

COUNCIL ON GOVERNMENTAL RELATIONS
1200 New York Ave., NW, Suite 460, Washington DC 20005
(202) 289-6655; (202) 289-6698 (FAX)

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TO: COGR Membership
FROM: COGR Staff
SUBJECT: December 2016 Update

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Procurement Standards and the Micro-Purchase Threshold: One Win Down, One to Go!

We are close to resolution on the stubborn Micro-Purchase Threshold (MPT) issue. The MPT, as specified in [2 CFR 200.67](#), defines the threshold to be consistent with the FAR (currently set at \$3,500). Furthermore, [2 CFR 200.320\(a\)](#), describes “*Procurement by micro-purchases*” as one of the five methods that can be used for procurement actions. While we successfully have delayed implementation of the MPT (and the entire suite of Procurement Standards) by obtaining grace period extensions, eliminating the MPT has remained an ultimate goal.

COGR’s primary focus has been on the highly anticipated Federal Register Notice, which should include a new procurement rule, via modifications to 2 CFR 200.67 and/or 2 CFR 200.320(a). More on that below. With Lewis-Burke Associates and the Association of Independent Research Institutes (AIRI) taking the lead, we have worked closely with them to pursue a legislative solution.

And on the legislative front, the research community has received a win! The National Defense Authorization Act for Fiscal Year 2017, approved by both Chambers of Congress in early December, contains a provision that raises the MPT to \$10,000 for grants, cooperative agreements, and contracts awarded (from all federal agencies) to universities and other research institutions universities. In addition, the provision provides use of a threshold of greater than \$10,000 when selected criteria are met. A summary of where we are as of the writing of this COGR Update is included below.

National Defense Authorization Act (NDAA) for Fiscal Year 2017

Since 2015, Lewis-Burke Associates and AIRI have pursued a legislative solution to the micro-purchase issue. Based on their insights to the legislative process, they determined the annual reauthorization of the NDAA was the right vehicle to address the MPT. COGR provided support as the legislation solution was pursued, and after months and months of hard work on the Hill, the culmination of the process is the following provision in the NDAA:

INCREASED MICRO-PURCHASE THRESHOLD FOR UNIVERSITIES, INDEPENDENT RESEARCH INSTITUTES, AND NONPROFIT RESEARCH ORGANIZATIONS

For purposes of this section, the micro-purchase threshold for procurement activities administered under sections 6303 through 6305 of title 31 by institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or related or affiliated nonprofit entities, or by nonprofit research organizations or independent research institutes is—

(A) \$10,000; or

(B) such higher threshold as determined appropriate by the head of the relevant executive agency and consistent with clean audit findings under 5 chapter 75 of title 31, internal institutional risk assessment, or State law.

The NDAA provision is applicable to funding from all federal agencies. Most research institutions are covered by (A). Those that have a threshold greater than \$10,000 can use a higher threshold, per (B), in coordination with the acceptability of the results of the single audit, internal institutional risk assessment, or State law.

As is the case with all legislation, the Executive branch implements the law. COGR's assessment is that OMB will be the responsible federal agency for implementation, and that the Uniform Guidance (2 CFR 200) will provide the specific implementation guidance.

An additional benefit of the NDAA provision relates to the language that states the MPT is applicable “*for procurement activities administered under sections 6303 through 6305 of title 31 ...*” Effectively, this language captures all funding instruments: Contracts (6303), Grants (6304), and Cooperative Agreements (6305). Our assessment is that even though the FAR, which covers Contracts, will continue to employ the current \$3,500 threshold for contractors, the NDAA language creates a FAR exception for universities and other research institutions when engaged in a contractual relationship with a federal agency.

OMB and the Federal Register Notice

While we had hoped to see the Federal Register Notice in October, OMB continues to assure us that a modified procurement rule will be available soon. In a November 28th update to the COGR Membership, we wrote that the delay has been related to other UG updates that OMB was attempting to incorporate into the Federal Register Notice. One of the other UG updates, specific to the “*Never Contract With the Enemy Act*”, was resulting in significant legal discussions within OMB. In order to expedite the release of the Federal Register Notice, OMB recently withdrew the “*Never Contract*” update from the UG, and final clearance of the Federal Register Notice now is on track.

