

# COUNCIL ON GOVERNMENTAL RELATIONS

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TO: COGR Membership  
FROM: COGR Staff  
SUBJECT: Summer 2012 Update

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### NIH/NCATS Announces New Programs

The new NIH National Center for Advancing Translational Science (NCATS) has announced several new programs. NCATS was established in the FY'12 Omnibus funding bill in late December 2011 that included funding for NIH (P.L. 112-74). The goal is to develop new approaches to translational research for therapeutic development

- a) Discovering New Therapeutic Uses for Existing Molecules – On May 3 NCATS issued an RFI and RFA for the new NIH—Industry 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. NIH has 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. Under the CRAs (which are not identical) the company will receive an option for an exclusive commercial license to any new drugs developed under the program. If successful, NCATS plans to expand the program to include additional pharma and biotech companies and new therapeutic agents.

Comments on the RFI (NOT-TR-12-002) are due June 1. The companion RFA (NOT-TR-12-001) is a Notice of Intent to publish a Request for Pre-Applications for the program. It contains additional details on the planned research program, for which pre-applications are

expected to be due in July. Both the RFI and RFA contain links to the template agreements mentioned above. The pre-applications will be peer reviewed with feedback provided investigators. Those with the most meritorious projects will be invited to submit UH2 applications for pre-clinical studies using the selected agent to provide sufficient evidence for the new therapeutic use, or UH3 applications for clinical trials. NIH will support the approved applications through cooperative agreements. Applicant institutions must agree to sign the CDAs and CRAs with the appropriate company.

The RFI asks for comments on options for NCATS to consider to encourage greater translation, views on the template agreements and the transaction costs of developing individual agreements, how NIH CTAs or NIH intramural investigators could advance drug rescue research projects, the sufficiency of the goals and incentives of the new program, the resources made available by the pharma or biotechnology company, and the access needed to test biological hypotheses.

We currently are analyzing the template CDAs and CRAs and have identified a number of potential issues and concerns. Of particular concern are the definitions of Confidential Information, and Technical Developments, the option period and indemnification provisions. Our preliminary review suggests some of these provisions may be “deal breakers” for many COGR member institutions. One complication is that the terms of both the CDAs and CRAs vary among the companies. We expect to provide comments to NCATS with regard to these concerns, and other points mentioned in the RFI.

Dr. Thomas Insel, Acting Director of NCATS and the Director of the NIH Institute for Mental Health, will discuss the opportunities and challenges associated with the new program and other NCATS initiatives in a panel discussion at the June COGR meeting. Joining him on the panel will be two COGR Board members, who will discuss the issues and concerns from our perspective. This will provide an opportunity for COGR members to learn firsthand about the challenges and concerns that may be presented by this new and highly visible NIH program.

- b) Proposed DEC for Preclinical Drug Development Services for NCATS/NCTT - On May 2 NIH published a request (NHLBI-CSB-RFC-TR-2013-19-KB) in *FedBizOpps* for comments on the proposed use of a Determination of Exceptional Circumstances (DEC) for the Preclinical Drug Development Services Program for the NCATS/NIH Center for Translational Therapeutics (NCTT). The proposed DEC would apply to two programs of the NCATS Division of Pre-clinical Innovation: Therapeutics for Rare and Neglected Diseases (TRND) and Bridging Interventional Development Gaps (BrIDGs), formerly the NIH RAID program. The justification for the DEC is that owners of materials or technologies will refuse to submit them for screening and preclinical development if there is a risk that NIH contractors will obtain related invention rights. These owners have argued that the risk of losing rights to inventions that would block commercialization of their own proprietary material and technologies is unacceptable.

COGR submitted comments on the proposed DEC on May 17. In our comments we expressed understanding of the rationale for the DEC and did not object (we anticipate that many of the contributors of materials or technologies to these programs may be COGR member institutions). However, we expressed concern about the description of the DEC in the NIH Notice. As worded, it is not clear where the rights actually reside under the

proposed DEC. We also noted the lack of clear definitions of certain terms, and questioned why NCATS should dispose of invention rights where the contributors of the materials decline title.

