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June 2012 COGR Meeting Report

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COUNCIL ON GOVERNMENTAL RELATIONS

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June 28, 2012

MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS

WASHINGTON MARRIOTT HOTEL

June 7 and 8, 2012

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GENERAL DEVELOPMENTS

National Research Council (NRC) Report on Research Universities – NOW AVAILABLE

The NRC Committee on Research Universities released the report: *Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Nation's Prosperity and Security*. The report was made available to the public on June 14th. The Full Report and the Summary version are available at:

<http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=13396>

In the report (see Summary version, page 3), the committee makes ten major recommendations, including a strong call for Revitalizing the Partnership: *“It is essential that we as a nation reaffirm, revitalize, and strengthen substantially the unique partnership that has long existed among the nation’s research universities, the federal government, the states, and philanthropy by enhancing their individual roles and the links among them and also by providing incentives for stronger partnership with business and industry. In doing so, we will encourage the ideas and innovations that will lead to more high-end jobs, increased incomes, and the national security, health, and prosperity we expect.”*

Of the ten recommendations (also see Summary version), three are of particular interest and two of these (Recommendations 6 and 7) are ones that COGR advocated to the NRC Committee. Recommendations 6 and 7 also are related to recent COGR interactions with OMB on grants reform and could provide leverage in that arena:

- **Recommendation 4. Improving University Productivity.** Increase university cost-effectiveness and productivity in order to provide a greater return on investment for taxpayers, philanthropists, corporations, foundations, and other research sponsors.
- **Recommendation 6. Full Federal Funding of Research.** The federal government and other research sponsors should strive to cover the full costs of research projects and other activities they procure from research universities in a consistent and transparent manner.
- **Recommendation 7. Reducing Regulatory Burdens.** Reduce or eliminate regulations that increase administrative costs, impede research productivity, and deflect creative energy without substantially improving the research environment.

Over the course of then next year, NRC Committee members will be meeting with stakeholders across the country to seek further input and implementation of the recommendations. We will invite Committee members to the October COGR meeting to discuss concrete actions needed to achieve the goals outlined in the NRC report.

NCATS: Acting Director Participates in Panel Session at COGR Meeting

Dr. Thomas Insel, Acting Director of the new NIH National Center for Advancing Translational Sciences (and Director, National Institute of Mental Health), participated in a panel session at the COGR meeting with Dr. David Wynes, COGR Board Chair, and Dr. Charles Louis, Chair of the COGR Contracts and Intellectual Property (CIP) Committee.

Dr. Insel noted that NCATS is the first new institute established at NIH in many years. It was established last December by the 2012 Consolidated Appropriations Act (P.L. 112-74). Dr. Insel characterized NCATS as an “experiment” in “disruptive innovation.” It seeks to catalyze innovative methods and technologies that enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of diseases and conditions. It has a budget of \$576M (2% of NIH overall).

Dr. Insel reviewed current issues with new therapeutics development, which have led some to characterize the drug development pipeline as “Pharmageddon”(i.e. 95% failure rate in the course of the Phase I—III clinical trial process (77% in Phase II) despite the deluge of recent discoveries of new potential drug targets). The pipeline should be viewed as a scientific problem ripe for experimentation and process engineering.

NCATS has 3 components: Clinical and Translational Science Activities (80% of NCATS funding through 60 sites in 30 states and D.C., managed through the Division of Clinical Innovation), Rare Diseases Research and Therapeutics, and Re-engineering Translational Science. The CTSAs have had a number of accomplishments, including Research Electronic Data Capture (REDCap) and a web-based registry for participation in clinical research (Researchmatch.org). The new Therapeutics for Rare and Neglected Diseases (TRND; formerly Human Genome Research Program)) program is intended to stimulate research collaborations for drug discovery and development between NIH and academic and nonprofit scientists and pharma and biotech companies. The Re-engineering translational science activities are aimed particularly at the toxicity issues in the high rate of Phase II failures, including a joint program with DARPA whose aim is to develop a tissue chip that mimics human physiology to screen for safe, effective drugs, and a joint program with EPA, FDA and the NIH Environmental Health Science Institute to screen compounds composed of environmental chemicals for their potential to disrupt toxicity (Tox21). Dr. Insel also mentioned the new drug rescue and repurposing program (see below). Finally Dr. Insel mentioned the new Cures Acceleration Network (CAN), funded at a 2012 level of \$10M, under which NCATS has Other Transaction authority to enhance its award flexibility. A copy of Dr. Insel’s presentation is posted on the COGR website.

Government to Propose Institutional/Local Policy on DURC

Amy Patterson, Associate Director for Science Policy at the National Institutes of Health (NIH) offered a broad outline of a policy under development that would define institutional responsibilities in the oversight of dual use life science research of concern (DURC). Participating on a panel addressing DURC issues at the June COGR meeting, Dr. Patterson reviewed what dual use research is and, using the recent case study linked to the publication of two papers concerning H5N1 avian influenza transmission, described the government’s response and responsibilities under the new US Government Policy on the Oversight of DURC.

Noting the difference between dual use research and dual use research of concern – that subset of life science research that has the highest potential for generating information that could be readily misused – Dr. Patterson described the process and principles that the National Science Advisory Board for Biosecurity (NSABB) brought to the consideration of the manuscripts concerning A/H5N1 virus. She recognized that oversight of DURC is a shared responsibility among researchers, institutions, publishers and the Federal government. The March 2012 US Policy establishes mechanism for regular review of Federally funded or conducted research focused on a clearly defined subset of biological agents that present the greatest risk of deliberate misuse that have established biosafety oversight. Acknowledging that the scope may need to be adjusted, the agencies will be testing mechanism of review and risk mitigation to inform future revisions.

As Dr. Patterson described the next steps, the roles and responsibilities of research institutions will be the subject of a proposed local policy to be issued for comment late this summer. The policy will be issued with companion documents that provide tools to assist in implementing the policy. Some of those tools are available now through the NSABB (<http://oba.od.nih.gov/biosecurity/biosecurity.html>) and, when complete, offer assistance in identifying and assessing the risk and benefits of DURC research, developing an institutional code of conduct, and providing guidance for responsible communications of DURC. Dr. Patterson pledged to get the oversight of DURC “right” by balancing the right amount of oversight on a focused set of research activities using mechanism that make sense. Throughout the process, the Federal government will be measuring the impact of the oversight and adjusting the policy and mechanisms as needed to preserve the benefits of life sciences research while minimizing the risks of misuse.

Some institutions began the review of DURC long before the publication of the US Policy. Wayne Thomann, Duke University, and William Mellon, University of Wisconsin-Madison, joined Patterson in the discussion of managing DURC. As home to one of the researchers whose work came under review, virologist Yoshihiro Kawaoka, the University of Wisconsin-Madison relied on a well-established review mechanism throughout the course of the research leading to the publication submitted to *Nature* in 2011. UW-Madison’s Institutional Biosafety Committee (IBC) and its Biosecurity Task Force both conducted reviews of the research proposed in response to the National Institutes of Allergy and Infectious (NIAID) solicitation focused on influenza and biodefense. The Biosecurity Task Force is engaged in the oversight of all aspects of select agent and toxin research at UW-Madison and is advisory to the institution’s responsible official. Dr. Mellon provided a timeline of the events leading to NSABB review and eventual publication of the Kawaoka paper in May 2012. Since this event, UW-Madison has refined its processes to engage the investigators in early and on-going discussions with the appropriate officials and the IBC and Biosecurity Taskforce and formalized communication of UW-Madison’s determinations to the appropriate sponsor, in this case, NIH.