Once the new OMB procurement rule is published, we believe that that Uniform Guidance (2 CFR 200) and the NDAA provision should dovetail nicely. The new OMB procurement rule will be specific to Grants and Cooperative Agreements. The NDAA provision covers both of these funding instruments, as well as Contracts. The FAR (specific to Contracts), will be amended to allow for an MPT of \$10,000 (or higher). And the language we expect to see in the new OMB procurement rule will reinforce OMB's permission to an institution to use a threshold of more than \$10,000, if appropriate to the institution.

Until we see and fully analyze the new OMB procurement rule, we can only make best guesses. Our expectation is that when the Federal Register Notice is released, we will have 60 days to comment. Obviously, there will be significant transition taking place in Washington as the new OMB procurement rule unfolds; however, our understanding is that the career, non-political professionals who are shepherding this through OMB will remain on the front-line and doing the regular day-to-day business of government.

Of course, this is Washington and little can be predicted with absolute certainty. We appreciate your patience and we will provide updates to the COGR Membership throughout the Holiday Season and into the New Year.

Other Uniform Guidance Updates and the Frequently Asked Questions (FAQs)

In addition to the expected new OMB procurement rule, it is likely that there will be other updates to the Uniform Guidance, which also will be published in the Federal Register Notice. Whether or not these are significant and/or impact our community cannot be predicted at this point. However, we know that OMB and the COFAR plan to release updates to the existing version of the [OMB/COFAR FAQs](#) (dated September 2015). Publication of new FAQs is independent of the Federal Register Notice process, and in theory, should be available with much less fanfare. Still, the FAQs remain delayed.

In August, at the request of OMB and the COFAR, COGR submitted proposed FAQs (the “question” and the proposed “answer”) to OMB. The [COGR Proposed FAQs](#) are available on the COGR website. While we cannot forecast how other updates to the Uniform Guidance and the release of new FAQs may interplay, COGR is cautiously optimistic that important areas of the Uniform Guidance will be addressed, in a positive manner, in the very near future. We will keep you posted on all developments.

F&A and the Uniform Guidance: Unresolved and New Issues

COGR continues to address both unresolved and new issues applicable to F&A, related costing issues, and negotiations. While we are uncertain if any of these issues will be attended to in the Federal Register Notice or in the FAQs, we will continue to pursue fair resolution to each. Our current list includes:

Facilitate the DS-2 Approval Process. We included this item as one of the COGR Proposed FAQs (see link above). We believe this issue could be addressed in either the Federal Register Notice or as an FAQ.

Fix the Utility Cost Adjustment (UCA) Research Weighting Factor. To date, OMB has not formally responded to the [November 2015 COGR letter](#), which proposed a more accurate calculation of the research weighting factor that is the basis of supporting a 1.3% UCA. We will revisit this issue in early 2017.

Use of On-Campus versus Off-Campus rates. The recent DOJ Settlement (see previous COGR Updates) has opened up a discussion on how On- versus Off- (as well as “Vicinity” rates) are defined at an institution and how this translates to the off-campus definition in an institution’s F&A rate agreement. If this requires more engagement between research institutions and the cognizant rate negotiation entities (HHS-Cost Allocation Services, ONR), we will engage, accordingly.

Software Capitalization Threshold. The HHS-Cost Allocation Services west coast region has interpreted a strict \$5,000 capitalization threshold for all forms of software acquired with federal funds. We included a detailed write-up in the [October Meeting Report](#). OMB appears to be interested in addressing this issue and we will engage further in the New Year.

ONR Guidance for F&A Rate Proposals. The Office of Naval Research (ONR) has made available F&A proposal guidance for FY 2018 (FY 2016 base year) and forward proposals. At least one ONR-cognizant institution has raised concern about ONR interpretations on the treatment of interest expense and on cost projections. If your institution has ONR as its cognizant agency, we invite you to contact David Kennedy at dkennedy@cogr.edu to address your perspective and possible concerns as it relates to the ONR guidance.

Post-Retirement Health Plans (PRHP) and Allowability in the Fringe Rate. This issue recently was brought to our attention and involves the allowability of current year PRHP payments associated with prior-year unfunded

liability amounts. The HHS-Cost Allocation Services initially questioned the allowability of these payments and their inclusion in the fringe rate. This issue (as well as Pension Plan payments) also is being pursued by the National Association of State Auditors, Comptrollers and Treasurers (NASACT). Recent correspondence with one of members suggests that there may be a positive resolution to this issue and that it could be addressed in either the Federal Register Notice or as an FAQ.

We will keep the Membership posted on all developments related to the above issues.

