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TO: COGR Membership

FROM: COGR Staff

SUBJECT: February 2016 Update

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NIH and Grant Closeouts: Update on February 25th during Thursday Morning Session

Michelle Bulls and Tony Corio from NIH will provide an update on the FFR/FCTR/PMS requirements and challenges under the new 120-day reporting deadline.

This dogged issue continues to be a priority for the Costing Committee and captures the interrelated topics of NIH subaccounting (i.e., award-by-award accounting), the 120-day grant closeout model, and the functionality of the Payment Management System (PMS). The transition to NIH subaccounting appears to be proceeding smoothly (see NIH Notice Number: NOT-OD-15-105 (May 28, 2015); *Reminder of Timeline for Administrative Changes to NIH Domestic Awards to Transition to Payment Management System Subaccounts*). However, we encourage COGR members to contact COGR staff if/when there are concerns.

The major challenge now is implementation of the new, 120-day NIH Grant Closeout policy. As described in section 8.6 CLOSEOUT of the 2015 NIH Grants Policy Statement: *Recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 120 calendar days of the end of the period of performance (project period). The reports become overdue the day after the 120 calendar day period ends.*

At issue is the complex reconciliation between the Federal Financial Report (FFR, expenditures report, submitted to NIH Commons) and the Federal Cash Transaction Report (FCTR, cash report, submitted to PMS). While the reconciliation between the FFR and the FCTR has always been a challenge, it is now elevated when placed in conjunction with the new HHS/NIH policy to initiate "Unilateral Closeout" actions at 180 days after the project end date. The unilateral closeout policy is described in NIH Notice Number: NOT-OD-15-136 (August 4, 2015); *Impact of Discrepancies Between Final Financial Reports for Grant Closeout.*

Integral to successful implementation of the 120-day NIH Grant Closeout policy is working with NIH, as well as the HHS Office of Grants and Acquisition Policy and Accountability (OGAPA). OGAPA provides HHS Department-wide leadership in grants and acquisition management to the 11 HHS operating divisions, which includes NIH. COGR is poised to work with NIH and OGAPA to address the following:

1) FFR and FCTR reconciliation. Grants closeout is contingent on this reconciliation, and as things currently stand, the FCTR requirements and the capabilities of PMS seem to impede completion in less than 180 days.

2) NIH Unilateral Closeout policy. As described above, NIH Notice Number NOT-OD-15-136 indicates unilateral closeout may be triggered at 180 days after the project end date. This creates a friction since the FFR and FCTR reconciliation normally cannot be completed in less than 180 days.

3) Grants Oversight and New Efficiency (GONE) Act. This legislation was signed into law by the President on January 28th and requires OMB, in coordination with HHS, to submit to Congress by December 31 a report that captures various metrics related to timely closeouts of all Federal agency grants. It is uncertain how non-compliance with timely grants closeouts will intersect with the GONE Act.

4) Federal Awardee Performance and Integrity Information System (FAPIIS). Requirements under FAPIIS no longer are applicable to contracts only; FAPIIS now encompasses grants. By February 16, 2016, NIH officials will begin using information in FAPIIS as part of the risk assessment process for making grant awards. It is uncertain how non-compliance with timely grants closeouts will intersect with FAPIIS.

5) Consistent 120-day closeout model across all HHS operating divisions? NIH has adopted the 120-day model, as have NSF and DOD. It would be helpful if HHS implemented this across all HHS operating divisions. Our analysis is that a consistent 120-day policy will improve accuracy of filing closeouts and that timeliness will be improved since the need to file revised FFRs will be reduced.

6) Sync 45 CFR 75.381(g) with 2 CFR 200.343(g). The more restrictive HHS policy effectively gives HHS operating divisions 270 days to complete closeout actions (90 days to submit the FFR + 180 days), rather than the 455 days (90 days to submit the FFR + 365) allowed under the Uniform Guidance. While OGAPA may not be inclined to address this, closer review of the HHS policy still may be appropriate.

   45 CFR, 75.381(g):
   The HHS awarding agency or pass-through entity should complete all closeout actions for Federal awards no later than 180 calendar days after receipt and acceptance of all required final reports.

   2 CFR, 200.343(g):
   The Federal awarding agency or pass-through entity should complete all closeout actions for Federal awards no later than one year [365 days] after receipt and acceptance of all required final reports.

7) Research/Class exemption from the FCTR requirement. COGR's understanding is that the FCTR is necessary if the award includes a cash advance. However, if it is a cost-reimbursement award, which is what we generally receive for research, the FCTR no longer is necessary since all the cash balance and related information is available in the subaccount. This exemption could be pursued.

COGR actively is engaged with NIH and OGAPA on these topics. The Thursday Morning presentation and discussion will be a helpful next step to address issues related to implementation of the 120-day grants closeout model at NIH.