Dr. Thomann expressed his relief that Duke University was not thrown into the spotlight like his colleagues at UW-Madison but proceeded to describe a process of education, review and assessment that would have ensured an equally positive outcome if/when its Duke University’s turn in the headlines. The review and assessment of DURC at Duke begins with the premise that its investigators are interested in conducting good science with positive intents but that increasing awareness and knowledge of DURC is appropriate. Focused on developing and

implementing an awareness and educational process since 2005, Duke considers a broader scope of research and educates its IBC members and investigators to consider not only the direct misapplication of research as a threat but to consider the continuum of the research process to identify incremental or sequential risks or threats. Duke participates in the Southeast Regional Center of Excellence for Emerging Infections and Biodefense (SERCEB) and uses its DURC training module, The Dual Use Dilemma in Biological Research, to train its IBC members and investigators (at: <http://www.serceb.org/dualuse.htm>). Since the publication of the US Policy, Duke has begun its own assessment of its research portfolio to identify DURC and is addressing mitigation planning for Duke-identified research.

The presentations from the discussion are available on the COGR website (www.cogr.edu, Meeting Presentations). COGR will notify the membership when the draft institutional policy is published for comment and we encourage you to assess research that falls under the US Policy and begin discussion of DURC on your campus.

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 and OMB Circular A-21 Update

The COGR Costing Committee met with Victoria Collin and Gilbert Tran, both from the Office of Management (OMB), Office of Federal Financial Management, during the Wednesday afternoon, June 8th, Costing Policies Committee Meeting. The focus of the meeting was to discuss the status of selected items that were addressed in the Federal Register, Advanced Notice of Proposed Guidance (ANPG), *Reform of Federal Policies Relating to Grants and Cooperative Agreements; Cost Principles and Administrative Requirements (including Single Audit Act)*, and to understand the next steps in the grants reform process.

There were over 350 responses to the ANPG (the COGR response can be found on the COGR home page at www.cogr.edu - see Latest News, April 27, 2012 link). In the COGR Update (May 23, 2012) prior to the COGR Meeting, we provided a preliminary assessment on the Composition of Responses (i.e., a broad-brush overview of the types of entities that responded), a Sampling of Responders (not including COGR institutions), and Observations and Anecdotes (based on a limited COGR review). We also encouraged COGR members to browse the <http://www.regulations.gov/> website and review the responses (to do so, go to the regulations.gov website and enter “OMB-2012-0002” into the initial Search window and you will have access to all of the comment letters).

The remarks provided by Ms. Collin and Mr. Tran during the Wednesday meeting, in conjunction with comments made by OMB Controller Danny Werfel in a conference call with COGR on the Monday prior to the COGR Meeting, provide interesting insight to the status of grants reform and the next steps. Some of COGR’s observations and understandings include:

- The responses to the Flat Rates/Discounted Rates idea were not positive (including those from non-university responders). According to Mr. Werfel in the Monday conference call, there is a “small likelihood of moving forward [on this reform idea]”.
- OMB is interested in some new ideas that were raised in the responses to the ANPG: 1) Automatic extension of an institution’s current rate for a period of 4 to 5 years, 2) “Minimum” Rate for those institutions that have never had a need to establish a rate, and 3) Requirement to have pass-thru entities (e.g., State agencies) pay the full negotiated F&A rate of the subrecipient entity (e.g., nonprofits, universities, etc.).

- OMB understands that the “examples” in Circular A-21 that describe acceptable payroll distribution systems are not helpful. As OMB consults with the IG community about alternatives to Effort Reporting, there still is interest in revising the requirements so as to emphasize principles and internal controls rather than prescribed methodologies.
- Direct Charging of Project Management Costs (i.e., administrative costs) appears to have a similar momentum as the alternatives to effort reporting – as OMB consults with the IG community on this topic, there is interest in an approach that would emphasize principles and internal controls rather than defining allowability of specific types of projects management costs.
- The responses to the Consolidation of Circulars idea were mixed – while the university and nonprofit research institution communities were not positive, some stakeholders such as the audit community and state and local governments apparently were. However, the biggest advocate for a consolidation of the circulars seems to be OMB and other federal entities. We believe, though not confirmed by OMB, that the next phase of grants reform will be the roll-out as a proposed consolidated circular (also see next section, below), with specific carve-outs/exceptions for cost and administrative treatments that are unique to specific types of entities.

In discussions with Mr. Werfel, Ms. Collin, and Mr. Tran, we continue to emphasize some of the issues that were not addressed in the ANPG – for example, better enforcement by OMB when agencies impose arbitrary agency F&A caps on selected programs, improving transparency in F&A rate negotiations, and other policy revisions that would be important to the research community. While some of these items disappointingly will not be addressed in this phase of grants reform, we will continue to remind OMB of the importance of establishing a forum to address all issues in a long-term, constructive forum.

The Next Phase of Grants Reform – A Consolidated Circular?

While not confirmed by OMB in any of COGR’s correspondences with Mr. Werfel, Ms. Collin, and Mr. Tran, we believe the next phase of grants reform will be the roll-out of a proposed consolidated circular. There will be specific carve-outs/exceptions for cost and administrative treatments that are unique to specific types of entities (i.e., definitions for organized research, application of the 1.3% UCA, the 26% administrative cap, etc. still would be applicable to colleges and universities only). On the other hand, other more generic cost treatments would be captured in a section of the circular applicable to all entities.

Note, this is COGR’s “sense” and is not official. However, the fact that OMB is considering the consolidated circular as a viable option suggests that much of the work has been completed already. Also, we believe that OMB would like to publicize “grants reform” prior to the November election, and to do so, may be planning to release a proposed consolidated circular by the end of the summer. If this is the case, the proposed consolidated circular would be published in a Federal Register Notice and would be available for public comment.

Again, this is COGR's "sense" and is not official. However, if this is the case, our community will need to engage quickly and be poised to complete a detailed and thorough review that requires a side-by-side analysis of the proposed consolidated circular with the existing circulars that currently apply to our community (i.e., a side-by-side with Circulars A-21, A-110, A-133, and to some extent, A-122 and the Hospital Costing Principles). We expect this would be an intense project with the greatest risk possibly being the unintended consequence where an "under the radar" change via consolidation results in change that has significant repercussions.

Officially, the Council on Financial Assistance Reform (COFAR) is responsible for shepherding the grants reform process through the next stages of completion. As many of you know, an October 27, 2011 OMB Memorandum M-12-01, *Creation of the Council on Financial Assistance Reform*, established the COFAR. The COFAR is comprised of OMB's Office of Federal Financial Management (Co-Chair) and the Chief Financial Officers from 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.

To date, COGR's primary correspondence has been with OMB and we believe this still is the critical point of contact. However, we will engage with the COFAR, as appropriate. If the proposed consolidated circular is published in the Federal Register at the end of the summer, we will need at least 60 days to do the side-by-side review, and we already have made this known to OMB. It would be a major community effort to develop the formal response to OMB and/or the COFAR. If events unfold as we have speculated, we will reach out to many of you for assistance. We are paying close attention to all developments and will keep the membership posted.

