

COUNCIL ON GOVERNMENTAL RELATIONS

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MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS

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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

1. F&A/Compliance Reform Update and Soon-to-be-Released COGR Paper

F&A/Compliance Reform, with a special emphasis on the F&A, has been a primary focus of the Costing Policies Committee for the past six months. In each of the COGR Updates over this time period, we have included detailed discussions on this topic. We anticipate keeping this focus over the foreseeable future and as long as there is momentum in the research community to continue this discussion.

Over the next several weeks, COGR will be engaged in a number of meetings that will allow us to address F&A and other Cost Reimbursement issues. One of those meetings is the November 22-24 meeting of the National Academies Committee that is addressing the “*Study on Research Universities.*” COGR staff, as well as some of our active COGR members, will have the opportunity to participate in several of the “focus group” discussions. We will also have the opportunity to present to the Study’s committee some of the specific COGR concerns related to cost reimbursement and the state of the Government-University research partnership. Additional information related to the National Academies Study can be found by following the link below: <http://sites.nationalacademies.org/PGA/bhew/researchuniversities/index.htm>

In the past several COGR Updates, we have shared updates on the ongoing Costing Policies Committee initiative: “The F&A Perspectives Series.” The goal is to develop a series of short, policy-based white papers that will serve as advocacy and educational resources. We have completed the first paper, entitled: “*Federal Funding Agency Limitations on Cost Reimbursement: A Request for Consistency in the Application of Federal Guidelines.*”

The paper identifies financial reimbursement policies imposed by Federal funding agencies that are inconsistent with official federal guidelines and results in the significant under-recovery of federal funds by research institutions. The Appendix to the paper includes a sampling of Federal agencies and/or programs where arbitrary agency policy results in the shift of financial burden from the federal funding agencies to research institutions. We expect to have the paper available for wide distribution shortly, and we will keep the membership posted on both the release of the paper and the outcomes of other activities related to F&A/Compliance Reform.

2. 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 presented an overview of their work at a Thursday afternoon session. In attendance from the GAO Acquisition and Sourcing Management Team were Penny Berrier Augustine, Assistant Director, Janet McKelvey, Senior Analyst, and John Needham, Director, all of whom were active in developing the GAO 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 targeted to the Director of OMB and the Secretary of Defense. The report can be accessed at: <http://www.gao.gov/products/GAO-10-937>

The GAO's presentation included background information on the GAO, specifics related to the *University Research* report, and a prospective look forward on potential topics for future study related to indirect cost reimbursement. Several insights from the session included:

- **Tone of the GAO Findings; Rate-Setting Variations.** While overall the report was favorable to research institutions, the GAO is very careful in how they word their findings. In the case of differences between the DCA and ONR methods for setting rates, the GAO presentation emphasized that their recommendation to OMB is not designed to show preference: *"Identify methods to ensure that the rate-setting process is applied consistently at all schools, regardless of which agency has rate cognizance."* Consequently, as COGR advocates for implementation of the GAO recommendations, we need to clearly articulate the pros and cons of the DCA and ONR approaches.
- **26% Cap and the Utility Cost Allowance (UCA).** Again, how COGR advocates for implementation requires a thoughtful approach. In the case of the 26% cap, the GAO presentation stated: *"We recommended that OMB reexamine and determine whether reimbursing administrative costs at a maximum rate of 26 percent achieves the appropriate level of cost control and achieves the government's objective that the federal government bears its fair share of total costs."* This surely will be welcomed by COGR. As to review of the UCA, the GAO emphasis to *"Clarify the roles and responsibilities of federal agencies (including DOD, HHS, and OMB) in accepting applications and reevaluating the eligibility of schools ..."* also would seem to be welcomed by COGR. Still, we will follow closely how OMB implements these recommendations.
- **DOD Oversight and the A-133 Audit.** The GAO presentation included a bullet point stating: *"4 of the 32 schools receiving the most DOD basic research funding in fiscal year 2008 were not subject to any of the three methods of oversight."* How this recommendation translates into revisions to oversight methods (e.g., the A-133 audit) is of interest to COGR.
- **Future GAO Studies.** The GAO indicated in their presentation at least three other areas of interest: *"Comparisons of indirect cost rates across sectors, Challenges research performers face in controlling indirect costs, Research for DOD versus other agencies."*

While it is uncertain if the team that worked on the study will have the time and resources to undertake future studies, COGR should have the opportunity to engage with members of the GAO team and provide input on future initiatives.

The GAO PowerPoint presentation is available at www.cogr.edu (under the Meetings/October 2010 Presentations tab).

COGR will closely follow actions taken by both OMB and DOD in response to the GAO recommendations and engage with these entities, as appropriate. We will keep the membership posted on all developments.

3. National Science Foundation Policy on Voluntary Committed Cost Sharing

COGR reported on the significant change to the treatment of Voluntary Committed Cost Sharing (VCCS) in proposals to the National Science Foundation (NSF) in the Fall Update (October 14, 2010). The link to the summary of “Significant Changes to the Grant Policy Guide” is shown below: http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/gpg_sigchanges.jsp

In her presentation to the COGR membership on Thursday afternoon, Jean Feldman, Head of the Policy Office at NSF, summarized the new VCCS policy. Some of the points from her presentation included:

- Inclusion of voluntary committed cost sharing will be prohibited in solicited and unsolicited proposals and Line M will be “greyed out” in FastLane.
- Organizations may, at their own discretion, continue to contribute any amount of voluntary uncommitted cost sharing to NSF-sponsored projects.
- The Facilities, Equipment & Other Resources section should be used to provide a comprehensive description of all resources (both physical and personnel) necessary for, and available to a project, without reference to cost, date of acquisition, and whether the resources are currently available or would be provided upon receipt of the grant.
- NSF program officers may discuss the “bottom line” award amount with PIs, but may not renegotiate or impose cost sharing or other organizational commitments.
- NSF Program Officers may not impose or encourage programmatic cost sharing requirements.
- Per Recommendation 7 of the National Science Board Report (August 2009), there is a continued expectation for grantees to continue the existing practice of sharing in the costs of faculty salaries.
- NSF grantees remain subject to the provisions of OMB M-01-06, “*Clarification of OMB A-21 Treatment of Voluntary Uncommitted Cost Sharing and Tuition Remission Costs*,” regarding requirements for committing and tracking “some level” of faculty (or senior researcher) effort as part of the organized research base.
- Mandatory NSF-required programmatic cost sharing will rarely be approved for an NSF program. Mandatory cost sharing has been implemented only for the following programs: Major Research Instrumentation Program; Robert Noyce Scholarship Program; Engineering Research Centers; Industry/University Cooperative Research Centers; Experimental Program to Stimulate Competitive Research. Cost sharing for these programs must be identified on Line M of the approved budget.