NIH Salary Limitation (Cap): Policy Update and Treatment of NIH Contracts

NIH Notice Number: NOT-OD-16-045 was posted on December 24, 2015; *Notice on Salary Limitation on NIH Grants, Cooperative Agreements, and Contracts*. Per the Notice, the Federal budget resolution for FY 2016 (signed into law on December 18, 2015) maintained the NIH Salary Cap at the Executive Level II. And effective January 10, 2016, the Executive Level II increased from $183,300 to $185,100. Also included in the Notice is a link to the Salary Cap history (FY 1990 to Present).

NIH Notice Number: NOT-OD-16-059 was posted on January 28, 2016; *Notice of Correction to Salary Limitation on NIH Grants, and Cooperative Agreements*. The correction notice removes

all references to NIH extramural research and development contract awards. ***However, the NIH salary limitation is still applicable to contracts.***

According to representatives from the NIH Division of Acquisition Policy and Evaluation, the Notice of Correction was issued to emphasize that application of the NIH salary limitation to contracts is handled differently than grants. For grants, the salary is required to be annualized to determine if the salary limit has been exceeded. For contracts, annualization is not required. Also, as it relates to consultants, for grants, the salary limit is not applicable to consultants (though the standards of reasonableness and consistency must be met). For contracts, the salary limit is applicable to consultants (though again, annualization is not required).

Salary Rate Limitation Q&As can be found on the NIH web site. The NIH Division of Acquisition Policy and Evaluation recognizes that there may be confusion due to the different application of the salary limit to contracts versus grants. As necessary, they will provide additional clarification for the community.

Other Recent NIH Notices of Interest (Fiscal Policy)

The following recent NIH General Policy Notices affecting NIH fiscal policy should be noted:

NOT-OD-16-062 (January 26, 2016): Revised: Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2016
NOT-OD-16-054 (January 20, 2016): Clarification: New Salary and Research Cost Allowances for K08 and K23 Career Development Awards
NOT-OD-16-046 (January 20, 2016): NIH Fiscal Policy for Grant Awards - FY 2016
NOT-OD-16-044 (December 24, 2015): Notice of Legislative Mandates in Effect for FY 2016 (note subsequent correction per NOT-OD-16-048, December 31, 2016)

Please contact COGR staff for additional detail, if needed.

Uniform Guidance and the Procurement Standards: COGR Letter to OMB

COGR submitted a letter to OMB requesting "Implementation of Sensible Procurement Standards". The letter is dated January 20, 2016 and is available on the COGR home page.

We made three specific requests in the letter:

1) Establish a "Grantee Exemption" process from 2 CFR 200.317-326; similar to the exemption offered to States.
2) Fix those sections of 2 CFR 200.317-326 that require common-sense improvements.
3) Increase the Micro-purchase threshold from $3,000 to $10,000, with an option for a higher threshold.

We addressed the COGR letter directly to David Mader, OMB Controller. Mr. Mader will be the keynote speaker during the Thursday, February 25 COGR meeting and this will be an opportunity to get an update on the status of the COGR letter. Several DC-based Associations supported the COGR letter, and there are a number of complimentary legislative strategies and other activities related to advancing this issue. We believe this may be the last, best chance to

influence the implementation of the procurement standards before the go-live date in FY 2018 and COGR will continue to take an assertively active role in all advocacy.

Uniform Guidance and F&A: COGR Letter to OMB to Update the UCA Methodology

The COGR leadership, on behalf of the COGR membership and the research community, submitted a letter to OMB, dated November 13, 2015, requesting that the methodology for calculating the Utility Cost Adjustment (UCA) be updated based on more current and accurate data. Per 2 CFR Appendix III, section B.4.c:

> *c. A utility cost adjustment of up to 1.3 percentage points may be included in the negotiated indirect cost rate of the IHE for organized research, per the computation alternatives in paragraphs (c)(1) and (2) of this section.*

And continuing at 2 CFR Appendix III, section B.4.c(2)(ii):

> *(ii) "Effective square footage" allocated to research laboratory space must be calculated as the actual square footage times the relative energy utilization index (REUI) posted on the OMB Web site at the time of a rate determination.*
>
> > *A. This index is the ratio of a laboratory energy use index (lab EUI) to the corresponding index for overall average college or university space (college EUI).*
> >
> > *B. In July 2012, values for these two indices (taken respectively from the Lawrence Berkeley Laboratory "Labs for the 21st Century" benchmarking tool … and the US Department of Energy "Buildings Energy Databook" … were 310 kBtu/sq ft-yr. and 155 kBtu/sq ft-yr., so that the adjustment ratio is 2.0 by this methodology {emphasis added}. To retain currency, OMB will adjust the EUI numbers from time to time (no more often than annually nor less often than every 5 years), using reliable and publicly disclosed data. Current values of both the EUIs and the REUI will be posted on the OMB Web site.*

In summary, COGR's position is that the "adjustment ratio" of 2.0, which is the weighting factor for research laboratory square footage, is flawed. With the help of Attain Consulting and using more current data and better methodological assumptions, ***COGR recalculated the adjustment ratio to be 4.2.*** Using this more accurate and fair adjustment ratio, most institutions will be able to support a 1.3% UCA.