In the case of the BrIDGs program, the DEC would apply to the NIH contract service providers who perform the services (and otherwise would receive normal Bayh-Dole rights). However, in the case of the TRND program we expressed confusion about the application of the DEC, since it envisions owners of proprietary materials or technologies providing the materials for collaborative preclinical studies for development of therapeutics for rare and neglected tropical diseases funded by NIH intramural funds. According to the TRND website, the collaborations will be supported by CRADAs or Research Collaboration Agreements. Bayh-Dole is not applicable to such agreements. We also pointed out to NIH, as we have with other proposed DEC's, that *FedBizOpps* is not necessarily the best mechanism to reach the NIH constituent community.

A copy of our comments is posted on the COGR website.

### **House Judiciary Committee Holds Hearing on AIA Implementation**

We noted previously discussions about possible “technical” amendments to the America Invents Act (AIA) to clarify the scope of the grace period in Section 102, address concerns about the estoppel provision for the new post grant review, and expand prior user rights (see COGR Spring 2012 Update). A House Judiciary Subcommittee hearing was held in February on the latter subject (see COGR Winter 2012 Update).

The full House Judiciary Committee held a hearing on AIA implementation on May 16. Witnesses included David Kappos, Director of the Patent and Trademark Office (PTO) and representatives of various stakeholder groups. Richard Brandon, Associate General Counsel at the University of Michigan, represented a number of higher ed. associations including COGR. Most of the discussion at the hearing involved the AIA Section 18 transitional program for review of business method patents, the need to reduce the backlog of patent applications, PTO fee setting, and the proposed rules for post grant and *inter partes* review. Other than Mr. Brandon’s testimony, there was little or no discussion of the issues that had been the subject of previous discussions with Committee staff. We understand staff is working on a possible technical amendment, but concerns were expressed by Committee Members at the hearing whether such changes are truly “technical.” We will continue to track developments. (See [http://judiciary.house.gov/hearings/Hearings%202012/hear\\_05162012.html](http://judiciary.house.gov/hearings/Hearings%202012/hear_05162012.html) for the hearing documentation and webcast.

### **Request for Comments on Patent Secrecy for Economic Security**

Pursuant to a request from the House Appropriations Subcommittee, the Patent and Trademark Office (PTO) has asked 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 (77*FedReg*23663; 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. PTO 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 notice asks for comments on 17 questions. The questions deal with issues such as criteria for determining what may be detrimental to economic security, by whom and by what mechanisms should such determinations be made, effects on U.S. treaty obligations, impacts on innovators, and possible alternatives. Comments are due June 19.

This matter came up in the May 16 House Judiciary Committee hearing on the AIA discussed above. Members of the Judiciary Committee expressed unhappiness about the Appropriations Committee intervening in substantive patent matters. We currently are discussing the issues with the other higher ed. associations. There is a view that some segments of industry may support the proposal (although strong opposition was expressed by one industry witness at the hearing). Given the political sensitivities we need to approach this with caution. 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. Offhand it seems expanded patent secrecy would restrict the ability of U.S. innovators to access new technical information and developments, which is the core of the patent system. However we have not come to a final view on responding to the request.

### **Grants Reform and OMB Circular A-21 Update**

The comment period for responses to 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*, is now closed. The COGR response can be found on the COGR home page at [www.cogr.edu](http://www.cogr.edu) (see Latest News, April 27, 2012 link).

Many of your institutions submitted a response. We appreciate your hard work and we are cautiously optimistic that the all of our efforts will help to advance the process to the next phase where substantive reforms and changes to Circular A-21 are discussed, and ultimately, implemented. While our understanding is that OMB is in the process of determining the next steps, the COGR Costing Committee expects to meet with OMB representatives during the Costing Committee's Wednesday afternoon meeting on June 6<sup>th</sup>. We will get a status update and report to the full membership during the Friday morning committee reports.

