

COUNCIL ON GOVERNMENTAL RELATIONS

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MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS

WASHINGTON MARRIOTT HOTEL

February 23 and 24, 2012

COSTING POLICIES**“Grants Reform”****A First Look****Advance Notice of Proposed Guidance****Comments Deadline, Flat Rates and COGR Perspectives****What’s Next?****Previewing the Circular A-21 Policy Changes****Accelerating Spending on ARRA Programs – FAQs from NSF****Audit Update****Other Costing Developments****CONTRACTS AND INTELLECTUAL PROPERTY****COGR Collaborates in Review of Proposed AIA Implementing Rules****NSF Technology Transfer Public Website Requirement Now in Effect****Kauffman Foundation Again Promotes Faculty “Free Agency” Concept****APLU CICEP Metrics Project Raises Interest and Concerns****RESEARCH COMPLIANCE AND ADMINISTRATION****NASA China Funding Restriction****NIH Financial Conflict of Interest: Questions to Consider****NIH Financial Conflict of Interest: Next Steps: Survey/Policies/June COGR Meeting****Air Force No-Cost Time Extension Available****USDA Post Final Determination Only in Appealed Inspection Reports****NABR Submits *Amicus* Brief in AETA Lawsuit**

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

“Grants Reform”

A First Look as Presented at the COGR Meeting - One of the Thursday afternoon sessions at the Thursday, February 23rd COGR Meeting was a presentation by OMB Controller, Danny Werfel. The session was entitled: *Status of the A-21 Policy Changes* and Mr. Werfel covered policy proposals that would be made public (see below) in an upcoming Federal Register, Advance Notice of Proposed Guidance. Mr. Werfel’s update included: 1) insights on the roles played by the original A-21 Task Force and the newly created Council on Financial Assistance Reform (COFAR), 2) timelines and logistics for final implementation of A-21 policy changes, 3) point-by-point listing of the policy recommendations, and 4) robust question and answer exchanges between Mr. Werfel and the COGR members.

However, the COGR session simply was a “first look.” Since the COGR Meeting in February, significant and important developments have unfolded. The sections that follow include an update on the current status of “Grants Reform”.

Federal Register, Advance Notice of Proposed Guidance (ANPG) - The Federal Register, ANPG entitled: *Reform of Federal Policies Relating to Grants and Cooperative Agreements; Cost Principles and Administrative Requirements (including Single Audit Act)* was released on February 28, 2012. The Notice is available at:

<http://www.gpo.gov/fdsys/pkg/FR-2012-02-28/pdf/2012-4521.pdf>

The ANPG is directed to many stakeholders, not just research universities. State, local, and tribal governments, non-profit research organizations, and hospitals also are addressed in the ANPG. Consequently, a variety of OMB Circulars have been opened for comment, including the audit circulars (A-133 and A-50), the administrative circulars (A-110, A-102, and A-89), and the cost principles circulars (A-21, A-122, A-87, and the Cost Principles for Hospitals at 45 CFR Part 74, Appendix E). As a surprising side note, the ANPG proposes consolidating all circulars into a “Super Circular” (note, COGR’s terminology only) where all eight circulars would be combined into a single document (see COGR’s perspective in the following section).

In Part I. Objectives and Background of ANPG, the recent history related to regulatory relief and reform ideas is introduced. Later in part I., the creation of the Council on

Financial Assistance Reform (COFAR) is described. This is an important development – the A-21 Task Force was tasked with developing initial recommendations; however, it appears now that the COFAR will be at the center of grants reform. As stated in the ANPG:

To “create a more streamlined and accountable structure to coordinate financial assistance,” the Memorandum [OMB M-12-01] established the interagency Council on Financial Assistance Reform (COFAR) as a replacement for two Federal boards (the Grants Policy Council and the Grants Executive Board). The 10-member COFAR is composed of OMB’s Office of Federal Financial Management (Co-Chair); the eight largest grant making agencies, which are the Departments of Health and Human Services (a Co-Chair), Agriculture, Education, Energy, Homeland Security, Housing and Urban Development, Labor, and Transportation; and one additional rotating member to represent the perspectives of other agencies, which for the first two-year term is the National Science Foundation. Since the COFAR’s first meeting on November 4, 2011, it has worked to formulate and further develop reform ideas for consideration to streamline and improve financial management policy for Federal assistance awards. These reform ideas are presented below, in Part II of this notice. In Part III, specific questions are posed regarding these reform ideas, for which comments are especially invited, along with other comments.

Part II. Reform Ideas for Comment describes the policy proposals (as were also covered by Mr. Werfel at the COGR meeting) and are categorized into three subsections: reforms to audit requirements, reforms to cost principles, and reforms to administrative requirements. Part III. Questions for Comment includes 20 questions (categorized as Overarching Questions, Single Audits, Cost Principles, and Administrative Requirements), which are directed to institutions and which seek institutional input on the reform ideas described in Part II.

The ANPG states: “*To be assured of consideration, comments must be received by OMB at one of the addresses provided below, no later than 5 p.m. Eastern Standard Time (E.S.T) on March 29, 2012.*” As of the writing of this COGR Update, the March 29, 2012 deadline remains in-tact. However, COGR, in collaboration with our Association partners (see below) have requested a deadline extension, and we have been assured that this will be granted. The deadline, process, and other issues are discussed in the next section.

Comments Deadline, Flat Rates and COGR Perspectives - We have been assured by senior leadership at OMB that the March 29, 2012 deadline will be extended. COGR, in collaboration with the Association of American Universities (AAU), the Association of Public and Land-grant Universities (APLU), and the Association of Independent Research Institutes (AIRI), wrote a letter to OMB Controller, Danny Werfel, requesting a 30-day deadline extension.

The extension request letter addressed to Mr. Werfel, dated March 7, 2012, was shared with COGR members via the ListServe on March 13th, and a copy of the letter is posted at www.cogr.edu (see Latest News, March 19, 2012). We expect a formal notice granting the extension will be published in the Federal Register within the next week.