In addition to sharing the COGR letter with OMB, the Cognizant Agencies for Indirect Costs were copied on the November 13th letter. However, OMB and the COFAR will take the lead in reviewing COGR's request.

The timing for review is uncertain, though OMB and the COFAR have committed to reviewing the request in early 2016. Institutions that are submitting an F&A rate proposal based on FY2015 data and that are required to use the current methodology (i.e., the 2.0 adjustment ratio) to support the 1.3% UCA should contact COGR regularly to get updates on the status of the OMB/COFAR review process. Per OMB, if the adjustment ratio is updated to reflect a more accurate research weighting factor after an institution's F&A rate proposal has been submitted,

OMB appears to be open to allowing use of the new factor to recalculate the impact on the 1.3% UCA, prior to finalizing the F&A rate between the institution and the Cognizant Agency.

Contact David Kennedy at dkennedy@cogr.edu for updates and we will keep the entire membership posted on all developments.

COGR Comments: 2016 DRAFT Compliance Supplement (Internal Controls and DS-2)

In the December 2015 COGR Update, we announced that a DRAFT version of the 2016 Compliance Supplement (CS) for the Single Audit was available for comment. Single audits applicable to FY2016 will represent the first time that institutions will be required to comply with 2 CFR Part 200, Subpart F – Audit Requirements.

The CS is a unique document that does not move through the normal Federal Register / Public Comment process. Instead, it is developed and vetted between OMB and representatives from the audit community (e.g., AIPCA, Public Accounting firms, Audit-centric Associations, etc.). However, OMB historically has provided COGR with a copy of the DRAFT version and the opportunity to provide comments.

Several of you requested the DRAFT version of the 2016 CS, and subsequently, shared your comments with COGR. Based on your comments and the COGR review of the DRAFT version, we provided the following two significant comments to OMB:

1) Part 6, Internal Controls. Part 6 was not available in the DRAFT version of the 2016 CS. This is a critical section as it directly relates to the new standards defined in 2 CFR 200.300, Internal controls. OMB currently is working on this section of the 2016 CS and has indicated they will share Part 6 with us, in its DRAFT version, as soon as possible.

2) Part 3, Compliance Requirements and the DS-2. Per our review of Part 3 (specific to the treatment of the DS-2), we shared with OMB our concern that Part 3 is inconsistent with 2 CFR 200.419(b), Cost accounting standards and disclosure statement and the related COFAR FAQs. OMB asked COGR to provide suggestions to clarify Part 3, which we have submitted. We also took the opportunity to provide suggestions related to clarifying the DS-2 approval process, with the understanding that CASB revisions to the DS-2 still may be months and months away.

During the Thursday morning session at the February 25th COGR Meeting, Mandy Nelson from KPMG is scheduled to provide a short update on her perspectives on the 2016 Compliance Supplement and the Single Audit process for FY2016. We will keep the membership updated on all issues related to these topics.

Affordable Care Act (ACA) Compliance and Graduate Research Assistants

We included a detailed update in the October 2015 COGR Meeting Report (dated November 6, 2015). The American Council on Education (ACE) and the College and University Professional Association for Human Resources (CUPA-HR) are the lead Higher Ed associations and are working closely with the IRS and the Department of Treasury to advocate for a fair and reasonable implementation of the ACA as it relates to higher education institutions. At this stage, their primary focus is on student employees, which includes research assistants. Also note,

compliance of subsidized graduate student health insurance plans (SHIP) with the ACA has been at issue. A recent IRS Notice states that Universities will have one full academic year to bring their SHIP into compliance with the ACA. If you have questions, COGR can connect you with the appropriate contacts at ACE and/or CUPA-HR.

OMB Metrics and Year-One Report Card for the Uniform Guidance

Year 1 of the Uniform Guidance implementation at our institutions is complete. Some of the questions the research community should be asking include: Where has administrative burden been reduced? Where has administrative burden increased? Has the PI-climate improved? (i.e., family-friendly, productivity and efficiency, goodwill and common sense improvements, etc.). Can we quantify cost impacts? FTE impacts?

In 2016, COGR hopes to analyze metrics related to the implementation of the Uniform Guidance. OMB and the COFAR are doing the same. Using 2014 as a baseline, OMB/COFAR published 2014 administrative metrics in a one-page report titled, Measuring the Impact of the Uniform Guidance. We expect that OMB/COFAR will use 2015 data as a point of comparison.

As appropriate, COGR will formalize an analysis that can be shared with various stakeholders and officials in the research community. ***We encourage you to share your institutional perspectives and experiences with COGR staff.*** Send comments to David Kennedy at dkennedy@cogr.edu or Jackie Bendall at jbendall@cogr.edu.

