

COUNCIL ON GOVERNMENTAL RELATIONS

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TO: COGR Membership

FROM: COGR Staff

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1. U.S. Solicitor General Supports University Position in Stanford v. Roche Case

On September 29 we reported to the COGR membership that the U.S. Solicitor General (SG) had filed an invited amicus brief with the Supreme Court strongly supporting the university position as expressed in our amicus brief on Stanford v. Roche filed with the Supreme Court last spring. The Federal Circuit held that the Bayh-Dole Act did not affect an inventor's ownership right to contractually assign his/her rights to future inventions. COGR joined other higher education associations and more than forty universities in an amicus brief urging the Supreme Court to review the Federal Circuit decision. The brief emphasized 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. The concern is that the effect is to cloud title to federally-funded inventions.

As we reported, the SG brief supports the grant of cert. by the Supreme Court. This is a very positive development, for at least two reasons: first, we understand that with the support of an

invited brief from the Solicitor General, cert. petitions historically have been granted over 80% of the time; second, if the Supreme Court takes this case, then the support of the SG on the merits often is also a powerful predictor of ultimate success. When we started down the road of supporting Stanford's cert. petition, the odds of getting heard by the Supreme Court were very small. This effort to overturn a potentially very damaging decision by the Federal Circuit has been extended and intense, engaging the concerted efforts of staffs from the higher education associations as well as valuable assistance from individual universities.

As noted in the SG brief, the Federal Circuit's decision held that patent rights to a federally funded invention vest in the inventor, not the contractor. While under general patent law ownership rights to inventions typically belong to the inventor(s), the presumption in Bayh-Dole is that ownership of patent rights to federally-funded inventions vests in non-profit grantees and contractors (or small business), assuming they comply with the Act's requirements. This is a crucial distinction, which the Federal Circuit did not understand (and perhaps has not been well understood by patent law practitioners generally). By its terms, Bayh-Dole takes precedence over any other disposition of rights in federally funded inventions. It established a hierarchy of rights, with priority ownership rights vested in contractors (grantees) which the government can override in specific cases. The inventor occupies the lowest position in the hierarchy.

It is ironic that 30 years after passage of the Bayh-Dole Act (see below); the ownership issue has not been definitively litigated until now. While universities typically have required assignment of rights from individual researchers, as the SG brief notes there is no way universities can adequately protect against prior assignments which under the Federal Circuit decision would be found controlling. The holding casts doubt on the ownership of a substantial number of federally funded inventions. We already have heard from universities that in license negotiations prospective licensees are raising issues of the ability of universities to warrant clear title due to the possibility of the researchers/inventors having made prior assignments as in this case. Thus there has been a real and immediate effect.

We expect the Supreme Court to announce its decision on the cert. petition on November 1. We will continue to keep the COGR membership informed of developments.

2. Celebration of Bayh-Dole 30th Anniversary Planned

COGR is joining with other higher education associations and AUTM in planning a celebration of the 30 anniversary of the enactment of the Bayh-Dole Act (the Act was passed in December, 1980). The event is planned for December 1, in conjunction with the National Council of Entrepreneurial Tech Transfer (NCET2) University Startups Conference at the Washington Convention Center. As currently planned, the first half of the event will be a retrospective with remarks from the original sponsors of the Act. Other Congressional representatives will comment on the importance of maintaining the strength of the Act to secure America's leadership position in innovation for the future. The second half of the event will be a moderated panel discussion of the impact of the Bayh-Dole Act in present terms. We expect that a BIO company CEO, venture capitalist, patient advocate, political figure, and university president will comprise the panel.

Sen. Birch Bayh has committed to participate, and Sen. Dole is planning to participate if his health permits. More information will be forthcoming shortly. The event will be open to the public and the hope is that there will be significant press coverage.

3. National Academy Releases Report on University IP Management

The long-awaited National Academy of Sciences (NAS/NRC) committee report on University Management of Intellectual Property was released on October 4. (We have reported on the activities of this committee several times, most recently in the COGR Summer 2009 Update #11B. COGR Board, CIP Committee, and staff representatives all made presentations to the committee during the course of its meetings and deliberations).

There are 15 numbered recommendations in the report. Most are consistent with our views and discussions with the committee. The report finds that the system put in place by the Bayh-Dole Act has been more effective than the pre-1980 system in making research advances available to the public and spurring innovation. Nevertheless, the current system needs improvements according to the committee. Among the principal recommendations are that university leaders should articulate a clear mission for intellectual property management -- one that stresses the responsibility to disseminate technologies for the public good and does not predicate licensing on the goal of raising significant revenue for the university -- and should evaluate their institutions' efforts accordingly (Rec.1). Universities also should consider additional ways to engage faculty in commercializing their inventions, as successful commercialization often depends on inventor involvement. In addition, because Bayh-Dole did not establish a stable, effective framework for government oversight, such responsibilities should be clearly assigned within the federal bureaucracy (Rec. 14).

The report concludes that the Bayh-Dole framework and university practices have not seriously undermined academic norms of uninhibited inquiry and that there is little evidence that intellectual property considerations interfere with other important avenues of transferring research results to commercial use. Nor has a persuasive case been made for shifting to a faculty "free agency" system. While the report does not support giving faculty ownership or the rights to market their inventions (see COGR February 2010 Meeting Report), it notes that such proposals reflect a feeling in some quarters that the current system does not sufficiently value faculty initiative. Universities seeking to encourage entrepreneurial initiative should consider creating expedited procedures and more standardized terms for licensing to start-up enterprises in which staff, faculty, or students are involved (Rec. 9). In addition, there should be independent oversight of the relationship between faculty and university technology transfer offices, and faculty who believe their inventions are being ignored or mishandled should have recourse within their institution. Such disputes should be resolved by an advisory committee composed of university faculty, employees, and administrators. Institutions with sizable research portfolios should also consider creating an additional standing advisory committee to help the technology licensing unit identify opportunities and develop practices consistent with the university's goals (Rec. 2).

