

COUNCIL ON GOVERNMENTAL RELATIONS
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March 15, 2017

February 23-24, 2017 COGR Meeting Report

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RESEARCH & REGULATORY REFORM

Committee: Sara Bible, Chair, Stanford University, Cindy Kiel, University of California-Davis, Kerry Peluso, Emory University, Lois Brako, University of Michigan, Suzanne Rivera, Case Western Reserve University, Ara Tahmassian, Harvard University, Daniel Shapiro, University of Southern California, Robin Cyr, University of North Carolina-Chapel Hill, Lynette Arias, University of Washington, Naomi Schrag, Columbia University, Marti Dunne, New York University, Martha Jones, Washington University – St. Louis, Charles Greer, University of California-Riverside

Regulatory Reform**Executive Order on Enforcing the Regulatory Reform Agenda**

The Trump Administration issued Executive Order 13777 on February 24 enforcing and augmenting existing Executive Orders involving retrospective review of federal agency regulations in a stated effort to reduce regulatory burden and enforce regulatory reform. The [order](#), which was also published in the Federal Register on March 1, requires federal agencies to designate an agency official as its Regulatory

Reform Officer (RRO) within 60 days to oversee regulatory reform initiatives and ensure that reform is effectively carried out. Relevant Executive Orders include 13771, Reducing Regulation and Controlling Regulatory Costs, 12866, Regulatory Planning and Review, and 13563, Improving Regulation and Regulatory Review. Federal agencies have been operating under the latter executive orders since 1993 and 2011 respectively. The new order effectively bolsters existing retrospective review efforts and offsets for new regulations (per Executive Order 13771, repealing two existing regulations when a new rule is promulgated). Agencies have been conducting retrospective review under previous administrations with oversight from the Office of Information and Regulatory Affairs (OIRA). Executive Order 13777 also requires agencies to create a Regulatory Reform Task Force to be chaired by the RRO unless otherwise designated by the agency head. Each Task Force will review existing regulations and make recommendations “regarding their repeal, replacement or modification” in consultation with the regulated community. Rules identified by this review as being outdated, unnecessary or ineffective are directed to be prioritized as regulatory offsets. Agency reports on these efforts are due within 90 days of the order and “on a schedule determined by the agency head thereafter.” Performance indicators related to these efforts are to be included in agencies’ annual performance plans.

Former OIRA Administrators on the New Administration’s Approach to Regulatory Review

The Washington Post published an opinion piece by former OIRA Administrator Howard Shelanski on February 16 titled “[Trump doesn’t seem to understand the rules about making rules.](#)” The article mentions the recent executive order requiring the repeal of two rules for every new rule proposed. Per Shelanski, due to Supreme Court precedent and the requirements of the Administrative Procedures Act “It generally takes a new rule to change or remove a regulation that is already on the books” and repealing rules “requires federal agencies to explain why the factual and scientific bases for the predicted benefits of their rules were wrong or no longer adequate to justify those rules.” Shelanski goes on to suggest that “In practice, it turns out to be hard for agencies to find rules to eliminate and, when they do, the repeal process can take significant time. The effect of the deregulatory executive orders may therefore be more to create roadblocks for new regulations than to eliminate existing rules.” Other former OIRA administrators have previously weighed in with [recommendations](#) for the Trump administration on strengthening regulatory review, including reaffirming the existing regulatory review process and encouraging new agency officials to “adopt collaborative and not adversarial relationships with OIRA”; directing agencies to “identify metrics of success for each new economically significant regulation they promulgate”; and “requiring independent agencies to prepare regulatory impact analyses for economically significant rules.”

COGR Session on Research Regulatory Reform

Kei Koizumi, Visiting Scholar for Science Policy, American Association for the Advancement of Science, and former Assistant Director for Federal R&D, White House Office of Science and Technology Policy, joined COGR members to discuss recent legislation and executive orders aimed at reducing research regulatory burden. Various provisions of the 21st Century Cures Act were discussed. Kei offered his thoughts on the Research Policy Board recommended by the National Academies and included in Cures, as well as how such a board might function in relation to the interagency working group established by the American Innovation and Competitiveness Act (AICA) and the existing Research Business Models interagency working group. Kei suggested that universities should be

proactive in seeking to advance the implementation of the laws and offered thoughts on regulation under the new administration. The [presentation](#) is available on the COGR website.

The Research and Regulatory Reform (RRR) committee discussed NIH's plans to implement provisions of the 21st Century Cures Act with Mike Lauer, NIH Deputy Director for Extramural Research, on February 22. NIH is directed to reduce administrative burden associated with subrecipient monitoring, conduct a joint review of animal research regulations with FDA and USDA, and seek to avoid duplication and reduce administrative burden associated with financial reporting procedures among other areas. In a Federal Register [notice](#) dated February 28 HHS Secretary Tom Price delegated authority for implementing section 2054 of the 21st Century Cures Act to the NIH Director. That section requires the agency to consult with stakeholders and seek recommendations with respect to enhancements to the clinical trial registry data bank.

COGR Administrative Burden Checklist

In June 2016 COGR distributed a [checklist](#) of approximately 100 actions that member institutions have taken to reduce institutional administrative burden associated with federal research regulations and requirements. COGR has consolidated and summarized responses received to date and will distribute the results to participating institutions to allow them to compare their actions to those of peer institutions. Institutions wishing to participate can send completed checklists to [Lisa Nichols](#). We would appreciate additional feedback from members even if you cannot complete all of the sections and items and are considering next steps, including possible general distribution of results received.

Human Subjects Research

COGR Session on the Common Rule with OHRP

HHS Office for Human Research Protections (OHRP) Director Jerry Menikoff spoke about the final revised Common Rule at the February COGR meeting; [slides](#) are available on the COGR website. Discussions of particular interest centered on the use of a single IRB for multisite studies and broad consent for biospecimens.

With respect to multisite research, OHRP has noted that the final rule does allow agencies to exempt broad categories of research, where the sponsor determines it is not appropriate for a "particular context." The NIH Single IRB Policy allows for few exemptions. However, as defined in the Common Rule, sIRB has the potential to be significantly more burdensome than the NIH policy because it appears to be applicable even where different aspects of the research with different protocols are being conducted at each site. Under such circumstances the single IRB model is not likely to provide the best protections and will not reduce the level of administrative work. This issue was raised at the meeting and in an email prior where COGR suggested a technical amendment to the Final Rule or other means to make the clarification that the rule applies only where each site will conduct the same protocol. At the COGR meeting, Dr. Menikoff indicated that he saw no reason why the rule shouldn't apply to multisite studies using different protocols and addressing different aspects of the research project.