With that extension, the date for finalizing any policy changes will be pushed back to approximately April 28, 2012. However, we expect the process as outlined in the Federal Register, Advanced Notice of Proposed Guidance (ANPG) will remain the same:

*Based on the feedback that is received, as well as on the ongoing discussions among Federal agencies (including their Inspectors General) as well as with other stakeholders, OMB in the coming months will develop a set of proposed amendments that, later this year, will be published for public comment in the **Federal Register**. The public comments on that proposed set of revisions will in turn be considered as OMB develops a final notice that will adopt a set of reforms. Following the implementation of these reforms, OMB will continue to monitor their impacts to evaluate whether (and the extent to which) the reforms are achieving their desired results, and OMB will consider making further modifications as appropriate.*

In effect, after our community (as well as those others affected by the ANPG) provides formal comments, OMB will accumulate all comments and develop their “proposed amendments” as they relate to grants reform. It is possible that the proposed amendments will be presented in the format of a revised circular. As stated in the ANPG:

In addition, OMB is considering implementing these reforms through the development and issuance of an integrated set of guidelines that would be contained in one consolidated circular, in which current administrative requirements that currently vary by type-of-recipient would be streamlined into one set of common requirements, while at the same time some provisions that vary among different types of recipients would be retained. The goal of such a streamlining would be to increase the consistency, and decrease the complexity, in how the Federal Government’s financial assistance programs are administered. Among other benefits, this will make it easier for applicants and recipients of Federal awards to understand and implement these requirements.

Our current thought on consolidating all circulars into a “Super Circular” (note, COGR’s terminology only) where all eight circulars would be consolidated into a single document is: “why?” However, as we develop a formal COGR response, we will be more thoughtful and articulate on this subject.

More significantly, COGR’s energy has been dedicated to aggressively engaging OMB on their proposed idea: *For indirect (“facilities and administrative”) costs, using flat rates instead of negotiated rates.* With our Association partners, we have spent the past three weeks meeting with OMB officials to express our great disappointment that the ANPG introduced the discussion of “flat rates.” We are unequivocally non-supportive of this idea. Unfortunately, rather than focusing energy on developing response to the potentially helpful issues addressed in the ANPG (e.g., single audit reform, effort reporting, direct charging of administrative costs, the utility cost adjustment, etc.), we have been forced to expend resources on refuting the flat rate idea.

The good news is that OMB appears to have heard our strong objection to any flat rate idea. However, our community must let OMB know, via our formal responses to the ANPG, that flat rates are unacceptable to research institutions. The COGR guidance (see next section) that has been shared with the membership articulates our perspective, and over the next month, we will continue to exhort your institutions to respond to the ANPG.

What's Next?

After the 30-day extension is officially granted, we expect that formal comments to the ANPG will be due on approximately April 28, 2012.

We encourage each of your institutions to respond to the ANPG. To help you respond, on March 14th we sent to the ListServe a document entitled *Template for COGR Member Responses to "Questions for Comment"*. That document also is available at www.cogr.edu (see Latest News, March 19, 2012). As we described in the Template, some of the broad themes to keep in mind as you craft your institutional response include:

- Grant Reform is important to the research community and many of the ideas presented to the A-21 Task Force over the past 9 months should be prioritized by OMB
- Any policy change related to Flat/Discounted F&A Rates is NOT SUPPORTED - we already are subject to discounted F&A rates due to arbitrary agency limitations, the 26% administrative cap, and discounts made during the negotiation of F&A rates.
- Specific policy changes that are most important to your institution should be highlighted in your response to the Questions for Comment – DO NOT feel as though you need to answer every question. Use your resources wisely as you write your responses!
- Question A4 asks for input on items not addressed in the ANPG. Don't hesitate to resurrect topics that originally were submitted to the Task Force (but omitted in the ANPG), as well as new topics.
- The official COGR Response WILL NOT directly answer the Questions for Comments. Instead, COGR will respond to each "proposal" per part II. Reform Ideas for Comment. However, the COGR responses will capture many of the talking points in the Template.
- In addition to the answers you develop in these Questions for Comment, we encourage you to endorse the COGR Response.

(You are welcome to cut and paste from the Template, into your institutional response, as you see fit.)

Initially, we expected to send a draft of the COGR Response to the COGR Membership on March 21 or 22. However, as it appears that there will be a deadline extension, we will target a draft of the COGR Response in early- to mid-April.

We will provide frequent updates on developments related to Grants Reform and if you have questions, contact David Kennedy at dkennedy@cogr.edu.

Thursday Morning Costing Session: Previewing the A-21 Policy Changes

The Thursday morning Costing Policies session at the February 23rd COGR Meeting was designed as a “preview” to the afternoon presentation by OMB Controller, Danny Werfel: *Status of the A-21 Policy Changes*, as well as a preview to the process lying ahead. Of course, at the time we could not anticipate each and every development that has unfolded since. Still, the Thursday morning preview session was a helpful reminder to where we have been and what may be important to focus on as we go forward.

Five members from the COGR Costing Policies Committee presented insights and case studies accentuating some of the most important areas we hope to be addressed in the A-21 policy changes. The presentations included “reminders” relevant to the original COGR recommendations that were in response to the NIH “*Request for Information (RFI): Input on Reduction of Cost and Burden Associated with Federal Cost Principles for Educational Institutions (OMB Circular A-21)*.” And in the case of Effort Reporting, a reflection on the more refined November 9, 2011, COGR proposal to the Task Force: “*Discontinuation of the Effort Reporting Requirement*.” In addition, each session reemphasized why each area is important to our institutions, and if a policy change was made, what implementation at an institution might look like.