Among other recommendations are that nonprofit research institutions cease using Materials Transfer Agreements (MTAs) when exchanging non-hazardous or non-human biological materials among themselves, or use the terms of the NIH UBMTA/SLA (Rec. 8). **This issue will be the subject of a Thursday morning session at the upcoming COGR October meeting.** The report also endorses the "Nine Points to Consider in Licensing University Technology," which COGR also has endorsed (Rec. 6). It points to the problems of measuring university technology exchange and recommends universities and federal science agencies

coordinate efforts to develop a more balanced set of measures, perhaps through the annual NSF R&D Expenditure Survey (Rec. 13).

Recs. 14 and 15 discuss the Bayh-Dole oversight issue and the need to reinvigorate the iEdison invention reporting system. The report points to the need for consistent implementation of the laws and regulations governing tech transfer. COGR has long supported this view, and the need for a single point of contact within the federal government for Bayh-Dole issues. AUTM agrees although it is not clear that this view is uniformly shared among the higher education associations. With regard to iEdison, the report states that the data should be available for analysis by qualified researchers. As discussed in our recent Summer [Update](#), we are concerned both about iEdison reporting compliance and that the system has a number of technical issues with no clear responsibility for it within the government. We would not support this recommendation pending resolution of these issues.

On the whole, however the report is highly positive for university technology transfer. We look forward to further discussion of the implementation of the recommendations. The report is available at <http://national-academies.org>.

4. Technology Transfer Issues Resurface with the VA

We have had longstanding concerns with the VA's Cooperative Technology Administration Agreements (CTAAs), now in place with 56 research institutions and 3 university systems comprising an additional 20 institutions. Under the CTAA approach the VA claims joint ownership with institutions of inventions made by dual VA—university appointees (DAPs) or university inventors who use significant VA facilities or resources. The university generally is responsible for patenting and licensing and distributing the inventors' shares of revenues received, with the university paying a pro rata share of the remaining share of revenues to the VA (after payment of administrative expenses). The VA claims this right even where the invention is a result of a federal funding agreement otherwise subject to the Bayh-Dole Act, on the basis that the Act does not preclude joint ownership. (We have long believed that the VA's position is contrary to the intent of Bayh-Dole, which is reinforced by the view of Bayh-Dole rights set forth in the Solicitor's General brief discussed above).

The VA recently has contacted a number of its CTAA partners requesting that the agreements be amended to have the VA share paid prior to distribution of the inventors' share, with the VA responsible for payment of its (pro rata) inventors' shares to VA inventors. The VA's request evidently is based on advice from the Office of Government Ethics that royalty payments from universities to VA employees raises issues under 18 USC 208, which governs outside financial interests of federal employees.

This concern may be justified with regard to salaried VA employees including DAPs (although the VA began putting CTAAS in place nearly 10 years ago without this issue arising). However, under the revised agreement DAPs apparently would continue to be paid a pro rata inventor's share directly by the university, which appears logically inconsistent. In addition, we understand that the VA has insisted that the revised policy also covers university employees who use VA facilities in their research but receive no salary compensation from the VA. Such employees are classified by the VA as "without compensation" (WOC) employees. The Department of Commerce determined some years ago that WOCs are not government employees for purposes of government rights in inventions, and the VA requires that the WOCs sign an agreement

assigning certain invention rights to the VA (which is a tacit recognition that they are not federal employees for this purpose). It appears inappropriate to have WOCs paid inventors' shares by the VA when they receive no other VA financial compensation, and could lead to anomalous results. Another issue is that there is an annual cap on royalty payments to federal employees, which also could lead to anomalous results since universities will continue to pay uncapped inventors' shares under university policy.

COGR is continuing to discuss this issue with affected member institutions. The complexities of the varying institutional arrangements with the VA are a complicating factor. We may try to develop a list of questions about the justification for the revised policy and the potential impact. We will report to the membership as the situation evolves.

5. Export Control Reform Initiative Proceeds

The April 2010 Update and June 2010 Meeting Report discussed the Administration's plans for a new export control system. Further changes were outlined by the President on August 30. New criteria will be applied for "tiering" items to be controlled, a "bright line" will be established between the Commerce "dual use" Commodity Control List (CCL) and the U.S. Munitions List (USML) to reduce jurisdictional uncertainty, and the lists will be structurally aligned along the current approach of the CCL so that potentially they could later be combined. The lists will be restructured to be positive lists using objective criteria that will split them into three tiers. The highest tier will be those items that provide critical military or intelligence advantage to the U.S.; the middle tier will be those that provide substantial advantage and are available almost exclusively from the U.S. or allies, and the lowest will provide significant advantage but are more broadly available. Once it is tiered, a corresponding licensing policy will be assigned for the controlled item.

The Administration has already completed the first phase of the process by overhauling Category #7 of the U.S. Munitions List. As a result, such items as brake pads for tanks have now been de-controlled from the munitions list. The Administration is now moving forward with the review of Category #15 of the USML; a category which includes research satellites. Research satellites formerly were under Commerce jurisdiction; however, language included in the 1999 Defense Authorization Bill moved research satellites to the USML— a shift which has had negative repercussions for space science research conducted at U.S. universities. We understand that there might be an opportunity for legislative changes to be enacted that provide flexibility to the President to determine if satellites are listed on the munitions or Commerce dual use list.

AAU has met with the NSC staff person leading the reform effort, and will be reconstituting its Export Control Task Force shortly. Stanford University President John Hennessey will serve as chair of the Export Control Task Force. We will work with AAU staff as the Task Force activities proceed and more information becomes available.

While we have been concerned about the prospects for the reform initiative with the rumors of DOD Secretary Gates' impending departure, we understand that the President has become personally engaged on this issue. Thus it is likely that the reform initiative will continue.

6. Troublesome Contract Clauses Continue to Proliferate

We noted in the June Meeting Report that the Federal Demonstration Partnership (FDP) had 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. For these purposes clauses containing restrictions on publications and/or participation in research by foreign nationals are considered troublesome, although other restrictions such as those involving intellectual property also may be included.

Data received by the FDP as well as information reported to COGR indicate that the situation with these clauses has not improved. While publication restrictions continue to be the most frequently faced issue for COGR member institutions, they are beginning to see an increase in information security requirements that are often not only inappropriate, but also nearly impossible to comply with. COGR has followed these issues for some time (information security requirements were discussed in COGR Updates and Meeting Reports beginning in 2004 and were the subject of two panels at COGR meetings; e.g. see June 2007 Meeting Report) and we will continue to monitor the situation. Interestingly, the case involving the dispute over required background checks on scientists at the Jet Propulsion Laboratory (JPL) was argued in the Supreme Court this month.