NSF Higher Education R&D (HERD) Survey for FY2014 is Available

The InfoBrief for the FY2014 NSF HERD Survey includes a summary of the results from the annual NSF survey. Some interesting notes from the InfoBrief include:

- *In current dollars, federally funded R&D at universities declined 3.9% to $37.9 billion in FY 2014 {emphasis added}. Excluding funding spent in FYs 2013 and 2014 from the one-time American Recovery and Reinvestment Act of 2009 (ARRA), federally funded R&D dropped 1.6% in FY 2014 (table 2).*

- *Since FY 2011, federally funded expenditures have dropped from 62.5% to 56.5% of total R&D expenditures {emphasis added}, which also represents a record low in the history of this data series.*

- *The universities' own funds used for R&D (institution funds) rose 5.3% to $15.8 billion in FY 2014 and have been the fastest-growing source for the past 5 years {emphasis added}. Institution funds now constitute 23.5% of total R&D, rising from 22.4% last year and from 19.5% in FY 2010.*

- *Institution funds comprise direct funding for R&D ($9.6 billion in FY 2014), cost sharing on externally sponsored projects ($1.4 billion), and indirect costs on external projects that are not reimbursed by the sponsor ($4.8 billion) {emphasis added}.*

Despite recent improvement in the budget situation for science and research agencies, the results of the FY2014 HERD Survey still reinforce the point made in the Executive Summary of the June 2014 COGR paper, *Finances of Research Universities*. The Full Version of the June 2014

COGR paper provides additional analysis on research funding trends and the corresponding financial implications to research universities.

> *The future of the federal government contribution to the research enterprise is highly uncertain in light of deep discretionary spending cuts. According to the National Science Foundation 2012 Higher Education Research and Development (HERD) survey, for the first time since the 1950s, the federal government contribution to the research enterprise dipped below 60%. As the percentage of total research expenditures funded by federal sources trends downward, research universities bear the additional expense {emphasis added}. The university contribution exceeds $13 billion, according to the 2012 HERD survey, and continues to grow.*

Finally note, the underlying Data Tables that support the FY2014 HERD Survey provide institutional specific results. Table 18 from the Data Tables page is the table that shows, by institution, total R&D expenditures by federal, state, institutional, business, nonprofit, and all other funding sources. We encourage you to read the NSF InfoBrief. As COGR regularly focuses on the topic of research funding trends and the corresponding financial implications to research universities, the annual NSF HERD Survey is a helpful tool that quantifies our concerns.

Attention Again Focuses on March-In Rights

On January 11 over 50 Democratic members of Congress co-signed a letter from Rep. Lloyd Doggett (D—TX) to HHS/NIH urging NIH to issue guidelines for the exercise of march-in rights under the Bayh-Dole Act to address drug price gouging. On January 14 a petition was filed jointly with HHS, NIS and DoD (Medical Research and Material Command) by Knowledge Ecology International (KEI) requesting march-in on a prostate cancer drug (Xtandi) developed with co-funding by NIH and DoD to UCLA. The petition alleges that the price of Xtandi is two to four times greater in the U.S. than other high income countries. In a related development, in a report last fall, the Center for American Progress (CAP) called for an independent entity certified by HHS to conduct comparative effectiveness research to develop value-based drug price benchmarks. If the final price of a drug exceeded the recommended range by more than 20%, it would be determined unreasonable and if resulting from federally funded research, would trigger march-in (*Enough is Enough: The Time Has Come to Address Sky-High Drug Prices*).

Calls for the exercise of march-in on drug pricing grounds are not new. March-in under the Bayh-Dole Act is triggered by the failure of a contractor or assignee to take within a reasonable time effective steps to achieve practical application of subject inventions (35 USC 203(a)(1)). "Practical application" means that benefits are available to the public on reasonable terms (35 USC 201(f)). A petition on an AIDS drug on grounds similar to the recent petition on Xtandi was filed with NIH in 2004. NIH held a public hearing at which COGR and many other groups testified. There also were calls at that time by a number of members of Congress for investigations of the pricing of the drug involved in the 2004 petition. Then Rep. Sanders attempted unsuccessfully to amend the HHS appropriations bill to require that all federally-funded drugs be marketed at a reasonable price.