Thursday Morning Costing Session: Financial Reporting, Cash Requests, Electronic Systems, and the Burdens they Bear – Managing a Federal Labyrinth

The Thursday morning Costing Policies session at the June 7th COGR Meeting was designed to document the many different federal reporting and system burdens that COGR institutions are required to manage. Three panelists presented Case Studies on those federal financial reporting and post-award management requirements that they view as most problematic and how each institution manages the disparate requirements across various federal agencies. The three panelists for this session were:

Sue Paulson, Finance Director, Sponsored Financial Reporting – University of Minnesota
Gail Ryan, Assistant VP, Sponsored Program Administration – Wayne State University
Tracy Walters, Director, Grant and Contract Financial Administration – Yale University

Enhancing accountability and transparency remains a critical driver to new requirements and expectations. And while research institutions are, and always have been, committed to the best oversight and stewardship practices, each new law and/or requirement results in the "accumulation effect" – i.e., each "small" incremental requirement leads to a final product that is overwhelmingly burdensome and requires significant institutional resources to effectively manage. FFATA (2006), ARRA (2009), Executive Order 13576 (June 2011, which created the Government Accountability and Transparency Board, or GATB), and the Digital Accountability

and Transparency Act of 2012 (DATA Act, passed by the House and working thru the Senate) are examples of well-meaning federal initiatives that, unfortunately, contribute to a federal reporting infrastructure that is inefficient and drains resources from the educational and research missions of the research university.

Also, we constantly must work around agency-specific activity (again, most likely, well-meaning) such as the expected 2013 release of the new NSF Award Cash Management Service (ACMS), ongoing system/access challenges with DOD's Wide Area Workflow system (WAWF), and other unique practices that affect how we conduct business with each federal agency.

In the Case Studies, each of the three panelists was asked to build his/her presentation around a series of questions. Below are the questions that were posed at the beginning of the session and some general themes and anecdotes that were provided:

How do institutions organize around Federal reporting and post-award management?

Differentiation of responsibility for federal versus non-federal reporting was a consistent theme, as was the establishment of a separate accounts receivable unit. Also, while not formally embedded into the organizational structures of each institution, there was a “de-facto” differentiation of duties relating to responsibility for specific federal systems (e.g., an individual dedicated to/expert on DOD's WAWF).

Which agency-specific reporting practices, expectations, and/or systems are the most problematic? The best?

First, the fact that there were so many unique systems and practices across federal agencies was particularly troublesome. At least 7 electronic/cash draw systems and 5 paper-based/invoicing systems were identified. In addition, at least 10 unique federal financial reporting systems were described. Compounding the vast array of systems were the federal reports (quarterly FFR, semi-annual financial, annual financial, final financial, etc.) to be filed over varying and inconsistent frequencies.

Second, and sadly, not one agency system or practice was volunteered as exemplary. However, the DOD WAWF system stood out as a leading candidate for most problematic. And even in situations where there could have been candidates for “best” systems or practices, the “overwhelmed” phenomenon prevailed – i.e., the front-line accountants at each institution who work with the agency systems are effectively frustrated to the point where it is difficult for them to identify the “best” systems or practices.

How did institutions organize around ARRA reporting and would these models be sustainable?

Each presenter shared their unique institutional approach to managing ARRA reporting. The theme for ARRA reporting was “get it done, and then move on”. In other words, the plan was not to make permanent organizational changes around ARRA reporting, as these changes would be expensive and not sustainable.

What are the greatest challenges we currently are experiencing? Organizational, Technological, etc.

There are many, many challenges specific to each agency's unique systems and/or practices – these were documented in the institutional Case Studies. The manifestation of these many challenges is the overriding challenge of making available the necessary level of institutional resources. While maybe “pie in the sky”, the ultimate solution would be consistent systems used across all agencies that would allow for redundancy and efficiency to be built into institutional organizational structures. The best anecdote of the panel discussion may have been the situation at one school where the DOD WAWF system expert at the school went on sick leave for 30 days, and during his absence, the institution was not able to invoice DOD because no one else at the school could figure out how to use the WAWF system, nor could DOD provide the necessary technical support.

How can our community quantify/demonstrate burden to Federal policymakers? In terms of cost of systems, cost of doing business, cost of compliance, etc.

The ARRA experience can serve as one definable, discreet activity where the cost of reporting compliance and burden can be reasonably quantified. As some versions of the DATA Act and other federal initiatives (such as the creation of the GATB, see above) have suggested “ARRA reporting for all federal funds,” the cost of ARRA reporting may be helpful in demonstrating burden. In addition, simple charts that document the number of unique federal systems, the number of reports and data elements we report on, the varying frequencies of reporting, and general inconsistency across agencies, can paint a picture of the inevitable burden. Finally, simple anecdotes (e.g., the inability of a resource-strapped institution to invoice the DOD because the institution's DOD WAWF expert was on sick leave) may be the best way to demonstrate burden by capturing real-life examples of how poorly coordinated federal systems create significant disruptions and dysfunctions at research institutions.

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

Audit Update: General

COGR regularly checks the HHS (NIH) and NSF Office of Inspectors General (OIG) websites (see links below). There are now six audits of NIH ARRA awards that are posted on the HHS (NIH) OIG website, the most recent one posted on June 14th. As has been the theme with each audit to date, there were no findings, no cost disallowances, and no recommendations.

<http://oig.hhs.gov/reports-and-publications/oas/nih.asp>

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

COGR continues to follow the status of the HHS OIG Administrative & Clerical Audits (no new developments) and the expected release of the 2012 A-133 Compliance Supplement (see update in next section).

COGR always is interested in audit experiences at your institution so that we can update the general landscape for the membership; do not hesitate to contact us. We have the most access to HHS OIG and NSF OIG initiatives, but also are interested in activity related to the OIGs at other agencies.

NIH Salary Limitation and an NHLBI Contract Clause – RESOLUTION

We have reported on an issue regarding contracts issued by the National Heart, Lung, and Blood Institute (NHLBI) over the past several months – NHLBI initially implemented the new NIH Executive Level II Salary Limitation in a manner inconsistent with prior NIH guidance. The following HHS Acquisition Policy Memorandum dated March 28, 2012 (see link below and scroll down to Acquisition Policy Memoranda, Attachment A, Interim Updates to HHSAR) was being cited by NHLBI contracting officers:

<http://dhhs.gov/asfr/ogapa/acquisition/acquisitionpolicies.html>

The Contract clause in question (352.231-70 Salary rate limitation) specifies: *(a) Pursuant to the current and applicable prior HHS appropriations acts, the Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date an expense is incurred.* The “date an expense is incurred” language would have required an institution to apply the Executive Level II salary limitation immediately to the contracts in question and further would have required the institution to correct for prior billings.

In the COGR Update (May 23, 2012) prior to the COGR Meeting, we reported on a resolution. After corresponding with staff from the NIH Office of Acquisition Management and Policy (OAMP) and the NIH Division of Acquisition Policy and Evaluation (DAPE), the Directors of OAMP and DAPE confirmed that NIH Acquisition and Contracts policy was meant to be consistent with the January 2012 NIH Notice (NOT-OD-12-035) and subsequent FAQs – i.e., the Executive Level I salary limitation should be used for FY2012 contracts in question. The contract increment/option period (analogous to the budget period of a grant) determines the trigger date for the applicable salary level. For example, if the increment/option period is November 24, 2011 (i.e., prior to the December 23, 2011 effective date of the Executive Level II salary limitation) through October 31, 2012, Executive Level I is applicable for that increment.

The Contract Clause in question is the responsibility of the HHS Office of Grants and Acquisition Policy and Accountability (OGAPA) – this office recently has been reorganized and will need to be active in modifying the current Contract Clause. While it is uncertain when the Contract Clause will be modified, institutions should utilize Executive Level I in the appropriate situations. Please contact David Kennedy at dkennedy@cogr.edu if your institution has not resolved this situation with NHLBI.