As we learned later in the afternoon and in the February 28th Federal Register, Advance Notice of Proposed Guidance (see previous sections), the final policy changes that OMB issues may not match exactly with what COGR and others proposed to the A-21 Task Force. However, there still is advocacy work to be done and some desirable policy changes could be achieved. Consequently, the presentations made during the Thursday morning Costing Policies session serve as useful guidance. A short recap of each presentation is shown below:

- Changes in Federal Costing and Audit Policy – John Shipley, University of Miami. Recap of the “Timeline” that has been followed over the past couple of years, and a preview of the items most likely to be addressed in the A-21 policy changes.
- Agency Limits on F&A Recovery – Cindy Hope, University of Alabama. An analysis of institutional cost subsidies that result when arbitrary agency limitations on F&A recovery are imposed (though as we later learned, this area of concern most likely will not be addressed in the A-21 policy changes).
- An Example of a Good and Healthy F&A Rate Negotiation – Sue Camber, University of Washington. A case study of an F&A rate negotiation “gone good”, with a reemphasis on where the negotiation process can be further improved (though again, these concerns most likely will not be addressed in the A-21 policy changes).
- Effort Reporting – Mary Lee Brown, University of Pennsylvania. Recap of the November 9, 2011 COGR proposal to the Task Force: “*Discontinuation of the Effort Reporting Requirement*”, with additional remarks on Effort Reporting versus Payroll Certification comparisons.

- Direct Charging of Costs Associated with Project Management Activities – Jim Luther, Duke University. A statement as to why this policy change can be particularly beneficial to institutions and their investigators, including important implementation considerations.

The five PPT presentations are available at www.cogr.edu (see Meetings | February 2012 Meeting Presentations tab).

Accelerating Spending on ARRA Programs: FAQs from NSF

COGR has reported on the status of “accelerating spending” guidance in the past two COGR Updates. As a reminder, the trigger came from a September 15, 2011 Office of Management and Budget (OMB) Memorandum M-11-34 (Accelerating Spending of Remaining Funds from the American Recovery and Reinvestment Act for Discretionary Grant Programs). Consequently, all affected agencies, including NSF and NIH, published notices to Revise the Terms and Conditions of ARRA awards to ensure completion of these awards by September 30, 2013 (see OMB, NSF, and NIH links below):

<http://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-34.pdf>

<http://www.nsf.gov/recovery/acceleration.pdf>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-014.html>

In a March 2, 2012 note posted on the COGR ListServe, we informed the membership that NSF issued “ARRA Acceleration Frequently Asked Questions (FAQ) for NSF Principal Investigators with awards funded under the American Recovery and Reinvestment Act of 2009 (ARRA).” Those FAQs can be accessed at: http://www.nsf.gov/pubs/policydocs/arra/faqs_pi.jsp

Two of important take-aways from the FAQs are: 1) Waivers that would allow an extension to the term of the award beyond September 30, 2013 will be difficult to obtain – in fact, waiver requests should have been made by March 2, 2012 (and March 9, 2012 for cooperative agreements), and 2) NSF CAREER awards are being recognized as the best candidates for extension beyond September 30, 2013; however, the fate of an extension is unknown at this time (see FAQ # 9, also shown below).

9. I am a PI for a CAREER award and have heard that these might be treated differently. What should I do?

NSF is encouraging responsible acceleration of funds for all ARRA awards, including CAREER awards. Recognizing that the entire portfolio of ARRA-funded CAREER awards were issued as five-year awards, which do not expire until 2014, NSF is working to develop a strategy for a programmatic waiver request to cover all CAREER PIs. Therefore, if you are the PI for a CAREER award, you do not need to contact your NSF Program Officer regarding submission of a waiver at this time. However, you are reminded that there is no guarantee that OMB will approve a waiver request.

As we have noted in the past COGR Updates, all agencies are under the same pressure to accelerate spending. COGR will continue to follow all issues related to NSF, NIH, and other agency guidance. As necessary, we will work with appropriate Federal agency staff to clarify concerns that arise.

Audit Update: General

Below are audit-related topics that are either new developments or items we have reported on in the past and/or continue to follow.

Audit Resolution and “Unusual” Audit Interpretations. COGR members regularly share with the COGR staff examples of “unusual” auditor interpretations and findings – examples of these situations span many of the agency Inspector General (IG) offices. While it is inappropriate for COGR to intervene with IG personnel, the audit resolution process falls outside the IG offices. Consequently, COGR can be helpful in tapping into each agencies audit resolution process. Recently, COGR members have shared examples of “unusual” auditor interpretations emanating from the USDA (two unrelated situations – subrecipient monitoring and spending rates), NIST (subrecipient monitoring), and the EPA (use of rental cars). There are no guarantees that the audit resolution personnel at an agency can reverse an “unusual” audit interpretations – however, it is an avenue that is available to your institution and it an avenue that should be pursued.

HHS OIG ARRA Audits. As reported previously, the HHS OIG is engaged in ARRA audits related to NIH programs. The results of these audits are being posted on the audit report section of the HHS OIG website. To date, three reports have been posted and in each case, there have been no adverse findings or cost disallowances. The audit reports can be found at: <http://oig.hhs.gov/reports-and-publications/oas/nih.asp>

HHS OIG Administrative & Clerical Audits. The eight schools that were selected for this audit work (officially entitled, *College and University Indirect Costs Claimed as Direct Costs*) are at different stages of completion, and each is assigned to one of the eight HHS OIG regional audit offices. There are indications that each HHS regional audit office has employed a unique approach to its audit work. Consequently, the audit experience for each school has varied from region to region. To date, three audits reports (August 2011, October 2011, and December 13, 2011) have been released and the audit findings have not indicated any systematic or serious issues:

<http://oig.hhs.gov/oas/reports/region10/11101500.pdf>

<http://oig.hhs.gov/oas/reports/region2/21102000.pdf>

<http://oig.hhs.gov/oas/reports/region5/51100030.pdf>

COGR is following the developments related to the Administrative & Clerical audits as well as any broader repercussions that could ensue.