2016 COGR F&A Survey: Results Available in Early 2017

Thank you for your help! Over 130 COGR member institutions have participated, and for those who were not able to, we expect to re-open the survey, periodically, during 2017.

We are compiling results now and will release reports and summaries beginning in January. F&A rates and related data will be shown by institution. In addition, we collected “Negotiation Experiences” (to be de-identified), which are captured by HHS-CAS region and for ONR-cognizant institutions. Both the F&A Rates and the Negotiation Experiences will be available to COGR MEMBERS ONLY and upon request. Stay-tuned for a COGR announcement for when the survey results are available.

Costing Policies Committee: Other Issues

The Costing Policies Committee is working on a number of other issues, and will add to the list below, accordingly. Most of these are ongoing issues, which require continued outreach to the stakeholders and the relevant Federal agencies. We have included detailed write-ups on each in past COGR Updates; most recently in the [October Meeting Report](#). Each one remains on our list for 2017 engagement.

Student Financial Aid (SFA) Cluster and the Single Audit. 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, recently wrote a letter to David Mader, OMB Controller. The [November 4th Letter](#) requests a meeting with OMB and the Department of Education (ED) to address ED’s position that a separate annual compliance audit of Title IV Student Aid Programs, including the SFA Cluster, is required. The Association position is that ED’s “separate annual” requirement is inconsistent with and inappropriate under the Higher Education Act, the Single Audit Act, and the Uniform Guidance. We hope to conference with OMB and ED right after the New Year.

F&A Rates and Nonprofit Research and Disease Foundations. COGR participated in a meeting on November 15th, 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. More to come on this initiative in 2017.

HHS Office of Grants Policy Update. Some of the issues we have raised, to date, with the HHS Office of Grants Policy include: 120-day grant closeout model across all HHS ODs, functionality of the Payment Management System (PMS), the prospects for other HHS ODs to join the Research Terms and Conditions, and applicability of the 10% de minimis rate to foreign recipients and training grants. Issues related to grant closeouts are being addressed internally by the HHS Office of Grants Policy and their “Closeout Workgroup”; a report should be available soon. Finally, the HHS Grants Policy Statement (last updated in 2007) is being revised and we expect to engage with the HHS Office of Grants Policy as this gets closer to completion.

Single IRB and Direct Charging. The COGR Research & Regulatory Reform (RRR) Committee is the lead on this issue (see applicable section of this COGR Update), with ongoing engagement by the Costing Policies Committee. With the recent approval of a 4-month deadline extension, which postpones the original May 25, 2017 implementation date of the Single IRB policy, we hope in early 2017 to address with NIH a variety of costing issues raised in NIH Notice Number: [NIH-OD-16-109](#).

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 Request for Application (RFA) or policy regarding Investigator initiated proposals limits costs in terms of maximum direct cost. COGR's position is that off-campus research centers are at a competitive disadvantage – by including the lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. We expect to reengage with NIH on this issue after the New Year.

We will keep the Membership posted on all developments related to the above issues.

COGR Comments on Proposed Bayh-Dole Regulation Changes

On December 9 COGR joined with four other higher ed. associations in submitting comments to NIST on proposed changes to the Bayh-Dole Act implementing regulations (37 CFR 401; <https://www.federalregister.gov/d/2016-25325>; see COGR [October Meeting Report](#)). COGR participated on behalf of the other associations in a public meeting/webinar that NIST held on November 21 to discuss the proposed changes.

The letter noted the success of the Bayh-Dole Act. It stated that any changes to the law and implementing regulations should be carefully considered to avoid undermining or adding unnecessary administrative burdens to this thriving and successful academic tech transfer system. It expressed appreciation to NIST for seeking to enhance the effectiveness and efficiency of the technology transfer infrastructure while protecting Bayh-Dole's basic framework.

The letter identified 10 concerns with the proposed changes. It expressed particular concern about the proposal to require 120 days' notice to agencies if a contractor decides not to continue to prosecute applications or to abandon patents. In addition to raising technical issues about the deadlines for this purpose, the letter expressed concerns about the ability to properly assess technologies for patenting and licensing purposes. Other concerns identified included proposals to change certain other time periods in the regulations, changes in the regulations governing situations with federal and contractor co-inventors, subawards, and invention reporting. Finally, the letter strongly urged that any changes be prospective only, and apply only to new awards made after the effective date, to avoid disrupting ongoing collaborations and other agreements.