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.

2012 A-133 Compliance Supplement and NSF Awards. Normally, the A-133 Compliance Supplement is available in March. There were a number of reasons for the delay; one item applicable to research institutions. For our community, at issue was a “last second” insertion of guidance that would have required all NSF awards to be reported on the SEFA as part of the R&D Cluster, and consequently, to be treated as “organized research” for F&A rate development purposes. Upon raising our concerns with OMB, the “organized research” treatment language was eliminated. Still, we objected to the requirement where all NSF awards be reported on the SEFA as part of the R&D Cluster (in short, some NSF awards are not R&D). After discussions with OMB, NSF, and NSF IG personnel, OMB agreed to remove the entire insertion from the A-133 Compliance Supplement. OMB is close to resolving all remaining issues with the A-133 Compliance Supplement and the release of the 2012 version is imminent.

NOTE ON NSF PAPPG (2012 DRAFT VERSION): The draft version of the 2012 NSF Proposal & Award Policies & Procedures Guide (PAPPG) includes the same insertion that NSF awards should be part of the R&D Cluster on the institution's SEFA (see page 3, Chapter II.F. Records Retention and Audit, per the link to the PAPPG below). Comments on the draft version of PAPPG are due to NSF by July 12, 2012 and COGR will request that this language be removed.

http://www.nsf.gov/bfa/dias/policy/papp/pappg2012_draft.pdf

Debt Financing Arrangements and Negotiation of F&A Rates with ONR. As you may recall, the OMB ANPG on Grants Reform (see earlier section) included the following “reform idea”: *Specifying that gains and/or losses due to speculative financing arrangements are unallowable.* COGR did not support this “reform idea” and maintained in the COGR response that thoughtful and effective use of all available debt financing arrangements can result in significant cost savings. The Office of Naval Research (ONR) and the Defense Contracting and Audit Agency (DCAA), however, recently have disallowed interest expense for at least two institutions based on what they consider unallowable debt financing arrangements. While COGR will not engage in a specific F&A rate negotiation, we will engage in similar situations if we believe the OMB policy guidelines are not being followed. The fact that the financing arrangements in question are legitimate, result in significant cost savings, and are not disallowed according to current OMB policy has compelled us to engage further on this issue. We are in contact with a number of federal officials and will keep the membership posted on developments.

Arbitrary Agency Policies, F&A Caps, and Grants Reform. COGR will continue to report on this topic and solicit feedback from the membership. In the past two COGR Updates, we have published many examples of recent “Arbitrary Agency Policies.” While we were disappointed that this was not addressed in the Advance Notice of Proposed Guidance on Grants Reform, we will continue to raise this concern with staff from OMB. Ultimately, our goal is for OMB to make available a “customer-oriented” mechanism to address the ongoing problem where agencies implement arbitrary cost reimbursement policies. We hope to leverage the Grants Reform process and work with OMB to develop solutions to this problem – the examples that you share with COGR will continue to be helpful. Until then, we will pursue these situations through a variety of means, including

contacting the applicable agency policy office and/or continuing to catalogue these examples with OMB.

Division of Cost Allocation (DCA) Organizational Update. The DCA, responsible for negotiating F&A rates for most COGR institutions, has announced that Arif “Mak” Karim is the new National Director for the DCA. Previously, he was serving as the Acting National Director. In addition, further developments suggest that there may be more changes announced. We will follow these developments and keep the membership posted.

NSF Survey Results on R&D Expenditures, FY2010. The National Science Foundation, National Center for Science and Engineering Statistics (NCSES), recently released results from the FY2010 Higher Education Research and Development (HERD) Survey. The FY2010 report represents the first year of the new survey format and includes new data points such as expenditures funded by nonprofit organizations and a more detailed breakdown on Institutional funded expenditures (i.e., unrecovered indirect costs, cost sharing, and internal research projects). The report can be found at:

<http://www.nsf.gov/statistics/infbrief/nsf12313/>

NASA 2012 Guidebook for Proposers. The 2012 Guidebook includes a new requirement (also see page i per the link below): *A required element of the Budget Narrative is a table of Personnel and Work Effort, summarizing the work effort required to perform the proposed investigation. The table must have the names and/or titles of all personnel necessary to perform the proposed effort, regardless of whether those individuals require funding. For each individual, list the planned work commitment to be funded by NASA, per period in fractions of a work year. In addition, include planned work commitment not funded by NASA, if applicable. Where names are not known, include the position, such as postdoc or technician.* There is some concern that this could result in a voluntary cost sharing commitment. On a separate topic, we understand NASA is considering a policy change that would eliminate the allowability of management fees charged to NASA grants and cooperative agreements. Please notify COGR if either of these changes are problematic for your institution.

<http://www.hq.nasa.gov/office/procurement/nraguidebook/proposer2012.pdf>

NIH and Selected “Fully-Funded” NIDDK Awards. We have reported on this issue in the past two COGR Updates. Several COGR members received letters from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) referencing the October 2011 NIH Grants Policy Statement (GPS), Chapter 8.1.1.1, *Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period*. By law, Federal agencies are required to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. Consequently, in order to close the accounts as required by law, NIH must report disbursements on the quarterly cash transaction report (using the FFR) of the fifth fiscal year after the year of availability, no later than June 30 (a highly unrealistic date for institutions).

COGR contacted officials from the NIH Office of Policy for External Research Administration (OPERA) and learned that this situation is exceptional and unique to NIH multi-year awards where the funding for all years is “fully funded” in the first year of the

award. At issue in these “fully-funded” situations is that the project period end date does not allow the grantee or agency sufficient time to submit final reports prior to the cancellation of the disbursements (i.e., September 30 as referenced above). OPERA has consulted with their grants colleagues at NIDDK to request that they reach out to institutions that are affected and to provide guidance on how to address the submission of the final FFR. We recommend that you contact your grant or program manager at NIDDK and ask them to clarify how this situation should be addressed. If this is not resolved, please contact COGR staff.

Gift Cards and the Dodd-Frank Wall Street Reform and Consumer Protection Act. A concern was raised at the COGR meeting that financial disincentives triggered by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 has resulted in credit card companies no longer issuing gift cards, which are used by your institutions to compensate participants in research projects. Consequently, this may result in more emphasis on store issued gift cards (which appear to be unaffected by the Act) when compensating participants in research projects. While there appears to be no immediate remedy to this situation, it is illustrative of how legislation can lead to unanticipated outcomes.

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

NCATS: RFI Raises Concerns

We mentioned in the Summer **Update** that NCATS had issued an RFI (NOT-TR-12-002) for a pilot program [Discovering New Therapeutic Uses for Existing Molecules](#). This is a limited pilot program to explore new therapeutic uses for drugs made available by three pharmaceutical companies (Eli Lilly, Pfizer, and AstraZeneca). Investigators will submit proposals for cooperative agreements to assess the efficacy of drugs rescued and repurposed for new disease areas (NCATS issued a companion RFA (NOT-TR-12-001) noting an Intent to Publish a Request for Pre-Applications). NCATS negotiated template Confidential Disclosure (CDA) and Cooperative Research (CRA) Agreements with each company, which will need to be executed by each investigator's institution with the company providing the drug candidate. The terms of the CDAs and CRAS are not identical. The Update noted that if successful, NCATS planned to expand the program to include additional pharma/biotech companies and new therapeutic agents. On June 1 COGR submitted comments in response to the RFI. While expressing support for the program concept, we also expressed a number of serious concerns. We noted that some of the prenegotiated terms are likely to present significant problems for our institutions. We identified six as potential "deal breakers" for many of our member institutions (scope of "Technical Developments" to which companies are given rights; Intellectual Property Ownership; Indemnification; Representations and Warranties; Publication; and Choice of Law). We also expressed concerns about several other provisions. While the concerns apply generally to all the agreements, we identified a number of terms in specific agreements that are particularly troublesome. An additional problem is that the CDAs do not reference the CRAs, which leads to anomalies such as differences in definitions.