We also understand that the Agency for Health Care Research and Quality (AHRQ) is insisting on use of the FAR Special Works clause (52.227-17) as a matter of policy in contracts with universities. As noted in the COGR Rights in Technical Data Guide, that clause is inappropriate for use in university contracts. The AHRQ Director has committed not to implement FAR 52.227-17 in a manner that would restrict an academic institution's freedom to publish so long as requirements of the contract pertaining to confidentiality and integrity of information are met. A number of universities have signed a statement to AHRQ confirming their freedom to publish and urging AHRQ to consider the fully acceptable data rights clause of FAR 52.227-14 with Alt IV, which is the appropriate clause for contracts for research and development with universities.

We will continue to discuss with FDP representatives and AAU appropriate responses to these issues. One possibility is to broaden the discussion to include representatives of OSTP and perhaps OMB.

7. NIH Policy on Genomic Arrays and F&A - Long-term Solutions for Similar Items?

COGR remains engaged in discussions on the new NIH policy for F&A reimbursement on Genomic Array (GA) purchased services. 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, dated May 13, 2010, can be found at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-097.html>

A number of time-intensive items taking place at NIH over the past several months (e.g., financial conflict of interest, stem cell research, and the release of a new Grants Policy

Statement) moved the GA discussion to the back-burner. However, NIH is now engaged with COGR and is interested in providing clarifications and/or modifications to the new policy. Some of the issues that could be addressed by NIH include:

- A more specific definition of “genomic arrays”
- Strict limitation of the policy to the specific definition
- Appropriateness of the \$75,000 threshold
- Differential treatment of GAs that are outsourced versus in-house (service center)

While COGR is on record that the new policy should be rescinded, the policy will most likely stand. Clarifications and/or modifications will be a compromised solution, but they will improve the current version of the policy. In addition, we believe this incident could provide a gateway for addressing similar situations where federal sponsors are unwilling to pay the full F&A rate on expensive-bulk purchases or similar cost items.

One discussion we could have with Federal representatives is if a new cost category for defining MTDC is appropriate. If NIH and other agencies begin to regularly disallow or limit F&A recovery on these types of expenditures, it could be in our interest to promote a new cost category for expensive-bulk purchases or similar cost items.

COGR IS INTERESTED IN MEMBER INPUT ON THE FOLLOWING: Using GAs as a benchmark, are there similar expensive-bulk purchases items that your institution charges to sponsored awards? If so, please provide examples and categorize as follows:

- Description of item
- Amount of Purchase
- Federal or Non-Federal
- F&A Rate paid (e.g., full rate, less than full rate, zero)

If you are able to help, please keep your analysis as simple as possible. As COGR continues to follow up on the broad issue of GAs and similar items, this information may be helpful. Please provide your analysis to David Kennedy at dkennedy@cogr.edu.

8. National Science Foundation Policy on Voluntary Committed Cost Sharing

The recently released NSF Grant Policy Guide includes a significant change on the treatment of Voluntary Committed Cost Sharing (VCCS) in proposals to the NSF. The link to the summary of “Significant Changes to the GPG” and a summary of the new policy are shown below:

http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/gpg_sigchanges.jsp

Chapter II.C.2.g(xi), Cost Sharing, has been revised to implement the National Science Board’s recommendations regarding cost sharing. Inclusion of voluntary committed cost sharing is prohibited, Awardees are informed, however, that they remain subject to the OMB A-21 Clarification memo regarding committing and tracking faculty effort (see footnote 22). In order to assess the scope of the project, all organizational resources necessary for the project must be described in the Facilities, Equipment and Other Resources section (II.C.2.i). The description should be narrative in nature and must not include any

quantifiable financial information. Mandatory cost sharing will only be required when explicitly authorized by the NSF Director.

The OMB A-21 Clarification memo, noted above, is in reference to the January 5, 2001 OMB A-21 Clarification memo (Clarification of OMB A-21 Treatment of Voluntary Uncommitted Cost Sharing and Tuition Remission Costs) and includes the following language:

“In addition, most Federally-funded research programs should have some level of committed faculty (or senior researchers) effort, paid or unpaid by the Federal Government. This effort can be provided at any time within the fiscal year (summer months, academic year, or both). Such committed faculty effort shall not be excluded from the organized research base by declaring it to be voluntary uncommitted cost sharing. If a research sponsored agreement shows no faculty (or senior researchers) effort, paid or unpaid by the Federal Government, an estimated amount must be computed by the university and included in the organized research base. However, some types of research programs, such as programs for equipment and instrumentation, doctoral dissertations, and student augmentation, do not require committed faculty effort, paid or unpaid by the Federal Government, and consequently would not be subject to such an adjustment.”

Going forward, an institution will need to comply with both the NSF policy and the OMB Clarification memo, and each should be viewed as a separate compliance matter. When proposing faculty or senior researcher time to an NSF award, voluntary committed cost sharing cannot be included. If the institution stills wants to document unpaid effort for internal purposes, the institution can do so. However, and to reiterate, voluntary committed cost sharing will not be considered by NSF. As to compliance with the OMB Clarification memo, the memo talks specifically to estimating effort in terms of defining the organized research base. In those situations where faculty and/or senior researcher salaries are not being charged to an NSF award, for F&A and organized research base purposes, the institution will need to comply with the OMB Clarification memo.

COGR was actively engaged when the National Science Board (NSB) began its review of NSF cost sharing policies three years ago. On February 7, 2008, the NSB published the “*Report to Congress on Cost Sharing Policies at the National Science Foundation*” and on August 3, 2009, the NSB published “*Investing in the Future: NSF Cost Sharing Policies for a Robust Federal Research Enterprise.*” The second report provided the impetus to the new NSF policy on VCCS. The NSB reports can be found at the links below:

http://www.nsf.gov/nsb/publications/2008/rprt_congress_cs_policy.pdf

<http://www.nsf.gov/pubs/2009/nsb0920/index.jsp?org=NSF>

COGR believes the new policy is an important step forward. As COGR pointed out several years ago when providing comments to the NSB: when voluntary cost sharing is “encouraged” or perceived to be necessary for competitive purposes, it can result in draining of institutional resources, creating unhealthy gamesmanship in the proposal and award process, and undermining well-conceived institutional strategic planning. We expect to have the opportunity to talk more about the new policy during the October 28-29 COGR Meeting.