We encourage you to browse the <http://www.regulations.gov/> website and review the responses. Go to the regulations.gov website and enter "OMB-2012-0002" into the initial Search window. There are 356 results. COGR has done a high level review of the responses and our unofficial, preliminary assessment is:

#### a) Composition of the Responses

- Approx. 10% were entered into the comment screen with no attachment. It is difficult to determine who submitted these responses – however, some seem to be from university faculty members.
- Approx. 10% were retractions or errors or not readable.
- Approx. 35% were from Research Universities, Nonprofit Research Organizations, and Hospitals. These include COGR members and their associations (e.g., AAU, APLU, COGR), other large research organizations, as well as smaller research entities.

- Approx. 45% were from other stakeholders, including State and Local government agencies, Indian Tribes, other associations writing on behalf of these entities, and other organizations.
- b) Sampling of Responders (not including COGR members)
- Michigan Department of Education
  - Minnesota Housing Authority
  - City of Woodbury MA
  - City and County of Denver
  - Missouri Department of Natural Resources
  - NY State Government Finance Officers Association
  - Danforth Plant Science Center
  - Texas Biomedical Research Institute
  - World Vision Christian Relief Agency
  - Pennsylvania Institute of CPAs
  - Oregon Society of Public Accountants
  - New York City Mayor's Office and OMB
  - Coquille Indian Tribe
  - U.S. Department of Justice, Office of Inspector General
- c) Observations and Anecdotes (based on the limited COGR review)
- Increasing audit threshold – widely negative responses from responders (primary concern is the increased work that will be created for prime recipients).
  - Flat/discounted rates – mostly negative from responders (a few smaller organizations seem to be OK with this, but even they prefer an option).
  - Consolidating Circulars – mostly negative, though some pockets of support for this.
  - Effort Reporting (i.e., discontinuation of) and Direct Charging of Administrative Activities (i.e., project management and computing devices) – widely popular with many responders.

While we hope to learn more on the next steps at our scheduled June 6<sup>th</sup> Costing Committee meeting with OMB representatives, the ANPG offered some clues:

*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.*

Also, the ANPG described the “COFAR” as the federal entity to guide the grants reform process. 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.

We are paying close attention to all developments and the June 6<sup>th</sup> Costing Committee meeting with OMB representatives should provide insights. We will keep the membership posted.

### **NIH Salary Limitation and an NHLBI Contract Clause**

Several COGR members have shared a situation unique to contracts emanating from the National Heart, Lung, and Blood Institute (NHLBI) – NHLBI is implementing the new NIH Executive Level II Salary Limitation in a manner that is 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, Appendix A) is being cited by NHLBI contracting officers: <http://dhhs.gov/asfr/ogapa/acquisition/acquisitionpolicies.html>

The Contract clause in question 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 is inconsistent with the prior NIH guidance – according to the prior NIH guidance, the applicable salary level is premised on the date the award was issued (i.e., Executive Level I salary limitation should be used for FY2012 awards issued before December 23, 2011). Application of the Executive Level II salary limitation on contracts, retroactive to December 23, 2011 (i.e., the effective date for the *Consolidated Appropriations Act, 2012*, Public Law 112-74), would require an institution to apply the Executive Level II salary limitation immediately to the contracts in question and further would require the institution to correct for prior billings.

The January 2012 NIH Notice of Salary Limitation on Grants, Cooperative Agreements, and Contracts (NOT-OD-12-035) and the subsequent FAQs (see links below) clearly state that for all awards issued before December 23, 2011, the Executive Level I salary limitation should be used for FY2012.

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

[http://grants.nih.gov/grants/policy/fy2012\\_salary\\_cap\\_faqs.htm](http://grants.nih.gov/grants/policy/fy2012_salary_cap_faqs.htm)

#### RESOLUTION:

COGR has corresponded with staff from the NIH Office of Acquisition Management and Policy (OAMP) and the NIH Division of Acquisition Policy and Evaluation (DAPE). Our understanding of this particular Contract clause and the resolution to this issue is as follows:

- 1) The Directors of OAMP and DAPE confirmed that NIH Acquisition and Contracts policy was meant to be consistent with the January 2012 NIH Notice and the subsequent FAQs – i.e., the Executive Level I salary limitation should be used for FY2012 contracts in question.
- 2) 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 Nov. 24, 2011 through October 31, 2012, Executive Level I is applicable for that increment.