As a bottom line, we noted that NIH officials negotiated these templates "on behalf" of the academic community, which places the recipient institutions in a difficult position when negotiating institution-specific requirements. We expressed the view that it is relatively unprecedented for federal agencies to prenegotiate the terms of contracts between two private entities. While it is certainly appropriate for the NIH to point out where provisions in the contracts must be consistent with the requirements of federal funding, we expressed deep concern that NIH's involvement in negotiating terms such as those related to indemnification, compensation for subject harm, or details of publication is an unwarranted intrusion into the

rights of universities and research organizations to manage such matters themselves. A copy of the comment letter is posted on the COGR website.

At the COGR panel session questions were raised about the goals of the RFI, why cooperative agreements were planned, and significantly, about the status of the templates. Dr. Insel noted that the RFI was issued because NCATS wanted to hear from the community and that cooperative agreements were planned because of the close relationship to the intramural program. NCATS views the templates only as a starting point for negotiations.

Following his presentation at the COGR meeting, the COGR Board Chair received a subsequent communication from Dr. Insel, expressing concern about the perception that universities would be required to use one of the CRAs provided in the RFI. Dr. Insel stated “**I hope I clarified that the templates provided were meant to streamline the process but can be modified via negotiation and mutual agreement between a university and its industry partner** (emphasis added). We may address this specifically in FAQs associated with the planned RFA.” Subsequently COGR staff also verified this understanding with NCATS staff who attended the presentation.

On June 12 NCATS announced five new industry collaborators in this initiative, funding opportunity information (<http://www.ncats.nih.gov/research/reengineering/rescue-repurpose/therapeutic-uses/funding.html>), and the 58 compounds (<http://ncats.nih.gov/therapeutics-directory.html>) the companies are making available. The total number of compounds has more than doubled since the launch of the pilot program. Abbott, Bristol-Myers Squibb Company, GlaxoSmithKline, Janssen Pharmaceutical Research & Development, L.L.C., and Sanofi now have joined Pfizer, AstraZeneca, and Eli Lilly and Company in participating in the program.

We remain concerned that the expectations of the participating companies will be that institutions will accept the terms substantially as is given the prenegotiation with NCATS. The bolded statement above may help COGR member institutions in negotiating specific terms with the companies, as may possible FAQs. We also have urged NCATS staff to also make this understanding clear to the companies participating in the program.

Startup Act 2.0 Introduced in Congress

We've mentioned in previous COGR Updates the Startup Act (S.1965) introduced by Senators Moran and Warner last December. They've now been joined by several other Senators in introducing Startup Act 2.0 (S.3217). Identical legislation (H.R.5893) has been introduced in the House by Rep. Grimm (R.—NY) and 8 co-sponsors.

There is much in the proposed legislation that COGR and the other higher ed. associations support, including provisions on STEM immigration and favorable tax treatment for startups. However, we are concerned about certain provisions in Section 8 of the bills on Accelerating Commercialization of Taxpayer-Funded Research. The original version of the bill included a new “Collaborative Commercialization Grants” program, to be administered by the Department of Commerce. This program would have provided funding to research institutions that choose to allow their faculty to use university technology transfer programs other than those based at their

home institutions to commercialize technologies they develop. The bill proposed to cover the cost of this and another new “Commercialization Accelerator Grants” program, by transferring to the Department of Commerce 0.15 percent of the budgets of existing research agencies with R&D budgets in excess of \$100 million. A 15-member Committee on Research Commercialization Improvement (chaired by the Director of NSF) would have developed the criteria for the grants programs and reviewed and recommended applications to the Secretary of Commerce (see COGR Holiday 2011 [Update](#) for more details).

In the 2.0 version, the Commerce National Advisory Council on Innovation and Entrepreneurship (NACIE) will review and make grant recommendations. However, the provision to tax other agencies to fund the program remains. The grant programs in the original program have been replaced with Commercialization Capacity Building grants and Commercialization Accelerator Grants. The bill indicates that the latter grants should be awarded “to support institutions of higher education pursuing initiatives that allow faculty to directly commercialize research in an effort to accelerate research breakthroughs.” Priority should be given to initiatives that encourage collaboration with other institutions of higher education or other entities with demonstrated proficiency in creating and growing new companies (Sec. 8(b)(2)(C)).

While less specific than the faculty “free agency” provision of the previous version, that version would have required a licensing revenue sharing agreement between the institution of higher education where the research originates and the institution that commercializes the research. In addition, the first right of refusal in commercializing research would belong to the institution of higher education where the research originates. These provisions are absent from the 2.0 version.

The language quoted above in the new version is vague and its meaning unclear. Assuming faculty were allowed to commercialize their own research results, this potentially would create significant issues for universities relating to conflict of interest and public accountability since federal research awards are made to the university and not the individual faculty members. Moreover, universities often work with faculty in supporting faculty startups which might not be the case under such a model. Startup 2.0 also provides that “nothing in this section may be construed to alter, modify, or amend any provision of chapter 18 of title 35, United States Code (commonly known as the “Bayh-Dole Act”)(Sec. 8(d)). But it is difficult to see how the quoted provision, if taken literally, is consistent with Bayh-Dole.

One ready fix that would address this problem would be to replace the directly commercialize language with something like “provide for innovative new approaches to accelerate innovation.” However, we also remain opposed to the funding provisions. If a new program such as this is created at Commerce, our view is that Congress should directly authorize such sums as necessary to carry out the program. Funding should not be taken from other important agency research programs, especially when agencies such as NIH (NCATS/CAN) and NSF (I-Corps) have their own initiatives underway to encourage greater commercialization. Finally, Sec. 8 contains a provision (8(b)(5)(A)) limiting project management costs of the new grant programs to 10%, which we also obviously oppose.

The higher ed. associations and institution federal relations representatives are continuing to discuss these issues with relevant Congressional staff. AUTM also has alerted its members to

the issues. Prospects for the legislation in this Congress are unclear, but we will continue to closely monitor the situation.

Patent Reform: AIA Implementation and Patent Secrecy for Economic Security

- 1) **CIP Committee Meets with PTO Patent Reform Coordinator** - On June 6 the COGR CIP Committee met with Janet Gongola, Patent Reform Coordinator for the U.S. Patent and Trademark Office (USPTO), to discuss the status of the America Invents Act (AIA) implementation. Ms. Gongola previously met with CIP last October (see October 2011 COGR [Meeting Report](#)).

Ms. Gongola discussed the status of a number of AIA implementation actions, including prioritized examination, supplemental examination, preissuance submissions, and the proposed rules for administrative trials for post grant and inter-partes reviews. Of perhaps greatest interest to COGR members is the proposed USPTO fee setting. Until its new AIA fee setting authority kicks in later this year, USPTO is forced to use a cost recovery model in setting fees. The result is very high fees proposed for the new post grant and inter-partes review requests that could range up to \$90k and higher, depending on the number of challenged claims. Ms. Gongola conceded that this is likely to discourage such requests. USPTO also has proposed alternative fee structures for basic patent applications and maintenance fees. One would backload the fees so that initial application fees would be set at a lower level with annual maintenance fees rising through the life of the patent.