In July 2004 NIH determined that since the drug was on the market practical application had been achieved, and that march-in is not an appropriate means of controlling drug pricing. NIH suggested that "the issue of drug pricing is one that would be more appropriately addressed by Congress." Three years ago the same AIDS drug was the subject of another march-in petition

filed by KEI and other groups. That petition cited the pricing disparities for the drug between the U.S. and other developed countries as the main basis for the march-in request. NIH acknowledged that drug pricing is a challenging issue, but again concluded that "the general issue of drug pricing is appropriately addressed through legislative and other remedies, not through the use of NIH's march-in authorities" (See http://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf),

We understand NIH is likely to respond in a similar way to the latest letter and petition. One potential complication is that the petition was jointly addressed to DoD, which is the first time that agency has considered a march-in petition. The Bayh-Dole Act does not clearly address a co-funding situation. We do not know what action DoD will take. Price comparisons between the U.S. and other countries are troublesome given the vast differences in drug delivery systems among countries. However, drug pricing is likely to be among the issues in the upcoming Presidential and Congressional elections. It is not inconceivable that legislation could be proposed or introduced that would include pricing considerations among the grounds for march-in.

COGR is discussing the situation with the other higher ed. associations as well as BIO and PhARMA. The California Life Sciences Association has written to the California Congressional delegation (which includes many signers of the Doggett letter) expressing concern. One possibility is for other state delegations to be similarly contacted by their state institutions.
In our 2004 statement for the NIH public hearing COGR stated:

> *"March-in rights accrue to the government only for the purpose of ensuring prompt commercialization of federally funded inventions and to avoid the possibility of companies stifling the development of new products. The legislation does not empower the government in any way to influence or to dictate licensing or commercialization terms for technologies."*

We further stated:

> *"COGR is concerned that a substantial reinterpretion of the Bayh-Dole Act's march-in provisons could undermine the ability of universities to make their federally funded technologies available for public use. Any such change in march-in authority or in expanding their exercise by government agencies could result in the loss of the very delicate balance of rights and obligations between the three parties—government, universities and industry—which has been the basis for the success of this legislation. History has proven how important incentives are for encouraging technology transfer from the universities. It would be ironic, indeed, if a change in the current understanding of march-in rights were to impare the dissemination of, and public benefit from, university research results."*

These statements still appear timely and relevant today.

DoD Delays Implementation of Cybersecurity Requirements

We mentioned in the December Update that DoD had issued a class deviation to allow a 9 month delay for contractors to comply with the multifactor authorization requirement in the revised DFARS 252.2004—7008 and 7012 Safeguarding clauses. On December 30 DoD issued a new

interim rule further postponing full implementation of the NIST SP 800-171 security requirements for protecting controlled unclassified information (https://www.federalregister.gov/articles/2015/12/30/2015-32869/defense-federal-acquisition-regulation-supplement-network-penetration-reporting-and-contracting-for). This followed on a public meeting held on December 14 where the attendees, mostly industry representatives, indicated to DoD that more time was needed to implement the new requirements.

The new interim rule revises the 7008 and 7012 clauses. Both require contractors to implement the NIST requirements by December 31, 2017. However, there are subtle but important differences between the clauses. The 7008 clause requires contractors to represent by submitting offers that they will implement the requirements by that date. If a contractor proposes to vary from any of the NIST requirements, a written explanation must be submitted to the DoD Chief Information Officer (CIO) either as to why the requirement is inapplicable or how an alternative but equally effective measure will be used. The CIO representative will adjudicate variance requests prior to contract award.

In contrast, the 7012 clause requires notification of the CIO within 30 days of contract award of any NIST requirement that has not been implemented or of alternative measures to achieve equivalent protection that have been accepted in writing by the CIO. This will help DoD monitor progress and identify trends in implementation that may require clarification or adjustment. This appears to result in a contradiction between the two clauses. The Discussion in the Federal Register notice specifically states that the requirement for CIO acceptance is removed in the 7012 clause. Given that the notification requirement is worded in the alternative, there appears little incentive under the 7012 clause to provide alternative measures for CIO acceptance at this time. The revised 7012 clause also limits the flow down requirement of the clause only to subcontracts whose efforts involve covered defense information residing in contractor information systems.

As stated in the Federal Register Notice, the revised clauses relieve contractors of the requirement to immediately implement the NIST requirements. In our comments to DoD when the requirements first were proposed, we expressed serious concerns about the compliance burdens. We also expressed uncertainly about when and how the DoD CIO would make determinations as to the effectiveness of alternative security measures. The revised 7012 clause appears somewhat responsive to our concerns. It also seems that DoD may be open to further modification of the requirements depending on contractor experiences.

However, concerns about the long-term compliance implications remain. Under the 7008 clause contractors still are representing that they will implement the NIST requirements by December 31, 2017 or obtain a variance from the DoD CIO that will be incorporated into the contract. There also may be situations where an institution receives a contract or subcontract determined to be fundamental research under DFARS 7000(a)(3) but also receives the 7008/7012 clauses. We had suggested in our comments to DoD that fundamental research should be specifically exempted from the safeguarding requirements as not involving covered defense information.
A panel discussion of the new cybersecurity requirements by DoD, NIST and NARA representatives is included in the agenda for the February COGR meeting. This will provide an opportunity to discuss the issues associated with the requirements directly with appropriate government representatives. Comments on the revised clauses are due February 29.