NSF OIG Activity. One COGR member has shared with COGR staff that they have been contacted by the NSF OIG for an upcoming ARRA audit that will be outsourced to and conducted by the HHS OIG’s office. We also are aware of new activity being conducted under NSF’s ongoing Award Monitoring and Business Assistance Program (AMBAP) program – this program is outside the scope of the NSF OIG and is designed to “*evaluate the effectiveness and efficiency of the policies and procedures that your organization has in place to manage federal funds, and to provide an opportunity for NSF to offer business*”

assistance.” Finally, the link below provides access to all audit reports released by the NSF OIG and can be a useful resource for following NSF OIG audit activity:

<http://www.nsf.gov/oig/auditpubs.jsp>

2012 A-133 Compliance Supplement. We expect that the 2012 A-133 Compliance Supplement will be available, shortly. We will keep the membership posted.

COGR is interested in audit experiences at your institution so that we can update the general landscape for the membership. We have most access to HHS OIG and NSF OIG initiatives, but also are interested in activity related to the OIGs at other agencies. Please contact David Kennedy if your institution has been contacted by any agency to conduct an audit or review. We will keep all correspondences confidential.

Other Costing Developments and Discussions

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

NIH and Genomic Arrays (GAs) – Request for Input. COGR has revisited this topic with officials from NIH. The NIH Office of Policy for Extramural Research Administration (OPERA) is interested in publishing clarification FAQs, including addressing those types of research where the GAs that are utilized are more F&A intensive and would not be characterized as a “*high-throughput commodity and service*” (as was defined in the May 13, 2010 NIH Notice, “Budgeting for Genomic Arrays for NIH Grants, Cooperative Agreements and Contracts”). **Please contact COGR if you have examples of research at your institution where an exemption from the current NIH policy could be appropriate.** The original NIH Notice can be found at:

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

Arbitrary Agency Policies and F&A Caps. COGR members regularly share with the COGR staff examples of arbitrary agency policies and F&A caps. This topic was the subject of the November 2010 COGR Policy paper “*Federal Funding Agency Limitations on Cost Reimbursement: A Request for Consistency in the Application of Federal Guidelines*” and was one of the early concerns we raised with OMB prior to the establishment of the A-21 Task Force. Recently, COGR members have shared examples from the Department of State, Bureau of Educational and Cultural Affairs, and USAID, Higher Education Solutions Network. We will pursue these situations through a variety of means, including contacting the applicable agency policy office and/or informing OMB. The concern remains that OMB does not have a formal process to address arbitrary agency policies, and this will be a concern that we continue to raise with OMB.

Department of Energy Salary Limitation. A COGR member shared with COGR staff correspondence from the Department of Energy (DOE), Office of High Energy Physics (OHEP), which indicated that OHEP is not providing salary support in new grants to any individual in excess of \$14,975 per month. This monthly rate corresponds exactly with the NIH Executive Level II statutory salary limitation. However, the HHS/NIH appropriations

legislation that mandates the NIH salary limitation does not legally extend to DOE OHEP policy. COGR is researching the basis for this policy and will keep the membership posted on what we learn.

NIH Salary Limitation. COGR reported on this issue extensively over the past three months. Many of your institutions have developed internal solutions to manage the new Executive Level II salary limitation, which applies not only to NIH awards, but to awards issued by all HHS operating divisions (with the exception of the FDA, funded under the USDA appropriations bill, and the Indian Health Service, funded under the Department of Interior appropriations bill). Both the initial NIH guidance issued on January 20, 2012 and the more recently released FAQs from February can be accessed at the links below:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html>

http://grants.nih.gov/grants/policy/fy2012_salary_cap_faqs.htm

Division of Cost Allocation (DCA) Organizational Update. The DCA, responsible for negotiating F&A rates for most COGR institutions, continues to settle on new leadership at both the National and Regional levels. Arif “Mac” Karim now is serving as the Acting National Director and a complete listing of the current staffing structure can be accessed at the following link: <http://rates.psc.gov/fms/dca/map1.html>

2011 COGR Survey of F&A Rates. The Data Tables that contain institutional data are available. There are two data tables, both in XLS format, that are available: Historical Rates and Components. The data in the tables is “Confidential and for Internal Institutional Purposes Only.” Our intent is for the survey to have a “real-time” element and to regularly update the tables, so please keep COGR posted on any updates.

Workplace Flexibility (“Family-Friendly”) Science Policy. This issue was addressed in COGR Updates throughout the Fall of 2011. We are following up on a recent NSF FAQ related to this topic (FAQ #4). Specifically, FAQ #4 is inconsistent with how many institutions account for sick leave, vacation time, and other leave time.

NIH and Costing on Core Facilities. After COGR responded to an NIH request for comments in December of 2010, internal reorganizations at NIH resulted in this topic being put on hold. Our understanding is the NIH will revisit this topic in 2012.

NRC “Study on Research Universities” Update. It’s been almost one-year since COGR began reporting on the study to be completed by The National Academies, National Research Council (NRC), to address the top ten actions that research university stakeholders and the nation can take to ensure U.S. global competitiveness. We initially reported that the study would be completed in the Summer 2011. Our current understanding is that a version of the report is being formally reviewed. After clearing review, it may be several months before release of a final version.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Charles Louis, University of California, Riverside, Chair; Elaine Brock, University of Michigan; Alexandra McKeown, The Johns Hopkins University; Cordell Overby, University of Delaware; David Winwood, University of Alabama at Birmingham; Marianne Woods, University of Texas at San Antonio; Catherine Innes, University of North Carolina, Chapel Hill; John Ritter, Princeton University; Wendy Streitz, University of California; Kevin Wozniak, Georgia Institute of Technology

Implementation of Patent Reform Continues

COGR Collaborates in Review of Proposed AIA Implementing Rules - We mentioned in the February Update that the Patent and Trademark Office (PTO) has issued a number of proposed rules implementing the America Invents Act (AIA). The Update listed the proposed rules. Several additional proposed rules subsequently were issued on February 10 (*77FedReg7028-7108*), including Derivation Proceedings, *Inter Partes* Review Proceedings, Post-Grant Review Proceedings, Transitional Program for Covered Business Method Patents and Definition of Technological Invention for Business Method Patents.