In the NPRM that proposed the changes, NIST also asked for comments on five questions. In response the letter suggested changes to accelerate the transfer of federally funded research, discussed issues with provisional patent applications, addressed information sharing mechanisms, and ways to incentivize invention reporting compliance. The many challenges in invention reporting to federal agencies and possible improvements also were discussed.

A copy of the letter is posted on the COGR website. A number of institutions submitted comments endorsing the joint association letter. We understand that the agencies that participate in the Interagency Tech Transfer Working Group will be meeting shortly to discuss the comments submitted on the NPRM.

Drug Pricing Issues Remain Contentious

At the NIST meeting/webinar mentioned above, a number of comments were submitted by James Love of Knowledge Ecology International involving drug pricing and march-in rights. The NPRM stated that it did not address the exercise of march-in rights. We believe NIST will find these comments non-responsive; otherwise it will need to reopen the proposed rule.

Legislative and public concerns about drug pricing continue (see [September](#) and [October Updates](#) for further discussion). In October 34 House Democrats sent a letter to the President urging him to exercise executive authority to lower the high costs of prescription medicines. [The letter](#) specifically urged that NIH be instructed to exercise Bayh-Dole march-in rights to medications developed using federally funded research. A recent online [New York Times article](#) asserted that NIH “has a right under the law to withdraw patents from companies that put drugs out of reach because of high prices” but “it has yet to intervene despite petitions calling on it to do so.”

We believe such statements are based on an erroneous understanding of the scope of the Bayh-Dole Act’s march-in authority. COGR together with the other higher ed. associations will continue efforts to educate Congress and the public about the importance of patents to innovation and university technology transfer, including the development and diffusion of new medicines and medical technologies. AAU and APLU also will encourage their federal relations representatives to work closely with tech transfer offices to develop materials that would be helpful, such as case studies, visuals, etc. It is not clear what position the new Administration may take with regard to these issues.

APLU Establishes Tech Transfer Evolution Working Group

APLU has established a Tech Transfer Evolution Working Group under the auspices of [CICEP](#) (Commission on Innovation, Competitiveness, and Economic Prosperity). The purpose is to catalog effective practices in engagement-oriented tech transfer, and to make recommendations about transforming practices in this direction. An emphasis of this work will be related to re-defining expectations of university leaders and governing boards with regard to the purpose and success indicators for university engagement in innovation and technology transfer. COGR (Bob Hardy) has been invited to participate in this effort, along with a CIP member (John Ritter) and representatives of other associations including AAU, AUTM and UIDP.

The group held its first meeting on December 7. The charge to the working group and the work plan was discussed. The goal is to publish preliminary effective practices in the spring of 2016, and a complete position paper and set of recommendations in conjunction with the APLU Annual Meeting in November 2017. Feedback/input sessions are planned for upcoming UIDP, AUTM, and BIO meetings.

The session on The Expanding Role of Technology Transfer Offices at the COGR October meeting was part of the inspiration for the group. The discussion of the evolution of tech transfer offices from simple patent and licensing functions to the integrated strategic range of activities that characterize those offices today was particularly cited.

Other Transactions Authority Included in CURES Act

The 21st Century CURES Act, signed by the President on December 13, includes authority for NIH to use Other Transactions (OT) authority for the Precision Medicine Initiative (PMI) or for research in emerging areas (“high impact cutting-edge research”) subject to advance approval of the NIH Director and an annual report (Section 2036, High-Risk, High-Reward Research). An evaluation of use of this authority is to be made in 2020.

NIH already was using Other Transactions for the initial PMI awards (see COGR [June Meeting Report](#)). COGR historically has been concerned about the use of OTs to circumvent the Bayh-Dole Act. So far NIH appears committed to normal Bayh-Dole rights under PMI, but we will continue to monitor the situation, including use of the new authority for high-risk, high-reward research.

Updates

Ed. Open Licensing Proposed Rule (See [September Update](#)).

The final rule has been pending for some months. It has not yet been issued. Our sense is there may be disagreements within the government about the advisability of the rule.

NETL Foreign National Approval Requirement.

We understand from COGR member institutions that some progress is being made on the approval of waivers pursuant to the process discussed with the DOE Undersecretary at the October COGR meeting (see [October Meeting Report](#)). We would appreciate hearing from other institutions as to their experiences with the waiver process.

Export Control Developments.