On May 30 USPTO issued proposed rules for the new micro-entity status provided by the AIA (77*FedReg*31806). When we met previously with Ms. Gongola, there was confusion as to whether institutions also would have to meet the income and other limitations in order to be eligible for the 75% fee reduction for micro-entities. The proposed rules clarify that micro-entity status for institutions of higher education is an alternative category to which these limitations do not apply. However, they also provide that applicants must certify that either a majority of their income is from an institution of higher education or that they have assigned or are under an obligation to assign any ownership interest in the patent application to an institution of higher education. In the case of multiple applicants all must meet these criteria. The USPTO notice specifically invites public comments on whether “inventor” should be used in place of “applicant.” We pointed out to Ms. Gongola that where an applicant is an institution of higher education itself the proposed rules do not make sense. We plan to suggest to USPTO that “applicant” be defined as either inventors or their assignees in the final rules.

Another issue identified in the discussion is that the proposed rules expressly require that in order to claim micro-entity status, an entity must first qualify as a “small entity” (eligible for a 50% fee reduction). Under current USPTO rules, small entity status is not available where a license has been granted to a large entity (37 CFR 1.127). Some institutions may not file patent applications until a licensee has been identified. In such cases micro-entity status will not be available (or entitlement will be lost once a license is executed) unless the licensee also qualifies as a small entity (e.g. start-up). Finally, micro-entity status is explicitly limited to institutions of higher education in both the AIA and the proposed rules, whereas the existing small entity rules apply to nonprofit scientific and educational organizations as

well as institutions of higher education. This means that nonprofit organizations such as university foundations will not be eligible for micro-entity status. In the discussion in the proposed rules USPTO indicates the intent to limit the benefits of micro-entity status to small entities that meet the micro-entity criteria. Given the explicit language of the AIA it does not appear that USPTO could broaden the definition in any event.

These issues led CIP to conclude that the advantages of the new micro-entity status may be more apparent than real. Many institutions may be limited in their ability to claim the status because of joint inventors who do not all meet the requirements or because of large entity licensees. However in the latter case the expectation is that the licensees normally would pay patent expenses anyway. Ms. Gongola noted that the Federal Laboratory Consortium had raised concerns that the rules on joint inventors might discourage collaborations between universities and federal labs, but in we expressed the view this is not likely to be a significant disincentive. Comments on the proposed rules are due by July 30, 2012.

- 2) **Discussions Continue on AIA “Technical Amendments”** - The COGR Spring Update discussed a number of possible “technical amendments” to the AIA. It noted concerns about the grace period in the AIA, which does not appear to cover obvious variants of the subject matter disclosed in a publication; the “could have been raised” estoppel for the new post-grant review procedure, which some claim was intended to apply only to inter-partes review; and prior user rights, which some industry groups want expanded. To date there has been no agreement among stakeholders as to these changes. The university community is pushing for changes in the grace period, is opposing expansion of prior user rights (although the existing university carveout would not be affected), and is split on the estoppel provision.

In the meantime Congressional staff has proposed a number of other technical changes. Those of most relevance to universities are to add a rule of construction that disclosures by the inventor during the grace period for licensing purposes would not constitute patent-defeating prior art; a change to the inventor’s oath requirement that would allow submission of the required inventor’s statement any time up to patent issuance and allow USPTO to eliminate the requirement entirely in the interests of harmonization, and changes in the new derivation procedures. We have not fully analyzed these proposed changes or come to a view on them. The window for accomplishing these or other changes to the AIA seems fairly narrow.

- 3) **COGR Submits Comments on Proposed Patent Secrecy for Economic Security** - The Summer Update discussed USPTO’s request for comments on whether patent applications that are detrimental to the nation’s economic security should be barred from publication, similar to the provisions for patent secrecy for national security reasons (*77FedReg23663*; 4/20/12). The concern is that with an average three-year processing time, the requirement to publish patent applications 18 months after filing allows foreign competitors to unfairly access the information. USPTO currently screens applications for national security pursuant to certain statutes. If secrecy orders are imposed, U.S. patent issuance is prevented and foreign filings prohibited (as are exports of any products covered by secrecy orders). The Update noted that COGR member institutions have occasionally been subject to patent secrecy orders for national security reasons, which also restrict the ability to publish and disseminate research results.

The notice asks for comments on 17 questions. COGR submitted comments jointly with AAU on June 19. We did not attempt to respond to the 17 questions, but in our comments we expressed the view that the proposal would undermine the patent system. Currently secrecy orders are placed only in very limited circumstances where the government determines that national security is at stake. Broadening this exception to encompass patents deemed to be economically significant would deprive U.S. inventors and innovators of new technical information vital to U.S. economic progress and competitiveness in the knowledge economy.

Moreover, the proposal also raises issues as to the definition of “national economic security” and what criteria should be used to make such determinations in advance or how government agencies would have the capabilities to make such determinations. Typically only in hindsight is the economic significance of new innovations clear.

A copy of the comments will be posted to the COGR website. It also may be found on the AAU website.

House Science Subcommittee Holds Hearing on Enhancing Innovation

On June 19 the House Science Subcommittee on Technology and Innovation held a hearing on “Best Practices in Transforming Research into Innovation: Creative Approaches to the Bayh-Dole Act.” Witnesses were Todd Sherer, Associate VP for Research Administration and Executive Director, Office of Technology Transfer, Emory University (and current President of AUTM); Catherine Innes, Director, Office of Technology Development, University of North Carolina (and member of the COGR CIP Committee); Ken Nisbet, Executive Director of Technology Transfer, University of Michigan; and Robert Rosenbaum, President & Executive Director, Maryland Technology Development Corporation (TEDCO).

It basically was a “friendly” hearing, although a number of the Representatives, particularly Congresswoman Edwards (D-MD) in her opening statement, cited the need to strengthen and speed up university technology transfer and better leverage federally funded research. Questions focused on metrics for evaluating technology transfer, ways to encourage young faculty and students to become involved in the process, best practices to promote entrepreneurship, possible changes to SBIR/STTR, and enhanced federal funding for proof of concept activities. With regard to possible changes to Bayh-Dole, questions were asked specifically about faculty “free agency” (all panelists were negative), recoupment of federal funding (also answered in the negative), and the possibility of establishing regional tech transfer offices (to which a number of panelists responding positively). The subcommittee is planning a follow-up hearing on technology transfer at the federal labs.

The witness statements and a webcast of the hearing may be found at <http://science.house.gov/hearing/subcommittee-technology-and-innovation-hearing-best-practices-transforming-research>

Export Control Developments

- 1) **Satellite Jurisdiction Could Be Transferred to CCL** - An amendment to the FY '13 Defense Authorization Act (H.R. 4310) would give the President the authority to remove commercial satellites from the U.S. Munitions List (SML) and transfer them to the Commerce Control List (CCL), subject to certain restrictions and limitations. A number of reporting requirements also are included. In effect this partly reverses the 1999 Congressionally-mandated transfer of satellite jurisdiction to the State Dept. and ITAR regulations (P.L.105-261; Sec.1513). It responds to the recommendations of a DOD/State Dept. report on space export policy (http://www.defense.gov/home/features/2011/0111_nsss/docs/1248_Report_Space_Export_Control.pdf) that was mandated in Section 1248 of the 2010 Defense Authorization Act (P.L.111-84).

