COGR

Council On Governmental Relations

An Association of Research Institutions

September 8, 2017

TO: COGR Membership

FROM: COGR Staff

SUBJECT: September 2017 Update

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New Appointees at OMB: Deputy Director & Controller

The President named Margaret Weichert to be deputy director for management of the Office of Management and Budget, as well as Frederick Nutt to be controller in OMB's Office of Federal Financial Management. Currently a senior advisor at OMB, Weichert has worked in business for over 20 years, including her time with Bank of America and First Data Corporation. She is listed as an inventor on 14 U.S. patents in payment technologies and earned a degree in Foreign Service at Georgetown University and a master's in business administration from UC-Berkeley. Nutt, also currently a senior advisor at OMB, has worked as a senior advisor to the chief financial officer at the Environmental Protection Agency and the Overseas Private Investment Corporation, and is a graduate of Virginia Tech.

The Administration's Efforts to Cut F&A: An Update

In the June Meeting Report and throughout the Summer, COGR has reported on the status of the Administration's efforts to drastically cut F&A reimbursement on federal awards. At the heart of this effort was the Administration's FY 2018 budget request, released in late May, which called for the National Institutes of Health (NIH) F&A reimbursement to be *"capped at 10 percent of total research"* in an attempt to *"bring NIH's reimbursement rate for indirect costs more in line with the reimbursement rate used by private foundations, such as the Gates Foundation, for biomedical research conducted at U.S. universities."*

An **Association F&A Working Group** comprised of COGR, the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), the Association of Public Land-grant Universities (APLU), and the Association of Independent Research Institutes (AIRI) joined forces, beginning in March, to develop educational and advocacy materials when the President's "skinny budget" first hinted at such a change and HHS Secretary Tom Price indicated in House testimony that the agency was considering a cap on F&A. As Spring turned into Summer, other associations joined the Working Group and leaders from your institutions became actively engaged to create a unified voice.

As we enter into the Fall season, here is where things stand:

1) The Working Group was successful in getting language into the HHS/NIH appropriations bill that would block HHS and NIH from imposing any restrictions on the payment of F&A on NIH grants. This was due to the extensive groundwork and collaboration by the Working Group to inform key legislators and Committee staff on the devastating impact the Administration's proposed cuts would have on research.

2) However, as announced this week, it appears that the Federal government will operate under a three-month Continuing Resolution (CR). Anticipating this outcome, the Working Group was successful in getting the language (see Section 138) that would block any reduction to F&A payments into the CR.

3) A Community Letter, dated August 21st, signed by 109 Higher Education Association and Scientific groups, was sent to OMB Director, Mick Mulvaney, and HHS Secretary, Dr. Thomas Price, to reiterate the value and importance of reliable F&A reimbursement to support the research infrastructure. The Community Letter demonstrates united opposition to the

Administration's proposal and follows over 115 letters written by your institutions to Director Mulvaney and Secretary Price earlier in the Summer. These letters have made a significant impact in shifting the dialogue from "harmless budget cuts" to "devastating cuts to research", and have prompted several Senators to speak out against F&A cuts. Again these efforts are the result of significant collaboration among the Association F&A Working Group and your institutions.

4) Ongoing outreach to the Private Foundation and Disease organizations continues. COGR is leading this outreach initiative to create a partnership where we can work together to better understand challenges and to develop solutions related to F&A reimbursement, reporting and administrative burden, and IP-related issues. The outreach effort is partly designed to refute concerns by public officials that research institutions provide preferential treatment to these types of organizations.

5) Bi-partisan support is key to successfully opposing any proposed cap on F&A reimbursement. The Association F&A Working Group is focused on outreach to both sides of the aisle, and while addressing F&A always is a delicate issue, bi-partisan support for our position has been encouraging. At the same time, we are in the process of updating and finalizing several documents related to regulatory reform. No matter who is in charge of the Administration or Congress, reducing regulations generally is a bipartisan issue.

Since the Working Group began meeting in the Spring, we have developed a wealth of robust and thoughtful documents. We will continue to make these documents available, including suggestions for how the Membership might use or adapt the materials.

Our combined efforts have had a significant impact and we are cautiously optimistic that we will be successful in turning back the Administration's effort to cut F&A. However, more work remains and the Association F&A Working Group will continue to meet on a weekly basis into the Fall, and beyond as necessary. As events unfold, at times rapidly, we will keep the Membership posted on all developments related to this work.

Procurement Standards: What's Next Now that the Grace Period has been Extended?

The May 17, 2017 Federal Register Notice confirmed a one-year grace period for implementation of 2 CFR 200.317-326 (Procurement Standards). For most COGR members, this means that 2 CFR 200.317-326 must be implemented on July 1, 2018. Per the Federal Register Notice:

> *For all non-Federal entities, there is an additional one-year grace period for implementation of the procurement standards in 2 CFR 200.317 through 200.326. This means the grace period for non-Federal entities extends through December 25, 2017, and the implementation date for the procurement standards will start for fiscal years beginning on or after December 26, 2017.*

In the June Meeting Report we provided OMB and COGR comments on what the grace period means, especially in the context of the Micropurchase Threshold (MPT). Per OMB: *Non-federal entities who wish to take advantage of this grace period must document this internally {emphasis added}, continue to*

follow the standards in prior OMB guidance, and begin preparing for implementation of the procurement standards prior to the end of this third and final extension.