The revised ITAR “heavy lift” definitions have not yet been issued (see [June Meeting Report](#)). On December 5, [several ITAR clarifications](#) were issued. They appear to have little impact on COGR members.

Department of Labor Overtime Rule Blocked

On November 22, a [preliminary injunction](#) was filed by a Texas Federal judge on behalf of 21 states and dozens of business groups blocking the Obama administration’s overtime rule which was to be made effective December 1. The rule would have more than doubled (\$23,660 to \$47,476) the Fair Labor Standards Act’s (FLSA’s) salary threshold for certain executive, administrative and professional employee classes eligible for exemption from overtime pay. The judge ruled that DOL exceeded its statutory authority by raising the salary limit so significantly. DOL has filed an appeal to the injunction, expected to drag the decision well into February after the new administration takes office on January 20, 2017. The College and University Professional Association for Human Resources (CUPA-HR) held an [informational webinar](#) on November 30 about these new developments and what institutions are doing in response. COGR will continue to provide updates as new information unfolds. Contact jbendall@cogr.edu for additional information.

Public Access Working Group

As a result of OSTP’s February 22, 2013 memorandum, [Increasing Access to the Results of Federally Funded Scientific Research](#), COGR has joined with AAU and APLU to form a Public Access Working Group. The working group, comprised of association representatives, campus representatives, provosts, senior research officers, chief information officers, librarians and compliance officers aims to review both challenges and opportunities for universities as they move to implement the public access standards agencies have imposed. The group held its first meeting on December 12 to go over the specific charge: mapping the current space against the OSTP memo that are currently occurring both for publication and data, framing the issues in terms of opportunities, challenges and threats, developing principles, guidance and effective practices, providing ongoing direction for the workgroup to engage with various stakeholders. The first meeting was successful in identifying other issues and opportunities. COGR will provide periodic updates to its members as necessary and welcomes any feedback you have in this area. Contact jbendall@cogr.edu for additional information.

NIH RFI - Preprints

COGR and AAU respond to a October 6, 2016 NIH Request for Information entitled, "[Including Preprints and Interim Research Products in NIH Applications and Reports, NOT-OD-17-006](#)". NIH sought input on the "use of interim research products in NIH applications and reports, and the standards for reporting them." For the COGR/AAU response, [click here](#).

Upcoming Notices

COGR will be responding to the upcoming notices. If you have questions or comments, please send them to jbendall@cogr.edu

DoD NPRMs (series of six, comments due February 6, 2017)

Revised Interim Implementation of Government-wide Guidance for Grants and Cooperative Agreements
<https://www.gpo.gov/fdsys/pkg/FR-2016-11-07/pdf/2016-25702.pdf>

National Policy Requirements General Award Terms

<https://www.federalregister.gov/documents/2016/11/07/2016-25700/national-policy-requirements-general-award-terms-and-conditions>

DoD Grant and Agreement Regulations

<https://www.federalregister.gov/documents/2016/11/07/2016-25717/dod-grant-and-agreement-regulations>

Format for DoD Grant and Cooperative Agreement Awards

<https://www.federalregister.gov/documents/2016/11/07/2016-25699/format-for-dod-grant-and-cooperative-agreement-awards>

Administrative Requirements Terms and Conditions for Cost Type Awards to Non Profit and Governmental Entities

<https://www.federalregister.gov/documents/2016/11/07/2016-25701/administrative-requirements-terms-and-conditions-for-cost-type-awards-to-nonprofit-and-governmental>

Definitions for DoD Grant and Agreement Regulations in Subchapters A-F.

<https://www.federalregister.gov/documents/2016/11/07/2016-25698/definitions-for-dod-grant-and-agreement-regulations-in-subchapters-a-through-f>

NIH

NIH Request for Information: "[Strategies for NIH Data Management, Sharing and Citation](#)." seeks public comments on data management and sharing strategies and priorities in order to consider: (1) how digital scientific data generated from NIH-funded research should be managed, and to the fullest extent possible, made publicly available; and, (2) how to set standards for citing shared data and software." The due date for responses is January 19, 2017.

COGR to Address Proposal Deadlines

COGR will be addressing the Department of Defense (and other agencies) that impose an 11:59 p.m. proposal deadline and request that proposal deadlines be uniformly set to 5 p.m. local submitters time. These later

deadlines place significant burden on research staff for reasons that will be outlined in the letter. If you have an example of a proposal to an agency with a proposal deadline after 5 p.m., please send the information to jbendall@cogr.edu. Stay tuned for information on COGRs listserv.