The topic of biospecimens and broad consent was also discussed. While the final rule does not include the proposal to make non-identified biospecimens subject to the rule, much of the language on

biospecimens is retained, applicable to “identifiable biospecimens” and “identifiable private information” the definitions of which will be re-examined within one year and every four years thereafter. Per the final rule, “If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.” A similar process will be followed to “assess whether there are analytic technologies or techniques that should be considered by investigators to generate “identifiable private information,” or “identifiable biospecimens.” The rule indicates that federal departments and agencies will consult with “appropriate experts (including experts in data matching and re-identification)” but there is no indication that stakeholders will be involved in the process. COGR has suggested that periodic reviews should not be made in the absence of stakeholder input and outside of the formal rulemaking process. We also believe that a review within one year is premature; following a multi-year rulemaking process. Dr. Menikoff sought to allay concerns, suggesting that any proposed changes to the definitions through guidance would be made available for public comment.

Another concern with respect to identifiable biospecimens and broad consent is that per the rule, “if an individual was asked to consent to the storage or maintenance for secondary research use of identifiable private information or identifiable biospecimens in accordance with the proposed broad consent provisions and such individual refused to consent, the IRB would be prohibited from waiving informed consent for the storage, maintenance or secondary research use of such biospecimens and information.” Dr. Menikoff clarified that the IRB would be prohibited from waiving informed consent for the storage, maintenance or secondary research use of identifiable biospecimens and private information but not from waiving consent for storage and secondary research use of non-identified biospecimens and private information.

COGR Sessions on the NIH Single IRB Policy

RRR committee members held a Thursday AM session on implementation of the NIH Single IRB Policy. Martha Jones of Washington University; Kerry Peluso of Emory University; Sara Bible of Stanford University and Cindy Kiel, University of California, Davis discussed the status of implementation at their institution. Universities are taking different approaches and this is something that is still very much in the planning stages even for those using an independent IRB.

The Costing Policies and RRR committees have been working together on issues regarding direct charging of the sIRB fees. Diane Dean and Samantha Tempchin of the NIH Office for Policy and Extramural Research Administration, discussed existing costing [guidance](#) and recent [FAQs](#). NIH provides guidance on charging primary and secondary costs but ultimately the institution makes these determinations. Among the costing topics discussed: Incremental costs above what is included in an institution’s indirect cost pool, such as the sIRB’s review of site-specific considerations, may be charged as direct costs.(FAQ 5); Universities can remove all IRB costs from their indirect cost pool at any time and direct charge all IRB costs, including sIRB. (FAQ 7); Institutions can establish standard fees/utilize a recharge center (FAQ 6); and sIRB costs can be included in an applicant’s budget prior to September 25 (FAQ 10). We understand that use of a regular recharge center should be adequate versus use of the more complicated and burdensome specialized service facility. The presentations on [implementation](#) and [costing](#) with respect to the NIH sIRB policy are available on the COGR website.

NIH Update on the Clinical Trial Funding Opportunity Announcement (FOA) Policy

NIH issued an [update](#) on February 17 to a previous notice issued in September 2016 (NOT-OD-16-147) that will require applications involving clinical trials to be submitted through a FOA specifically designed for clinical trials. The notice includes a new effective date of Jan. 25, 2018.

COGR Meeting with the AAHRPP President and Executive Vice President

The RRR committee met with Elyse Summers, President and CEO of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and Michelle Fiege, Executive Vice President, on Wednesday, February 22, to discuss AAHRPP's ongoing efforts to streamline and make less burdensome the accreditation and reaccreditation processes. AAHRPP provided feedback on issues COGR raised in a February 2016 meeting. Elyse and Michelle reported that new staff have been hired to ensure the quality and consistency of reports with AAHRPP standards and to create education and guidance materials, including expanded continuing education for site visitors. AAHRPP is also piloting a streamlined review process for "legacy organizations" with shorter site visits, fewer documents to review and fewer interviews. Regarding the Common Rule, [Guidance for AAHRPP Organizations that Comply with the Common Rule](#) is now available. The guidance notes that "new regulations promulgated near the end of a Presidential term are subject to a streamlined repeal process that involves Congress and the new President" and that "uncertainty as to the ultimate fate of the new rule may well continue until late May or June 2017." The guidance describes how the transition to the new rule will be handled with respect to the accreditation/reaccreditation process and annual reports.

Audit

NSF Office of Inspector General (OIG) Audit Reports

The NSF OIG recently published two audit reports for universities receiving NSF grants. In a [report](#) published March 6, auditors questioned \$135,695 in costs in an audit of over \$182 million in costs claimed to 1,079 NSF awards over a three year period. Among the most significant questioned costs were \$63,472 in senior salary, fringe benefits, and related indirect expenses that exceeded two months. The OIG recommended that the university "strengthen the administrative and management controls and processes over the allocation of senior personnel salary to ensure compliance with NSF policies." Additional questioned costs included \$57,600 in indirect costs associated with data storage space rental. Per the report, although the universities award budget included funding for this expense under the category of equipment, the university accounted for the expense as a purchased service. "Per 2 Code of Federal Regulations (CFR) 220, Section G.2, the MTDC base excludes equipment, capital expenditures, and rental costs; PSU's application of indirect expenses therefore appears to be unreasonable." The university indicated "that by its nature, high-performance computing capacity includes a component of database administration, programming, and hardware/software/helpdesk support, and the expense should therefore be classified as a purchased service." The university disagreed with all but \$3,102 of the \$135,695 in questioned costs.

An [audit report](#) covering \$142 million in expenses charged to NSF awards over a three year period by a research university was reported on February 27. Auditors questioned \$2,330,503 in costs, including \$1,810,627 of salary, benefits, and associated indirect costs for senior personnel in excess of two months, and \$382,646 of equipment charges. The university agreed with \$20,156 of the \$2,330,503 in questioned costs. While it was our understanding that the NSF OIG is no longer pursuing audit findings of senior personnel salary exceeding two months, consistent with NSF audit resolution findings indicating that the charges are in line with agency policy, per the report, “Generally accepted government auditing standards require us to perform and report on our work independent of outside influences that might compromise our professional judgment, including NSF’s past actions on audit findings and recommendations. With respect to the \$1.8 million of questioned salary, benefits, and indirect costs, similar charges have been questioned in several prior audits. NSF did not agree with the auditors and did not sustain the questioned costs, even when the auditee university agreed to repay the disputed amounts. In line with auditing standards that require us to maintain independence of mind and appearance, we continue to question these charges for the reasons detailed in Finding 5 of this report.” Regarding equipment charges, \$188,352 in questioned costs were reportedly not included in the approved budgets, including \$175,000 in expenses that the OIG suggests amounted to a change in project scope without explicit approval from NSF, and \$194,294 charged within 60 days of the awards’ expiration dates or after awards expired. Regarding charges not included in the approved budget, the report recognizes that the university contacted the program officer regarding the purchase but indicates that “there is no indication in the written record that the Program Officer was aware of the magnitude of this purchase — 36 percent of the total grant budget — or advised [the university] this was not a change in scope.” Regarding equipment purchased in the final 60 days of the award period or after the award had expired, the university “included text from NSF’s Award and Administration Guide, stating, ‘commitment of project funds is valid when specialized (research) equipment is ordered well in advance of the expiration date but where, due to unusual or unforeseen circumstances, delivery of such equipment is delayed beyond the expiration date.’” The OIG retained the questioned costs. The report also included questioned costs on cost transfers, workshops and purchase card transactions.