Ms. Feldman also emphasized that if, for example, an institution describes in the Facilities, Equipment & Other Resources section that a significant piece of equipment is necessary to conduct the research, it becomes an obligation of the institution to ensure that piece of equipment is available. So while VCCS is strictly prohibited, an institution is still expected to honor any claims it has made in its proposal to NSF. COGR understands that this could raise some questions on audit repercussion, and as questions are raised, COGR will pursue clarification.

Also, as a follow up to Ms. Feldman's point on OMB M-01-06, "*Clarification of OMB A-21 Treatment of Voluntary Uncommitted Cost Sharing and Tuition Remission Costs*," 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 believes the new policy on VCCS is an important step forward. As COGR pointed out several years ago when providing comments to the National Science Board: 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.

4. NIH Policies Update: Genomic Arrays, Core Facilities, Proposal Preparation Costs

COGR is following three separate costing policy issues applicable to the National Institutes of Health (NIH). Each one is at a different stage of resolution and each was addressed by Sally Rockey, NIH Deputy Director for Extramural Research, and Joe Ellis, Director of the Office of Extramural Research, during the Thursday afternoon session of the COGR Meeting. Below is an update on each topic:

- **Genomic Arrays (GA).** COGR remains actively engaged with the GA issue (see prior COGR Update letters to the membership for detailed discussions). We expect NIH shortly will issue Frequently Asked Questions (FAQs), and where appropriate, modify the policy. While clarifications and/or modifications will be a compromised solution, they will improve the current version of the policy. In addition, COGR believes 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. We will keep the membership updated on all developments. The current version of the NIH policy, dated May 13, 2010, can be found at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-097.html>
- **NIH Request, Costing on Core Facilities.** The NIH "Request for Comment on FAQs to Explain Costing Issues for Core Facilities" includes 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. We will have a draft of the COGR response by the end of November and will share the draft with the membership. The NIH notice can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-138.html>

- **Proposal Preparation Costs on Mentored Career Development Awards.** As presented by NIH during the Thursday afternoon session, and also described in a recent NIH policy notice, the costs associated with effort devoted to proposal preparation are allowable as a direct cost to mentored Career Development Awards (K awards). The NIH notice can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-002.html>

5. Audit Update: Inspectors General Workplan Status for HHS and NSF

COGR Staff had the opportunity to meet with Inspectors General (IG) staff from the Department of Health and Human Services (HHS) and the National Science Foundation (NSF) in two separate meetings in October. During the Friday Committee Reports, we provided a brief update on those meetings, and below we have provided additional detail.

The Department of Health and Human Services IG, responsible for auditing NIH programs, has not yet focused on NIH ARRA 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 FY2011 Workplan is 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. 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)

The first two items were described to COGR staff as pilots that will be initiated in FY2011, if HHS IG resources are available. Extra Service (i.e., Supplemental) Compensation was the focus of a large settlement between a university and the Department of Justice two years ago, and it is an area that poses challenges for research institutions. Recharge Centers seem to be an area that is recycled as an audit concern every ten to twenty years. In fact, the HHS IG published a series of audit reports on recharge centers in FY1995 and FY1996. If interested, these can be found at: http://oig.hhs.gov/oas/nih_archive.asp

As described above, Indirect Costs Claimed as Direct Costs is an item we should pay close attention to. This initiative started as a pilot on four institutions several years ago, and based on the two most recent audits, the HHS IG believes more work should be done in this area. Classifications of Federal Pass-Through Funding may be more of a pilot at this stage, though the following summary in the HHS IG Workplan should be noted: *“There is an advantage to the recipient of the pass-through funds if the recipient is treated as a vendor. Vendors may enter into fixed-price contracts that allow retention of unused funds, whereas subgrantees must return unspent Federal funds to the State agency. In one State we will examine why the State awarded funds to a university as a vendor when the State had previously treated this university as a subrecipient.”*

Finally, in our meeting with HHS IG staff, they indicated an interest in looking at how institutions charge Tuition and Fees to federal awards. While this item was not included in the Workplan, their interest appears to be driven by a current case specific to how tuition remission costs were treated in an institution’s F&A reimbursement methodology.

The National Science Foundation IG, responsible for auditing NSF programs, has not yet released their FY2011 workplan. Unlike HHS where a significant portion of the IG operating budget is dedicated to Medicare and Medicaid audit work, the NSF IG contributes its entire effort to research universities and other research performers. As it relates to ARRA audit activity, NSF has actively engaged research institutions in the areas of capacity to manage the influx of ARRA funds and the corresponding internal controls that have been established. In contrast, HHS has not yet focused on research institutions and ARRA funded NIH programs.

We expect the NSF IG to release their FY2011 workplan soon. However, in COGR’s meeting with NSF IG staff, we were able to get a sense of some of their focus and priorities for FY2011.

- ARRA audit focus to move away from internal controls to a focus on program expenditures.
- Effort Reporting “capstone report” to be released in the first half of 2011 – the report will be a summary of findings from the effort report audits between 2006 and 2010.
- Shift away from the “outsource” audit model, to one where more NSF IG audits are done in-house by NSF IG personnel.
- Broadly speaking, the NSF IG is interested in Responsible Conduct of Research, Institutional credibility and “tone from the top”, Responsible professional practices, International collaborations and compliance with U.S. standards for research, Research Integrity, and External activities for faculty.
- Some NSF IG staff expressed concern that our institutions do not effectively self-disclose situations that should be reported to the IG.

In both meetings, NSF IG and HHS IG staff expressed a growing interest in Information Technology (IT) Security. While it does not seem likely that IT Security will be an immediate focus for either IG office, it is an area to which we should pay attention. Also note, both IG offices spend significant time looking at management and control practices of the agencies,

themselves. While this does not directly impact our institutions, depending on the findings, it can impact how the funding agencies interact with the research community.

In past COGR reports, we have updated the membership on ARRA audit activity from several IG Offices, including the Departments of Energy and Education. In addition, we continue to follow developments related to the A-133 audit and the A-133 Compliance Supplement. 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.

6. ARRA Update

The sixth cycle of ARRA Section 1512 reporting will be initiated on January 1, 2011. COGR is in regular contact with the OMB staff that is responsible for implementing ARRA reporting. Below is a list of those items that we are tracking.