- 3) The Director of DAPE has met with the NHLBI Office of Acquisitions Director, and the policy has been circulated with staff at NHLBI – the actual timing of the “trickle down” to the contracting officers is not certain.
- 4) 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.

The Director of DAPE, Mr. Terry Frederick, (301) 496-3997 / [terry.frederick@nih.gov](mailto:terry.frederick@nih.gov) and the Director of Acquisitions for NHLBI, Mr. John Taylor, 301-435-0327 / [taylorjc@nhlbi.nih.gov](mailto:taylorjc@nhlbi.nih.gov) are the point people for correcting this issue. We encourage you to contact both individuals if you have any further issues with NHLBI contracting officers. COGR is interested to know that this issue has been resolved and you can contact David Kennedy at [dkennedy@cogr.edu](mailto:dkennedy@cogr.edu) at your convenience. We also will reach out to the appropriate individuals at OGAPA and pursue the process for modifying this Contract clause.

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

The momentum behind enhancing accountability and transparency at the Federal government level remains strong. This has been demonstrated over the past five years in the form of FFATA, ARRA, and most recently, the DATA and GRANT Acts. In fact, the DATA Act, or more specifically, the Digital Accountability and Transparency Act (H.R. 2146), was passed by the House on April 26<sup>th</sup> and a separate version currently is being prepared for consideration by the Senate. If the DATA Act becomes law, it could create a new layer of federal reporting.

Also, we constantly must work around agency-specific activity such as the expected 2013 release of a new NSF Cash Payment system, recent system/access changes with DOD’s Wide Area Workflow system (WAWF), and other unique practices that affect how we conduct business with each federal agency.

And if that is not enough, Executive Order 13576, "*Delivering an Efficient, Effective, and Accountable Government*" (issued June 13, 2011) reinforces the theme of accountability and transparency. Building upon the foundation of the ARRA Recovery Accountability and Transparency Board (RATB), E.O. 13576 created the Government Accountability and Transparency Board (GATB), which in a recent report, referenced the lessons learned from ARRA reporting and the importance of a “Governmentwide Accountability Framework.”

The Thursday Morning Costing Session will include several Case Studies on how institutions manage the Federal financial reporting and post-award management burden, and will address these questions:

- How do institutions organize around Federal reporting and post-award management (e.g., financial reporting, invoicing/payment systems, etc.)? Are there “effective practices”?
- Do differences in practices employed, expectations, and systems used by each Federal agency create inefficiencies?
- Which agency-specific reporting practices, expectations, and/or systems are the most problematic? The best?
- How did institutions organize around ARRA reporting and how sustainable would these models be if similar reporting is implemented under the DATA Act?

- How can our community quantify/demonstrate the reporting and post-award management burden to federal policymakers? Can we quantify the burden in terms of cost of systems, cost of doing business, cost of compliance, etc.?

The Case Studies will be presented by several COGR members and we will utilize the Case Studies to help answer some of the questions above. While one important take-away could be the identification of “effective” practices currently being employed at research institutions, even more important may be the crystallization of new advocacy and talking points that can succinctly demonstrate the real cost burden associated with federal financial reporting and post-award management.

### **Arbitrary Agency Policies, F&A Caps and Grants Reform – NEW EXAMPLES**

In the Spring Update (April 25, 2012), COGR shared with the membership our persistence on the topic of “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 the Office of Management and Budget (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 have asked COGR members to continue to share examples of arbitrary agency policies and F&A caps. Prior to the Spring Update, you shared examples from: 1) Department of State, Bureau of Educational and Cultural Affairs, 2) USAID, Higher Education Solutions Network, 3) U.S. Fish and Wildlife, White-Nose Syndrome Research, 4) U.S. Geological Survey, National Institutes for Water Resources, 5) Center for Medicare & Medicaid Services, Health Care Innovation Challenge, and 6) Department of Energy, Office of High Energy Physics (see next section).