Research Regulatory Reform

Legislative Efforts to Reduce Federal Research Regulatory Burden

The [21st Century Cures Act](#) was signed into law on December 13. The bill provides funding for the Precision Medicine and BRAIN Initiatives and for the Cancer Moonshot. The Cures Act also includes provisions recommended by the National Academies, National Science Board (NSB) and Government Accountability Office for reducing research regulatory burden, including the creation of a Research Policy Board. A [matrix](#) with recent legislative actions taken to reduce research regulatory burden has been posted to the COGR website. Aspects of the Cures bill specific to the NIH mission were highlighted in a New England Journal of Medicine [article](#) by Francis Collins, NIH Director, published on December 13; among them, lifting restrictions on travel for government scientists, making NIH research exempt from Paperwork Reduction Act requirements, and providing the NIH director the authority to require data-sharing for NIH-supported research. The Cures Act also requires Certificates of Confidentiality (COCs) for research involving identifiable, sensitive information. In response to the initial amendment on COCs from Senator Warren, COGR asked that the COCs issue automatically. The COCs will issue automatically and we understand the notice of award will include COC language. We are told that NIH will look to transition from an application to an automatic process within the next few months.

The American Innovation and Competitiveness Act (“COMPETES”) passed the Senate on December 10 and the House on December 16 and will be signed into law. The bill also includes research regulatory reform measures, as indicated in the COGR matrix, including the creation of an interagency working group on research regulations, and additional efforts to streamline both pre- and post-award requirements. Like the National Defense Authorization Act, which was passed by the House and Senate, the bill increases the micropurchase threshold to \$10,000 with the opportunity for higher thresholds.

Maximizing Investigator’s Research Award (MIRA)/NIH R35 Awards

COGR reached out to NIH staff in early June regarding language in NIGMS funding announcements for the MIRA awards. The announcements stated that “because the MIRA grant is to provide support for the research in an investigator's lab related to the mission of NIGMS, the investigator is required to devote at least 51% of his/her *research effort*...” Similar language was used for the Director’s Pioneer Awards and NHLBI Outstanding Investigator Awards, all R35 awards.

COGR reached out to staff from the NIH Office of Policy for Extramural Research Administration (OPERA) in early June to express concern about the use of the term “research effort” and how it might be converted to institutional base salary, consistent with the Uniform Guidance and institutions’ processes and systems. COGR members Naomi Schrag, Kim Moreland, and Dick Seligman joined COGR and NIH OPERA staff on several calls. NIH staff understood COGR’s concerns and indicated that the term “research effort” will not be used in future solicitations and awards for any NIH Institute or Center. Going forward NIH will only refer to “person months” to align with its current business processes and Grants Policy Statement. COGR understands that with respect to current MIRA/R35 awards, what was outlined in the proposal or revised budget in terms of effort, if accepted by the IC, constitutes acceptance from NIH.

COGR Administrative Burden Checklist

As previously reported, COGR has distributed a [checklist](#) with over 100 actions that have the potential to reduce the administrative work associated with sponsored awards at member institutions. A number of institutions have submitted completed checklists to COGR. We are very interested in hearing about actions your institution has implemented or may implement and actions that might be added to the list. Checklists, whether fully or partially completed, can be submitted to [Lisa Nichols](#). COGR will provide an assessment of the use of the checklists in future communications.

Human Subjects Research

NIH Single IRB Policy Effective Date

On October 24, COGR, AAMC, APLU and AAU submitted a joint [letter](#) to NIH requesting that the effective date for the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research, scheduled to take effect on May 25, 2017, be extended by one year. COGR and NIH staff discussed the letter on an October 28 call and additional information was provided via email on November 8.

As indicated in a December 8 email to the listserv and announced in an NIH [notice](#) issued on December 16, the effective date for the NIH Single IRB Policy will be extended to September 25, 2017. In addition, NIH has released [FAQs](#) related to the implementation of the policy. COGR appreciates this extension and the opportunity to continue discussions with NIH to resolve remaining questions and concerns.