- **Subrecipient and Vendor Guidance.** As we reported in the Fall Update (October 14, 2010), the updated OMB Guidance M-10-34 released on September 24, 2010 created significant confusion for the entire grant recipient community. COGR worked effectively with OMB to rescind the updated guidance specific to subrecipient and vendor reporting. Our understanding is that there will not be new guidance related to this issue, though we will pay attention as the next reporting period draws closer.
- **Davis-Bacon and Buy American Provisions.** As work related to construction awards becomes more active, questions related to these two provisions have become more frequent. OMB has shared with COGR that these provisions have raised challenging questions and that it may often require a combination of working with OMB and the funding agency to resolve issues. As appropriate, COGR can be involved to facilitate issues that arise.
- **Above-and-Beyond Agency Reporting Requirements.** We are still following this concern. In the Fall Update we reported that several COGR members have indicated that ARPA-E may be again requiring extraordinary data requests upon submission of invoices to ARPA-E, despite the fact that ARPA-E retracted their original request for additional ARRA reporting requirements in July. Also, a COGR member shared that the Agency for Healthcare Research and Quality (AHRQ and part of DHHS) has asked for additional data to be entered into an electronic portal (the AHRQ Research and Reporting System, or ARRS). In these situations, COGR will continue to engage OMB and ask for clarification on OMB's approval of agency requirements.
- **Final Reports.** As institutions begin to wind-down ARRA projects, categorizing reports as "final" and following the required steps to do so necessitates special care. The timing of submitting final reports is important. In one case, a COGR institution was using the correction period to submit their final reports, and consequently, NIH generated an automated email that indicated that these reports were classified as missing reports. The volume of data being managed by federal agencies is massive, and some of these

situations will persist. However, if there are concerns with how an agency approaches your institution in these situations, contact COGR staff.

- **Reporting Deadlines and Late Reports.** Since the statutory requirements of ARRA require reports to be completed in ten calendar days, OMB and the Recovery Accountability and Transparency Board (the RATB) have limited flexibility in extending reporting deadlines. Still, with the use of somewhat cryptic OMB/RATB language, there has been some form of an extension in the prior reporting periods. However, deadline extensions and availability of a late reporting period should not be assumed and institutions should pay close attention to the new reporting schedules that are posted on FederalReporting.gov.
- **Narrative Description Fields.** The updated OMB Guidance M-10-34 from September 24, 2010 emphasized the importance of narrative reporting. From OMB's perspective, this is necessary to enhance the transparency of the narrative descriptions. As narrative reporting requires some subjectivity, institutions should approach this requirement in a manner that is consistent with institutional policies and that is compliant with OMB and agency requirements.

We do not expect OMB to release new reporting guidance with significant changes for the January 1, 2011 reporting cycle. However, we will follow closely as the next reporting cycle nears. The OMB Recovery Act site includes all current guidance, including the OMB Guidance M-10-34 released on September 24, 2010. The OMB Recovery Act site can be found at:

http://www.whitehouse.gov/omb/recovery_default/

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 for research-related issues 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.

7. 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, please contact David Kennedy at dkennedy@cogr.edu.

Recapture Audits to Recover Improper Payments. OMB is instructing federal funding agencies to intensify their efforts in the area of "recapture audits." The goal is to reduce the government-wide amount of improper payments to recipients of federal funds, and when they do occur, try to recapture as much as possible. While legislation and regulatory requirements have existed since at least 2002, several recent Executive Orders and the Improper Payments Elimination and Recovery Act (IPERA, Public Law 111-204, and

signed by the President on July 22, 2010) have elevated this topic. It is too early to determine how research funding agencies will be required to respond to directions from OMB and how it might affect our institutions. However, COGR is following this issue and will update the membership if there are any significant developments.

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 as Congress acts during the remainder of the 2010 calendar year.

Analysis of a Gates Foundation Award. 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, we are asking members to 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.

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.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Michelle Christy, Chair, Massachusetts Institute of Technology; Michael Amey, The Johns Hopkins University; Kelvin Droegemeier, University of Oklahoma; Anne Hannigan, Stanford University; 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

1. NSF Clarifies New Requirements Including Data Management, FFATA and RCR

During the October COGR meeting, Jean Feldman, head of the Policy Office at the National Science Foundation (NSF), along with her colleague Daniel Bogden, program director of the Office of Cyberinfrastructure, reviewed the recent changes to NSF's Proposal and Awards Policies and Procedures (PAPP). She was joined for this Thursday afternoon federal agency session on Changes to Grant Policies at NSF and NIH by Joe Ellis, director of the National Institutes of Health (NIH) Office of Policy for Extramural Research Administration, and Sally Rockey, NIH Deputy Director for Extramural Research. Copies of the slides used during these presentations are available on the COGR website as "October 2010 Presentations" under the "Meetings" tab at www.cogr.edu.

A. Data Management:

As noted in the update sent to the membership before the October meeting, NSF 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. The two notably 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 and is discussed in greater detail in the Costing Policies Committee report elsewhere in this document.

As outlined in the pre-meeting Update, NSF has "clarified" its long-standing policy calling for descriptions of plans for data management and the sharing of research products. The data management plan or justification for the absence of a need for such a plan is now a not-more-than 2 page supplement to all proposals submitted to the agency and 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. Fastlane will not accept a proposal missing a data management plan.

Data management requirements and plans specific to a Directorate, Office, Division, Program, or other NSF unit, will be consolidated and made available on a single NSF website at: <http://www.nsf.gov/bfa/dias/policy/dmp.jsp>. If the guidance related to a

specific program is not available, then applicants should follow the general requirements described in the GPG. Applicants should check the web site before completing an application to determine if there are specific requirements. There are Frequently Asked Questions (FAQs) available on the site as well.

B. NSF RCR Resources:

In addition to discussing the changes to the GPG, Feldman provided updates on other new or recent requirements and changes to NSF's policies and procedures. To assist the community in meeting the requirement to provide training in the Responsible Conduct of Research (RCR) for undergraduate and graduate students and post-doctoral fellows supported (i.e., paid a salary or stipend) on an NSF research grant, NSF has developed a website, as promised, at: <http://www.nsf.gov/bfa/dias/policy/rcr.jsp>. The site includes information on the policy and FAQs concerning the policy. Links are provided to several non-NSF sites as well as access to the National Professional and Research Ethics Portal, the new online resource center for ethics in science, mathematics, and engineering. The University of Illinois at Urbana-Champaign will develop the site with support from NSF and in collaboration with Howard University, the National Academy of Engineering and Public Responsibility in Medicine and Research (PRIM&R).

As a part of a global effort to harmonize international standards concerning research integrity, NSF co-sponsored along with other US government and private organizations the Second World Conference on Research Integrity that took place in Singapore in July 2010. In an approach similar to the development of the Belmont Report addressing human research participants' protections, the conferees in Singapore are developing a statement on research integrity. Information on the meeting is available at <https://www.wcri2010.org/index.asp>. The statement will be available after review and approval by the delegates. The final statement will cover a broad range of topics, including peer review, proper credit for publications, and practices to preempt research misconduct.

C. Public Outcomes Report IN ADDITION TO Final Annual.

As another step in the implementation of America COMPETES Act requirements, Feldman provided a useful flow-chart and overview of the Public Outcomes Reporting site on www.research.gov. Investigators are required to submit a brief (200 – 800 words) final project outcomes report that will be made available to the public along with citations, etc., previously posted in the annual reports submitted by investigators in FastLane. Feldman urged us to remind investigators that the **Public Outcomes Report is IN ADDITION TO the final annual report posted to Fastlane**. Investigators should go to www.research.gov, check the status of various reporting requirements, and click on the appropriate link to submit the report. This report should be written for the general public and summarize the activities supported by NSF over the life of the project.