And per COGR: The MPT you are using (e.g., $5,000, $10,000, $25,000, etc.) remains effective until the new implementation date. For those institutions that exceed $10,000, the one-year extension gives you cover to continue following your policies implemented under OMB Circular A-110. However, COGR recommends documenting your justification for exceeding $10,000 so that you are in compliance with the National Defense Authorization Act (NDAA; i.e., *(A) $10,000; or (B) such higher threshold as determined by the head of the relevant executive agency and consistent with clean audit findings under chapter 75 of title 31, internal institutional risk assessment, or State law*). As necessary, COGR recommends you consult with your Single Auditors and/or General Counsel for your institution.

Still, COGR's position is that OMB Implementation Guidance of the MPT is necessary. We believe OMB is sensitive to the need for this guidance. Further, in addition to the NDAA (which applies to grants and contracts for all agencies), the American Innovation and Competitiveness Act (AICA) passed in January has similar (though not identical) language. The AICA defines the same $10,000 MPT and is applicable to NSF, NASA, and NIST. Ideally, we'd like to see OMB guidance via revisions to the Uniform Guidance (2 CFR Part 200.317-326), though at a minimum, some form of an OMB "instructional guidance" document would be helpful.

COGR will reach out to OMB throughout the Fall to determine status and we will keep the Membership posted on all developments.

OMB Releases Updates to the Uniform Guidance FAQs

OMB released updates to the Frequently Asked Questions for the Uniform Guidance (2 CFR Part 200). The FAQs are dated July 2017 and include 24 new FAQS and 4 revised FAQs.

Below is an initial assessment of those FAQs identified by COGR as possibly raising questions. Feedback from the COGR Membership is encouraged! As appropriate, we will reach out to OMB to request clarification and/or updates.

1) ***FAQ .33-1 Capitalization Level for Software.*** COGR has raised the concern over the past year that Cost Allocation Services (CAS) has interpreted the UG to mean that all software meets the definition of equipment and, therefore, $5,000 is the maximum capitalization threshold in all situations. This would be inconsistent with GAAP and longstanding and accepted institutional-specific definitions. The FAQ seems to support COGR's position by stating that a $5,000 threshold only "… *encompasses purchased software that comes with the hardware with a unit cost greater than $5,000*." For example, MS Word should be capitalized when bundled into a hardware acquisition for $5,000 or greater. However, if, for example, current institutional policy specifies a $1 million software capitalization threshold, the following situations would not require software to be capitalized: $40,000 software acquisition purchased on federal funds that is necessary to do research; $500,000 financial applications software product used in the general administration of the institution; and other situations where the software acquisition is less than $1 million.

2) ***FAQs .56-1 and .56-2.*** These two FAQs attempt to clarify definitions and applications of indirect and administrative costs, as well as indirect and administrative caps. Initial analysis suggests that neither FAQ is applicable to typical research awards that our institutions receive; however, as some non-research programs may be affected, additional clarification from OMB may be necessary.

3) ***FAQ .320-1 Methods of Procurement – Micro vs. Small vs. Over Threshold.*** NOTE, this FAQ was not revised. However, it continues to refer to a $3,000 micropurchase threshold. This suggests that once OMB officially addresses the new micropurchase threshold as specified by Congress in recent legislation (see previous section), this FAQ will need to be updated.

4) ***FAQ .430-3 Methods for Documenting Personnel Costs.*** This clarifies that federal entity approval of new methodologies to document personnel costs (2 CFR 200.430(i)(1)) is not required. Still, when institutions make changes to their effort reporting and/or payroll documentation systems, COGR recommends completing due diligence, which includes working with your single auditors and other appropriate entities.

5) ***FAQ Appendix III-5 Effective Square Footage and UCA Calculations – Single Function.*** This FAQ is narrowly focused by stating that a building cannot be classified as 100% organized research. Generally, this is true and institutions rarely would classify a building as 100% organized research. What is confusing about this FAQ is that it continues by addressing students and their use of space, which seems irrelevant to the intent of the FAQ. As appropriate, COGR will request additional clarification from OMB.

COGR wrote a letter to OMB last August, at OMB's request, entitled Proposed FAQs for the Uniform Guidance. Unfortunately, none of the proposed FAQs (including the DS-2, "Safe Harbor" for Subrecipients, and the Utility Cost Adjustment) raised in this letter were addressed in the recently released FAQs. Still, COGR's view is that the Uniform Guidance will require updating (sooner rather than later) to incorporate new federal policies and statutes, including statutory requirements under the NDAA and AICA (see previous section), so there could be opportunities to address Uniform Guidance issues that still are of concern.

Single Audit Update

The 2017 Compliance Supplement (2 CFR Part 200, Appendix XI) was officially posted to the OMB web site in August. The 2017 CS provides direction to your single auditors to guide the single audit process taking place at your institution for the 2017 fiscal year. COGR is engaged on several issues related to the single audit and these are summarized below. Also note, OMB is accepting public comments on the 2017 CS and these can be submitted as specified below:

Public Comments to 2017 CS due October 31, 2017. Comments may be submitted to Gilbert Tran at hai_m._tran@omb.eop.gov. Include "2 CFR Part 200 (select citation) Subpart F-Audit Requirements, Appendix XI-Compliance Supplement-2017" in the subject line and the full body of your comments in the text of the email and as an attachment. Include your name, title, organization, postal address,

telephone number, and email address in the text of the message. Comments may also be sent through regulations.gov.

Reimbursement/Advance Payment Methodology – COMMENTS TO OMB, GILBERT TRAN, ARE ENCOURAGED. Recently, auditors have challenged COGR member institutions by suggesting that grants and cooperative agreements should be subject to a strict interpretation of the reimbursement methodology. Specifically, the auditor position is that prior to billing a federal sponsor for reimbursement, the institution must have evidence that the institution's payment to the vendor has been cleared. This is in conflict with the longstanding practice where reimbursement is requested after a vendor has been billed and the transaction has been posted in the Accounts Payable system. The source of this new audit approach has been generated by the IG community. COGR actively has pursued this issue with Federal government representatives, as well as representatives from KPMG, PwC, and the AIPCA. **COGR will be providing comments to OMB, Gilbert Tran,** and we will share a template of our letter with the Membership later in September.