9. ARRA Section 1512 Reporting: Changes and (Un)changes per OMB Guidance M-10-34

The fifth cycle of ARRA Section 1512 reporting was initiated on October 1, 2010. While OMB Guidance had landed at a relatively stable point prior to the October 1 reporting cycle, updated OMB Guidance M-10-34 released on September 24, 2010 created significant confusion for the entire grant recipient community.

At issue were two requirements specific to Subrecipient and Vendor reporting. For Subrecipient reporting, the new guidance required multiple subawards to a single subrecipient to be aggregated into a single reporting record. For Vendor reporting, the new guidance required multiple payments to a single vendor to be aggregated for the purposes of triggering the \$25,000 reporting threshold – under the previous guidance, multiple payments were not aggregated. In both cases, the updated guidance was going to create challenges for COGR members – data collection challenges, as well as information technology system challenges.

COGR engaged OMB throughout the week of September 27 to share concerns and to advocate for relief from these two changes. On Wednesday, September 29, we were able to report on the COGR ListServe that the Recovery Board approved a late reporting period from Monday, October 11 through Wednesday, October 13. OMB confirmed that reports submitted after October 10 would be considered “late”, but would still be considered “compliant” and be accepted by FederalReporting.gov. We also reported early in the day on Friday, October 1, that in consideration of the short notice for the significant reporting changes, recipients should implement the new reporting requirements to the “full extent that is practical.” If an institution could not implement the reporting changes during the initial submission period, the institution should submit initial reports and then provide corrections during the subsequent review and correction periods. While OMB endorsed this approach, we recognized that this “solution” was at best a “band-aid” and only provided temporary relief.

However, late in the day on Friday, October 1, OMB contacted COGR and asked us to share with the COGR membership that the updated Subrecipient and the Vendor reporting requirements had been rescinded. In a somewhat confusing manner, the reposted guidance on the OMB website remained dated as September 24, 2010. However, the two guidance statements specific to the Subrecipient and Vendor reporting requirements were eliminated from the reposted guidance.

Consequently, the updated OMB Guidance M-10-34, is still posted with a date of September 24, 2010 and is available at:

<http://www.whitehouse.gov/sites/default/files/omb/memoranda/2010/m10-34.pdf>

As we stated in the COGR note to the ListServe later on that Friday afternoon, if you open the guidance and scroll to page 11, you will notice that the final two sections, Sub-Recipient Section and Vendor Section, have been removed. NOTE, all other sections per the original guidance are still valid. In our note to the ListServe, we also shared comments from OMB Controller, Danny Werfel, and the interesting dynamics of this issue. In short, States, Universities, and other recipients all had divergent interests. States would have preferred revised guidance, but a more extreme version that included even more aggregation. Rather than trying to accommodate any

single interest, OMB concluded it was best to revert to the original data model, which was the most favorable outcome for us.

COGR has developed a productive relationship with the OMB Recovery Act team, and we are able to provide a unifying voice to OMB that reflects the concerns and issues of the COGR membership. This does not translate automatically to favorable outcomes as OMB must respond to a wide range of interests including other grant recipients (e.g., State and Local governments), the Recovery Accountability and Transparency Board (RATB), the funding agencies, and of course, Congress. However, because OMB recognizes COGR as a unifying voice of the research community, they have indicated a strong interest to work with us and to rely on us during the remaining tenure of ARRA reporting. As always, we encourage the COGR membership to raise concerns, and when appropriate, we will pursue the issues at-hand.

10. ARRA Reporting Requirements - DOE and ARPA-E

COGR has followed developments for the past six months related to DOE, ARPA-E, other DOE programs, and the ARRA reporting requirements. In COGR's Late Summer 2010 Update (August 19, 2010), we shared the favorable ARPA-E response from early July where ARPA-E retracted their request for additional ARRA reporting requirements:

As you know, the Advanced Research Projects Agency – Energy (ARPA-E) published a notice in the Federal Register on June 25, 2010 requesting public comment on a proposal to request monthly reporting from ARPA-E performers. We would like to thank everyone who submitted a response to the Federal Register notice. We value your input, and always welcome suggestions for improvements to ARPA-E's operations and management.

We have carefully evaluated the responses received to date, and decided not to require monthly reporting. In making this decision, it is ARPA-E's intent to minimize the administrative burden on our performers and ensure maximum resources can be dedicated to achieving transformational advances in energy technologies.

Although ARPA-E is not requiring monthly reporting, ARPA-E will continue to require quarterly financial, programmatic, and technical reporting. In addition, OMB will continue to require quarterly reporting on use of American Recovery and Reinvestment Act (ARRA) funds, on federalreporting.gov.

*Regards,
ARPA-E*

However, several COGR members have indicated to COGR that ARPA-E may be working around the official retraction and is still requiring extraordinary data requests upon submission of invoices to ARPA-E. If you have ARPA-E awards and have experienced these ARPA-E requests, please contact David Kennedy at dkennedy@cogr.edu.

11. Audit Update: ARRA and 2011 Inspectors General (IG) Workplan Status

We have consistently reported for over six months that the most active audit activity from the University perspective is coming from the NSF IG. The February 2010 Meeting Report

contained a detailed update on the NSF IG audit approach, and it appears that many of those areas described in that report are still applicable. We have also reported that the Department of Education IG initiated audits of State Fiscal Stabilization Funds in all 50 states; half of those audits were on-site and the other half were desk audits. The Department of Energy IG also initiated audits at several universities, while the Department of Energy, Office of Science has conducted at least one ARRA program review, to-date.

The Department of Health and Human Services IG, responsible for auditing NIH programs, has not yet focused on NIH award recipients, though that may soon change. The “*College and University Indirect Costs Claimed as Direct Costs*” audit initiative (see below) likely will be used to leverage a review of ARRA activities at the selected institutions. Our understanding is that 8 institutions will be selected under this audit initiative. Based on those leveraged ARRA reviews, this will help the HHS IG determine the scope of additional ARRA-related audits.