Executive/Agency Meetings, Requests and Orders

National Science Board Meeting

The National Science Board (NSB) met February 21-22. The meeting [agenda](#) and [webcast](#) are accessible via the NSB website. The Board has developed a new committee structure to balance workload, refocus attention on strategic issues, and for more effective engagement with external stakeholders. The Committee on External Engagement discussed efforts to engage Congress. Meetings with members of Congress are now an integral part of the Board’s activities. Senators Gardner and Peters and Representatives Smith and Johnson will be invited to speak at this year’s award ceremony to be held at the U.S. Institute for Peace. There was discussion of the American Innovation and Competitiveness Act and its implications for NSF. It was suggested that the AICA benefited from greater engagement between NSF and the NSB and members of Congress. The NSB also sent a letter to the Trump transition team in December and had an opportunity to meet with transition team staff. On March 21, Acting COO Joan Ferrini-Mundy and Board Chair Maria Zuber will testify at a hearing before the House Committee on Science, Space and Technology. NSF Director France Cordova and OIG Allison Lerner testified before the committee on March 9 in a hearing titled “[NSF Part 1: Overview and Oversight](#).”

In the Committee on Oversight meeting Allison Lerner provided a brief overview of additional reporting requirements under the IG Empowerment Act that passed in December 2016. These include statistics about reports where the agency hasn't provided comments within 60 days and on reports with outstanding unimplemented recommendations; detailed descriptions of investigations involving senior government employees where allegations were substantiated; and instances of whistle blower retaliation. There was a presentation on NSF's external audit resolution process from Dale Bell and Joan Ferrini-Mundi. All audit findings are to be resolved within 180 days of receiving the OIG audit report. An audit resolution memorandum with management decisions is produced and, following a 10-day closeout period, a final agency determination letter is sent to the awardee and posted to the agency website. Data from an eight year period were presented. During that time there were 75 audits, with 213 findings and 465 recommendations, of which NSF concurred with/sustained 392 recommendations or 84% (\$7 million of \$28 million was sustained). Among the audit themes identified: salaries were a prime target – including how effort is documented and calculated; subawards – how is the prime managing the sub; participant support – prior approval needed for rebudgeting; and equipment purchases toward the end of an award – whether they are needed to achieve award objectives. When audit findings are not sustained it is typically due to disagreement on policy; new information obtained or research performed during audit resolution; calculation/citation issues; or disagreement on documentation adequacy – where NSF believes it is adequate. Bell suggested that overall the analysis suggests core alignment between the agency and the OIG with 84% concurrence. In terms of the discrepancy in the funding amount sustained, 50% of all questioned costs in 2015 were related to the two-month policy which the agency and the OIG disagreed on. Going forward Allison suggested that audit periods will get to the point where they won't encompass the period prior to NSF's policy clarification and that the OIG is not specifically looking for this in ongoing activity.

NSF Requests Comments on Reporting Requirements for Facilities and Programs

NSF has published a [second notice](#) for public comment on a request to renew an information collection titled "Grantee Reporting Requirements for National User Facilities managed by the NSF Division of Materials Research" and a [second notice](#) for "Grantee Reporting Requirements for the Emerging Frontiers in Research and Innovation program." Interested parties can submit comments through April 13 and April 12, 2017 respectively. Comments are sought on the necessity of the collections, how to improve the quality of the collection and how to reduce associated burden among others.

GAO Seeking Nominations to Health IT Advisory Committee

The Government Accountability Office is seeking [nominations](#) to a Health Information Technology Advisory Committee created by the Cures Act. Nominees might include providers; health information technology developers; researchers; and individuals with technical expertise on health care quality, system functions, privacy, and security. Nominations must be submitted by April 14.

COGR Session on the Intergovernmental Personnel Act (IPA) Program

Erwin Gianchandani, Deputy Assistant Director of the NSF Directorate for Computer and Information Science and Engineering, provided an overview of the agency's IPA Program and the management of the program following OIG audit reports published in March 2013 and January 2016 and increased congressional interest. Audit reports acknowledge the benefits of the IPA program but also highlight the

additional cost of using IPAs instead of permanent employees and made recommendations for reducing costs. Dr. Gianchandani highlighted policy changes NSF is piloting this year to address these issues including mandatory 10% cost share rather than 15% voluntary and 12 trips back to the home institution rather than unlimited trips. IPAs have the opportunity to continue their research and to regularly visit their home institution via the Independent Research and Development Program, which allows IPAs to spend up to 50 work days a year on independent R&D, and have the option to expand time spent at the institution through telework. Sixty-five percent of current NSF IPAs are COGR members, serving primarily as program directors and executives within the agency.

Executive Order to Reorganize Federal Agencies

The Trump administration released a Presidential Executive Order detailing a [Comprehensive Plan for Reorganizing the Executive Branch](#) on March 13. The order directs OMB Director Mick Mulvaney to “propose a plan to reorganize governmental functions and eliminate unnecessary agencies.” The head of each agency is expected to submit a proposed plan “to reorganize the agency, if appropriate, in order to improve the efficiency, effectiveness, and accountability of that agency” within 180 days of the order. Public comments on the organization and functioning of the executive branch will be invited.