Space-related items are the only dual use items required by law to be controlled as defense articles. The report notes that the law forces the government to protect commonly available satellites on the USML, disadvantaging U.S. manufacturers. The U.S. aerospace industry has strongly pushed for the transfer of commercial satellites from ITAR jurisdiction. The report finds that other countries have fewer controls on commercial space-related items and that since the transfer to State a substantial number of commercial satellite technologies have become less critical to U.S. national security. Transferring them to the CCL would provide less stringent controls while still protecting national security.

Unfortunately the 1248 report does not specifically address research (or educational) satellites. It recommends that satellites that perform purely military or intelligence missions or remote sensing satellites with certain performance parameters (and related systems and components) remain on the USML. It includes two appendices. Appendix 1 is a draft revised USML Category XV that sets forth satellites and related items and services that should continue to be protected under the USML. Appendix 2 is a proposed CCL ECCN Category 9X515 for spacecraft and related commodities. Informal feedback from a few COGR institutions with extensive space research indicates their research does not typically involve most of the technologies included in the draft revised USML Category XV.

Sen. Bennet (D-CO) has introduced legislation (S.3211) that would give the President authority to transfer satellites and related items from State to Commerce jurisdiction without the limitation to "commercial" satellites in the House bill. Both bills would restrict or prohibit transfers of CCL-controlled satellite items to China and to North Korea and other state sponsors of terrorism (Cuba, Iran, Sudan, Syria).

The Bennet legislation obviously is preferable from our perspective. However, we understand that concerns remain both in DOD and in Congress that some research satellites in fact may have military uses, and that the narrower House approach based on the 1248 report is preferred (although specific references to the report that were included in the early drafts of the House legislation have been deleted). We are continuing to discuss the issues with other associations and Congressional staff.

- 2) **Export Control Reform: Commerce Proposes Transition Rules** - Last July Commerce Bureau of Industry and Security (BIS) proposed a regulatory framework for the transfer of items from the ITAR/USML to the EAR/CCL pursuant to the President's Export Control Reform Initiative. We and AAU jointly submitted comments in September, generally supporting the proposed framework but noting concerns that the proposal did not indicate that existing ITAR license exemptions would continue to apply to the transferred items. We expressed particular concern about the ITAR "bona fide" employee exemption for institutions of higher education (see COGR Summer and Fall 2011 Updates).

On June 21 BIS proposed rules for the transition of control over transferred items (77*FedReg*37524). In response to our comments, BIS is adding the bona fide employee exemption to the EAR License Exception TSU (EAR 740.13(f)). The exception applies to the release of technology and source code subject to the EAR by U.S. universities to foreign persons who are their bona fide and full time regular employees. To qualify, the employee's permanent abode throughout his/her employment must be in the U.S., the employee cannot be a national of a country subject to a U.S. arms embargo, and the university must inform the individual in writing that the technology or source code may not be transferred to other foreign persons without prior government authorization. Certain other restrictions and exclusions apply.

Other principal features of the proposed rule are to establish a General Order No. 5 (Supplement No. 1 to part 736 of the EAR) allowing continued use of State ITAR licenses for transferred items, harmonizing certain other ITAR license exemptions with EAR license exceptions, extending BIS licenses from two to four years to harmonize with ITAR four year licenses, establishing a new 25% *de minimus* U.S. content in foreign-made items in order to be subject to the EAR (except for U.S. arms embargoed countries where there is no *de minimus*), expanding the military end use definition for exports to China, and requiring that transactions involving all of the new CCL "600 series" items be entered into the Automated Export System.

We plan to further analyze the proposed rule and consider submission of possible comments. Comments are due August 6.

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 Posts China Restriction FAQs

The National Aeronautic and Space Administration (NASA) has posted some Frequently Asked Questions (FAQs) addressing the Restrictions on Activities with the People's Republic of China. The FAQs are available at: <http://science.nasa.gov/researchers/sara/faqs/prc-faq-roses-2012/> (this address is a link to the NASA Service and Advice for Research and Analysis [SARA] website through the corrections and clarification to ROSES 2012 FAQs. You can reach the SARA homepage at: <http://science.nasa.gov/researchers/sara/>).

Linked to a clarification to Section III(c) (Eligibility Information) in the Research Opportunities in Space and Earth Sciences (ROSES) 2012 solicitation, NASA outlines the statutorily required restrictions on the use of NASA FY 2011 and FY 2012 funds for work involving bilateral participation, collaboration, or coordination with China or any Chinese-owned company or entity, whether funded or performed under a no-exchange-of-funds arrangement. In updating the ROSES solicitation, NASA references the Grant Information Circular (GIC) 12-01 and notes that submission of the proposal is a “represent[ation] that [the applicant is] not China or a Chinese-owned company, and that they will not participate, collaborate, or coordinate bilaterally with China or any Chinese-owned company, at the prime recipient level or at any subrecipient level” which is echoed in the Assurance of Compliance that accompanies the solicitation.

The FAQs may not provide sufficient clarity to entirely relieve research institutions' concerns with the language concerning restrictions on Chinese nationals and implied status of Chinese universities and colleges as Chinese institutions that appears in GIC 12-01. The answer to Question 3 concerning the status of Chinese students and other scientific staff states unequivocally that “the statute does not restrict individual involvement based on citizenship or nationality.” The answer goes on to note “individuals are subject to the restriction if they are affiliated with institutions of the People's Republic of China or Chinese-owned companies incorporated under the laws of China. Thus, a team member who is a Chinese citizen may work on a NASA project, but an individual affiliated with an institution of the Chinese state will be subject to the statutory restriction.” This clarity concerning nationality is important. The statement implies, however, that a visiting scholar affiliated with a Chinese university or college is restricted from participating on a NASA project.

NASA highlights in the FAQs the distinction between bilateral and multilateral activities. For purposes of the restriction, multilateral activities, including authorship of papers and publications, meaning “work that involves investigators from other countries in addition to the PRC and USA and/or work done under the auspices of a multilateral organization is generally permitted.”

NASA has indicated it will continue to post FAQs to assist the research community. Institutions should submit questions directly to NASA at SARA@NASA.gov; questions concerning existing awards should be directed to cognizant contracting officers and inquiries regarding solicitations should be directed to the NASA point of contact for that solicitation.

NSF Requests Comment on Draft PAPP Guide Revisions

In a May 25, 2012 *Federal Register* notice (77FR31401) and a June 12, 2012 email to the community, the National Science Foundation (NSF) invited comment on upcoming revisions to the NSF *Proposal & Award Policies & Procedures Guide* (PAPPG). A copy of the proposed revised PAPPG is available at: http://www.nsf.gov/bfa/dias/policy/papp/pappg2012_draft.pdf . Comments are due no later than July 12, 2012 and instructions for submission of comments are in the *Federal Register* notice.

One of the principal changes to the PAPPG is the incorporation of the National Science Board’s (NSB) recommendations concerning merit review. Throughout the document, as appropriate, NSF has clarified and enhanced the description of its two, current merit review criteria, the intellectual merit and broader impacts of the proposed research. In addition to revising the sections on merit review, NSF has made other significant changes that warrant review and, as appropriate, comment from the community. COGR will submit comments to NSF.

NSF has made a clear statement that the applicable negotiated indirect (facilities and administration – F&A) cost rate(s) “must be used” in computing indirect costs. Except for limits explicitly spelled out in a specific funding announcement, NSF notes that institutions are entitled to reimbursement of the indirect costs and “NSF program staff may not negotiate indirect costs” or “suggest or request that PI/PDs seek reductions or waivers of indirect costs.” This statement of policy is a welcomed clarification.