Since the Spring Update, you have shared three new examples: 1) NASA, Space Technology Research Opportunities for Early Career Faculty (*Cost sharing is not required. However, NASA strongly encourages the university to contribute to the cost ...*), 2) DOJ, NIJ, Data Resources Program 2012 (*Indirect costs are allowable ... In light of the size of this award, waiver of or modified indirect rates will be viewed favorably ...*), 3) HHS, ACF, Head Start Graduate Student Research Grants (*Due to the small amount of the grant, the applicant institution is encouraged to voluntarily waive indirect costs.*)

We hope to leverage the Grants Reform process to 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.

### **Department of Energy Office of High Energy Physics – Effort and Salary Limitation**

The Department of Energy (DOE), Office of High Energy Physics (OHEP) recently initiated a practice to reduce the levels of effort, and ultimately, the salary amount, proposed by individual PIs on selected grant applications. In one example, the PI was informed a budget revision was necessary and that OHEP was not providing salary support in excess of \$14,975 per month (note, this amount corresponds to the Executive Level II salary limitation). According to staff from OHEP, this action was taken due to “budget constraints.” In correspondences with OHEP staff,

COGR objected to this practice – unfortunately, this appears to be another example of an arbitrary agency policy with little recourse to formally protest or appeal the agency practice.

COGR’s position on this situation is:

- 1) The OHEP practice creates a cost share burden if the PI/institution determines a reduction in scope is inappropriate. However, according to OHEP staff, there will be no cost share burden – if the institution cannot reduce the scope of work, the award will not be made.
- 2) While this example is not explicitly spelled out in the June 2003 OMB Policy Directive on Financial Assistance Program Announcements, COGR believes the OHEP practice is in violation of the 2003 Directive which requires funding restrictions to be explicitly defined in agency funding announcements.
- 3) According to OHEP staff, this practice is not OHEP or DOE Office of Science policy. Instead, “This is a practice used by the HEP office in this year’s process, driven by funding balance considerations. What HEP does in future years depends on circumstances.”
- 4) OHEP officials understand that some of the communications to grant applicants may not have adequately described this process and they intend to clear any confusion prior to the actual award of the research grant or cooperative agreement.
- 5) It is not clear if the OHEP effort/salary limitation is applicable in the context of PIs proposing effort associated with summer salary only, though this appears to be the case. And if this is the case, PIs may find themselves in the awkward situation of not receiving full salary support in the summer.

If your institution was affected by this OHEP practice, we are interested in how you communicated concerns with OHEP and how you resolved any internal issues that transpired. Contact David Kennedy from the COGR staff at [dkennedy@cogr.edu](mailto:dkennedy@cogr.edu).

### **Audit Update: General**

COGR regularly checks the HHS (NIH) and NSF OIG websites (see below), and the only recent activity relates to a new ARRA audit report (no findings, no cost disallowances) posted on the HHS OIG website.

<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 (not yet released). In the past several COGR Updates, we have asked members to keep COGR updated on “unusual” audit interpretations and findings. While it is inappropriate for COGR to intervene with personnel from Federal Offices of the Inspectors General (OIGs), we can help you tap into each agency’s audit resolution process and provide other guidance, as appropriate.

COGR always is interested in audit experiences at your institution so that we can update the general landscape for the membership. 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. Please contact COGR 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](mailto:dkennedy@cogr.edu).

**NRC “Study on Research Universities” – Report Release Date on June 14<sup>th</sup>.** The National Academies, National Research Council (NRC) has announced that the NRC will publicly release *Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Prosperity and Security* on June 14, 2012, at 11:00 am. The release event will be held in the Lecture Room of the National Academy of Sciences building at 2101 Constitution Avenue, NW, Washington, DC 20418. You can register to attend the release event or to view a webcast by accessing the following site.