COSTING POLICIES

Committee: Kim Moreland, Chair, University of Wisconsin, Joseph Gindhart, Washington University-St. Louis, Cindy Hope, University of Alabama, Lynn McGinley, University of Maryland-Baltimore, Jeffrey Silber, Cornell University, Cathy Snyder, Vanderbilt University, Michael Daniels, Northwestern University, Dan Evon, Michigan State University, Amanda Dotson, Texas A&M University, Michael Legrand, University of California-Davis, James Fortner, Georgia Institute of Technology, Vivian Holmes, Broad Institute

Procurement Standards: Update by Gil Tran, OMB, at the COGR Meeting

Gil Tran, from OMB, presented an update at the COGR Meeting on Friday, February 24th. The following is of note:

- 1) A Federal Register Notice to provide updates to [2 CFR Part 200](#) (i.e., Uniform Guidance) remains in pending status. In addition to updates to the [Procurement Standards](#) (2 CFR 200.317-326), other updates are included in the pending Federal Register Notice. However, under the President’s regulatory freeze, these updates to the Uniform Guidance will not be released until they have been approved by senior leadership at OMB. At this stage, an exact date is uncertain.
- 2) Included in the pending Federal Register Notice is an extension of the grace period for implementation for the entire suite of the Procurement Standards for one more year (i.e., July 1, 2018 for most research institutions). As presented by OMB on Friday, OMB is working to decouple the extension of the grace period from the main Federal Register Notice. If successful,

we can expect to see a separate notice, focusing specifically on the extension of the grace period, in the near future.

- 3) We further expect the separate notice on the extension of the grace period to clarify how the Micropurchase threshold, as specified under the National Defense Authorization Act (NDAA) and under the American Innovation and Competitiveness Act (AICA), are to be implemented. Our understanding is that the grace period will be applied to the Micropurchase threshold, as defined in the NDAA and the AICA (see Summary below) and that research institutions will not be required to change their Micropurchase threshold policies for one more year (i.e., July 1, 2018 for most research institutions).

NDAA and AICA Micropurchase Threshold Summary:

NDAA: \$10,000 or higher threshold as determined by the head of the relevant executive agency and consistent with clean audit findings, institutional risk assessment, or State law. Applicable to grants, cooperative agreements, and contracts for all federal agencies.

AICA: \$10,000 or higher threshold as determined by the head of the relevant executive agency and consistent with audit findings, institutional risk assessment, or State law. Applicable only to NSF, NASA and NIST.

The intersection of the pending Federal Register Notice, the Administration's regulatory freeze, the grace period extension, and the NDAA and AICA have made for a regularly changing and confusing narrative. However, COGR views the presentation by OMB at the COGR Meeting as a potentially positive development. We are closely monitoring the release of any OMB notice or clarification that will address the extension of the grace period, and we will keep the Membership posted on all developments.

Single Audit Under the Uniform Guidance: Thursday Morning Session on February 23rd

Mandy Nelson, Partner at KPMG; Ralph DeAcetis, Managing Director at PwC; and Mary Foelster, Director, Governmental Auditing and Accounting at the AICPA, participated in a panel session to discuss topics related to the Single Audit and the Uniform Guidance (UG); specifically, [Subpart F – Audit Requirements](#). Below are some of the items that were discussed:

Major (Type A) Programs. Subpart F, section [200.518](#), *Major program determination*, defines the expectations for auditing Type A and Type B programs. In the case of Type A Research & Development (R&D) and Type A Student Financial Aid (SFA), the UG has removed some of the judgment auditors used to have with regard to defining the R&D and SFA Clusters as high risk due solely to their size and complexity. The result of this change is that auditors may have to more frequently audit Type B programs. Consequently, institutions should be diligent in ensuring that their Type B programs include the same level of internal control as their Type A programs so as to minimize risk of audit findings.

SFA and Annual Audit Requirement. The Department of Education (ED) has been vocal in their position that the SFA cluster requires an annual compliance audit regardless of whether it meets the requirements as a major program under the UG. ED's basis for this position is described in a "*Dear*

Colleague Letter” (written by ED, to the community). During the 2016 audit season, ED required entities to contact ED if the SFA program did not meet the UG’s criteria to be a major program. To the best of the panel’s knowledge, ED provided a waiver to the audit requirement in those cases. ED has not issued any definitive guidance for the 2017 audits. However, panelists suggest that until such time that ED issues definitive guidance, entities should continue to contact ED if the SFA program would not meet the major program criteria under the UG.

Securing Student Information. This is a new section that has been added to the DRAFT version of the 2017 Compliance Supplement (Section N. Special Tests and Provisions, pages 5-3-52 through 5-3-55) to introduce audit requirements over entities’ systems for securing student information. Effectively, if this section were to be included in the final version of the Compliance Supplement, it would greatly expand the scope of audit testing and could further open the door to other agency requests to include other forms of cybersecurity audit assurance. A number of organizations have objected to this potential new requirement, and at this stage it is uncertain if it will be included in the final version of the 2017 Compliance Supplement.

Internal Controls Testing. The UG more clearly states the requirement for entities to have internal control over compliance and describes the best practice of entities using COSO and the GAO Green Book as internal control frameworks. There is no audit opinion on internal control required by the UG. Instead, the evaluation of an entity’s internal control over compliance by an auditor will involve the use of risk assessment and auditor judgement.

Audit Quality. Federal funding agencies and their Inspectors General play a major role in directing the focus areas of single audits and assessing the quality of single audits. Confidence in audit quality is critical. The UG requires a periodic study on audit quality and the first study could occur in 2019 or 2020 and cover audits submitted to the Clearinghouse as early as 2018. A resulting report will be issued to address important issues and concerns noted. Separately, a recent GAO report (February 16, 2017), *Improvements Needed in Selected Agencies’ Oversight of Federal Awards* ([GAO-17-159](#)), was critical by stating that some agencies did not effectively design policies and procedures to reasonably assure the timely submission of single audit reports, and consequently, this adversely affected timely management decisions and corrective action plans.

Payroll Certification and Auditor Reaction. The UG has introduced a more principles-based approach to compensation/personnel costs. As a result, effort reporting is not specifically required under the Uniform Guidance. It also was not required under Circular A-21, though under A-21, it had become the de-facto expectation. While there has not been a major shift away (yet) from effort reporting, systems such a Payroll Certification are becoming more prominent. While formal acceptance of an alternative system may not be officially provided by (nor the role of) the single audit, there is significant value in an institution demonstrating changes being made to their legacy systems (or new systems being implemented) to their auditors. In turn, constructive feedback can be conveyed by the auditors, which can help to ensure compliance with the UG.

This session was informative and provided valuable insight into the larger picture of Single Audit and the role of federal agencies and their Inspectors General. COGR appreciates the relationship we have with leaders in the Single Audit community, and we expect to have more of these types of discussions as we navigate through changes in the Single Audit and the UG.

2017 COGR Survey of F&A Rates: Results Available

We presented the 2017 Survey - Executive Summary during a Thursday afternoon session at the February COGR Meeting. The Executive Summary provides a primer on F&A (i.e., Research Operating Costs) and the F&A reimbursement process, including a high-level analysis of F&A rates and trends. The Executive Summary also includes Appendix B: Survey Data Sheet, which captures selected results of the survey summarized in tables and graphs.