Securing Student Information, Department of Education (ED). COGR has worked with several of our Association partners to raise concerns as to how ED has proposed audit objectives related to safeguarding data specific to an institution's information security program (i.e., Safeguards Rule). ED withdrew their initial inclusion of audit guidance from the 2017 Compliance Supplement. While COGR's position is that the Compliance Supplement is not the correct vehicle for this guidance, ED is now working with the community to include more reasonable language in the 2018 Compliance Supplement.

Annual Compliance Audit, Student Financial Aid (SFA) Cluster. A Department of Education *Dear Colleague Letter* from last August was the basis for an ED position that an annual compliance audit of the SFA is required. This is inconsistent with the 2 CFR Part 200. However, we have been notified that in at least one state, the State Auditor's Office (SAO) indicated the Participation Division of the Department of Education has decided that all higher education institutions covered by the statewide single audit for fiscal year 2017 will be considered compliant with the Title 34 CFR 668.23 annual compliance audit requirement for HEA Title IV programs, even if the institution has not been selected to have their specific federal student aid programs audited by the SAO. Prior to this development, schools covered by the SAO for their single audit would have been required to contact their Participation Division for further guidance. This is a positive development, though at this stage we are uncertain if this is an isolated case.

Again, we encourage your institutions to submit comments on the 2017 Compliance Supplement to OMB, Gilbert Tran. Contact David Kennedy at dkennedy@cogr.edu if you have questions on how to best craft your concerns to OMB.

Costing Policies Committee: Other Issues

The Costing Policies Committee is working on a wide range of other issues. Some of these are ongoing and have been covered in past COGR updates. As appropriate, each one will remain on our list for 2017 engagement.

Update on "Alternatives to Effort Reporting." A national cohort of institutions and their leadership group is actively reaching out to the research community to present alternatives to effort reporting, with a focus on the internal control framework. In the backdrop of the national cohort's work is the consistent message from OMB encouraging institutions to pursue alternatives. However, buy-in from the IG Community remains uncertain. A June 21st NSF OIG Memorandum from Mark Bell, Assistant IG, addressed to OMB, was noncommittal in the NSF IG's support of the FDP Pilot Payroll Certification Program. The NSF IG highlighted two observations in their memo: monthly/bi-monthly reconciliations and provide full allocations to PIs. COGR's position is that alternatives that comply with 2 CFR 200.430(i)(1), **and equally important, that significantly can reduce burden,** should be advanced. We expect to continue this discussion with the COGR Membership at the October COGR Meeting.

Single IRB and Direct Charging. The Research and Regulatory Reform (RRR) Committee continues to follow this topic, including developments related to the new January 25, 2018 implementation date. From a costing perspective, the primary focus has been on the costing FAQs. The most recent version of FAQs for the NIH Policy on the Use of a Single IRB for Multi-Site Research Costs is available at the NIH Office of Science website.

Equitable Treatment of Off-Campus Research Centers in NIH RFAs. This has been an ongoing "niche" issue to encourage NIH to devise a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. Off-campus research centers are at a competitive disadvantage; i.e., by being required to include lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. We hope to resolve this longstanding issue soon.

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.

COGR Submits Comments on DFARS 7000 Clause

On August 29 COGR/AAU submitted comments on the DFARS 7000 clause. The comments were in response to the Executive Order 13777 regulatory review request for comments on DFARS solicitation provisions and contract clauses that may be appropriate for repeal, replacement or modification.

The comments focused on the parenthetical statement in the revised version of the clause last year that fundamental research "…by definition cannot involve any covered defense information…" We expressed the view that it is possible for fundamental research to take place using covered defense

information as background information only, with the intention of unrestricted dissemination of the research results. Examples were provided in the comments.

We asserted that in such cases it is possible to ensure the necessary safeguarding or dissemination controls for the covered defense information while still providing for unrestricted dissemination of the research results, citing experience with export controls. Our bottom line was that conflating the *input* of any covered defense information, with the conduct or output of research in making the determination of fundamental research is overly broad and absolute. This is to the detriment both of universities and DOD. We suggested that the DFARS be modified accordingly.

A copy of the comment letter is posted on the COGR website.

Debate Over March-In Rights and Drug Pricing Continues to Heat Up

Developments continue to heat up involving the possible use of march-in rights under Bayh-Dole to control drug prices.

FDA Hearing

A hearing was held by the Food and Drug Administration (FDA) on July 18. The focus was to be on balancing innovation and access under the Hatch-Waxman Act. However, the Director of KEI was one of the presenters. He suggested expanding march-in rights to cover any product regulated by the FDA. He was asked to further expand his comments. Hatch-Waxman author Henry Waxman suggested use of march-in to address unreasonable pricing, and another witness suggested further expansion of march-in. See https://insidehealthpolicy.com/daily-news/experts-push-expanded-%E2%80%98march-rights%E2%80%99-way-bring-down-prices.

KEI has long advocated and petitioned NIH to use march-in rights to address drug pricing concerns (see COGR May Update). In our view this is a misinterpretation of the statutory language and legislative history of the Bayh-Dole Act. The FDA meeting docket is open until September 18. We plan to submit comments jointly with AAU, APLU and AUTM, stressing this point. The letter also will state that use of march-in for this purpose would seriously threaten university technology transfer and adversely affect innovation.