NIH Good Clinical Practices Training Requirements

On October 6, COGR sent a [letter](#) to NIH requesting an extension of the January 1, 2017 effective date for the Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials and suggested that the policy should apply only on a go-forward basis. In a November 21 [letter](#), NIH opted not to extend the January 1 implementation date or to apply the requirement only to new awards. Per the letter, “We understand that the first of the year is fast approaching, but we continue to believe that meeting the expectations of the policy will be manageable for institutions. Since GCP training can be beneficial at any point in the life cycle of the trial, we did not limit the policy to new awards. However, institutions should not regard the policy’s effective date as a deadline by which we would expect all staff involved in the conduct, oversight, and management of clinical trials to be GCP trained. Rather, as long as steps are being taken to meet the expectation, e.g., staff who have not yet been trained have signed up for a course, the training itself can be taken in a timely fashion after the effective date.” While not the response we had hoped for, we do appreciate the flexibility provided with respect to the suggestion that institutions not regard the policy’s effective date as a deadline by which all pertinent staff should be GCP trained and anticipated clarification of the policy in the form of FAQs.

NIH has made GCP [training modules](#) specific to social and behavioral research available for download. The modules must be uploaded into a learning management system. If you have difficulty uploading the modules, send an email to [Jessica Krogstadt](#) at NIH for assistance.

The GCP policy indicates that [NIAID](#) or [National Drug Abuse Treatment Clinical Trials Network](#) GCP training courses are acceptable training courses. Per the FAQs for the NIAID training, “A score of 90% on the optional Pre-test allows you to immediately earn a certificate of completion. Once the course has begun, the Pre-test will no longer be available. You will only be given a Pre-test score, but no feedback on each question. You may also demonstrate understanding of individual topics, allowing for navigation through the understood topic.” More experienced personnel may want to opt to take the pre-test.

HHS Office for Human Research Protections (OHRP) Guidance and Notices

OHRP and the Food and Drug Administration (FDA) published the final guidance *Use of Electronic Informed Consent in Clinical Investigations-Questions and Answers; Guidance for Institutional Review Boards, Investigators, and Sponsors* on December 15. Per a Federal register [notice](#), “the guidance provides recommendations on the use of electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products...” The guidance can be found on the [HHS website](#).

OHRP has also announced the appointment of new members of the Secretary’s Advisory Committee on Human Research Protections (SACHRP). They include Sandra Berry, Chair, Human Subjects Protection Committee, RAND Corporation; James Giordano, Chief, Neuroethics Studies Program, Pellegrino Center for Clinical Bioethics, Georgetown University Medical Center; Aviva Katz, Director, Consortium Ethics Program, University of Pittsburgh; and Leslie Wolf, Professor and Director of the Center for Law, Health & Society, Georgia State University College of Law. Stephen Rosenfeld, Chair, Quorum Review IRB replaces Jeff Botkin as SACHRP Chair.

Audit

National Science Board November 2016 Audit and Oversight (A&O) Meeting

The NSB Committee on Audit and Oversight [met](#) on November 8. Among the areas discussed were NSF’s use of management fees, new rules under consideration by Members of Congress that could restrict their use, and the agency’s response to the NAPA report and plans for use of management fees going forward.

Joanne Turnow, NSF’s Chief Human Capital Officer, discussed change pertaining to the agency’s Intergovernmental Personnel Act (IPA) Program including the creation of an IPA Steering Committee and three task forces. Discussion on changes to the IPA Program was included in the October COGR meeting report. NSF will be piloting a mandatory 10% cost share for new IPAs in 2017 in response to recent OIG recommendations. Currently NSF employs a voluntary 15% cost share. Concerns were expressed about a potential decline in the quality of applicants and the ability of some institutions to cost share but others thought it was reasonable. NSF will assess the impact of the pilot on recruitment and retention over the coming year. Some institutions (42 of 110 will be paying less than in prior years); 60% of those that will be paying less are public institutions.

HHS and NSF Office of Inspector General (OIG) FY17 Audit Work Plans

The HHS OIG posted its [Work Plan](#) for FY17 on November 10. COGR and HHS OIG staff met on December 12 to discuss the work plan. The OIG plans to review colleges’ and universities’ compliance with the Uniform Guidance cost principles and NIH controls over subrecipient monitoring. The HHS OIG has initiated audits of subrecipient monitoring. The OIG is currently auditing one university but is looking to audit additional institutions with respect to risk assessments and monitoring. They will be looking at adherence to the requirements in the Uniform Guidance while taking into consideration evolving expectations for subrecipient monitoring with respect to 21st Century Cures and planned FAQs/OMB efforts but still anticipate moving forward with these audits. The HHS OIG will also be looking at NIH controls to ensure the privacy and protection of data for individuals participating in the Precision Medicine Initiative or other initiatives, including oversight of third party data providers.