The Executive Summary, Appendices, and the Rate and Negotiation reports are listed at www.cogr.edu (see Policy Issues / Financial Management). Most of these reports, initially, have been set-up as **COGR Members Only** and are designed for Internal Use Only. Contact Toni Russo at trusso@cogr.edu to obtain copies of those reports restricted to COGR Members Only.

The “Historical Rates by Institution” report (a COGR Members Only report) is in the same format as the 2011 report. All institutions that completed the survey are named, and all F&A rates (as you reported per the survey) are included. **Institutions that did not complete a survey** should consider submitting their historical rates to Toni Russo so that they can be included on the next version of this report. Of course, your institution is not required to do so; however, many who have completed the survey have done so with the intention of sharing results with peer institutions. Also note, COGR has not edited the survey data that you provided, so if there are errors, please contact us and we will update.

Negotiation Experiences (also a COGR Members Only report) are de-identified; each answer to a survey question is presented anonymously (e.g., Question 22, Respondent # 18). Right now, everyone is opted-in. If one of your peers is reviewing the Negotiation Experiences and asks to contact Respondent # 18, we will provide the contact information. However, you can opt out by contacting Toni Russo at trusso@cogr.edu. If you opt-out, your anonymous responses will remain part of the Negotiation Experiences report, but we will not share your contact information if it is requested

We appreciate the great response from the Membership to the 2017 Survey! If you have additional questions or concerns, contact David Kennedy at dkennedy@cogr.edu

Costing Policies Committee: Other Issues

The Costing Policies Committee is working on a wide range of other issues, some of which were addressed throughout the February COGR Meeting. Some of these issues are ongoing and have been covered in past COGR updates. As needed, each one will remain on our list for 2017 engagement.

Single IRB and Direct Charging. Recent [FAQs](#) posted by NIH provide additional clarification to the June 2016 NIH Notice Number: [NIH-OD-16-109](#). Notably, FAQs 6 and 7 seem to provide flexibility for institutions to remove all IRB costs from an indirect cost pool and, in turn, establish a direct charging methodology. While use of a Specialized Service Facility (SSF) is suggested in FAQ 6, at the February COGR meeting, NIH representatives indicated a more generic recharge center model also could be appropriate. The COGR Research & Regulatory Reform (RRR) Committee is the lead on this issue, with ongoing engagement by the Costing Policies Committee.

HHS Office of Grants Policy Update. We have several unresolved issues with the HHS Office of Grants Policy, including: 120-day grant closeout model across all HHS ODs, improving functionality of the Payment Management System (PMS), and prospects for other HHS ODs to join the Research Terms and Conditions. Also prominent is assessing the value of the Federal Cash Transactions Report (FCTR), which effectively is a duplicative report when considered in the context of “real-time” cash balances available under PMS subaccounting. The COGR Research & Regulatory Reform (RRR) Committee is leading the effort to respond to specific mandates in the 21st Century Cures Act, Section 2034, which directs the Secretary of HHS to minimize financial reporting administrative burden. **The Costing Committee will work with RRR to explore the possibility of raising the FCTR as report that could be eliminated (among other issues) to the Secretary of HHS.**

F&A Specific. COGR will continue to address both unresolved and new issues (see details in the [COGR December 2016 Update](#)). Our current list includes: 1) Facilitate the DS-2 Approval Process, 2) Fix the Utility Cost Adjustment (UCA) Research Weighting Factor, 3) Definitions of On-Campus versus Off-Campus rates in F&A Rate Agreements (within the context of the DOJ Settlement from last summer), **4) Interpretation of the Software Capitalization Threshold** (i.e., a strict \$5,000 capitalization threshold for all forms of software acquired with federal funds), and 5) other issues as raised by the Membership.

Cost Allocation Services (CAS) Best Practices Manual, January 2017. The updated HHS-CAS manual has been published. Per initial comments from the Membership, **we are concerned that a strict interpretation of a \$5,000 software capitalization threshold, inconsistent with standard and accepted accounting practices, has been defined in the manual.** COGR has met with OMB on this topic, and OMB is aware of our concerns. As F&A experts at your institutions read through the entire CAS manual, we invite you to share additional concerns or questions that arise. Contact David Kennedy at COGR at dkennedy@cogr.edu.

Student Financial Aid (SFA) Cluster and the Single Audit (also see previous section; Single Audit under the Uniform Guidance). The four Associations, the National Association of State Auditors, Comptrollers and Treasurers (NASACT), the American Institute of Certified Public Accountants (AICPA), the National Association of College and University Business Officers (NACUBO), and COGR, continue to monitor this issue. We were concerned that the Department of Education (ED) position (requirement for a separate annual compliance audit of Title IV Student Aid Programs) might be included in the 2017 Compliance Supplement. However, in the DRAFT version provided to COGR, it is not included. Still, ED is using its “*Dear Colleague Letter*” from last year as the basis for their position that an annual compliance audit is required.

Securing Student Information, Student Financial Aid (SFA) Cluster (also see previous section; Single Audit under the Uniform Guidance). This is new section that has been added to the DRAFT version of the 2017 Compliance Supplement (Section N. Special Tests and Provisions, pages 5-3-52 through 5-3-55). NASACT, the AICPA, and leaders from the Single Audit firms have risen significant concerns as this could be a complex and expensive audit activity.

F&A Rates and Nonprofit Research and Disease Foundations. COGR participated in a meeting in November, led by [FasterCures](#), a DC-based center of the [Milken Institute](#). The meeting included

a diverse workgroup of representatives from nonprofit research and disease foundations, and research universities, to address issues of common ground. Issues related to data sharing, intellectual property and licensing previously were addressed by this workgroup, and the current initiative being explored is to develop better methodologies for recovering F&A-related costs.

Equitable Treatment of Off-Campus Research Centers in NIH RFAs. A COGR Workgroup continues its work with NIH to devise a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. At issue is the treatment of lease costs when a Research Funding Announcement (RFA) or Investigator initiated proposal limits costs in terms of maximum direct cost. COGR's position is that off-campus research centers are at a competitive disadvantage; i.e., by including the lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. Note, for on-campus research centers, similar F&A costs are excluded. NIH is reviewing our request to address this issue.