NDAA Directs DOD to Use March-In for DOD-Funded Drugs

An amendment was added by Sen. King (I—ME) to the Senate Armed Services Committee Report for the FY ’18 National Defense Authorization Act. It directs DOD to use march-in authority to compulsory license inventions “that benefited from DOD funding whenever the price of a drug, vaccine or other medical technology is higher in the U.S. than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the U.S.” (https://congress.gov/congressional-report/115th-congress/senate-report/125 p. 173).

This directive raises similar issues as the FDA discussion. (For a good analysis see https://www.natlawreview.com/article/senate-armed-services-committee-directs-dod-to-reduce-drug-prices). There are obvious issues in interpreting and implementing this provision (e.g. what constitutes

"inventions that benefitted from DOD funding;" how and by whom median price is to be determined). It is not clear whether DOD has statutory authority to use march-in compulsory licensing for this purpose. It also raises potential jurisdictional issues within Congress, since the Armed Services Committee does not have jurisdiction over Bayh-Dole.

We contacted DOD to express these concerns. We suggested they contact NIH to learn more about NIH's experience and concerns about the use of march-in rights. We also discussed with AAU and APLU federal relations representatives the possibility of having this issue addressed in the House—Senate conference on the NDAA this month.

However, should this language not be further addressed or modified, DOD presumably will have to determine whether and how to comply. We expect to have further discussions with DOD as events unfold.

Legislative Initiatives on March-In—Sanders/DeFazio bills (S. 1681; H.R. 3536)

These bills would prohibit conveying any federally-funded patent for a drug, biologic or other medical technology until the receiving entity agrees to a reasonable pricing agreement with HHS or receives a determination that a waiver is in the public interest. The reasonable pricing formula is to be determined with reference to prices charged in other OECD countries.

The June Meeting Report mentioned the concerns raised by Sen. Sanders about the Army's plans to exclusively license a Zika vaccine to Sanofi. Sen. Sanders and others had asked for a delay until Sanofi agreed to a reasonable pricing provision. The proposed legislation appears primarily aimed at this situation, although similar legislation has been introduced by Sen. Sanders and Rep. DeFazio in previous years. It presumably also is intended to impact drugs developed by universities and other non-profit institutions under the Bayh-Dole Act. (Note: on September 1 Sanofi announced it no longer planned to seek a license to the Zika vaccine. This followed on HHS's decision to curtail further development, based on the slowing of the Zika epidemic. See http://www.fiercepharma.com/vaccines/contract-revamp-sanofi-s-zika-collab-u-s-government-to-wind-down).

The Sanders bill is at https://www.congress.gov/bill/115th-congress/senate-bill/1681/text?q=%7B%22search%22%3A%5B%22sanders%22%5D%7D). The DeFazio bill is identical (https://www.congress.gov/bill/115th-congress/house-bill/3536?q=%7B%22search%22%3A%5B%22defazio%22%5D%7D).

Other March-In Legislative Developments

During the House mark-up of the Labor-HHS Appropriations bill in July Rep. Kaptur (D—OH) offered an amendment that would have directed HHS to exercise march-in on any HHS-funded drug, vaccine or medical technology under the same circumstances as set forth in the King NDAA Senate Report provision. The amendment was not accepted. Rep. Doggett (D—TX) proposed a similar amendment to the House version of the NDAA that was not accepted.

As a reminder, the COGR April Current Developments mentioned that on April 4, 51 Democratic members of Congress, led by Rep. Doggett, sent a letter to the President urging him to invoke "taxpayer protection rights" allegedly provided by the march-in authority. We are not aware of a response to that letter.

DEI Request for Reconsideration of March-In Petition Still Pending

The May Update mentioned that in April KEI submitted a new petition jointly to HHS and DOD requesting reconsideration of the denial of the petition by the Obama Administration last year for march-in on the prostate cancer drug Xtandi. To date there has been no response to this request.

COGR Discusses Implementation of Open Licensing Requirement with ED.

Recent COGR Updates and Meeting Reports have discussed the Dept. of Education (ED) open licensing requirement for grant deliverables developed with Ed. discretionary grant funding. The requirement was effective May 21. The June Meeting Report noted that ED had invited COGR, AAU, and APLU to discuss further our concerns with them, particularly with regard to the exception process. (See May Update for additional discussion of our concerns).

ED previously had suggested that we look into the TAACCT DOL program, which also has an open licensing requirement. We did so. The TAACCT program is a highly specialized program that funds development of job training materials mostly by community colleges in collaboration with local businesses. All materials are subject to a Creative Commons license. The materials are designed for specific industry partnerships in specific fields. Our view was that this model is of limited relevance to the ED requirement, which affects a much broader range of activities and participants.

On August 24 a conference call was held between the associations (including AUTM), several institution representatives, and an ED representative. We were advised that while the requirement still is in effect, ED is reorganizing its administrative structure and facing a reduction in discretionary grant funding. At this point they plan to take a limited case-by-case approach to implementation, working with the responsible program officers. They also plan a greater focus on outcomes. ED also is planning to hold two public hearings on regulations and guidance relating to postsecondary education as part of the EO13777 review process. In addition, the EO 13777 public comment period has been extended to September 20

Each ED grant application notice beginning October 1 will include specific instructions on licensing. Dissemination plans in proposals should document how materials will be distributed, and distinguish new materials that will be developed if to be added to existing platforms. In response to a question about requests for waiver of the open licensing requirement based on quality control concerns, the Ed. representative stated that after a grant is awarded, a waiver request could be made based on a number of criteria that purport to accelerate access and use of the content. ED also recognizes that proposals involving public—private partnerships (e.g. an institution working with a publisher) may be appropriate for waiver requests.