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

**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 in the budget narrative (see page i per the link below): *The [Personnel and Work Effort] 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.* 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 this policy change would impact your institution.

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

**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. We reported earlier in the year that Arif “Mak” Karim is serving as the Acting National Director. Further developments suggest that there may be more changes announced in the near future. We will follow these developments and keep the membership posted.

**Debt Financing Arrangements and Negotiation of F&A Rates.** As you may recall, the recent 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 that thoughtful and effective use of all available debt financing arrangements can result in significant cost savings. We have heard from several COGR members that F&A rate negotiators are raising concerns related to SWAP interest costs. COGR believes that is inappropriate for this issue to be raised by an F&A rate negotiator and it is a premature application of a proposed “reform idea.” We will follow this development and keep the membership posted.

**NIH and Selected “Fully-Funded” NIDDK Awards.** We reported on this issue in the Spring Update (April 25, 2012). 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, NIH must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability.

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 (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 there still are concerns, please contact COGR staff.

**NIH and Genomic Arrays (GAs) – LAST CHANCE FOR INPUT.** As we reported in the Spring Update (April 25, 2012), the door appears to be open to work with NIH to designate certain types of research that utilize GAs to be exempt from the policy. However, to advance this issue, COGR needs several examples where the NIH policy has been enforced, but where it is questionable if the use of GAs meets the definition of “high-throughput.” More specifically, if the research in question is facilities intensive and very expensive and the financial implications to your institution are problematic, COGR would like to document these situations. If you have an example that meets the criteria, please share this with David Kennedy at the June COGR Meeting.

**Accelerating Spending on ARRA Programs: NSF CAREER Awards.** NSF CAREER awards are being recognized as the best candidates for extension beyond September 30, 2013. Currently, NSF is working with OMB to develop a strategy for a programmatic waiver request to cover all CAREER PIs – however, there is no guarantee that OMB will approve a waiver request. We will keep the membership updated on this development.

### **NIH Piloting Review of \$1.5m PIs**

In a NIH Guide notice issue May 18, 2012, the National Institutes of Health announced a Piloting of Procedures for Special Council Review of Research Applications from PD(s)/PI(s)

with More than \$1.5 Million in Total Annual NIH Support (NOT-OD-12-110). In announcing this special Council review, NIH notes the pilot is one initiative designed to manage resources “during austere times,” and is quick to point out that the review “does not represent a cap on total NIH funding for any one investigator.”

The pilot procedures will be used principally for investigator-initiated research project grants (RPGs) and will exclude response to requests for applications (RFA), and other multi-project programs. Initially, Council members will receive a list with a justification for a consideration for funding, or not. Council members will be asked to assess the applications in the context of affording a unique opportunity to advance the science. In the case of renewals, Council members may look at the value of continuing the project among other criteria. Following the review, Council members will provide feedback to NIH as it further refines this process. Investigators should continue to submit applications as planned but be aware of the new layer of review for some applicants during the May 2012 Council meetings.

### **Changes to CCR and ORCA**

NIH, through its eRA Communications Office, posted a notice to any applicants using Grants.gov that the Central Contractor Registration (CCR) is going to “change” in May 2012. The notice announced a May 29, 2012 migration of CCR services to the new System for Award Management, or SAM. This transfer is being delayed until the end of July 2012. The SAM announcement is available at: <https://www.sam.gov/sam/>.

SAM is a new government-wide system designed to streamline processes and eliminate data redundancies. It will draw together eight procurement systems and the Catalog of Federal Domestic Assistance (CFDA) into a single system. What it means for applicants is that during the first phase the CCR, Online Representations and Certifications Application (ORCA) and Excluded Parties List (EPL) will be accessible through SAM.

Because an active CCR registration is required to submit applications through Grants.gov and that information must be renewed annually, applicant organizations will need to create a new SAM user ID and password to access the systems. When the transition occurs, you will be redirected to SAM when you enter the current CCR or ORCA websites and will need to follow the instructions for create the new SAM account there.