We will keep the Membership posted on all developments related to the above issues. We encourage you to raise issues not covered to the COGR staff or to members of the Costing Committee.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Alexandra McKeown, Chair, The Johns Hopkins University, Elizabeth Peloso, University of Pennsylvania, Patrick Schlesinger, University of California-Berkeley, Kevin Wozniak, Georgia Tech Research Corporation, David Winwood, Louisiana State University, Cathy Innes, North Carolina State University, Fred Reinhart, University of Massachusetts-Amherst, John Ritter, Princeton University, Wendy Streitz, University of California, Wendy Montgomery, University of Maryland, Melanie Roewe, Washington University – St. Louis; Michael Moore, University of North Dakota

COGR Meets with NARA to Discuss CUI

We've mentioned in previous Updates and Reports that that the National Archives and Records Administration (NARA) was developing a FAR rule to implement compliance requirements on Controlled Unclassified Information (CUI) for non-federal entities including contractors based on NIST SP 800-171. The FAR rule will apply government-wide and is supposed to supersede individual agency clauses. NARA is the Executive Agent for the government-wide CUI Program established by EO 13556. On February 24 several COGR and AAU representatives met with the Director of the NARA Information Security Office and other NARA representatives to discuss the FAR clause and related concerns. We mentioned the FDP white paper that was sent to NARA the previous month (see [February Update](#)). We noted the persistent confusion among agencies on FISMA, and the misapplication of FISMA requirements to non-Federal information systems in agency contracts.

The NARA Final Rule on CUI (81 FR 63323) draws a clear distinction. FISMA requirements apply to protection of Federal information and Federal information systems and are subject to FISMA

Publication 200 and NIST SP 800-53. Situations where non-executive branch entities handle CUI but are not using or operating an information system or maintaining or collecting federal information “on behalf of” an agency are covered by the NIST SP 800-171 security requirements. It is vitally important that the FAR rule also make this distinction clear, and instruct contracting officers accordingly. We noted the importance of also providing appropriate training to government contracting officers and other federal officials. The NARA representatives noted this is required in the NARA CUI rule.

With regard to compliance we suggested self-certification. NARA indicated they are exploring that possibility. Liability for breaches would be with the contractor. If the system is validated by the government the liability would shift to the government; however, we expressed concerns about who in the government would be responsible for validation and timeliness of decisions.

The NARA representatives reiterated their desire to work with COGR and FDP on the development of the FAR clause. This includes developing language both for the policy prescription and actual clause. They stated concerns about “federalizing” contractor information systems through overreaching security requirements. They reiterated that sharing CUI information with contractors when it is incidental to providing a service or benefit to the government is covered by NIST SP 800-171, not FISMA. They agreed with the importance of clarifying these distinctions in the FAR clause. We mentioned that with “CUI specific” information, the FAR clause definition should be drawn from the underlying legislation or regulation, not the CUI Registry description (e.g. the Registry description of export controls is not fully consistent with the regulations).

We stressed the importance of having an entity in the government as the arbiter of CUI requirements. NARA expects to play this role. They will try to protect against agencies identifying information as CUI when it is not included in a CUI Registry category or using other labels. If our member institutions encounter these situations they should refer them to NARA.

In that connection the proposed DHS safeguarding requirements (see below) were discussed at the meeting. NARA is greatly concerned by the proposed DHS rule. In their view it undermines the CUI Program. Agencies are not supposed to label information as CUI when it does not correspond to the CUI Registry. As the first agency acquisition regulation issued subsequent to the issuance of the NARA CUI rule, it sets an unfortunate precedent. We had expressed concerns about the scope of the rule in the [February Update](#). NARA encouraged COGR and other higher ed. associations to submit comments, which we will do.

Proposed DHS CUI Requirements Raise Concerns

As noted above, in January DHS issued a new [clause for the HSAR](#) on CUI (82 FR 6429). [Unfortunately](#) the proposed rule appears to confuse rather than clarify the applicability of government security requirements applicable to CUI. Many of the proposed new categories of CUI set forth in the proposed rule do not correspond to categories in the NARA CUI Registry. This conflicts with the standardized approach established by NARA under Executive Order 13556.

Included among the new categories in the proposed DHS rule is information that DHS receives pursuant to information sharing agreements with state, local and private sector partners (3052.204-7X(a)(4)). The parameters of this type of information are very uncertain, and seemingly could apply to any information included in such agreements. It is difficult to reconcile with the uniform CUI structure envisioned in the

NARA Rule. Also the effect would be to subject any shared information to security requirements for Federal information systems, which appears counter to the objectives of the NARA CUI Program. A footnote in the proposed rule distinguishes the information system security requirements in the proposed rule focused on Federal information systems including contractor information systems that are operated on behalf of an agency, from the requirements of NIST SP 800-171 that apply to non-federal entities that handle, process, use, share or receive CUI. Unfortunately this distinction is not fully reflected in the proposed rule. The proposed HSAR policy statement states that the requirements apply to “any situation where contractor employees may have access to CUI (3004-470-3(a))” and the instruction to contracting officers to insert the HSAR Safeguarding clause is stated in terms of when “contractor ... employees will have access to CUI” (3004-470-4(b)).

We plan to submit comments on the proposed rule suggesting that the scope be clarified. While the proposed rule states that “Neither the basic clause or its alternates should ordinarily be used in contracts with educational institutions,” given the confusion over the scope of the rule, there may be some impact on the COGR membership, especially if other agencies follow DHS’s lead. Inconsistent and inappropriate application of CUI requirements by agencies will result in undue burdens and unnecessary costs for COGR member institutions. We plan to suggest that the content of the footnote be moved upfront, and that the proposed rule be revised for consistency with the NARA requirements. Comments are due March 20.

Because of the confusion and overall lack of clarity on CUI and FISMA, we are considering developing a white paper on points to consider that will address these issues.

New DFARS Cybersecurity Regulations Complications

In October of last year DOD issued a final rule amending the Defense Federal Acquisition Regulations Supplement (DFARS) requirements for safeguarding covered defense information (CDI). The [October Meeting Report](#) discussed the changes. (Unlike the proposed DHS rule discussed in #2 above, the CDI definition in the DFARS is linked to the CUI Registry).

Among the changes in the final DFARS rule was an amendment to the DFARS 252.204—7000 clause that attempted to respond to concerns that COGR had expressed to DOD that our member institutions were inappropriately receiving safeguarding requirements in fundamental research projects. The clause was amended to provide that fundamental research “by definition cannot involve any covered defense information” (7000(a)(3)). The discussion in the final rule states “A contract or project that is appropriately scoped as fundamental research will not contain any covered defense information.” The determination that a project is fundamental research must “ensure that it is clear that no covered defense information is involved”

A problem has arisen with regard to DOD contracts whose performance involves access to or use of information in CUI categories such as protected health information or student records. Apparently in such instances DOD contracting officers are taking the position that the contracts cannot be fundamental research. The 7000 clause prior approval requirements therefore apply.