D. FFATA/Transparency Act Reporting

As we described in the pre-meeting Update, NSF included changes in the Grant General Conditions (GC-1) to enable the reporting of subrecipients as required by the Federal Funding Accountability and Transparency Act (FFATA/Transparency Act). Effective October 1st, all NEW NSF awards incorporate the Reporting Subawards and Executive Compensation Award Term; and Central Contractor Registration and Universal Identifier Requirements Award.

Details on the presentation by Joe Ellis are included in the Costing Policies Committee report elsewhere in this document. Sally Rockey described NIH's progress in finalizing the revision of NIH's Objectivity in Research/Financial Conflicts of Interest policy. NIH received 136 unique, substantive comments on the proposed policy. NIH is in the process of responding to the comments received and making the final revisions to the policy. It will be reviewed by the Secretary of the Department of Health and Human Services and, following her review and approval, sent to OMB for review before it is finalized. OMB can take up to 60 days to complete its review. The final rule will be available early in the next calendar year.

2. Federal Reporting – Systems Approach

The Thursday morning discussion, *Reporting to the Federal Government*, focused on the need for a more system-based approach to addressing the increasing flood of reporting requirements issued by the federal government. As David Kennedy noted in his overview of the challenges, the administrative and cost burdens of complying with these requirements was briefly addressed in the Government Accountability Office's report on *University Research: Policies for the Reimbursement of Indirect Costs Need to be Updated* (GAO-10-937). The GAO notes that schools have responded to the challenge by ““hiring new staff to, for instance, report data on grants and subrecipient monitoring, opening new offices to monitor compliance with federal regulations, implementing new information technology systems, developing processes for improving security and safety, and training staff on new systems and compliance efforts.”

Jim Luther, Duke University, and Michelle Christy, MIT, described their campuses responses to the Recovery Act reporting requirements as examples of how institutions can create new mechanisms and organize current data systems to report. As a part of the discussion, Carol Blum highlighted the two newest reporting requirements and offered some advice on meeting the requirements using the lessons learned from Recovery Act reporting.

A. FFATA Subrecipient Reporting

As noted above, NSF modified its Grant General Conditions (GC-1) to implement the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA, Transparency Act) requiring Financial Assistance Use of Universal Identifier (DUNS numbers) and Central Contractor Registration (CCR). Article 19 of the GC-1, 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.

As Joe Ellis, noted in his presentation on Thursday afternoon, NIH made similar modifications through three recent notices posted in the *NIH Guide* (NOT-OD-11-004, 005 and 006, issued October 22, 2010). Like NSF, NIH requires the use of DUNS numbers and CCR registration as a new term of an award (NOT-OD-11-004), requires reporting of subawards and executive compensation, if appropriate, for subawards at/above \$25,000 (NOT-OD-11-005), and revised all currently open Funding Opportunity Announcements (FOA) to incorporate these as eligibility and/or award requirements (NOT-OD-11-006).

The pre-meeting Update provided a long discussion of the FFATA/Transparency Act reporting requirements. During the Thursday morning review of the FFATA requirements and the then-recently available reporting system at www.fsr.gov – Federal Subrecipient Reporting System – Carol Blum urged prime awardees to pass on to their subrecipients the CCR registration requirement. Using the DUNS number (all recipients are required to have a DUNS number – prime and sub), the FSR system will pre-populate many of the fields in the system from the CCR database, including the questions concerning executive compensation. This pre-population of many of the fields will significantly ease the reporting burden for single reports. NSF and the other federal agencies have not required that subrecipients to register in the CCR but, again, we strongly recommend that institutions, as prime awardees, require their subrecipients to register in CCR.

At the time of the meeting, the only available batch file system was a computer value system (CVS), which did not offer the advantage of pre-population. A new XML format for batch reporting has been made available recently and as members test the new system, we will let the membership know if this is a useful alternative particularly for those grants with multiple subawardees. The Federal Demonstration Partnership (FDP) Subawards Committee is developing materials to assist the community with Transparency Act reporting requirements as well (<http://sites.nationalacademies.org/PGA/fdp/index.htm>).

B. FAPIIS Reporting

Revisions to the CCR have been made to accommodate another new reporting requirement, recipient integrity and performance. Section 872 of the Duncan Hunter National Defense Authorization Act of 2009 (PL 110-417), as amended, required the development of a government-wide data system of information concerning the integrity and performance of entities on federal grants and contracts; and the use of the information by federal officials making awards. Since September 2009, we have reported on our responses to requests for comment on the implementation of these requirements; first on changes to the Federal Acquisition Regulations (FAR) and, in April 2010, to proposed Office of Management and Budget (OMB) guidance for financial assistance

mechanism. The FAR rule at 52.209-7/8 was finalized in March 2010 (75FR14059); the OMB guidance is still pending.

To accommodate the FAPIIS required reporting of criminal convictions or findings of fault in civil and/or administrative proceedings that resulted in the payment of a fine at various levels, the federal agencies have established the Federal Awardee Performance and Integrity Information System (FAPIIS). The process for reporting these convictions or findings has been incorporated into the CCR registration under the heading "Proceedings." When an institutional representative enters the CCR to update the information, as needed, semi-annually (a requirement under FAPIIS), they can complete the "Proceeding" section and meet the requirements. As with completing the Executive Compensation section of the CCR registration for FFATA compliance, this Proceedings information will be available to and reviewed by federal officials making awards. The information is to be made available to the public but the mechanism for public access is not entirely clear at this time.

There are criteria for who reports on what – entities with \$10 million in current federal contracts and grants; for the entity and its principals – and a time frame – the past five years. Institutions will want to determine who is a "principal" of the organization for general FAR provisions and establish a process for completing the response.

The Thursday morning discussion raised important questions concerning FFATA and FAPIIS reporting and compliance and we will convey those questions to the federal agencies. The presentations from Duke and MIT highlighted the value of an on-going consultation through a standing committee or advisory body among those offices delegated compliance responsibilities. Such an advisory group can be used to assess compliance, in general, and to address specific new reporting or compliance requirements, in particular, to determine the best mechanism to meet the challenge. The presentations made during the Thursday morning session are available on the COGR website under "Meetings."

3. NABR Reviews the Landscape of Animal Research

Frankie Trull, President of the National Association for Biomedical Research (NABR), described the status of legislation focused on the use of animal-models in research at the October meeting during the Association Update on Friday morning. With the change in control of the House and changes in the Senate, Trull analyzed the likelihood of passage of various pending bills. The Great Apes Protection Act (GAPA, H.R. 1326, S. 3694) which prohibits "invasive" research with chimps and other species is likely to be reintroduced in the 112th Congress. NABR has provided leadership in opposing GAPA including writing to members of Congress for and with the community. The Pet Safety and Protection Act which would eliminate Class B dealers as providers of random source dogs and cats and which has been introduced in every session of Congress since 1996 will likely be introduced again.