The HHS Office of Inspector General 2011 Workplan is now available at:
<http://www.oig.hhs.gov/publications/workplan/2011/>

The 2011 Workplan highlights several initiatives, shown below. However, the Workplan will expand and contract as the HHS IG does ongoing risk assessment. COGR will follow the status of the list below, accordingly. The published Workplan items include:

- Review of Extra Service Compensation Payments Made By Education Institutions (page V-9)
- Recharge Centers at Colleges and Universities (page V-9)
- College and University Indirect Costs Claimed as Direct Costs (page A-8)
- Classifications of Federal Pass-Through Funding Recipients (page VII-7)

COGR staff is scheduled to meet with representatives from the HHS IG and the NSF IG before the October 28-29 COGR meeting (the NSF IG should release its 2011 Annual Audit Plan shortly). In those meetings we will raise issues of the timing, scope, and Federal concern as it relates to each audit initiative, and also learn of additional audit initiatives not shown on the Workplan. As always, COGR is interested in audit experiences at your institution so that we can update the general landscape for the membership. Please contact David Kennedy at dkennedy@cogr.edu if your institution has been contacted by an agency to conduct an audit or review. We will keep all correspondences confidential.

12. GAO Report on Indirect Costs and GAO at the COGR Meeting

Representatives from the United States Government Accountability Office (GAO) team that completed the study on Indirect Costs will present an overview of their work at the COGR Meeting during a Thursday afternoon session. In attendance from the GAO Acquisition and Sourcing Management Team will be Penny Berrier Augustine, Assistant Director, Janet McKelvey, Senior Analyst, and John Needham, Director, all of whom were active in developing the final report.

The GAO released its study on Indirect Costs in September. The report, *University Research: Policies for the Reimbursement of Indirect Costs Need to be Updated* (GAO-10-937), looked at a number of topics specific to the F&A reimbursement process and provided recommendations

(pages 38-39 of the report) targeted to the Director of OMB and the Secretary of Defense. Recommendations to the Director of OMB included:

- identify methods to ensure that the rate-setting process is applied consistently,
- clarify the roles and responsibilities of federal agencies in ... reevaluating the eligibility of schools to receive the utility cost adjustment, and
- reexamine and determine [if the] 26 percent [limitation] achieves the appropriate level of cost control and achieves the government's objective that the federal government bears its fair share of total costs.

The report can be accessed at: <http://www.gao.gov/products/GAO-10-937>

Two other items of interest: The GAO report includes a short analysis, based on responses from the GAO survey that was completed by university officials, on what has caused administrative costs to grow (page 22). Also, based on how some State systems are organized, the GAO report stated that the A-133 single audit does not get conducted at some campuses on an annual basis (page 30). We expect that there will be an opportunity for Q&A during this session, and the above topics and other related items can be addressed during this session.

13. F&A/Compliance Reform: Next Steps – F&A Perspectives Series

The past two COGR Updates, the June Meeting Report (dated June 24, 2010) and the Late Summer 2010 Update (August 19, 2010), included significant discussion on the topic of F&A/Compliance Reform. We anticipate focusing on this topic over the next year, or as long as there is momentum in the research community to continue this discussion.

The F&A Perspectives Series is an initiative that the COGR Costing Policies Committee has undertaken with the goal of developing a series of short, policy-based white papers that will serve as advocacy and educational resources. As we wrote in the previous COGR Updates, the timing is right in that the current economic conditions have highlighted the fragile state of university finances. Consequently, University Presidents and Senior Administrators are motivated to look closer at F&A reimbursement.

At the same time, the Obama Administration views research, science and technology as a critical factor toward long-term economic well-being. The President's Office of Science and Technology Policy (OSTP) has taken on a more prominent role than it did under the prior Administration, and OSTP has expressed interest in learning more about F&A/Compliance reform ideas. In addition, an unexpected source of support was provided by the GAO Report on Indirect Costs (see previous section), which promoted several favorable recommendations.

Even more significant could be the upcoming study by the National Academies. In June 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. On June 23, 2010, the National Research Council announced the launch of the "Study on Research Universities". This project is underway and a final report should be completed within one year. A summary of the National Academies initiative can be found at:

<http://sites.nationalacademies.org/PGA/bhew/researchuniversities/index.htm>

Finally, two of COGR's association partners, the Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU), are both Presidents' organizations that are championing some of the same issues that we will highlight in the F&A Perspectives Series. As we make progress on the F&A Perspectives Series, we will work with AAU and APLU to channel appropriate material to the National Academies.

The COGR Costing Policies Committee has discussed 8 topics (listed below) that we could address through the F&A Perspectives Series. Below is the original action plan and timeline that was presented in the previous COGR Updates. Note, as events dictate, the plan will be subject to modification.

Topics that COGR plans to initiate over the next several months:

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, as an alternative to eliminating the 26% cap (i.e., in case discussions on the 26% cap are unsuccessful).
3. Advocacy for Extension of the 1.3% Utility Cost Adjustment (UCA) to all Institutions, with an understanding that excluding institutions is inherently unfair.
4. Improving the Rate-Setting Process with DCA and ONR, focusing on a diplomatic analysis of how the F&A rate setting process could be improved under the current DCA and ONR models.

Topics that COGR is considering to initiate over the next six months:

5. Documentation of Administrative Practices Necessary under Tight Budgets, with an emphasis on cost savings, administrative efficiencies, and institutional practices required under growing compliance burdens and the 26% administrative cap.
6. "De-coupling" F&A Application to Awards from the Recovery Mechanism/Use of F&A Reimbursement, with a focus on describing how F&A application to a specific award must be viewed separately from institutional expenditures on research infrastructure.

Topics that COGR will track and work with other organizations, as appropriate:

7. Feasibility of Direct Charging Research Specialists, and how this can be reconciled with current practices on direct charging administrative support.
8. New Financial Research Models, including consideration of direct charging methodologies and presentation tools that better account for how research is funded.

COGR MAY SOLICIT MEMBER INPUT. There could be situations that require your feedback and we will keep the membership posted on all developments.