We have reviewed a number of the proposed rules in collaboration with the AAU Patent Reform Implementation Task Force. Some of the proposed rules involve areas of patent practice that are not of significant concern to the higher education community. Others such as the proposed rule on Inventor's Oath or Declaration (*77FedReg982*; 1/6/12) appear to closely track the AIA and not require comment. However, the AAU Task Force believes the proposed rules for post grant and *inter partes* reviews require comment from the university community, given there has been a great deal of commentary about reported efforts by the Congressional Judiciary Committees to make a substantive change to the post grant estoppel provisions. In the AIA currently, both post grant and *inter partes* estoppel include issues that were raised or **could have been raised** (35USC325(e) and 315(e)). The Judiciary staff assert that post grant estoppel should be limited only to issues raised and that the inclusion of "could have been raised" was a drafting mistake. The principal rationale of the more limited estoppel is to encourage post grant review to be used. In January, a preliminary comment period was provided, in which several IT companies issued an extraordinary commentary that basically argued that PTO should implement the statute by moving provisions back as close as possible to prior law. Our reading of the USPTO proposed rule is that it conforms to the intent of the statutory provisions as enacted, contrary to the requests of the IT commentary. The university community supported the AIA provisions of these two procedures. Therefore, we think our comment on these provisions should be focused on endorsing the PTO proposed rules, to help provide support to counter expected critics.

Associations Endorse PTO Fee Setting Proposal Concept - On February 7 PTO submitted a proposed concept paper to its Patent Public Advisory Committee (PPAC) for implementation of the patent fee setting authority given it under the AIA. The concept would set fees with the goals of accelerating progress in reducing the backlog of pending applications and application pendency, realign the fee structure to tailor fees to specific activities at specific points in time, and provide more stable funding for PTO. The concept paper lists considerations in setting the fee structure. It contains a summary of significant proposed changes in fees, with examples, scenarios, and anticipated benefits and outcomes. It also discusses the alternative of setting fees at the current rates plus the 15% surcharge added by the AIA and the new micro entity fees (for which universities will be eligible). (Go to http://www.uspto.gov/aia_implementation/fees.jsp for a copy of the concept paper. PTO held public hearings on the concept paper on February 15 and 23; the webcast is available on the PTO website).

On February 21 COGR joined the other higher ed. associations with which it has been working on patent reform in a statement supporting the basic policy dimensions of the PTO fee proposal. We noted that the approach of targeting fees to match service cost recovery and public policy goals was thoughtful, and commended PTO for its careful crafting of the proposal and the process for public comment. The process includes the public hearings and a PPAC report, followed by a proposed rulemaking, anticipated in June.

Concerns Continue About AIA Grace Period - The February Update discussed concerns that have arisen about the grace period for publications in the AIA. The AIA is unclear as to whether the one year grace period covers only disclosures of subject matter identical to the original disclosure, or also covers subsequent disclosures of obvious variants. PTO also has raised two concerns: 1) the elected printed publication for purposes of determining the patent application filing date not be construed as a national filing under the Paris Convention of 1883, and 2) the patent applicant establish by clear and convincing evidence the date on which the printed publication qualified for the exception from prior art. Judiciary Committee staff are working on technical amendments to the AIA that would address these points. We will review any such amendments in collaboration with the other associations.

NSF Technology Transfer Public Website Requirement Now In Effect

The COGR Summer 2011 Update noted that the COMPETES Act reauthorization included a requirement (Section 520) that any institution of higher education that received NSF research support and at least \$25M in total federal research grants in the most recent fiscal year must maintain and report annually to NSF the URL for a public website for technology transfer and commercialization of research.

NSF has included the requirement in its February 1 2012 Research Terms and Conditions (http://www.nsf.gov/pubs/policydocs/rtc/nsf_212.pdf). It applies to all new NSF grants and funding amendments to existing NSF grants awarded on or after February 1, 2012. The award term (#19) states: "Any institution of higher education....that receives NSF research support (i.e., any grant or cooperative agreement awarded by NSF) and has received at least \$25,000,000

in total Federal research grants in the most recently completed Federal fiscal year shall keep, maintain, and report annually to the National Science Foundation the universal resource locator (URL) for a public website that contains information concerning its general approach to and mechanisms for transfer of technology and the commercialization of research results, including:

1. contact information for individuals and university offices responsible for technology transfer and commercialization;
2. information for both university researchers and industry on the institution's technology licensing and commercialization strategies;
3. success stories, statistics and examples of how the university supports commercialization of research results;
4. technologies available for licensing by the university where appropriate; and
5. any other information deemed by the institution to be helpful to companies with the potential to commercialize university inventions.

For purposes of determining whether an institution meets the threshold for this requirement, both the NSF research support and the Federal research grants must have been active at some point during the most recently completed Federal fiscal year.

The institution's URL containing the information required... must be electronically submitted to...ACA520@nsf.gov."

Institutions are not required to include trade secret or proprietary information.

The URLs will be available to the public at <http://www.research.gov/acasection520>. Compliance is the responsibility of the institution; NSF does not plan to monitor compliance. Review of the website indicates that about 50 COGR member institutions now have posted their URLs. **We urge other COGR members to submit their URLs on a timely basis.** We sent a reminder to the COGR listserv on March 5, with a clarification on the email address for URL submission on March 6. AUTM also has reminded its members about the requirement.

Kauffman Foundation Again Promotes Faculty "Free Agency" Concept

We have discussed a number of times the concept promoted by the Kauffman Foundation that faculty should have freedom of choice in how and where to license inventions. A Kauffman representative discussed this concept in a panel at the COGR February 2010 meeting.

The concept was again promoted in a State of Entrepreneurship Address at Kauffman's annual Entrepreneurship luncheon on February 9 in Washington, D.C. by Kauffman Interim President Benno Schmidt (formerly President of Yale University). While the event focused largely on state-level entrepreneurship activities, it was the one policy recommendation related to universities that Dr. Schmidt singled out in his remarks. The Chair and Vice Chair of the National Governors Association (NGA) were present (the governors of Nebraska and Delaware respectively).