New Service Contract Reporting Requirements Continue to Cause Confusion

The December Update discussed the new labor hours reporting requirements for service contracts. Two new clauses have been added to the FAR, 52-204-14 and 15, to implement the requirement. While effective January 30, 2014, agencies just now are modifying contracts to include the requirements.

There appears to be confusion about the difference between the Service Contract Act, which exempts most R&D contracts, and the new requirements which apply to how agencies report R&D contracts for annual Federal Activities Inventory Reform (FAIR) Act inventory purposes. For years agencies have been reporting research contracts with universities as service contracts in their inventories. In the past agencies populated the inventories themselves. What has changed is the new requirement for reporting labor hours. This has made it necessary for agencies to go back to contractors including universities to obtain this information.

We understand that the requirement is burdensome and the information not particularly useful since universities can only report estimates which are converted by the government to FTEs by some unknown algorithm. However, it is unlikely agencies will agree to back these contracts out of their inventories after all these years. As discussed in the Update, the requirement is statutorily based. With regard to possible audit concerns, some years ago there was a similar situation with Army manpower reporting requirements. We obtained a statement that the numbers reported should not be considered binding for audit purposes (see June 2007 COGR Meeting Report). The same approach might be followed here in submitting the information, especially since the conversion to FTEs will be done automatically by the government rather than institutions.

Final Lab-to-Market Workshop Held

We have reported several times recently on the Administration's lab-to-market initiative (e.g. see COGR October 2015 Update). NIST has overall implementation responsibility for the initiative. NIST's basic interest is on how to make transfer of government-funded technologies in general more effective. After several discussions with NIST that included a number of higher ed. associations, three workshops have been held over the past six months under APLU auspices led by the Purdue Center for Regional Development Agile Strategy Team. The workshops included participants from NIST, NIH, NSF, DOE, OSTP, and academic institutions as well as from the associations including COGR.

The last workshop was held on February 5. The emphasis has been on finding solutions to strengthen university innovation ecosystems. The activity began on the premise that three types of solutions might be possible: collaborative solutions within universities such as multidisciplinary research teams as well as joint collaborations between university, industry and government; administrative solutions involving actions by federal agencies; and legislative solutions. Several possible initiatives were developed within this framework. As noted in the October Update, one involves an SBIR "Phase Zero" program that would fund teams that would go through I-Corps like experiences as a first step in the SBIR/STTR process. We understand NSF now is exploring implementing such a program. Another is to connect APLU's network of universities involved in economic growth (IEP) with federal partners. Another is to develop an innovation guide to better align innovation ecosystems with funding opportunities. Others include appointing "migration managers" to help coach researchers through the

commercialization process, and developing a corps of federal "Innovation Fellows" and/or Entrepreneurs in Residence at federal agencies.

A final report with recommendations will be developed. One of these will be to identify a "network of networks" of organizations involved in university-based innovation and economic growth. These groups then might be convened at regular intervals to discuss new initiatives.

NIST Plans Bayh-Dole NPRM

At the last workshop meeting discussed above, NIST revealed plans to issue a NPRM with a number of proposed changes to the Bayh-Dole Act regulations (37 CFR 400). These mostly will involve technical changes or issues that primarily involve federal agency implementation. Examples include new guidelines for agency Determinations of Exceptional Circumstances in small business set-aside programs involving companies that do not commercialize technologies (e.g. lab service providers); clarifying the ability of federal agencies to file for patent protection where an invention is disclosed but the funding recipient has not waived rights but also does not proceed with a patent application (government ethics rules governing third party beneficiaries have complicated the ability of agencies to act in these circumstances); and addressing reporting problems that have arisen with i-Edison in situations involving co-inventors funded by different agencies. The NPRM also may address certain issues that have arisen under the Stevenson-Wydler Act, such as the inability to support existing partnership intermediaries under 15 USC 3715.

NIST views these changes as part of continuously improving the infrastructure for tech transfer. The changes discussed by NIST appear to have relatively little impact on universities. However, at the workshop association representatives expressed concerns about the timing of the NPRM, given the current controversy over march-in rights and drug pricing. Our concern is that it could become a vehicle for other more threatening changes to Bayh-Dole. The NPRM currently is planned for early spring. However, after discussion, the NIST representatives agreed to consider further delaying its issuance.

Obviously we will need to thoroughly review the text of the NPRM in the event it is issued, and seek to assure that any proposed changes do not raise serious concerns. NIST is very open to dialogue on these issues. We will keep the COGR membership informed.

Managing Externally Funded Research Programs

COGR's latest revision of Managing Externally Funded Research Programs: A Guide to Effective Management Practices is due to be released this spring. The new Guide will be available in both hard copies and on-line with periodic updates, as applicable. A notice will be sent to the member community when the Guide is available. The July 2009 version of the Guide is still available here. We'd like to express our sincere thanks to those that have contributed time and effort to make the Guide an informative, user-friendly resource for the research community. Questions regarding the Guide can be address to Jackie Bendall at jbendall@cogr.edu.