14. Other Costing Developments and Discussions

Below are topics that are either new developments or items we have reported on in the past and continue to follow. If there are cost-related or financial topics that you would like COGR to raise during the October 28-29 meeting, please contact David Kennedy at dkennedy@cogr.edu.

DOD 35-percent F&A Limitation. This statutory requirement remains in effect under the FY2010 DOD Appropriations Act. Currently, DOD is operating under a Continuing Resolution, so the FY2010 requirements still apply. As it relates to the FY2011 appropriations legislation, there is active discussion that the F&A limitation language will either be eliminated or modified to state that the limitation no longer applies. We will learn more after the midterm elections and when Congress returns to Washington.

NIH Request, Costing on Core Facilities – MEMBER INPUT REQUESTED. The NIH “Request for Comment on FAQs to Explain Costing Issues for Core Facilities” includes a series of draft FAQs that address costing issues applicable to core facilities (shared resource facilities) that are frequently utilized at institutions to support NIH activity. Comments to NIH are due by December 10, 2010 and COGR will respond. If you have comments on the draft FAQs, please contact COGR by mid-November. The NIH notice can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-138.html>

Analysis of a Gates Foundation Award – MEMBER INPUT REQUESTED. COGR is working on an internal analysis to better demonstrate F&A reimbursement practices by Non-Profit Research Foundations. If you have a “typical” Gates award and are interested in sharing data with COGR, could you summarize the final budget into the following categories: Direct costs, Indirect costs being paid as Direct, and F&A costs. All data shared will be kept confidential.

2009 Results, NSF Survey of R&D Expenditures. Data tables and a brief narrative for the 2009 NSF Survey are available at <http://www.nsf.gov/statistics/infbrief/nsf10329/>. The results show that colleges and universities continue to make a significant and growing contribution to the research enterprise. Of the \$11 billion+ university contribution, the NSF report states: “*This amount includes separately budgeted organized research funded solely by the institutions (\$6.3 billion) and almost \$5 billion in unrecovered indirect costs related to sponsored research and direct cost sharing.*” Note that these numbers apply to all sponsored programs – however, a significant portion are applicable to federal awards.

Miller Amendment and Possible GAO Study. During the reauthorization proceedings for the America COMPETES Act bill earlier in the summer, Representative George Miller (D-CA) attached an amendment to the bill that would prohibit payment of F&A on awards funded by the Act (i.e., NSF funds) in situations where a public university was not negotiating in “good faith” with its employees. A motivation for the amendment was stalled contract negotiations between a university system and their postdoctoral employees (and the union, the UAW, representing the postdoctoral employees). Since the amendment was first attached, the contract negotiations have been resolved in a favorable manner. At this time, the status on the reauthorization of the Act is uncertain, as is the fate of the Miller Amendment. In addition, Representative Miller and several of his colleagues from the House, in June, asked the GAO to study how universities track spending on federal research funds – though not an obvious connection, the motivation seems to have been based on the stalled contract negotiations from earlier in the summer. We will keep the membership posted on developments.

COGR Paper on University-VA Joint Appointments. The COGR publication, *Faculty Appointments at Academic Medical Centers: A Focus on University-VA Joint Appointments*, is now available to the COGR membership and can be found on the COGR website at

www.cogr.edu under the Educational Materials / Financial Management tabs. The paper focuses on University-VA joint appointments and those issues related to compensation and effort commitments. The Working Group that contributed to this paper included members of the COGR Costing Policies Committee and a number of individuals from your institutions. This is a highly technical paper and required significant scrutiny. A special thanks to Bruce Elliott from Northwestern University, Allen DiPalma from the University of Pittsburgh, and Robert Kenney from the law firm of Hogan Lovells for providing substantial edit and rewrite support during the final push to complete the paper. All authors and contributors are recognized on the final page of the document.

15. NSF Changes to Grants Proposal Guide

On October 1, 2010, the National Science Foundation issued a revision of the Grants Proposal Guide (GPG), a part of the Proposal and Award Policies and Procedures (PAPP) Guide, effective for proposals submitted on or after January 18, 2011. There are a number of changes to the GPG to facilitate compliance with new Federal-wide policies and some changes made to reflect changes or clarifications to NSF policies and procedures.

The changes to the GPG will be discussed at the October COGR Meeting during the Thursday afternoon session featuring NSF and NIH policy staff. In addition to the NSF changes described briefly here, NIH anticipates issuing a new Grants Policy Statement which, we understand, will principally incorporate changes that have been implemented since the last version of the GPS published in 2003. The COGR session will be held Thursday, October 28, 2010 from 3:45-5:30 PM.

Two notable changes, or clarifications from NSF address cost sharing and data management. The cost sharing policy implements the National Science Board's recommendation to prohibit voluntary committed cost sharing. A complete discussion of the cost sharing provisions is included in the Costing Policies Committee report elsewhere in this update.

With regard to data management, NSF has "clarified" its long-standing policy calling for descriptions of plans for data management and sharing of research products. NSF now requires the data management plan or justification for the absence of a need for such a plan as a supplement document to all proposals submitted to the agency. Fastlane will not accept a proposal missing a data management plan. The data management plan will be reviewed as part of the intellectual merit or broader impacts of the proposal or both, as appropriate for the scientific community of relevance. Collaborative proposals or proposals with subawardees in a single unified project should submit a single plan.

In describing the plan (of not more than two pages), NSF suggests a plan could include: the types of data, samples, physical collections, etc., that will be produced in the course of the project; any standards to be used for data and metadata format and content; policies for access and sharing including intellectual property provisions; provisions for re-use, re-distribution, and the production of derivatives; and plans for archiving data and for preservation of access to them. A valid plan may include only the statement that no detailed plan is needed, as long as the statement is accompanied by a clear justification.

NSF has created a website (<http://www.nsf.gov/bfa/dias/policy/dmp.jsp>) that includes the policy, links to requirements and plans specific to some individual directorates (Engineering, Geological

Sciences and Social, Behavioral and Economic Sciences have links at this time), and Frequently Asked Questions (FAQs).

16. NSF Modifies the Grant General Conditions

NSF issued a revision of the Grant General Conditions (GC-1) effective October 1, 2010. We notified the membership by email on October 1st that the changes had been implemented and the revised GC-1 is available on the NSF website at: http://www.nsf.gov/pubs/gc1/oct10.pdf?WT.mc_id=USNSF_109.