The OIG is in the final stages of completing its report on the FDP payroll certification pilot at the University of California, Riverside, and plans to release the report in a few weeks. The HHS and NSF OIGs will not release a

capstone report as previously planned. OIG staff suggested that OMB and universities have moved forward and such a report would not be as relevant in the current environment. They suggested that there are core principles that can be derived from the individual pilot reports. NSF OIG staff indicated in a meeting with COGR staff on December 13 that they are preparing a letter to OMB in lieu of the capstone report and anticipate that this letter will be made publicly available.

Mark Bell, who replaced Brett Baker as the Assistant Inspector General for Audit, presented on the NSF OIG [FY17 Audit Work Plan](#) at the November NSB meeting. Mark previously served in the same role at the Department of Homeland Security. He indicated that it was his goal to work cooperatively with the agency; to offer an outside look at economies and efficiencies that the agency can attain; and to look for fraud, waste and abuse.

In 2017, the OIG plans to focus on internal controls, not just incurred costs, as a means to prevent repeat findings and at subrecipient monitoring. The NSF OIG's Semiannual Report to Congress suggests that some subrecipients have provided incomplete information in their incurred cost submissions. The NSF OIG is in the early planning stages of this audit. Regarding disallowed costs for senior personnel salary, NSF OIG staff indicated in a December 13 meeting with COGR that they will no longer audit on senior personnel salary exceeding two months {emphasis added} unless the data has already been compiled.

OIG Semiannual Reports to Congress

The NSF OIG released its [Semiannual Report to Congress](#) on December 1. The report includes recent audits of three NSF awardees and questioned costs of close to \$3million in senior personnel salary charges exceeding two months. The report briefly describes the audit resolution process, in particular, that if NSF does not agree with OIG recommendations, the OIG can elevate the recommendation to the agency's follow-up official (senior management) for resolution. The report indicates that during the applicable period for this semiannual report, a recommendation related to questioned costs for senior personnel salaries exceeding two months was elevated. The follow-up official indicated that the university treated all instances of excess salary in accordance with agency policy. Per the report, "This is the fourth time since March 2015 that we have referred matters related to questioned senior salary costs that exceeded the two-month limit to the Audit Follow-up Official. None of the \$2.4 million referred on those four audits has been sustained. Although we continue to disagree with NSF's final decisions in these cases, we will not refer similar findings to the Audit Follow-up Official in the future" {emphasis added}.

An NSF OIG review of single audit findings for 86 audit reports with expenditures of approximately \$3.6 billion identified \$1.1 million in questioned costs and reports of 65 "material weaknesses and/or significant deficiencies in internal control over compliance." As noted above, the OIG will audit internal controls and subrecipient monitoring in FY17 and are likely to include a focus on those areas found to be deficient in single audit. The OIG is seeking to stem repeat findings by focusing on internal controls. Thirty of the findings were repeated from the prior audit.

The semiannual report also raised the Intergovernmental Personnel Act Program as a top management challenge for NSF, highlighting turnover, higher costs for salaries and benefits that exceed federal limitations, greater use of IPAs by NSF than similar federal agencies, in particular for management positions, and that the program permits IPAs to continue their research raising "questions about their ability to fulfill their responsibilities at NSF and to be fully engaged in the agency's mission." The report also raises concerns about conflicts of interest and the need for strong controls to identify and mitigate them and indicates that the OIG will audit NSF's controls over IPA's COIs. This issue is also addressed in the COMPETES bill that is expected to be voted on early in the next session of Congress. The bill would require the Director to update policies and procedures to improve documentation and management of conflicts of interest for IPAs and others on temporary assignment.

The bill would also require the agency to submit written justification for each IPA paid at a rate exceeding that for the Senior Executive Service to the appropriate committees of Congress and to report within one year of enactment on NSF's efforts to control costs associated with employing rotators.

With respect to Responsible Conduct of Research (RCR) training, the report indicated that information collected during investigations, site visits and reviews of RCR plans suggest that "some institutions have not adopted an effective approach" to training or "emphasized research integrity as a core value." The semiannual report suggests that a primary challenge for NSF is to ensure institutions implement effective RCR programs. The NSF OIG hopes to issue a report on their review of responsible conduct of research this month or next. The HHS OIG also released its [Semiannual report to Congress](#) on November 10. University and related audits were not a focus of this report.