NSF makes equally clear that certain categories of costs are excluded from the indirect calculation, notably participant costs, unless included in the negotiated indirect cost rate agreement. COGR will not dispute this particular exclusion except to challenge the underlying premise that asserts that participant costs are considered flow-through and thus generally excluded from indirect recovery. We understand that these costs are considered by many institutions as educational as opposed to research costs and, as such, excluded from the calculation. But we are concerned with the underlying rationale used by NSF. The assertion that participant costs are flow-through is inaccurate and we believe it is and would be inappropriate for NSF to use this rationale for this and other cost categories.

The changes to the Conflicts of Interest policy describe how the NSF Office of General Counsel (OGC) will follow up on reported unmanageable financial conflicts of interest. The first step to

be taken by the OGC is a review of institutional policies to “ascertain” if the institution’s policy includes procedures for addressing unmanageable conflicts. Since such procedures are not currently required by NSF’s policy, this statement suggests a new policy requirement. We believe it’s inappropriate for NSF to make policy changes through a revision of the PAPPG and will ask NSF to delete or modify this section.

The PAPPG includes a new requirement that all NSF awards be included in the Research and Development (R&D) cluster on the Schedule of Expenditures for A-133 audits. This requirement is included in the Office of Management and Budget (OMB) Circular A-133 Compliance Supplement as well. COGR has requested that this requirement be removed from the A-133 Compliance Supplement and will make a similar request to NSF. (See the Costing Policies Committee Report here for a fuller discussion of this question.)

There are a number of other comments COGR will offer including: requesting clarification that the certification requirements concerning tax liability and criminal convictions refer to the organization (“corporation”) as defined in OMB Circular A-110; eliminating the reference to the Institutional Biosafety Committee as the mechanism for identifying dual use research of concern (DURC) to afford institutions greater flexibility in making those identifications; and expressing concern that the requirement that “products” (publications, etc.) must be citable and accessible will make it difficult to present submitted/accepted and not-yet-published products as a part of the biographical sketch.

We welcome other suggestions from the membership. Send comments and suggestions to cblum@cogr.edu no later than July 6, 2012.

OHRP and FDA Propose Guidance for Transferring Human Subjects Research

The Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) have requested comment on proposed guidance on *Considerations In Transferring a Previously-Approved Research Project t to a New IRB or Research Institution* (OHRP) or *When Transferring Clinical Investigation Oversight to Another Institutional Review Board* (FDA). The requests for comment are available in the *Federal Register* [77FR 34940(OHRP) and 34958(FDA)]. Comments are due to the agencies by August 13, 2012. The guidance documents themselves can be accessed on the agencies’ websites at: for OHRP, <http://www.hhs.gov/ohrp/newsroom/rfc/index.html>; for FDA, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm307757.htm>

The guidance documents outline the agencies’ expectations when oversight is transferred and cover the elements of a written agreement between IRBs (as necessary), the responsibilities for the retention of records, establishing the approval/continuing review date, and the updating of documents and notification of subjects concerning the change in oversight.

COGR is reviewing the draft guidance and, if appropriate, will offer comment. We welcome members’ suggestions and comments to cblum@cogr.edu no later than August 1, 2012.

FCOI Implementation

During the June meeting, the membership continued its discussion of the implementation of the PHS/NIH Financial Conflicts of Interest regulations. Carol Blum discussed some of the recent Frequently Asked Questions (FAQs) posted to the NIH website (at: <http://grants.nih.gov/grants/policy/coi/>) and responses to separate questions sent directly to NIH by institutions.

Subrecipient Relationships - The management of the subrecipient relationship poses particular challenges. PHS/NIH did not make significant changes to this section of the regulations but the anticipated increased scrutiny raises concerns. In ensuring that all investigators have disclosed significant financial interests at the time of application, institutions believe they need to have assurance from potential subrecipients that the organization has a policy that is in compliance with the PHS/NIH regulations and that appropriate disclosures have been made to the subrecipient organization. Some institution will request that assurance in the exchange of information for the application – a cover letter or certification that accompanies the budget, biographical sketches and other proposal materials. The only step that needs to be complete at the time of application is investigator disclosure. The review of the disclosure and development of a management plan and reporting to NIH needs to be complete before the expenditure of funds. NIH confirmed that pre-award costs are allowable without violating this restriction on expenditures; the costs are transferred or applied after the review and determination/reporting are complete.

If the subrecipient does not have a policy, some institution will allow the investigators to disclose to the prime institution and will manage any conflicts of interest as related to a narrow definition of “institutional responsibilities” – only those responsibilities related to the specific research project. The challenge of the prime managing the financial conflicts for the subrecipient is exacerbated in the case of foreign subrecipients. To avoid the problems, other institutions will require subrecipients to adopt a policy and two models or sample policies were distributed at the meeting – one developed by Gunta Lidars and Jane Youngers for the FDP and posted to the FDP website; the other developed by Yale University.

Relatedness and a Reasonable Decision - Ann Pollack and Elizabeth Boyd, University of California at Los Angeles and San Francisco, respectively, lead a discussion of assessing the relatedness of research under the regulations. Each campus in the University of California system will implement the regulations individually but the campuses have identified some common steps. In general, they adopt web-based disclosures processes and use a just-in-time approach to reviews. In confronting the criteria for determining whether the financial interests are related to the research, they sought advice on the meaning of charge to make a reasonable determination of relatedness.

The assessment of the meaning of “reasonable” by UC resulted in an interesting mantra for implementing the entire regulations – determinations are reasoned decisions made as the result of a regular process and not done in a capricious or arbitrary manner. Most UC campuses will involve the investigator in the assessment by asking them to identify

which financial interests are related to PHS-funded research but the investigator identification will not be sufficient. The criteria being developed by the UC campuses are included on the slides of the Pollack/Boyd presentation on the COGR website.

Additional topics included how to address consultants with some institutions treating them like vendors with no responsibilities for the design, conduct and reporting of research; others will ask the investigator to indicate the level of responsibilities; and still others will assume a level of responsibility and require disclosure.

COGR is considering the development of an on-going collection and preservation of data related to the implementation of the new regulations to have information to respond to NIH when it evaluates the regulations in three years. We will coordinate any such data collection with the Association of American Medical Colleges (AAMC) activities to collect similar data and will communicate with eth membership as these efforts proceed.

NIH Updates Position Statements on Animal Care

As noted in a separate email to the membership, NIH's Office of Laboratory Animal Welfare (OLAW) has updated and clarified Position Statements: 1) Cost, 2) Housing, 2a) Nonhuman Primate Housing, 2c) Rodent Housing and 3) Non-Pharmaceutical-Grade Substances. In response to the December 2011 posting of the Position Statements, COGR expressed its concern that the endorsement of the housing requirements for rodents included in the 8th Edition of the Guide for the Care and Use of Laboratory Animals as "starting points" could be viewed as setting a minimum standard. OLAW's Position Statements have been clarified to note that the space recommendations are "accepted reference points" for addressing space needs.

The notice, Clarification of Position Statements on Implementation of the Guide for the Care and Use of Laboratory Animals: Eighth Edition (NOT-OD-12-112) appears in the June 1, 2012 issue of the NIH Guide. A summary of the changes and the complete text of the Position Statements are available at: <http://grants.nih.gov/grants/olaw/olaw.htm>