ED does not plan to issue additional formal guidance, but is open to developing FAQs or q's and a's, particularly in the initial application notice. These also could be included in subsequent notices. ED

also recognizes that there could be complexities in projects that include support both from IES (which is not subject to the open licensing requirement but rather to the public access requirement for deposit in ERIC) and other ED programs. These will be addressed case-by-case.

Our conclusion was that ED's current implementation is tentative, and may be subject to further change as structures and organizations evolve within ED. Given the additional budget uncertainties, it is not clear what if any impact the open licensing requirement ultimately will have. Still, while the impact may be limited, the rule has not been rescinded. In response to the EO 13777 review, we will again urge ED to rescind the requirement.

Supreme Court Grants *Cert* in Oil States Case

A number of concerns have been expressed about the *Inter Partes Review* (IPR) procedure established by the American Invents Act (AIA). As mentioned back in the February 2012 COGR Meeting Report and other previous meeting reports and updates, COGR and the other higher ed. associations had been proponents of the IPR procedure during the AIA process. However, there is a growing perception that IPR has been used abusively mainly by large companies to challenge and/or invalidate a large number of patents including university patents (See also COGR June Meeting Report on sovereign immunity and IPR challenges).

In June the Supreme Court granted *certiorari* in the case of *Oil States Energy Services v Greene's Energy Group* (No. 16—712). The case focuses on the constitutionality of IPRs. The issue identified by the Court is "Whether IPR, an adversarial process used by the PTO to analyze the validity of existing patents, violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury." See http://www.iam-media.com/blog/Detail.aspx?g=b68adc68-cdb9-4a2d-a957-1c9bce7dfedb . For more details on university perspectives see http://techtransfercentral.com/2017/08/30/supreme-court-takes-up-inter-partes-review-is-relief-in-sight/.

BIO has filed an *amicus* brief on the side of the petitioners. AUTM has joined the BIO brief. The main issue discussed in the brief is whether patents convey private rights or "public rights" like Social Security benefits. The BIO brief contends it is the former, and the IPR process does not offer sufficient safeguards to protect them. Another related case pending before the Supreme Court, *SAS Institute v. Lee*, involves whether IPRs can be instituted on less than all claims of a challenged patent. This case may be moot if the Court dismantles the IPR system in its decision on the *Oil States* case. Legal commentators differ on the likely outcomes.

Updates

Controlled Unclassified Information

According to the latest open FAR Case (2017—016), the report due date for the draft FAR clause has been delayed again, until September 13. Also as a reminder, the requirement of DFARS Clause 20.252-7012 to notify the DOD CIO of any NIST security requirement not implemented by the time of contract award expires October 1. According to DOD, after that contractors should be preparing for full implementation by December 31 (see COGR October 2016 Meeting Report) for further discussion). Presumably the December 31 deadline does not apply to approved variances.

Revised Bayh-Dole Implementing Regulations Remain on Hold

The revised Bayh-Dole implementing regulations that we discussed with the NIST General Counsel in February (see COGR February Meeting Report) remain on hold. According to NIST they still are under review by the Commerce Department. While NIST is optimistic they should be issued within a month, they also may require another round of agency comments. This is likely to result in further delay. Also there are rumors that OMB may be considering ways to better facilitate technology transfer. This obviously could have an effect.

Co-Sponsors Sought for STRONGER Patents Act

The June Meeting Report discussed the STRONGER Patents Act introduced by Sen. Coons. Bipartisan co-sponsors are being sought as well as for a House companion bill. The higher ed. associations plan to endorse the bill.

AAU and APLU to Host University Innovation and Entrepreneurship Showcase

On November 13 and 14 AAU and APLU will host the inaugural "University Innovation and Entrepreneurship Showcase," highlighting university affiliated startup businesses. The event will be held in Washington in conjunction with the APLU Annual Meeting.

This showcase will promote the importance of federally-funded university research and demonstrate how university-led entrepreneurial engagement contributes to the innovation economy. Startups must be nominated by an APLU or AAU institution and demonstrate a connection to federally-funded university research. Preference will be given to startups affiliated with APLU Innovation & Economic Prosperity (IEP) universities and/or those which are seeking to advance innovative new technologies with the potential for significant economic or societal impact. For more information see https://docs.google.com/forms/d/e/1FAIpQLSfQq2rAL3VIphmCeymjw_v1Sp_WoGzlERtfdiuBPvc59OOaEA/viewform.

UIDP Contracting Forum Reminder

Also on November 13 and 14, the UIDP is holding a contracting forum hosted by Arizona State University. COGR and AAU are among the partnering organizations. For more information see https://www.uidp.org/event/contracting-forum/.

Department of Labor Overtime – Texas Court Strikes Again

On August 31, the US District Court for the Eastern District of Texas struck down the DOL's May 2016 regulation scheduled to take effect on December 1, raising the salary limit below which workers automatically qualified for overtime pay to $47,476 from $23,660. The Court stated that "a permissible salary level would need to be set somewhere near the lower end of the range of prevailing salaries for these employees and used to simply screen out the obviously nonexempt employees, making an analysis of duties in such cases unnecessary." CUPA-HR and other associations including COGR have all along urged the DOL to reconsider and set a salary level more in line with historic trends. The District Court

has suggested that adjusting the salary threshold DOL set in 2004 for inflation would be permissible. As a result of this ruling (previously under a temporary injunction), the DOL can now proceed with the gathering of responses from the recent July 26 release of the Request for Information. Comments to this RFI are due September 25th. CUPA-HR will take the lead in this effort and COGR will endorse the letter. For more information, contact jbendall@cogr.edu.