Trull noted that the Farm Bill (Food, Conservation, and Energy Act of 2008) which includes the Animal Welfare Act (AWA) will be up for reauthorization in 2012; congressional hearings will occur throughout 2011. The reauthorization of the Farm Bill is always an opportunity for animal welfare activities to push for changes to the Animal Welfare Act. You will recall during past

reauthorization hearings and deliberations that there has been consideration of including rats, mice and birds bred for research under the provisions of the AWA; currently these research animals are excluded from the AWA and covered under the provisions of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and the referenced *Guide* published by the National Research Council.

Some observers have suggested that the AWA provision excluding rats, mice and birds bred for research from the AWA is less significant now because of research institutions' compliance with the PHS Policy which affords protections for these species. There are, of course, distinct differences in enforcement and inspections between the AWA and PHS Policy. We welcome your thoughts and observations on this question and any questions as we anticipate the Farm Bill hearings process.

Trull reminded the meeting attendees that one of the consequences of the US Department of Agriculture's (USDA) Age of Enforcement (described in the June 2010 COGR Meeting Report) is an increase in the number of citations for non-compliance that are being included in the reports of the inspectors. Under this USDA initiative, the agency has shifted from an education focus to an enforcement focus, removing 'no action' as an enforcement option and requiring inspectors to photograph direct and repeated noncompliant items. It's important to remember that the number of citations and repeated citations in the same category or section of the AWA inspection report will lead to fines leveled against the organizations. Thus, minor infractions can add up to major concerns. In addition, the inspections reports are posted for public access on the USDA website – almost simultaneous with the conclusion of the site visit.

It is particularly important, as a consequence, that institutions avail themselves of the opportunity at the conclusion of the inspections to review the information to affirm that the security and safety of the facility and individual members of the research and animal care staff are protected. Exact locations of facilities and the names of individuals are not generally needed for the inspection report. Similarly, inspectors' pictures of violations can be posted to the USDA website as well. Institutions should ensure that any picture to be posted is accurate and does not pan too widely to expose the location of facilities and/or individuals.

Recently, animal welfare activists including People for the Ethical Treatment of Animals (PETA) and the Humane Society of the US (HSUS) have used the Freedom of Information Act (FOIA) to gain access to documents – reports, allegations, etc – from both the USDA and NIH's Office of Laboratory Animal Welfare (OLAW). Agencies need not notify institutions when a FOIA request is received concerning the institution and/or members of its staff. NABR, in collaboration with the Federation of American Societies for Experimental Biology (FASEB) and Society for Neuroscience, has prepared a guide for responding to FOIA requests from animal activists. A copy of the guide, *Responding to FOIA Requests: Facts and Resources*, offers ten steps or effective practices for understanding and responding to FOIA requests. The guide is available on the NABR website at: <http://www.nabr.org/>.

Some COGR members have begun to make FOIA requests of certain agencies and units within agencies like NIH's OLAW and the USDA's Animal and Plant Health inspection Service (APHIS) to determine who is requesting what documents about the institution. Each agency will have a link on its home page for making FOIA requests.

Trull concluded by encourage institutions to review state statutes and state legislative initiatives to ensure that research using animal models can be conducted in their home state. HSUS has chapters working to pass restrictive legislation across the country. NABR is preparing a *Model State Legislation* guide that will address targeting for harassment and stalking of individuals and institutions, state open records laws and targeted residential picketing. In addition NABR maintains a database of state laws affecting the use of animals in research.

4. RCA Looking at Access and Retention of Research Data and Research Misconduct

COGR has maintained web-based materials on *Access to and Retention of Research Data: Rights and Responsibilities* (available under Educational Materials from the COGR homepage: www.cogr.edu). Last updated in March, 2006, the information reviews federal policies and provides case scenarios on topics like data sharing, restricted access and data disputes. The COGR Board's Research Compliance and Administration (RCA) Committee in collaboration with the Contracts and Intellectual Property Committee is initiating a review and, as appropriate, revision of these materials. As a part of the effort, we welcome any observations or comments and suggestions you might have to help inform the revision. Send your ideas to cblum@cogr.edu.

In a separate effort, the RCA is reviewing the federal agencies implementation of the Federal Policy on Research Misconduct (December 2000) and developing some examples of effective practices that institutions can consider in ensuring compliance with the agency policies and regulations. Since 2000, agencies have slowly established individual policies to meet the federal standards. The HHS Office of Research Integrity and the NSF Inspector General offered some observations on areas in which they believe research organizations could strengthen their practices to meet the policy and regulatory requirements. The RCA working group will use these observations as a starting point for its work. We welcome your suggestions for areas in the management of research misconduct compliance that you would find examples of effective practices most useful. Send those suggestions to cblum@cogr.edu.

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

1. Supreme Court Grants *Certiorari* in *Stanford v. Roche*

On November 1 the U.S. Supreme Court granted *certiorari* to hear Stanford's appeal of the Federal Circuit decision in Stanford v. Roche. We have extensively discussed this case and its problematic interpretation of Bayh-Dole in recent COGR Updates and Reports. In the Fall 2010 Update we discussed the U.S. Solicitor General's *amicus* brief to the Court which strongly supported the position expressed in the higher ed. association *amicus* brief. The support of the Solicitor General undoubtedly was a large factor in the Supreme Court's decision to hear the case. (We understand that only 2% of *cert.* petitions typically are granted by the Supreme Court; 40% where *amicus* briefs have been filed; and 80% where the Solicitor General urges the Court to take the case).

As we noted in the Update, the question of whether title to federally-funded inventions automatically vests in the institution rather than the inventor under the Bayh-Dole Act (assuming compliance with its conditions) has not been definitively litigated in the 30 years since the Act was passed. We understand that the patent bar may have concerns about the potential effect on inventors' rights, and we fear that patent law associations may file briefs with the Court expressing those concerns. The associations currently are discussing strategies to respond to such concerns. We expect we may file another *amicus* brief that focuses on the critical need to assure certainty of title to federally funded inventions. It also would be helpful for some university licensees to file a separate brief reinforcing this point. *Amicus* briefs will be due to the Court on December 23. The case is expected to be argued next spring.

2. U.S. Solicitor General Files Brief Opposing Human Gene Patents

On October 29 the Justice Department filed a brief with the Federal Circuit on Myriad Genetics' appeal of the Federal district court decision invalidating Myriad's patents on BRCA 1 and BRCA 2 genes, which have been linked to breast and ovarian cancers. This case was discussed in the COGR 2009 Holiday Update. COGR declined to participate in an *amicus* brief, for reasons discussed in the COGR Late Summer 2010 Update.