We noted in the COGR Holiday 2011 Update that legislation has been introduced in the Senate (S. 1965—Startup Act of 2011) that includes a new Collaborative Commercialization Grants program that features a modified form of faculty free agency. The provision is based on the Kauffman concept, as Dr. Schmidt noted in his address. We understand that companion legislation may be introduced in the House, but it is not clear the Collaborative Commercialization grants will be included.

As discussed in the Update, there are many provisions in the Startup Act that we support. However, the purpose and content of the Collaborative Commercialization Grants program is unclear in the bill. With regard to “free agency,” as we have repeatedly pointed out, institutions in general lack the resources or capabilities to manage inventions for other than their own faculty. Tech transfer offices at a number of universities that Kauffman has singled out for praise have expressed no interest in doing so. There also are concerns about the potential impact on local and regional economic development, if faculty were free to take inventions to institutions in other states or regions for commercialization. The NGA is developing a report on innovation and entrepreneurship that will be released this summer. The higher ed. associations have informally discussed these concerns with NGA representatives. They have indicated the report will not include any recommendations along these lines.

While it is unlikely that the Startup Act will go anywhere in this Congressional term, we will continue to follow the status. We are discussing with other higher ed. associations the possibility of reorienting the Collaborative Commercialization program to focus on regional consortia for building capacity in technology commercialization.

APLU CICEP Metrics Project Raises Interest and Concerns

APLU’s Commission on Innovation, Competitiveness and Economic Prosperity ((CICEP) has launched a project to develop appropriate tools to better communicate the complete array of higher education contributions to regional economies. The aim is to develop a “template” of potential new measures which institutions can adopt to better communicate their role.

These tools are being developed for both internal and external constituencies, i.e. they are being developed to allow universities to look at themselves to see how they can improve themselves; and how they can better communicate the economic contributions of the institution to both the region and nation. The plan is to reach into more nuanced (but detailed) aspects of university-community / industry engagement that are typically omitted when institutions try to communicate their contributions. To that end they hope to go beyond and complement the traditional count of patents, licenses and revenues but recognize that we need more than a narrative – stakeholders want metrics. (See <http://www.aplu.org/CICEPMetrics> for more information).

The project currently is in a pilot phase. 53 data elements have been identified for the pilot, with approximately 35 universities participating in the data collection. Regional stakeholder workshops will be held in April. The stakeholder meetings are intended to provide opportunities for feedback regarding the value of the proposed data element reporting. This will be followed by final review at the summer CICEP meeting, with the final template (10—20 items) published

by the November APLU Annual Meeting. It is important to point out that the intention is to develop a final product/template that is customized to provide the most useful and valuable information for the specific institution rather than a one size fits all; e.g. measures of clinical trial activity would not be relevant to a largely agricultural land grant school with no medical school.

The CIP Committee discussed the project with APLU representatives. A number of concerns were identified. One key issue that may get lost is that these metrics are NOT thought of being how to compare e.g. university A with university B (as with the AUTM licensing survey) because every region has a different environment of industry groups, VC funding, socioeconomic status, etc. Different metrics will be more applicable for some institutions than others. The goal is “impact” metrics rather than numbers. The concern is that the data will be used to benchmark institutions’ performance inappropriately. Other issues identified were concerns about the potential intrusiveness of some of the pilot data elements and the difficulty of tracking some of the information (e.g. alumni data), data “creep” concerns, the relationship with other surveys and initiatives such as STAR Metrics, and the fact APLU represents only public institutions (although it was noted that for obvious reasons, the publics are more pro-economic impact metrics than the privates). While it was agreed that to have one set of data to be collected that can be found in one location in all institutions is the ideal; the reality is that the type of data that CICEP has proposed is found in multiple offices across a university campus.

The APLU representatives indicated that they found the discussion with CIP valuable. Subsequently a report on the project was made at the full membership meeting. We will keep the COGR membership informed as the project develops.

RESEARCH COMPLIANCE AND ADMINISTRATION

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

NASA China Funding Restriction

COGR is working with its Washington-based association colleagues to address the National Aeronautics and Space Administration (NASA) implementation of the restrictions limiting the use of NASA (and OSTP) funds for activities with China or any Chinese-owned company as required by the statutory language in the Department of Defense and Full-Year Appropriation Act, Public Law 112-10 Section 1340(a); and the Consolidated and Further Continuing Appropriation Act of 2012, Public Law 112-55, Section 539. The Assurance presented as a part of the proposal and award process by NASA is consistent with the statutory language.

What is causing significant concern is the Grants Information Circular (GIC) prepared by NASA for its grant and technical officers. The GIC 12-01 goes beyond the statutory requirements to apply the restrictions to Chinese nationals such as students, fellows, researchers, faculty or principal investigators. In its instructions, the GIC acknowledges that while the restrictions may not apply to such individuals, participation by Chinese nationals will be reviewed on a case-by-case basis.

The associations and the research community have received additional answers and “guidance” from NASA concerning this Assurance and the related GIC. In response to one inquiry, the Contract Management Division of the NASA Office of Procurement noted that, in the future, NASA will provide “specific instructions” in each announcement of a funding opportunity/solicitation concerning the applicability of these restrictions. This approach would suggest that, absent a specific instruction in the ORIGINAL solicitation, new awards, any modifications to or additional funds from FY 2011 or FY 2012 appropriations to current on-going agreements and new solicitations may require only the assurance. The GIC is provided as “documentation” and referenced in the award terms and conditions but may have no effect in the absence of “specific instructions” in the solicitation.

However, the export control regulations must be considered if the restriction on the participation of foreign nationals – in this case Chinese nationals – is perceived as limiting access to the research activities. The fundamental research and public domain exemptions to the export control regulations apply only if there are no restrictions on access to, dissemination of, or participation in research. Most recently, NASA has suggested that contractors and grantees

engaged in fundamental research should sign the Assurance but also provided a statement, in a cover letter or on the Assurance, that:

"This letter of assurance is predicated on the understanding that the NASA Class Deviation [implementing NASA Restrictions on Funding Activities with the People's Republic of China] does not apply to the participation of Chinese students, faculty and staff engaged in fundamental research in open laboratories as such research does not raise national security or economic security concerns."