Webinar on Release of the Report of the Committee on Dual Use Research Concern (DURC)

The Committee on Science, Technology, and Law is hosting a webinar of the release of the report of the Committee on Dual Use Research of Concern: Options for Future Management.

The release of the report, *Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies*, will take place at 11 a.m. Eastern on Thursday, September 14, 2017. To register for the webinar click here.

Stakeholder's Workshop on Dual Use Research of Concern

The U.S. Government and the National Science Advisory Board for Biosecurity (NSABB) will co-host a workshop on September 25-26 to engage with stakeholders and facilitate information sharing among research institutions regarding their approaches to, and experiences with, implementing the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)*. Attendees will share their challenges, best practices and solutions regarding policy implementation.

In January the National Academy for Sciences hosted a workshop on Dual Use Research of Concern: Options for Future Management. After consideration of the NSABBs's findings, the USG released the following policy guidance. COGR staff will be attending the September workshop and will inform the membership of any new developments. COGR staff will also comment on any subsequent policy guidance as a result of the January 9 recommended policy guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO).

Webcasting of the conference will not be available; however will be recorded for future viewing on the OSP Website. For additional details about the conference, click here: workshop website.

Data Sharing Policy Developments

In order to create a better evidence base for decision-making around data sharing policies and procedures, The NIH Office of Science Policy and the NSF Science of Science and Innovation Policy (SciSIP) program will be hosting a one day workshop on October 13, 2017. Attendees will include NIH, NSF and external participants with expertise in data sharing, data management, measuring scientific outcomes, and capturing the behavior and dissemination of knowledge among researchers.

The goal of the workshop entitled, "**The Value of Data Sharing"** is to identify approaches and frameworks in order to inform a research agenda and future policy directions including a set of recommendations for further study, as well as any immediate recommendations about improving the value of data sharing systems. Other considerations for outcomes of this workshop include the development of a white paper as well as key considerations for a potential Funding Opportunity Announcement (FOA) soliciting research on generating evidence for and determining the value of data sharing. The FOA will also seek to address the conflicting purposes of sharing diverse types of data with benefits of connecting them, identifying appropriate policy and oversight mechanisms that incorporate best practices for privacy, ethics, and security, discussing methods and metrics for analyzing the impact of data sharing, understanding costs and benefits, and return on investment, of data sharing, and drawing out lessons learned from existing data sharing systems.

COGR staff has been invited to participate on the Policies, Oversight, and Best Practices panel. For more information about this conference, please contact jbendall@cogr.edu.

Ad Hoc Committee on Confidentiality in Research Misconduct

In the June Meeting Report COGR indicated that a new ad hoc committee on Confidentiality in Research Misconduct was being formed to address and seek solutions to issues related to confidentiality during and after the active assessment, inquiry, investigation, and determination process. The working group will meet on September 8th to discuss topics including whether the committee should review all other agency policies (non HHS) around confidentiality (see https://ori.hhs.gov/federal-policies) to determine if policies are different and unclear in addressing members concerns. In addition, the committee has been asked to review a plethora of redacted letters from ORI addressing only the confidentiality statement to determine if patterns exist and/or differences are present, how institutions interpret the language, and whether the committee should move forward with preparation of a letter to ORI seeking clarification and/or suggesting alternative language. The committee plans to finalize the deliverable(s) and will communicate the results to the COGR membership. For more information, please contact jbendall@cogr.edu.

Research Regulatory Reform

Federal Agency Efforts to Reduce Regulatory Burden

In the June COGR meeting report we reported that Federal agencies are seeking comments on regulations, paperwork requirements and other obligations that can be modified or repealed to reduce administrative burden as part of the implementation of Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs," issued on January 30, 2017 and Executive Order 13777, "Enforcing the Regulatory Reform Agenda," of February 24, 2017.

On July 14, 2017, COGR, AAU and APLU, submitted comments on Department of Energy regulations, paperwork requirements and other regulatory obligations. Comments on DFARS solicitation provisions

and contract clauses were submitted on August 29. USDA has similarly requested "ideas on regulations, guidance documents, or any other policy documents that are in need of reform" pursuant to Executive Order 13777. Comments will be reviewed at four time points with cut-off dates of September 15, 2017, November 14, 2017, February 12, 2018 and July 17, 2018. COGR has previously submitted comments to USDA identifying areas for reform in response to similar efforts under the previous administration and executive orders and plans to submit comments again this fall.

COGR Resources on Research Regulatory Reform

COGR has had the opportunity to comment on areas of research regulatory burden in response to requests from federal agencies and offices. We recently posted a number of these documents on the Regulatory Reform page of the COGR website, including recommended reform specific to HHS and NIH and general reorganization and non-HHS areas for reform. Discussion points on facilities and administrative (F&A) costs and research regulatory burden are also available. COGR will continue to update these documents over time.

Efforts to Reduce Administrative Burden Associated with Foundation Awards

COGR staff and several representatives from institutions met with Faster Cures and other foundations in Boston in July to discuss F&A costs. At that meeting there was also discussion on streamlining and harmonizing administrative requirements and processes. COGR has agreed to take the first steps on identifying opportunities to reduce administrative work associated with foundation awards and a draft document has been circulated among the COGR committees. We anticipate follow-up with foundations on this and other topics later this month.

Administrator Office of Information and Regulatory Affairs (OIRA) Confirmed

The Senate confirmed Neomi Rao to be Administrator of OIRA on July 10. Rao is an Associate Professor of Law and Founder of the Center for the Study of the Administrative State at George Mason University. The New York Times published an article on Rao just prior to her confirmation.