The Justice brief does not fully support the lower court decision, but takes the position that unmodified genomic DNA sequences expressing the BRCA proteins are products of nature ineligible for patents. In Justice's view, isolating the BRCA genes is equivalent to removing

coal from beneath the earth, or isolating cotton fibers from cotton seeds, but is not transformed into a patent-eligible invention by simply isolating it from the body. (The Justice brief agreed with Myriad on the validity of modified or combination DNA claims also included in the BRCA patents, contrary to the district court decision).

In reaching its conclusion on the ineligibility of the isolated genomic DNA claims, the Justice brief states: “We acknowledge that this conclusion is contrary to the longstanding practice of the Patent and Trademark Office, as well as the practice of the National Institutes of Health and other government agencies that have in the past sought and obtained patents for isolated genomic DNA.” In fact, estimates are that the Patent and Trademark Office (PTO) has issued patents on 20% of human genes. It is not clear what the effect of the Justice brief will be on PTO’s view of the continued patent eligibility of isolated DNA claims. Unsurprisingly, concerns have been expressed about the potential impact on the biotechnology industry, and the Justice brief already has been strongly criticized by industry groups and commentators. The American Intellectual Property Law Association (AIPLA) has filed a brief in full support of Myriad. The AIPLA brief takes that position that naturally occurring biological substances when isolated and purified, including isolated and purified DNA molecules, are different than found in nature even if they have similar characteristics, and therefore should be patent eligible.

Obviously the case has important implications for university patenting and licensing. While potential concerns about negative effects of gene patenting on research and access to genetic testing have been expressed by various groups, there is a lack of clear evidence to support these concerns (see COGR October 2009 Update discussion of SACGHS Report). Obviously we cannot predict the outcome at the Federal Circuit, but the majority of commentators on the district court decision appear to believe the case was wrongly decided from a patent law view. Whether the Justice brief will influence the Federal Circuit decision is unknown. We will keep the COGR membership informed.

3. CIP Meets with NAS Official on University IP Management Report

The COGR Fall 2010 Update summarized the recent NAS Report on “Managing University Intellectual Property in the Public Interest.” The CIP Committee met with Steve Merrill, Executive Director of the NAS Board on Science, Technology and Economic Policy (STEP), co-staff director for the report, to further discuss the findings and recommendations.

Dr. Merrill noted three ancillary activities related to the report: a legal landscape analysis of treatment of IP in public institutions, a survey of technology transfer offices that correlated relationships between their structure and outside entities, and a very preliminary study based on 5-year data from the University of California system used to assess the distribution of disclosures by technology. All of these will be available from NAS.

As for the report itself, without repeating the summary in the COGR Update, Dr. Merrill noted there were 4 themes in the committee’s findings: 1) formal IP-based technology transfer is only one of many mechanisms for transferring knowledge from universities to the public but it gets disproportionate attention because of the availability of data on patenting, licensing and revenues; 2) Bayh-Dole has not seriously undercut other technology transfer mechanisms or research, despite concerns about the proliferation of patents on upstream research—Dr. Merrill expressed the view that it was important for NAS to state that finding; 3) for the range of

discoveries that need patent protection to induce further development Bayh-Dole is better than the predecessor regime; and 4) no case has been made for faculty ownership or control of inventions (although some committee members were “agnostic” about this finding because of the lack of data on faculty attitudes). Dr. Merrill expressed the view that even if this approach were to be effective, it raises policy concerns about accountability and conflict of interest.

Dr. Merrill noted 5 themes in the report recommendations: 1) better integration is needed between technology transfer offices and university missions; lack of guidance has led to internal tensions and too much inclination to pursue revenues; 2) technology transfer offices should be opened up to external input and rely more on outside resources, with formal advisory committees and periodic evaluations and in the case of smaller institutions, consideration of outsourcing functions in particular technology fields; 3) technology transfer offices should be more supportive of entrepreneurs and should make startups easier; 4) more effective interactions should be encouraged with other institutions (e.g. MTAs; see discussion below); and 5) there is a need for more accountability at the national level; metrics, federal oversight, and iEdison invention reporting all need strengthening.

In discussion Dr. Merrill indicated that the feedback on the report so far has been positive. The next steps will be to discuss the findings and recommendations with university groups including AAU, APLU and AUTM as well as university trustees (perhaps through the National Association of Governing Boards) and policymakers at Commerce and OSTP and the research agencies. He also mentioned meetings with academic researchers. One issue raised in the CIP discussion not discussed in the report is the lack of resources for technology transfer offices. In response to the report discussion of the issue of metrics and the need for better measures of performance, Dr. Merrill indicated that another NAS activity is looking into STAR metrics. He expressed the strong view that academics who study technology transfer need to refocus and stop looking for negative consequences of university technology transfer practices, as numerous studies have already been done and have failed to find such outcomes.

CIP members noted the conflicting federal policy objectives in promoting more financial disclosure and regulation of conflicts of interest vs. enhancing commercialization of university research. Dr. Merrill indicated that NAS might be interested in addressing that issue through the Committee on Science, Technology and Law. There also was some discussion of issues with federal oversight and the iEdison data.

The AAU Presidents have discussed some of the issues raised in the report and the new Commerce National Advisory Committee on Innovation may provide another opportunity for discussion. The NAS Report provides a good starting point.

4. COGR Holds Second IP Roundtable with NIH

The June 2009 Meeting Report reported on a roundtable discussion between COGR and NIH representatives on technology transfer and IP issues. Both the COGR and NIH participants felt the discussion was valuable and should be continued. We held another roundtable in October of this year immediately preceding the COGR meeting. COGR participants (drawn from the CIP Committee) were Wendy Streitz, University of California (Chair, COGR CIP Committee); Robert Hardy, COGR; Cathy Innes, University of North Carolina; Jennifer Murphy, George

Mason University; and Alex McKeown, Johns Hopkins University. NIH participants were Ann Hammersla, Director, Division of Policy, Office of Technology Transfer (OTT); Bruce Goldstein, OTT; Michael Mowatt, Director, Office of Technology Development, National Institutes of Allergy and Infectious Diseases (NIAID); Jeffrey Thomas and Laurie Whitney, Office of Technology Transfer, National Cancer Institute (NCI); JP Kim, Director & Policy Officer, Office of Extramural Research (OER); and Lili Portilla, Senior Advisor for Technology Transfer, National Center for Research Resources (NCRR).

Issues discussed included the following:

Determinations of Exceptional Circumstances (DECs). The issue of NIH use of DECS to provide awardees with less than normal Bayh-Dole rights was discussed in the previous Roundtable. NIH is revising its internal Technology Transfer Manual. In response to the previous discussion, NIH had solicited COGR comments on the DEC Chapter (Chapter No. 607) and we provided comments in September. At this meeting NIH indicated that the revised Manual is in the NIH clearance process, and that many of the COGR comments on the DEC chapter have been incorporated.