As we noted, the new conditions apply to all new NSF grants and all new funding amendments to existing NSF grants, except for the following: Article 18 (Responsible Conduct of Research), was effective January 4, 2010; Article 19 (Reporting Subaward and Executive Compensation for FFATA – see discussion below), which applies to new grants of \$25,000 or more awarded on or after October 1, 2010; and Article 20 (Central Contractor Registration [CCR] and Universal Identifier [DUNS]Requirements), which applies to new grants awarded on or after October 1, 2010.

NSF has made these changes to implement the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA, Transparency Act) and the related but separate action of the Office of Management and Budget (OMB) requiring Financial Assistance Use of Universal Identifier and Central Contractor Registration as published in the Federal Register on September 14, 2010 (75FR55671) and incorporated at 2 CFR Subtitle A, Chapter 1, Part 25.

- Article 19, Reporting Subawards and Executive Compensation, requires recipients to report information regarding first-tier subawards in excess of \$25,000, and executive compensation information under those awards.
- Article 20, Central Contractor Registration and Universal Identifier Requirements, requires recipients to maintain current Central Contractor Registration at all times when they have an active award with NSF. Recipients also may not make a subaward to an entity, unless the entity has provided its Dun & Bradstreet (DUNS) number to the recipient.

The revision of Article 18, Responsible Conduct of Research, “catches up” the General Conditions with the requirement to provide training and oversight in the responsible and ethical conduct of research (RCR) to undergraduates, graduate students, and postdoctoral researchers supported by NSF to conduct research, as required by the America COMPETES Act.

17. OMB Guidance on FFATA, CCR and DUNS

Federal Funding Accountability and Transparency Act (Transparency Act) – FFATA - As we described in an email to the membership on September 14th, OMB issued interim final guidance for the Federal agencies on the Requirements for Federal Funding Accountability and Transparency Act (Transparency Act) Implementation for financial assistance funding mechanisms. The notice of the interim final guidance appeared in Federal Register on September 14, 2010 (75FR55663); comments were due October 14, 2010. This guidance serves as the basis for the changes made by NSF to the Grant General Conditions (described above).

We will discuss the Transparency Act/FFATA reporting requirements during the October COGR meeting at a Thursday, October 28, 2010 morning session from 10-11:45 AM, **Reporting to the Federal Government**. The session will outline these requirements in addition to the Federal Awardee Performance and Integrity Information System (FAPIIS) Proceedings Report requirements as examples for a discussion of the challenge of reporting, particularly in those cases where information is held by multiple offices/units.

The OMB guidance establishes the Reporting Subaward and Executive Compensation Information requirements for all financial assistance agreements. The requirements apply to any prime grant that exceeds \$25,000 and first-tier subawards of \$25,000 or more issued by the prime. A subaward for the purposes of financial assistance agreements means “a legal instrument to provide support for the performance of any portion of the substantive project or program.” For financial assistance agreements, subaward does not include “procurement of property and services needed to carry out the project.” This requirement is effective for new awards issued on/after September 14, 2010, and on applications due after October 1, 2010.

Reporting of subawards will be done electronically at www.fsr.gov – the system will be available for financial assistance awards on October 29, 2010; the system is current live for contracts. There are some exceptions to the subaward reporting. The Transparency Act/FFATA requires the reporting of the total compensation of the prime and subrecipient’s five most highly compensated executives must be reported. Prime awardee compensation information is to be reported in the Central Contractor Registration (CCR) database. Any subrecipient registered in the CCR will be prompted to provide the compensation information. Fsr.gov is designed to pre-populate the reporting fields with information stored in the CCR. The recipient’s DUNS number serves as the link. There are exceptions to the compensation reporting requirement as well. The notice/guidance includes greater detail on the elements to be reported and additional definitions.

These requirements are similar to but notably different from the requirements recently issued as interim rules for contracts and subcontracts under the Federal Acquisition Regulations (FAR). We will discuss the difference during the COGR session but the key difference is the definition of a subrecipient. For the purposes of compliance with the FAR rule, first-tier subcontracts means “a subcontract awarded by the contractor to furnish supplies or services for performance of a prime contract” but excludes long-term supplier agreements with vendors.

Central Contractor Registration (CCR) & Dun and Bradstreet Data Universal Numbering System (DUNS) - In the same Federal Register (September 14, 2010), OMB finalized the requirement for financial assistance recipients to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number as a universal identifier and to register in the Central Contractor Registration (CCR) database. First-tier subrecipients must have a DUNS number as well. This guidance is incorporated into 2 CFR Subtitle A as Subchapter B Part 25. These requirements are not new or unexpected. What will seem new is the requirement to report the compensation of the five highest compensated employees within the CCR, if necessary. In COGR’s comment on the Transparency Act/FFATA reporting requirements, we expressed our concern about the requirement for a DUNS number in the case of foreign entities. The new requirements provide for an

agency waiver of the requirement for a DUNS number for foreign subrecipients for subawards under \$25,000. We've asked OMB to provide agencies with greater discretion in terms of subawards greater than \$25,000 and to request that agencies describe the process for requesting an exemption.

In addition to asking for greater flexibility with foreign entities, we asked that OMB work at refining the use of batch-file submission of reports into the FSRS. As currently configured all information in the report – agency provided, prime recipient and subrecipient information – would need to be keyed into the batch-file for submission. All the advantages of pre-populating fields via the DUNS number link to the CCR registry are lost.

We will keep the membership informed as the OMB Guidance on reporting is finalized and the FSRS reporting system is refined by OMB.

18. OHRP Guidance on Subject Withdrawal

The Department of Health and Human Services' (HHS) Office for Human Research protections (OHRP) announced the availability of Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues" on September 21, 2010 in the federal register (75FR57469). The Guidance document is available on the OHRP website: <http://www.hhs.gov/ohrp/policy/index.html>.