Gain-of-Function Studies

Institutions with Investigators performing Gain of Function (GoF) studies are aware of the current climate, the moratorium on all new funding and the public's concern regarding the risk

and benefits of performing GoF research. The National Science Advisory Board for Biosecurity (NSABB) met in January to discuss the preliminary findings and draft recommendations of the NSABB's Working Group Report. The group will continue to convene over the coming months to determine if GoF studies can be incorporated into existing frameworks or whether additional federal and institutional oversight is needed for specific pathogens. Efforts to strengthen biosafety and biosecurity, the need to foster a culture of responsibility to ensure GoF studies are conducted safely will continue to be discussed in the months ahead.

Next Steps:

- National Academies meeting (March 10-11, 2016)
- Additional working group deliberations to refine recommendations
- NSABB working group to present an updated draft report in spring 2016 including recommendations for further discussion and potentially for finalization by the full Board
- USG to consider Board's recommendations as it formulates policy for GoF studies.

Click here for additional information on NSABB's January meeting.

Centers for Disease Control (CDC) Notice of Proposed Rulemaking (NPRM)

The CDC released an NPRM on January 19th, "Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins and Enhanced Biosafety Requirements." The CDC proposes to remove six biological agents; add provisions to address the inactivation of select agents; add specific provisions to the section of the regulations addressing biosafety; and clarify regulatory language concerning security, training, incident response and records. Comments are due March 21, 2016. COGR plans to submit a response. Submit your comments to jbendall@cogr.edu no later than March 16, 2016.

Department of Agriculture NPRM

The Animal and Plant Health Inspection Service (APHIS) releases NPRM "Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List proposing to remove three Plant Protection and Quarantine (PPQ) select agents from the list, adds provisions to address the inactivation of select agents, biocontainment and biosafety, and clarifies regulatory language regarding security, training, incident response, and records. Comments are due March 21, 2016. Send your comments to jbendall@cogr.edu no later than March 16, 2016.

Conflicting Conflict of Interest Requirements

COGR continues to receive a number of funding opportunity announcements from our membership containing onerous, conflicting and administratively burdensome COI requirements. In addition, various COI terms are also appearing in award notices. Our approach will remain consistent, i.e., to document these requirements and to work with the membership to draft responses notifying agencies of our concerns (see COGR's recent letter to U.S. Fish and Wildlife seeking clarification on several key COI issues). Per § 200.112 Conflict of interest, "The Federal awarding agency must establish conflict of interest policies for Federal awards. The non-Federal entity must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy."

We are continuing to monitor any agency policy updates, though they have been somewhat slow to be released. At times, we are finding the use of terms without definition, adding ambiguity to already sometimes conflicting requirements. COGR will continue an open dialogue with OMB on our concerns. In the meantime, we have been informed by OMB that a federal-wide training will be held to train agency personnel on 2 CFR 200. Information will be posted on the COFAR website and we will continue to keep the membership informed.

Department of Labor NPRM

The College and University Professional Association for Human Resources (CUPA-HR) will be hosting a free webinar February 16 regarding the Department of Labor's Notice of Proposed Rulemaking (NPRM) "Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees." The NPRM proposes to more than double the current salary level ($23,660) for certain classes of employees eligible for overtime pay. Among several concerns being echoed from the research community include the potential for mass reclassifications, lost benefits for Post Docs, the impracticality of having to track hours as wage hour employees, and the potential reduction of Post Doc and other affected positions if the new cap passes legislation. Tune into the free webinar for more information, and we will provide an update to the membership on any relevant developments.

Agency Updates

National Science Foundation (NSF) Notice on Sexual Harassment

NSF issued a statement on January 25 reiterating the agency's commitment to eradicating gender-based harassment in science. The statement indicates that the agency may terminate funding to institutions found to be in noncompliance with Title IX regulations. NASA issued a letter on this topic earlier in the month. The letter indicates that the agency does not tolerate sexual harassment and seeks to ensure that the programs it funds provide equal opportunity to all participants, regardless of race or gender. The agency encouraged institutions to review related policies and procedures and address allegations promptly.

National Science Board (NSB) Science and Engineering Indicators

The NSB released Science and Engineering Indicators earlier this month. The 2016 Indicators report includes the latest data and information on science education, research and development, academic R&D, public attitudes and understanding of science and technology and other areas.

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

The Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) issued a notice on January 21seeking nominations for appointment to SACHRP. The committee provides advice and recommendations to the HHS Secretary on a wide range of issues related to human subjects protections in research. Per the notice, the committee is also responsible for reviewing "selected ongoing work and planned activities of the OHRP and other offices/agencies within HHS responsible for human subjects protection." Nominees must possess demonstrated experience and expertise in disciplines and fields pertinent to human subjects protection and/or clinical research. Four positions will become available in 2016, including the position of Chair. Nominations are due by March 21.