One could argue that without "specific instructions" in the solicitation imposing limits or restrictions on the participation of Chinese nationals including a limitation requiring "case-by-case review to determine whether restricted funds can be used," the fundamental research exclusion is preserved and an export license is not required for the activity. Signing the Assurance and explicitly asserting the recipient's understanding of the fundamental research exclusion could mitigate the risk related to export controls regulations. Each institution must weigh the approach that meets its assessment of the risks. We suggest members consult with institutional legal counsel.

Establishing that the institution is conducting fundamental research and the NASA restrictions do not apply may avoid a violation of Title VII non-discrimination policy. The non-discrimination requirements prohibit discrimination based on national origin and this prohibition protects foreign nationals employed in the US if the individual has work authorization. Applicants and grantees are required by NASA to sign a separate non-discrimination assurance (NASA Form 1206, November 2011) affirming that the institution is in compliance with the applicable non-discrimination national laws and policies. As with the export controls questions, each institution must consider the risk and, before signing, consult with institutional legal counsel.

We will keep the membership informed as NASA continues to implement its China Funding Restrictions.

NIH Financial Conflict of Interest – Questions to Consider

The Thursday morning discussion of the implementation of the Public Health Service/National Institutes of Health financial conflicts of interest regulations dealt with a series of questions raised and presented by the membership. The slides for those presentations that used slides are available on the COGR website at www.cogr.edu under Meeting Presentations.

In describing how to define who an "investigator" is and, thus, required to disclose, Judy Nowack reviewed the 1995 and 2011 regulations and various Frequently Asked Question (FAQs) issued to support both versions of those regulations. That review suggests that: a) an individual, including post-doctoral fellows and graduate students, may be "involved in performing research funded by the NIH" but not be an Investigator, "responsible for the design, conduct, or reporting" of the research; and b) an individual may be a collaborator, consultant, subgrantee, subcontractor, or subrecipient performing research funded by the NIH but not be an Investigator "responsible for the design, conduct, or reporting" of the research. The definition of investigator will likely hinge on the task assigned and, in particular, the significance of that task with regard to the design, conduct, or reporting of the research, and the degree of independence

that individual has in performing that task. Most institutions will confer with the principal investigator to identify the individuals, in addition to the principal investigator(s), who are responsible for the design, conduct and reporting of the research.

In describing how to define “institutional responsibilities,” Naomi Schrag described using the definition of total compensated effort to establish the meaning of institutional responsibilities. This type of definition can include “all professional activity for which an individual is compensated” by the institution, such as “sponsored activities, teaching, University administrative duties, private practice, and other activities.” [More information is available in the Effort reporting homepage at Columbia University under the Reference materials tab at: <http://www.effortreporting.columbia.edu/index.html>]

Many discussion participants agreed with the a definition that relied on compensation by the institution arguing that the non-compensated activity information is obtained through other processes at the institution and need not be combined in the policy directed at PHS/NIH regulations. Thus, if consulting activity is captured under other department or college level disclosure requirements, the first level of review of the investigator disclosure will be conducted by a person familiar with those other reports, e.g., the department chair.

The discussion of institutional responsibilities became intertwined with a discussion of the travel disclosure requirements, as they are currently written. Many institutions will collect information but only conduct formal reviews and make formal determinations when those disclosed travel reimbursements reach either a defined threshold and/or involve specific types of entities, e.g., for-profit companies. Most institutions are trying to limit the level of review conducted on the required disclosures.

Andy Rudczynski offered one model for assessing financial interests to determine whether a conflict with PHS/NIH funded research exists. Built on a “branched” policy approach that retains a \$10,000 threshold for disclosures in the main institutional policy, the institution has established “branched” policies for specific agencies. Thus, the policy for PHS/NIH funded research uses the required \$5,000 threshold. In addition to establishing differing thresholds, the institution has identified for special consideration “large significant financial interests” at a value of \$100,000 or more.

In making a determination concerning whether an interests constitutes a conflict with PHS/NIH funded research, Rudczynski described a series of questions that would be raised on a case-by-case basis. These factors include those focused on the investigator’s (the discloser) interest and those that assess the interest in light of the research. For example, whether the Discloser’s ongoing role is necessary to continue advancing the research, and their opportunity to bias the results; whether the work is funded by an entity in which the Discloser holds a significant financial interest (SFI) and the value of the SFI in relation to the size and value of the entity. The questions focused on the nature of the research ask, for example, whether the research is of a basic or fundamental nature and the likelihood of immediate commercialization or clinical application; or whether the goal of the research is to evaluate an invention linked to the SFI; or, when it involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board. Such questions can assist institutional officials and

members of review committees examine the SFI in way that balances the financial interest and the activity in making the determination of a conflict.

Because of the extensive PHS/NIH requirements, institutions are considering creating separate policies and/or separate procedures for differing sponsors in an effort to isolate the PHS/NIH requirements to those individuals who have or are seeking PHS/NIH funds. For those investigators with multiple sponsors including PHS/NIH, institutions will apply the most “restrictive” policy; in this case, the PHS/NIH regulations.

Pam Caudill outlined the various reporting requirements that are incorporated into the PHS/NIH regulations and compared the regulatory language with the FAQs and webinar information provided by NIH. Her review offered a discouraging recognition on the level of contradictory information. Members asked COGR to pose a specific question to NIH for clarification (and for consistency between the regulation and FAQs) concerning the timing of “annual” disclosures. Currently, the link for annual is to the progress or continuation funding application submission (e.g., the Type 5 submissions) which will likely be different from annual (fiscal or calendar year) disclosures anticipated by the institutions. Relying on “annual” submissions tied to progress reports would mean that institutions would have an unlimited number of annual reporting deadlines. Institutions would argue for an FAQ that makes clear that the meaning of “annual” can be set by the institution and that the institution has the flexibility and responsibility to affirm the accuracy of the annual disclosure at the time of the submission of progress reports or continuation requests. Anticipating a release of FAQs in the very near future, we have delayed making this request of NIH until that release. If this issue is not resolved, we will forward and immediate request for clarification.