OHRP issued a draft of the guidance at the same time similar guidance was proposed by the Food and Drug Administration (FDA) in December 2008. In finalizing the guidance, OHRP removed content regarding the management of biospecimens in part to harmonize the guidance with the FDA which focused on data retention as opposed to biospecimens. Recently, the HHS Office of Civil Rights (OCR) proposed extensive revisions to the Health Insurance Portability and Accountability Act (HIPAA) that address the authorizations necessary for the use and disclosure of protected health information that will affect the management of data, in general, as well related to biospecimens. OCR indicates that it is working closely with a number of agencies including OHRP in making the revisions. It is, thus, no surprise that OHRP has delayed any further guidance on biospecimens until the revisions to HIPAA become clearer.

In addition to removing content concerning biospecimens, OHRP has added examples using social and behavioral science situations and included a recommendation that investigators plan for potential withdrawals and include those plans in the protocol and informed consent documents. Most notably, OHRP had aligned the guidance with the FDA in terms of the continued use of data collected about a subject before the withdrawal from the study. Maintaining and analyzing the complete data, including that of withdrawn subjects, is a requirement of the FDA to ensure scientific validity. For studies not tied to FDA regulations, OHRP leaves it up to the investigator to determine whether or not to eliminate data collected prior to the withdrawal of the subject.

OHRP encourages investigators to include it their protocol and in the informed consent documents a description of the processes the investigator will follow if a subject withdraws or is withdrawn from a study by the investigator. The inclusion of information in the protocol and consent documents and the recommended reporting of a subject's withdrawal to the Institutional Review Boards (IRB) are not required by the regulations. It is important to remember that

guidance provides agency “current thinking” and/or suggestions on a topic but cannot set new policy or regulation. Investigators, IRBs and institutions are not required to implement guidance but are encouraged to consider modifications to institution procedures in light of the guidance.

19. OHRP FWA Revision

OHRP announced a draft revision to the **Federalwide Assurance for the Protection of Human Subjects** form and terms and invites comments no later than October 25, 2010. The notice appeared in the September 23, 2010 Federal Register and the draft form and terms are available on the OHRP website at: www.hhs.gov/ohrp/requests/.

In designing the revision, OHRP has eliminated the requirement to list all IRBs, both internal and external, relied upon by the institution. The institution is asked to commit to using only registered IRBs as the alternative to the prior approach. The proposed forms/terms combine the current separate documents for US and non-US entities and the Terms take a plain language and streamlined approach to the text. Some of the ‘plain language’ actually clarify the applicability of the FWA. For example, in Section 3, Compliance with Laws, etc., the proposed text commits the institution to comply with the Common Rule for research to which the FWA applies. The current text calls for compliance with the Federal Policy for the Protection of Human Subjects (the Common Rule) “when the institution becomes engaged in federally conducted or supported research to which the FWA applies.” Same thing; greater clarity. The current Terms of the FWA unnecessarily repeats elements of the regulations throughout the document; those statements have been eliminated. The new FWA will require electronic submission.

The most significant change in the proposed revisions is the approval period – OHRP proposes to increase the approval period from the current 3-year period to a 5-year period.

COGR’s comments will endorse the changes to the time period and elimination of the requirement to list all external IRBs relied upon in an institution’s assurance and will recognize the simplified language of the Assurance and its related Terms. We will use the change in the requirement to list all IRBs as an occasion to renew our comments on OHRP’s consideration of changes in the accountability of individual IRBs.

Described in an advanced notice of proposed rulemaking issued in March 2009 (74FR9578), OHRP offered observations and raised questions concerning the relationships between external IRBs and institutions, the accountability and liability of the institution and the IRBs, and the nature of agreements and assignment of responsibilities within these relationships. COGR offered comment including the elimination of the listing of external IRBs on an institution’s FWA, flexibility in the design of agreements and assignment of responsibilities and, a reallocation of accountability and the related liability between the institution and an external IRB. We will keep the membership informed as OHRP continues to refine its relationship with the research community and if it proposes changes to the regulations.

20. NIH Grants Submission and Policy Changes

NIH and its cooperating agencies have announced changes in the application format for electronic submission. NIH, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, FDA & National Institute for Occupational Safety and Health are transitioning to updated electronic application forms packages (ADOBE-FORMS-B1). For

deadlines on or before May 7, 2011, most applicants (exceptions listed below) may use either ADOBE-FORMS-B or ADOBE-FORMS-B1 forms. For deadlines after May 7, all applicants will be required to use ADOBE-FORMS-B1 forms (NOT-OD-11-007). In an accompanying notice, that agencies are requiring the use of ADOBE-FORMS-B1 for F, K, T and D Submissions with Due Dates of January 25, 2011 and Beyond (NOT-OD-11-008).

As explained in the recent October *NIH Extramural Nexus*, NIH must periodically implement updated versions of SF424 (R&R) application forms to stay current. Beginning this month, NIH will begin adding a new form package, referred to as ADOBE-FORMS-B1, to all funding opportunity announcements (FOAs). The updating of this forms package is a useful moment to remind applicants to check the FOA before the preparation of a submission to ensure that they are using the current, appropriate application forms.

NIH has announced a series of changes to its policies and procedures over the past few months. Most recently on October 6, NIH established new procedures and instructions for submitting annual progress reports for multi-year funded awards (NOT-OD-11-010). Progress Reports for MYF awards are now due annually on or before the anniversary of the budget/project period start date of the award. These changes apply to MYF awards with an annual progress report due on or after 12/22/2010. On October 1, 2010, NIH established *New Time Limit for NIH Resubmission Applications* (NOT-OD-10-140). NIH set a new time limit between the submission of a New, Renewal, or Revision application and a Resubmission (A1 version) of that application at no later than thirty-seven months after the date of receipt ("receipt date") of the initial New, Renewal, or Revision application.

Investigators and Sponsored Program staff will want to review these notices and other addressing just-in-time submissions, and, most notably, the elimination of the error correction window from the application submission process (NOT-OD-10-123). All policy and procedure notices are posted to the NIH Office of Extramural Research (OER) website at: <http://grants.nih.gov/grants/policy/policy.htm>

We understand that NIH will be issuing a revised Grants Policy Statement (GPS) very shortly. One of the principal goals in the revisions to the GPS is to incorporate all the changes to policies and procedures, including peer review procedures that have been implemented since the last version was issued in 2003. The changes to the GPs will be discussed at the October COGR Meeting during the Thursday afternoon session featuring NIH and NSF policy staff. The COGR session will be held Thursday, October 28, 2010 from 3:45-5:30 PM.