National Institutes of Health (NIH) Certificates of Confidentiality

The Consolidated Appropriations Act of 2016 mandates that NIH require investigators to obtain a certificate of confidentiality for "new and competing research projects designed to generate and analyze large volumes of data derived from human research participants" (see page 367). The certificates are currently encouraged by the agency in some instances, such as when submitting large-scale human genomic datasets to NIH-designated repositories.

Regulatory Reform

National Academies Committee on Federal Regulations and Reporting Requirements

The National Academies Committee on Federal Research Regulations and Reporting requirements held a meeting on January 14-15 with a brief open session. Dr. Jeffrey Botkin, Professor of Pediatrics and Associate Vice President for Research, University of Utah, and SACHRP Chair spoke about Reforming the Human Subjects Oversight System. Dr. Botkin noted the success of the peer review system and IRB review in virtually eliminating systematic breaches of ethical standards. In terms of challenges, he noted that the current regulations permit substantial flexibility while a focus of the Common Rule Notice of Proposed Rulemaking (NPRM) is to reduce burden. He suggested the NPRM would be better focused on promoting institutions' ability to be flexible. Regarding proposed changes to the treatment of biospecimens, governance models that promote public awareness but do not rely on individual consent were discussed. Dr. Botkin suggested that unspecified future research of low to moderate risk (i.e., with non-identified biospecimens) would be ethically acceptable without permission and that notice and opt-out would be an acceptable alternative to informed consent. He noted that where broad consent is required in Michigan only 60-65% of the public are consenting. Dr. Botkin suggested that those who aren't are simply not offered the form, that staff don't have time to consent, and that urban samples may be disproportionately affected.

Howard Shelanski, Administrator, Office of Information and Regulatory Affairs (OIRA), spoke about the committee's recommendation for a Research Policy Board (RPB). Administrator Shelanski suggested, as a possible alternative, a working group of agency officials that OIRA might co-chair with John Holdren. Universities could have an advisory role via an ad hoc group developed by the associations, but would not be participants. It was suggested that this could be stood up quickly and occur in parallel with the formation of an RPB. Administrator Shelanski acknowledged the potential for failure and suggested that this might hasten the development of an RPB. The committee is expected to release Part 2 of its report by spring of 2016.

Identifying and Reducing Regulatory Burdens at the U.S. Department of Agriculture (USDA)

The USDA issued a notice on January 26 requesting comment on which regulations should be modified, expanded, streamlined, or repealed to make the USDA's regulatory program more effective or less burdensome in accordance with Executive Orders on improving regulations and reducing regulatory burden. The agency is also seeking comment on measures that can be taken to increase flexibility which could include pilot projects, safe harbors, sunset and trigger provisions and exceptions. The notice indicates that the agency's 2015 Fall Regulatory Agenda provides a summary of regulations under development or review for the coming year and that the agency's 2015 Statement of Regulatory Priorities provides a list of actions being considered for

issuance in proposed or final form in FY16 (for retrospective review see item 5). Comments are due March 28 and must refer to "Retrospective Review." Agency Regulatory Agendas and Statements of Regulatory Priorities are published twice a year and posted on the OIRA website.

Audit

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

The NSB A&O meeting included a presentation from the NSF Office of Inspector General (OIG). The OIG is performing a "rebudgeting analysis" during the course of an ongoing audit of a research university that receives NSF funding using data from the institution's financial ledgers. The identity of the university was withheld. The OIG looked at rebudgeting from senior personnel to students and from students to senior personnel, budget to actual expenditures, for several hundred awards. It was suggested at the outset that broader impacts could be affected if there are fewer research opportunities for emerging scientists. The OIG found that 63% of funds were budgeted to students and 37% to senior personnel while 41% were expended for students and 59% for senior personnel. Board members suggested that the analysis is oversimplified and that funds may be expended in other categories, that fully expended grants and contracts will provide a better picture, and asked that the OIG provide a ratio of budget to actual expenditures. The OIG indicated that these awards were 55% expended. They will continue their analysis, including review of the 4th and 5th years of the awards, and provide additional data.

NSF Audit Resolution

The NSF Cost Analysis and Audit Resolution Branch has published audit management decisions on the NSF OIG audits of the Federal Demonstration Partnership Payroll Certification Pilot at Michigan Tech and George Mason University. NSF sustained the findings and determined that the corrective actions proposed by both institutions to improve the timeliness of certifications and internal controls over information technology were "reasonable and acceptable."

NASA Audit

NASA recently completed an audit of a multimillion dollar grant. The audit found appropriate management of the grant, strong internal controls, and fulfillment of performance goals, but suggested that $264,399 in payments to a vendor lacked adequate support. The NASA Associate Administrator for the Science Mission Directorate requested the university take corrective action to ensure that future invoices paid with NASA funds are adequately supported.