We had a broad and generally non-conclusive discussion of the problem of manage subrecipients’ compliance with the PHS/NIH regulations. The most troubling problem is with foreign subrecipients. There are two options: require the subrecipients, domestic and foreign, to have a PHS/NIH compliant FCOI policy or have the subrecipients, domestic and foreign, comply with the prime institution’s policies. Clearly, the challenge of collecting and reviewing disclosures, developing and monitoring management plans and making the information on FCOI publically available is daunting and for domestic organizations most institutions plan on requiring the development of a subrecipient policy. The issue of foreign entities is significantly more complex as the uniquely US consideration of financial interests and relationships and the idea of those conflicting may not align with that of a foreign country. This circumstance is exacerbated by the limitation on expending funds until all disclosures, review and determination and reporting, if appropriate, is complete. With regard to the expenditures by the prime, in a recent email to a university, NIH clarified that:

The prime Institution may expend funds issued under an NIH grant or cooperative agreement award to support activities conducted at the prime Institution, **if** a subaward agreement has not been executed. In this example, once the subaward agreement is executed, it is expected that the subrecipient Institution will submit any FCOI reports, if applicable, to the prime Institution for submission to the NIH prior to the subrecipient’s expenditure of funds. Therefore, the prime Institution can record expenses in the official records of the Institution for costs incurred at the prime Institution but not for costs incurred at the subrecipient Institution until the subaward agreement is executed and the

FCOI report(s) for any subrecipient Investigators, if applicable, are submitted to the NIH.

This clarification provides much needed time to complete the subrecipient FCOI review without hindering the start of research at the prime institution.

NIH Financial Conflict of Interest Next Steps: Survey/Policies/June COGR Meeting

COGR hopes to receive a response to its request to re-open the rule for re-consideration of the travel provisions shortly. We understand additional FAQs will be posted to the NIH website at: <http://grants.nih.gov/grants/policy/coi/> at the same time.

We will continue to assist the membership in implementing the new regulations. During the Thursday morning session, participants said they were willing to entertain a member's request to complete a brief nine question survey on the process (electronic or paper) institutions are using for the collection of investigator disclosures implementation. The link to the Survey Monkey survey organized by Ann Mathias, Carnegie Mellon University, is at: <http://www.surveymonkey.com/s/5DYVQP8>. Ann promises to share the results with the COGR membership. Participants indicated that they'd like to see draft policies under consideration by their colleagues. Since posting to a publicly accessible website signals full implementation under the regulations, COGR has volunteered to post those we receive in the next several weeks on the members-only section of the COGR website. If you're willing to make your draft policy available to other COGR members, forward a copy to cblum@cogr.edu. Finally, participants said that another Thursday AM session at the June meeting would be useful. By June, most institutions will/should have their policy and procedures designed and ready for implementation. A session in June could examine a few of those policies and procedures. We'd welcome other topics if we decide to have another discussion.

Air Force No-Cost Time Extension Available

In a letter to grantees, Thomas P. Russell, Director of the Air Force Office of Scientific Research (AFOSR) reassures the research community that AFOSR will continue to issue no-cost time extensions but program managers and grants officers have been directed to issue NCE only when properly documented and truly warranted. A copy of Mr. Russell's letter concerning NCEs will be posted to the COGR website with this meeting report at www.cogr.edu under the Meetings tab.

USDA Post Final Determination ONLY in Appealed Inspection Reports

The US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) announced by posting a revised fact sheet that it will delay posting animal facilities inspection reports if an appeal is pending. If an appeal is received after the 21-day window, the posted final report will be removed until the appeal is resolved. If the original final report is amended based on the appeal, APHIS will post only the amended report.

The delay in posting an inspection report under appeal and the decision to post only the amended report is a significant change in APHIS policy. In the past, the original report filed at the time of

inspection would have been posted and remained on the APHIS inspection site during and after a successful appeal. The online access to all inspection reports has provided significant misinformation about the inspected facilities and this change will ensure that the most accurate information is available the interested public.

APHIS encourages animal care facilities operators to raise concerns with the inspector during the exit interview. If an issue is resolved during the exit interview, the inspection report can be amended before being finalized and posted to the APHIS website. After the report is finalized, the institution can contact the inspector and discuss and, if possible, resolve disputed items. If an appeal is not received within 21 days of the finalized report, the report will be posted to the APHIS website. If an appeal is submitted, the report will be held until the appeal is resolved; if an appeal is received by APHIS after 21 days, the final reported will be removed from the website while the appeal is reviewed. The process is described on the APHIS Animal Care Fact Appeals Process (February 2012) available through the APHIS Publication link at: http://www.aphis.usda.gov/publications/animal_welfare/2012/appeals_process.pdf

NABR Submits *Amicus* Brief in AETA Lawsuit

The National Association for Biomedical Research (NABR) joined with ten other organizations in submitting an *amicus* brief in a federal lawsuit challenging the constitutionality of the Animal Enterprise Terrorism Act (AETA). The brief urges the US District Court for the District of Massachusetts to uphold the constitutionality of the AETA and argues the law is a measured and important response to threats, bombings, arson, and vandalism committed by animal rights extremists against research facilities and scientists who conduct life-saving research with laboratory animals. In addition to arguing the AETA's constitutionality under the First Amendment, NABR's *amicus* brief provides the court with the historical context necessary to understand why the AETA received bipartisan support in Congress in 2006.

COGR's Board approved participation in the *amicus* brief but NABR elected to delay broad participation at this time. If the suit continues toward trial (if the Federal government motion to dismiss the complaint fails), COGR will continue to offer its support and participation.