- 1) **IP Option to Collaborator (CTEP Program).** We provided comments last May in response to the April Federal Register notice. NIH indicated that the comments received are still under consideration by NCI.
- 2) **Stem Cells.** NIH is concerned about the proliferation of stem cell transfer agreements with varying terms and conditions. This includes agreements used by NIH-funded repositories with terms that in some cases are unacceptable to NIH! It was agreed that COGR and NIH should work together in this area (see MTA discussion below), pending resolution of the current court challenge to NIH funding.
- 3) **Gene Patenting.** The Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) has disbanded. However, NIH may be proactive with regard to some of the SACGHS recommendations, such as developing a statement of effective practices along the lines of the University Licensing 9 Points. Obviously the outcome of the Myriad case discussed above could affect the situation.
- 4) **iEdison.** Recommendation 15 in the NAS Report on University IP Management calls for reinvigorating the iEdison invention reporting requirements and making the data available for analysis by researchers. However, there are problems with the accuracy and completeness of the iEdison data, as discussed both in the NAS Report and the COGR Late Summer 2010 Update. Use of inaccurate and incomplete data by researchers would be problematic. In the Roundtable NIH expressed concerns about discrepancies between grant closeout reports and iEdison data. This may cause NIH increasingly to go back to institutions to resolve the discrepancies. Technical issues, resource issues, and "ownership" issues all have arisen with iEdison. Given its identification in the NAS report and the increased attention to university commercialization by policymakers, this topic needs further discussion

- 5) **U.S. Manufacturing Waivers.** Universities have expressed concerns to COGR that NIH (and a few other agencies) have been issuing time-limited (typically 3-year) waivers of the U.S. manufacturing requirement for products resulting from federally funded inventions under Bayh-Dole. Three years often is insufficient time for licensees to recover their investment in production facilities, and is proving a particular problem for startups trying to partner with multinational firms. In the Roundtable discussion it appeared that there are internal differences within NIH on this matter. **(Note: in a subsequent meeting with COGR NIH confirmed it no longer will issue time-limited waivers. However, NIH may become somewhat more stringent in approving waivers).**

- 6) **Fabrazyme March-in Request.** Several Fabry's disease patients have petitioned HHS to exercise Bayh-Dole march-in rights to require licensing of Fabrazyme, the only drug approved for treatment of the disease in the U.S., to another licensee. The current licensee, Genzyme, holds an exclusive license from Mt. Sinai School of Medicine. Genzyme has encountered problems with its manufacturing facility and currently only one-third of the normal dosage is available to patients. The ground for the march-in request is failure to meet health and safety needs because of the drug shortage. The case thus is different from the petitions that NIH rejected in 2004 that were based on drug pricing. HHS referred the request to NIH and the NIH representatives indicated that it is under serious consideration. (Another drug for Fabry's disease, Replegal, is available in Europe and the manufacturer is trying to obtain FDA approval to market it in the U.S., but evidently there are shortages of this medication as well). Bayh-Dole march-in has never been exercised by a federal agency. We will inform the membership of NIH's decision on this request.

- 7) **MTAs.** See discussion below.

5. **Materials Transfer Agreements**

Materials Transfer Agreements (MTAs) were the subject of discussion both at the COGR/NIH IP Roundtable and at a subsequent session at the October COGR meeting in which NIH participated. A representative of Howard Hughes Medical Institute (HHMI) also participated in the COGR session.

NIH, together with the academic community, developed the Uniform Biological Materials Transfer Agreement/Simple Letter Agreement (UBMTA/SLA) about 15 years ago and remains a strong advocate for sharing materials. Currently over 400 institutions in the U.S. and abroad have signed the UBMTA. However, recent surveys done by both NIH and AUTM have found that about 60% of incoming MTAs use their own institution templates (including modified versions of the UBMTA). NIH is concerned about the inefficiencies in the lack of use of standard agreements and the problems occasioned by having to negotiate terms on a case-by-case basis. As discussed in the COGR Fall Update, one of the recommendations in the recent NAS Report on University IP Management was that nonprofit research institutions cease using MTAs when exchanging non-hazardous or non-human biological materials among themselves, or use the terms of the NIH UBMTA/SLA (Rec. 8). Questions raised for discussion at the COGR session include why institutions are not using the UBMTA/SLA; what should be done to

improve the current situation; and the possible use of other tools for transferring materials more efficiently.

A variety of approaches were discussed, including the “treaty” approach developed by Stanford and other institutions to which 15 institutions now have agreed. This approach commits the institutions to not use MTAs when non-hazardous or non-human biological materials are exchanged for in vitro research use or to use the UBMTA/SLA, with the terms of the UBMTA presumed when transfers are made without a specific MTA. However, neither NIH nor a number of institutions feel they can use this approach because of the lack of documentation and inability to track transfers, and/or because of legal issues related to the undocumented “presumption” of the UBMTA/SLA terms. There also are potential liability concerns. Discussion at the COGR session indicated that the participating institutions do not use this approach when the materials are tied to patents or license agreements or do not clearly meet the “non-human, non-hazardous” criteria. Among the other issues with this approach identified at the session are faculty preference for MTAs to control materials and foreign provider issues.

HHMI is a treaty institution but cannot use this approach for many of its labs at host institutions, because of the need for concurrence by the host. In such cases HHMI seeks to use the UBMTA/SLA or its own “short form” transfer agreement. The University of North Carolina has developed a provider letter of transfer mechanism that does not require counter-signature by the receiving institution, but it has not been widely used. Other new models that have been developed recently include those developed by the Institute of Medicine and by the Science Commons, but neither seems to have received wide acceptance.

NIH/NCI indicated that that for non-human non-hazardous materials it is encouraging its investigators to document transfers through emails that include a short statement of just a few terms of use. NIH also has an electronic MTA (EMTA) project underway that will be based on the SLA. Currently it is completing the requirements phase. Ultimately NIH intends to make the system available extramurally.

The outcome of the session was agreement on the importance of developing new tools to facilitate transfers, and reduce the 60% number of transfers between research institutions that currently involve individual institution template agreements. Stem cell transfers pose particular problems that are not well-addressed by the UBMTA. COGR and NIH will continue to discuss these issues within the COGR/NIH MTA working group, and will invite HHMI and the AUTM MTA Special Interest Group (SIG) to participate in the group. A session on MTAs is planned for the AUTM Annual Meeting next year, which we envision as part of this process.

6. PTO Humanitarian Patent Reexamination Proposal Provokes Lively Discussion

On September 20 the U.S. Patent and Trademark Office (PTO) requested comments (75FR57261) on a proposal to institute a fast-track (six months) *ex-parte* patent reexamination voucher pilot program for patented technologies that address humanitarian needs. The proposal is modeled to some extent on the FDA priority review voucher program for entities that develop drugs to treat neglected tropical diseases. Under the PTO proposal, a voucher would be offered to patent holders who demonstrate practices that qualify either as humanitarian use (based on subject matter, effectiveness, availability and access) or humanitarian research (based on

significance and access) with regard to the patented technology. The FDA priority review vouchers are transferable on the open market and one possibility is for the PTO vouchers also to be sold on the open market.