The definition of “covered defense information” in the final DFARS rule refers to “controlled technical information or other information” in the CUI Registry “that requires safeguarding or dissemination

controls pursuant to and consistent with law, regulations, and Government wide policies and is ...collected, developed, received, transmitted, used, or stored by or on behalf of the contractor in support of the performance of the contract” (204.7301; 252.204--7012). The rule Summary states that “Covered defense information includes all of the categories of information that are considered CUI.”

The CUI Registry defines controlled technical information as “technical information with military or space application that is subject to controls on the access, use, reproduction, modification, performance, display, release, disclosure, or dissemination.” Examples are included such as research and engineering data, specifications, software code, etc.

We suspect that the amendment to the 7000 clause may have been intended primarily to cover only controlled technical information, and not the other categories of CUI. Also the degree of CUI that must be “involved” in the contract for purposes of triggering the 7000 (a)(3) exception provision is unclear. In some cases only incidental access to such information may occur. While the information must be protected, we do not believe it is appropriate to assert that such contracts cannot be fundamental research.

We plan to request clarification from DOD. This may require further DFARS revisions.

COGR and Other Associations Ask Ed. to Reconsider Open Licensing Rule

The [February Update](#) discussed the Department of Education (Ed.) [final rule published](#) on January 19 requiring open licenses to the public of copyrightable grant deliverables created with Department competitive grant funds (82 FR 7376). As discussed, Ed. responded to some of our concerns in the final rule, by somewhat narrowing the scope and adding exemptions. However, we disagree with the basic approach that open licensing should be the default in all cases unless they fall under specific exemptions.

On February 15 COGR joined by AAU, APLU and AUTM wrote to the new Secretary of Education requesting reconsideration of the rule. The final rule adds two new broad exemptions. One is based on submission of dissemination plans that the Department determines are likely to achieve meaningful dissemination equivalent to or greater than open licensing, or that compliance would impede the grantee’s ability to form necessary partnerships. The other is when compliance would conflict with, or materially undermine, the ability to protect or enforce the grantee’s other intellectual property rights or obligations to third parties. In our letter we expressed concerns about the lack of clarity or predictability of the exemption process. We expressed the view that the exemptions as written are likely to result in lengthy delays and uncertainties in implementation. We also expressed concerns about the issue of validation. We stated that the validation of educational technologies is extremely important, especially when developed with government funding. There is a critical need for evidence based assessments that are peer reviewed and published. Open licensing could result in modifications without the necessary follow-on review and validation by the original developers, which could lead to undesirable and possibly dangerous outcomes.

We urged the Department to reconsider the final rule with these concerns in mind. Grantees should have the ability on a case-by-case basis to propose dissemination appropriate for the particular grant objectives or nature of the materials, subject to the peer review process. In some cases, this might well

include open licensing, as is now the case. If individual Department programs believe open licensing will best achieve their goals, this should be clearly stated in solicitation documents with the ability of grantees to propose alternative approaches to the management of intellectual property created under the grants.

The rule was supposed to be effective March 20. The effective date has been delayed one day by the current regulatory freeze, since the rule was determined to have an annual effect on the economy of more than \$100M. We do not know how the new leadership at Ed. will view the rule, or if they will respond to our letter. Most of the senior staff positions at Ed. currently are listed as “Vacant.”

Revised Bayh-Dole Regulations Remain on Hold

The COGR CIP Committee met with Henry Wixon, NIST Chief Counsel, at our February meeting. He confirmed that the proposed changes to the Bayh Dole Act implementing regulations (37 CFR 401; see [December 2016 Update](#)) remain on hold due to the regulatory freeze. They are not subject to the mandatory 60-day delay in implementation since they were not determined to have major economic impact. But their publication date remains uncertain.

From the discussion it appears that the final regulations may address positively some but not all of the concerns we had [expressed in our comments to NIST](#). We extensively discussed invention reporting issues. One issue is the lack of i-Edison use by all federal agencies. Mr. Wixon noted that DOE and NASA have their own invention “vesting” statutes, which allows them to require separate reporting. The i-Edison issues require new resources to fully address. One possibility that might be explored is a private-public partnership (NIST has joint venture authority). We brought up the lack of timely responses by agencies to requests for waivers of the U.S. manufacturing requirement and/or waivers of title to inventors. While the requirements are statutory, we suggested NIST consider setting time limits for agency responses. The small business preference and issues with small entity status were among other items of discussion.

The views of the new Administration on IP are unclear. It is possible we may see more emphasis on traditional forms of IP protection rather than the open forms of access favored by the previous Administration. However, the future direction is uncertain.

KEI Holds Webinar on Compulsory Licensing of Medical Patents

On February 24 Knowledge Ecology International (KEI) held an all-day webinar on the *History, Experiences and Prospects on Compulsory Licensing of Medical Patents in the U.S.* KEI long has advocated that the government use the Bayh-Dole Act “march-in” authority to set prices for drug patents resulting from federally-funded research. It has filed a number of march-in petitions with NIH (see February Update for the most recent developments).

AUTM was invited to participate in the workshop session that focused on march-in rights. Past President Ashely Stevens, President, Focus IP Group, represented AUTM. In his remarks Dr. Stevens made three main points: 1) march-in was never intended as a price control mechanism; 2) march-in would seriously damage the U.S. innovation system; and 3) march-in is not economically justified. He cited a number of studies and examples to support these points. He stressed that academic institutions

are a critical source of innovation and that given the success of Bayh-Dole, changes should be approached very carefully. He also stressed the importance of exclusive rights in the development of high risk early stage university biomedical inventions into therapeutic products by the private sector. His bottom line was that once exclusivity is taken away by a march-in, no company will invest in federally-funded academic technologies.

In response James Love, President of KEI, questioned the actual degree of commercialization enabled by the Bayh-Dole Act, particularly with regard to drugs. He cited the policy objective of Bayh-Dole to protect the public against both non-use and **unreasonable use** of government-funded inventions. He pointed to price disparities between drugs in the U.S. and other countries. He asserted the “reasonable terms” provision of Bayh-Dole should include the pricing. He claimed that universities minimize the contributions of taxpayer funding for the research leading to drug development. He reviewed the history of previous march-in requests under Bayh-Dole, criticizing both Senators Bayh and Dole for allegedly changing their positions on march-in according to their clients’ interests. His bottom line was that NIH is biased against march-in requests based on pricing concerns (perhaps because NIH has a large number of scientists who themselves are patent holders), and that other entities should handle march-ins. A number of related statutory and regulatory reforms also were suggested.