Audit

NSF OIG Report on Implementation of Responsible Conduct of Research Requirements

The NSF OIG released its report *OIG Review of Institutions' Implementation of NSF's Responsible Conduct of Research Requirements* on July 25. The OIG contacted 53 institutions to see how they implemented the agency's responsible conduct of research training requirements.

The report suggests that one quarter of institutions were not in compliance with NSF's RCR requirements and that 23% did not have an RCR plan at initial contact or a designated person to oversee compliance with the requirement. The majority of institutions without RCR plans were smaller institutions. The report notes that several indicated that they infrequently receive NSF grants. Per the report, "NSF's policy requires all institutions that apply for research funding, not just those who receive

it, to certify that they have an RCR training program in place…" The OIG suggests that "Given the effort required to create, implement, and maintain a training plan that may seldom be used, NSF may want to consider whether there is a funding level or number of grants below which institutions will not be required to implement a formal RCR training program, but could be required to provide more informal RCR training." Such action would require congressional approval.

The report indicates that 18% of institutions could not adequately track whether its students were receiving the required training, another NSF requirement, and that 73% of institutions allowed trainees to complete all or most of their training online, with approximately 87% using CITI training. The report suggests that "the lack of guidance from NSF as to what constitutes 'appropriate training' means that NSF cannot guarantee that the instruction provided in response to the RCR training requirement meets a minimum level of quality" and that "To ensure the integrity and consistency of the RCR training provided in response to the America COMPETES requirement, NSF could identify and share with the community minimum standards…" The report also includes several "promising or best practices" such as involving faculty in training and repeating training. The OIG suggests that all students and postdocs participating in NSF research should receive training, not just those that receive NSF funding. The report also suggests that NSF consider "encouraging RCR training, or at least plagiarism training, for all new faculty."

NSF OIG Letter to OMB on the FDP Payroll Certification Pilot

The NSF OIG sent a letter to OMB staff on June 21 on the Federal Demonstration Partnership's payroll certification pilot. The letter suggests that it is in response to informal OMB inquiries on whether the pilot program meets the requirements of the Uniform Guidance. As we understand it, the letter is also in lieu of a previously proposed capstone report that was to be published by the NSF and HHS OIGs. It references only NSF's audit work at George Mason University and Michigan Technological University.

The letter suggests that the OIG cannot determine whether the pilot meets the requirements of the Uniform Guidance because the pilot was audited under circular A-21 and offers "observations which could help universities comply with the new requirements." These include: "The addition of interim (monthly or bi-monthly) reconciliations of budget to actual personnel costs for each award" and that providing investigators "with information reflecting full allocations for each individual who charged to the PI' s projects would help ensure that no more than 100 percent of an employee's salary was collectively charged to Federal awards." The letter also cautions institutions to consistently implement internal controls.

HHS OIG Report on OHRP Independence

The HHS OIG published a report on a review of Office for Human Research Protections (OHRP) independence on July 27, 2017. The review was conducted at the request of Congress. The OIG found that OHRP carries out "compliance activities for protecting human subjects while maintaining its independence from the HHS agencies that fund the research and the institutions conducting the research." The OIG suggests that HHS could address factors that limit OHRP independence by

clarifying the office's role, evaluating its position within HHS, and considering including OHRP's budget as a line item in the President's budget, and that the agency consider "seeking statutory authority for OHRP's independence."

DATA Act

The Office of Management and Budget (OMB) submitted its report to Congress on the DATA Act Pilot Program on August 10. The report has been made available to the public and can be found here. The DATA Act charged OMB with carrying out pilot studies with the goal of reducing financial reporting burden on awardees through greater interoperability of financial systems in a process that began with soliciting suggestions through the National Dialogue and progressed to the development of test models that a number of institutions engaged in. Test models included five specific to procurement and contractors and six specific to grants. Descriptions of the models and results to date are included in a table beginning on page 8 (Phase 3 – Data Collection and Analysis).

The procurement pilot focused on use of a uniform submission process and centralized entry point through which contractors could provide FAR-required data, and use of information technology to pre-populate forms using existing federal data. Data collection is ongoing. Pilots findings specific to grants suggested that a Common Data Element Repository Library with defined data standards may allow for more accurate and timely reporting; identified duplicative data elements across and within forms; found that allowing grantees to submit federal financial reports once and through a single point of entry increases reporting accuracy and reduces submission time; that standardized notice of awards would allow grantees to more easily and accurately complete grant information collections; that access to grants lifecycle information in one website would improve "access to grants resources and knowledge of the grants lifecycle process"; and that eliminating duplicative input of the Schedule of Expenditures of Federal Awards (SEFA) and Standard Form - Single Audit Collection (SF-SAC) by allowing information reported once to be auto-populated would improve reporting accuracy and reduce the time it takes to submit the annual Single Audit. The report indicates that OMB "will modify the current standard SF-SAC/Data Collection Form to allow for a consolidated submission that includes the SEFA, the Auditor's Summary, the entity ID, and the SF-SAC."

Recommendations include continuing "to standardize data elements, conditions, and attributes" with the indication that OMB and Federal partners will build on DATA Act progress to-date; and using information technology to streamline reporting through auto-population and other approaches.

National Science Board Meeting

The National Science Board (NSB) held a meeting August 15-16. The agenda is available on the Board's website and archived webcasts can be viewed here.

