide for greater security measures for those that cause the most risk; removal of a agents/toxins from the list; changes in the security risk assessment to better vet foreign nationals, etc.; guidance to better define “pre-access suitability” and to develop systems for periodic reassessment of reliability; tools for continuous physical facilities evaluation; and regulatory standards for Tier 1 agents physical and cyber security.

29. DHHS/NIH Revisions to Financial Conflict of Interest Regulations Stalled

The Office of Management and Budget announced on June 9 that completion of its review of pending regulations on financial conflicts of interest proposed by NIH has been delayed indefinitely. Our understanding is that the potential additional compliance burden of the proposed revisions is the cause of the delay, given the President’s January 18, 2011 Executive Order on Regulation and Regulatory Review, and the subsequent Directive from the Administrator of the Office of Information and Regulatory Affairs that establishes new review criteria for proposed regulations and requires a review of existing regulations using the new criteria. COGR will provide an update as more information becomes available.