In the notice PTO poses 12 questions for which comments are sought, including the transferability option. It is convening stakeholder groups to discuss the proposal and provide comments on these questions. PTO convened a group of university stakeholders on October 27 in which two members of the COGR CIP Committee participated.

This proposal led to a surprisingly lively discussion both in the CIP committee and the full COGR meeting. Universities do not typically request reexamination so the direct effect is likely to be small. However, if the vouchers are transferable and can be sold on the open market, they could prove extremely valuable. IT companies, for example, are frequently involved in reexaminations and might pay a premium for a fast track voucher (by way of comparison, the FDA priority review vouchers are estimated to be worth \$300M each). For universities to sell the reexamination vouchers on the open market, however might lead to negative public perceptions and raise tax and legal issues, as well as questions such as whether the normal inventor share should apply. The main utility of the vouchers for universities might be as an incentive for licensees. License agreements could provide for award of vouchers to the licensees if they can demonstrate humanitarian use or research.

Based on the discussion, COGR will submit a comment letter suggesting that PTO consider instituting a competitive review process for voucher issuance to assure quality and effectiveness. We also will suggest that the number issued on an annual basis be substantially limited, at least until the results of the pilot program are known. While possible transferability of the reexamination vouchers on the open market would substantially enhance their value, we will point to concerns that auctioning the vouchers off to the highest bidder could lead to negative public perceptions and questions about public vs. private benefit. We may provide answers to the specific questions to amplify these points.

7. Progress Reported on Troublesome Clauses, But New Problems Arise

- 1) **DOD Developments.** At the COGR meeting in June our guest speaker was Robin Staffin, Director for Basic Research at DOD/DDR&E. Among other things Dr Staffin discussed the May 24 memorandum on Fundamental Research issued by the DOD Undersecretary for Acquisition. The memo reinforces an earlier (6/26/08) memorandum on Contracted Fundamental Research and provides additional clarifying guidance. As discussing in the June Meeting Report, the memorandum reiterates earlier guidance that DOD awards for contracted fundamental research should not involve classified items or be subject to export controls. It states that “The performance of contracted fundamental research also should not be managed in a way that it becomes subject to restrictions on the involvement of foreign researchers or publication restrictions.” Exceptions require high level DOD component management approval. An important clarification in the memo is that research performed with funds other than budget category 6.1 or 6.2 might still be fundamental research, and that “the DOD must not place restrictions on subcontracted unclassified research that has been scoped, negotiated, and determined to be fundamental research within the definition of NSDD 189 according to the prime

contractor and research performer and certified by the contracting component...”. Where DOD components appear not to be following this policy, Dr. Staffin is listed as the person to be contacted. We understand that in a number of cases Dr. Staffin and his staff have been helpful with such issues, and we encourage COGR members to continue to contact him. As also discussed in the Meeting Report, FDP has established a website (<http://nrc59.nas.edu/clauses2/login.cfm>) that will allow COGR/AAU/FDP to continually monitor the occurrence of troublesome clauses in university agreements.

FDP and DARPA are discussing creating updated templates for BAAs. There would be three forms: classified research, unrestricted fundamental research, and a middle area that might be restricted through publication restrictions or data security requirements. Institutions proposing in that third category must have the capability of conducting controlled research. We understand that DARPA also has implemented a training program for DARPA and other DOD contracting officers on DOD policy pertaining to contracting of fundamental research. Hopefully the results will be fewer instances where COGR institutions received contracts with inappropriate restrictions.

- 2) **Problems with Other Agencies Arise.** While we appear to have made progress with DOD in this area, a number of COGR institutions report having received the FAR Rights in Data--Special Works (52.227-17) clause in contracts from the Agency for Healthcare Research and Quality (AHRQ). This clause requires the government’s written permission for release, distribution and publication of data first produced under the contract. Contractors also must seek government permission to claim copyright ownership in such data and indemnify the government for liability arising out of their publication or use of the data (these provisions can be deleted).

In response to concerns expressed by the institutions, the Director of AHRQ has responded stating that AHRQ considers “a consistent approach to all contracts to be essential, so we include these clauses in any contract awarded for work of this nature, to any entity – be it a privately held company, non-profit organization or university to protect the integrity of research sponsored by AHRQ under contract mechanisms. It is important that all ... contracts have the same terms and conditions. As stated in the clause, the purpose of this clause is to assure:

(A) Identifiable information is being used exclusively for the purpose(s) for which it was supplied or appropriate consents have been obtained; (B) The confidentiality promised to individuals and establishments supplying identifiable information or described in it is not violated; and (C) The quality of statistical and analytical work meets statutory standards. AHRQ does not intend for this clause to restrict an academic institution’s freedom to publish. It should be noted that the clause allows for publication of research conducted under this contract without AHRQ permission with the use of the appropriate disclaimer. AHRQ values and believes in academic freedom and the integrity of the research process.”

We understand that the institutions have responded to the Director by confirming their freedom to publish. While this may resolve the immediate problem, the Special Works clause is inappropriate for use in university research contracts, as discussed in the COGR Rights in Technical Data and Computer Software Under Federal Awards Guide. It also

violates the FAR prescription (27.404(a)), stating that no restrictions may be placed upon the conduct or reporting on the results of unclassified research in contracts for basic or applied research with universities or colleges. One issue may be that AHRQ does not regard itself as a research-supporting agency. However, we also understand that the Special Works clause has appeared recently in a contract from the Center for Medicaid Services, another HHS component. We will consider bringing these concerns to an appropriate level within HHS.

8. DOD Issues Revised Regulations on Patents and Data in DOD Contracts

On September 27 DOD published a proposed rule revising the Defense Federal Acquisition Regulation Supplement (DFARS) Part 227 on Patents, Data and Copyrights (75FR59412). From our perspective, the main effect of the revision is to reorganize and streamline the DFARS coverage of Rights in Technical Data (227.71). It removes the separate clauses on rights in computer software and consolidates the coverage in the Rights in Technical Data clauses DFARS 252.227-7013 (noncommercial) and 7015 (commercial). It also relaxes the current rigid marking prescriptions for data delivered to DOD with government purpose or other limited rights.

Interestingly, the revised DFARS rule asserts that DOD has privity of contract with subcontractors with regard to IP rights. This means that DOD may transact business directly with subcontractors on such matters. DOD long has asserted that it does not have such privity, and often has refused to deal with university subcontractors with regard to flowdown requirements from DOD primes. When coupled with the May 2010 memorandum discussed above, which also contains prescriptions related to subcontractors, the effect is to undercut DOD's claims not to have a direct relationship with subs. This may help institutions that encounter problems with flowdown restrictions in DOD subcontracts.

The other changes in DFARS Part 227 do not appear substantive. Comments are due November 26. COGR is not planning to submit comments. Once the proposed rule is finalized, we will revise the COGR Rights in Technical Data Guide to incorporate the revised DFARS provisions.