The NSB Committee on Oversight reviewed the NSF FY 2016 Annual Report on Merit Review. Per the report, the success rate for competitive proposals remained stable from the previous fiscal year at 24% with a 21% success rate for research proposals which make up 83% of competitive proposals. The report indicates that approximately $4 billion in proposals rated "very good" were denied funding in FY16 and about $23 billion overall. In terms of pilot projects, several divisions are piloting elimination of proposal deadlines. The NSF Earth Science division is reported to have increased success rates from 19% to 26% by eliminating program deadlines while reducing burden on investigators and reviewers. At the meeting, members of the oversight committee voted to have NSF develop the merit review report only once every two years rather than annually, noting that the data doesn't change significantly from year to year.

NSF OIG Allison Lerner presented data from the recent OIG review of institutions' implementation of NSF's responsible conduct of research training requirements which is detailed in the audit section of this COGR update. Allison noted that while NSF has recommended in guidance that institutions conduct a risk assessment of which students should be trained they found that none of the 48 institutions included in this review had conducted this risk assessment. She also suggested that the results of the report raise the question of an implementation problem and again mentioned several best practices: involving faculty in training (noting that only 15% require faculty involvement while 96% of plagiarism cases involve faculty); training all students regardless of funding source; periodic refresher training; and administering training before students begin the research. Allison indicated that what they heard from institutions was that they appreciate the flexibility that NSF provides with respect to implementation but would like additional guidance. There was discussion among oversight committee members on whether this was an NSF issue or a university issue and whether university organizations should be more engaged in setting standards and addressing concerns.

Human Subjects Research

Common Rule

We reported in the June COGR update that COGR, AAMC, AAU and APLU sent a letter to Jerry Menikoff, Director, HHS Office for Human Research Protections, on June 21, requesting a one year delay in the compliance date of the Federal Policy for the Protection of Human Subjects (Common Rule). In a September 1 email, Dr. Menikoff indicated that the request is "certainly receiving consideration" but that no further information is available at this time. The full text of a recent *Science* article on the rule and the challenges of implementation is available on the COGR website.

NIH Definition of a Clinical Trial

COGR previously reported that the NIH Clinical Trial Funding Opportunity Announcement (FOA) Policy requires all applications involving clinical trials to be submitted through an FOA specific to clinical trials effective January 25, 2018. Applications that meet NIH's definition of a clinical trial that are not submitted in response to a clinical trial specific FOA will be returned without review.

Earlier this summer, NIH made additional resources available to assist investigators in determining whether their proposed research meets the NIH clinical trial definition, revised in October 2014, and would be subject to existing requirements and those effective in January 2018. Among the resources provided were case studies that many in the research community believe inappropriately classify basic research as clinical trials thereby subjecting these basic research studies to the clinical trial FOA policy, registration and results reporting in ClinicalTrials.gov, Good Clinical Practice Training, ineligibility for training awards and additional oversight and restrictions.

On July 12, the Federation of Associations in Behavioral and Brain Sciences (FABBS) sent a letter to Francis Collins expressing serious concerns about the breadth of NIH's definition of a clinical trial and the implications of associated policies and requirements for basic research. FABBS requested that NIH delay implementation of the Clinical Trial FOA policy and seek additional feedback from the scientific community. Similar concerns were raised in an open letter and petition posted on August 31 that to date has received close to 3,000 signatures.

In a July 19 article in *Science*, Carrie Wolinetz, NIH Acting Chief of Staff, indicated that NIH's interpretation is evolving and that "the agency expects to offer guidance within a few months on which behavioral studies will now be called clinical trials." A recent article in Nature indicated that NIH may revise the case studies as soon as this week but concern remains that any revisions may not address the overall concern that basic human research is being reclassified as clinical trials.

At the NIH Council of Councils meeting held on September 1, Mike Lauer presented data (5:09:15) on low publication rates for NIH-funded clinical trials. The discussion focused more on resistance to the definition of a clinical trial than to the recent perceived broadening of the definition via the case studies published by NIH although questions on the case studies were raised at the end of the presentation. Mike indicated that NIH was revising the case studies in response to feedback received but also suggested that if investigators are going to do an experiment on people they should register with CT.gov and report results and if they can't they shouldn't be doing the study. It was suggested that FABBS misunderstood the situation, that the only regulations relate to reporting, but there are clearly related policies that apply. COGR anticipates submitting a letter to NIH Director Dr. Francis Collins on this topic in the near-term.

Secretary's Advisory Committee on Human Research Protections (SACHRP) Guidance

In an August 2, 2017 letter to HHS Secretary Tom Price, SACHRP submits for consideration recent recommendations in relation to the Common Rule made on compliance dates and transition provisions; benign behavioral intervention; broad consent guidance; a broad consent template; FDA draft guidance, "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices"; and recommendations on reporting incidental findings. The recommendations are available on the SACHRP website.

Next Generation Researchers Initiative

NIH issued its Policy Supporting the Next Generation Researchers Initiative on August 31, 2017. Consistent with previous communications, the policy, which is effective immediately, prioritizes awards for Early Stage Investigators (ESIs) and Early Established Investigators (EEIs). Both are defined in the policy. Per the policy, "ESIs are encouraged to enter the date of their terminal research degree or the end date of their post-graduate clinical training in their eRA Commons" and "NIH will identify EEIs in their eRA Commons profile by January 2018." Requests for an extension of ESI or EEI status will be considered under certain circumstances.

We reported in the June COGR meeting report that the National Academies Next Generation Researchers Initiative Committee has issued a letter seeking feedback on actions that universities are taking to improve, incentivize and sustain transitions to independent research careers as well as the barriers next generation researchers will face. The committee is seeking feedback on four core issues, including levels, sources and stability of funding; grant awards and review; training and mentoring; and underrepresented groups. Responses are requested by October 1 and can be submitted using this link.