There were a number of staffers present who work for members of Congress who have been concerned about drug pricing issues, particularly march-in. It is not clear what their takeaways may have been. The President also continues to focus publicly on drug prices. On March 8 he met with two ranking minority House members (Rep. Cummings, D—MD; Rep. Welch, D—VT) along with the President of Johns Hopkins Hospital to discuss drug prices. In addition, Rep. Doggett (D—Texas) and other House members recently sent the President a letter urging him to direct NIH to issue guidance on march-in to discourage drug price gouging (“Taxpayer Protection Rights”). We expect continued attention in the Congress and Administration to these issues.

The KEI webinar may be viewed at www.youtube.com/watch?v=-stSKXmY-Wc. Dr. Stevens’ remarks begin at the 4:26 minute mark. James Love’s response is at 4:42.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Pamela Webb, Chair, University of Minnesota; Michael Ludwig, University of Chicago; Jeffrey Friedland, Princeton University, Pamela Caudill, Harvard University, Walter Goldschmidts, Cold Spring Harbor Laboratory, David Norton, University of Florida, James Tracy, University of Kansas, , Jennifer Lassner, University of Iowa, Steven Martin, Indiana University – Bloomington, Lisa Mosely, Arizona State University, Allen DiPalma, University of Pittsburgh; Jeremy Forsberg, University of Texas-Arlington

COGR Panel on Public Access, Thursday afternoon session on February 23rd

Tobin Smith, VP for Policy at the Association of American Universities (AAU), James Luther AVP Finance & Compliance Officer, Duke University, Stephanie Endy, Assoc. VP for Research, Case Western University, and Jackie Bendall, COGR convened a panel discussion Thursday afternoon to share concerns and seek audience participation on the data aspects of the [OSTP memo](#). The panel provided a regulatory overview of the OSTP Public Access requirements for publications and data, current status of various agencies, the AAU and APLU public access working group initiative and a discussion on the costing implications and implementation and operationalization aspects of the public access mandate. Below are some of the key issues identified:

- Lack of harmonization of agency Public Access Plans;
- Unknown and unclear requirements at time of proposal submission;
- Institution infrastructure and IT strategy, the ability to expand and contract based on life (short-term) of award or long-term repository needs;
- Faculty burden in development of multiple Data Management Plan requirements;
- Administrative burden of negotiating and administering various, onerous, and lengthy Data Management and Use Agreements

As Tobin Smith indicated, the charge of the AAU and APLU Public Access working group (which COGR is part of) is to help guide AAU and APLU on legislative and policy positions by engaging federal agencies, policy makers, and institutional representatives to identify best practices, develop minimum standards/requirements; through consensus building for both universities and government. The next working group meeting will be held mid-April. For questions or issues in this area, please submit to jbendall@cogr.edu.

Research Compliance and Administration (RCA) Committee: Other Issues

The RCA Committee met to discuss the following issues which were addressed in the Friday morning COGR Committee reports. COGR is looking for “at large” participation on these issues.

Foreign Subrecipient Monitoring. RCA will be forming a small working group to address the challenges, burdens and costs associated with foreign subrecipient monitoring. If your institution has a high volume of foreign subawards and you're interested in being a participant in the working group, please contact jbendall@cogr.edu.

Data Management and Sharing. Carrie Wolinetz, Ph.D., Associate Director for Science Policy, OSP, NIH and Dina Paltoo, Ph.D., Director, Division of Scientific Data Sharing, joined RCA to discuss the current and future climate of Public Access at the NIH and comments received from the recent RFI on Data Sharing and Management. Dr. Wolinetz indicated that her office is primarily responsible for data policy not storage or other aspects. The recent RFIs have been a real attempt (not political) to obtain information from the research community to develop an overarching policy that will allow for more detailed implementations based on the types of data (e.g., baseline criteria for databases and how they should be shared). She indicated that this could be done by NIH institute. Data sharing plans as part of the proposal may become enforceable in the near future. NIH may consider the plans as part of merit review. NIH is considering the possibility of hosting a workshop in conjunction with the NSF in the near future. COGR will update the community when more information is available.

Fixed Price Subawards. RCA recently submitted an email to Samuel Ashe, Director of the Division of Grants Policy, NIH to get clarification of the change in the NIH Grants Policy Statement relative to the prior approval requirement for fixed price subawards up to the simplified acquisition threshold (\$150,000). See section [8.1.2.11](#) of the NIHGPS, and the [Significant Changes Document](#).

RCA sought clarification on whether prior approval to enter into fixed price subawards applied only to NEW subawards issued on awards with budget periods beginning on or after 10/1/16 since the latest Grants Policy Statement is applicable only to awards with budget periods beginning on or after that date. NIH confirmed that prior approval is only required for **NEW** fixed amount subawards issued on or after October 1, 2016. Existing subawards with incremental funding or other modifications will not be subject to the prior approval requirement **UNLESS** the modification constitutes a change in the scope of work. RCA further asked in its email what the NIH needed from the pass-through entity in order to consider the prior approval request. NIH responded that pass-through entities should provide information demonstrating that any fixed amount subawards proposed in the application or approval request will meet the acceptable conditions [outlined in the Uniform Guidance](#) as identified in 45 CFR 75.201 *Use of grant agreements (including fixed amount awards), cooperative agreements, and contracts*.

Procurement Conflict of Interest. Procurement COI continues to be a problem with agencies such as Department of Justice and Centers for Medicare and Medicaid Services (CMS). The onerous requirements to provide disclosures and other associated forms and assurances are being addressed. COGR plans to meet with the OMB in the near future in order for OMB to gain a better understanding of the issues and burden associated with the Uniform Guidance [provision](#) and the [COFAR FAQs](#). If you have encountered problems in this, please contact jbendall@cogr.edu and share your examples. For more information related to this issue, [click here](#).

Pending items:

Department of Labor Overtime Rule. COGR mentioned in its February update that on 1/25/17 Department of Justice requested that a Louisiana federal appeals court delay case, Nevada v. DOL, 5th Circuit for 30 days in order to allow the Trump Administration to file its brief to defend or kill the rule. The extension to delay the brief, if approved, would have been until March 2nd. No update at this time, however COGR will continue to follow.

Research Terms and Conditions. COGR will be reviewing and summarizing the [Research Terms and Conditions](#) implementing the Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal awards and its associated companion resources (Appendices A – C) when the agency specific terms are available for review. Stay tuned for further updates.

Preprints. COGR will be monitoring the NIH [Open Mike](#) blog and other policy/guide announcements for news related to the most recent [RFI on Preprints](#). COGR expects that overarching guidance will be coming in the near future.