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TO: COGR Membership

FROM: COGR Staff

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HHS Office of Grants Policy and Closeouts: Thursday Morning Session on June 9th

Jeffrey Johnson, Associate Deputy Assistant Secretary for Grants, Department of Health and Human Services (HHS), will provide an introduction on the roles and responsibilities of the HHS Office of Grants Policy and how his office works with all of the HHS Operating Divisions. As appropriate, Mr. Johnson also will provide an update on an analysis being conducted by the HHS Office of Grants Policy as it relates to the grants closeout process.

The February Meeting Report (dated March 14, 2016) provided the most recent COGR update on the ongoing and intertwined topics of HHS (including NIH) subaccounting (i.e., award-by-award accounting), the 120-day grant closeout model implemented by NIH, reconciliation between the Federal Financial Report (FFR) and the Federal Cash Transaction Report (FCTR) at closeout, and the functionality of the Payment Management System (PMS).

COGR is actively engaged with HHS and NIH on these topics. This session will provide an HHS Office of Grants Policy perceptive and also will allow for those in the audience to raise questions and provide specific examples of institutional challenges related to grant closeouts.

COGR F&A Survey: Thursday Morning Session on June 9th

After the presentation by Mr. Johnson, we will transition into a separate session on the revival of the COGR F&A Survey. The tentative plan is to finalize the survey format soon after the June COGR Meeting and to roll-out the survey this summer. The session will cover the survey format, logistics and timeline, and provide an opportunity for those in the audience to give input.

Procurement Standards and the COGR Procurement Survey

At the February 25th COGR meeting, David Mader, OMB Controller and Acting Deputy Director of Management, presented the key-note, post-lunch presentation. Mr. Mader focused his presentation on brief comments, leaving significant time for Q&A with the COGR membership. Concerns related to implementation of the procurement standards (effective FY2018, i.e., July 1, 2017 for most research institutions) dominated the Q&A.

Strong and compelling anecdotes raised by the Membership during Mr. Mader's Q&A, in combination with the ongoing advocacy by COGR and the Association of Independent Research Institutes (AIRI) have proved to be effective. Representatives from COGR and AIRI were invited to meet with OMB in March to discuss implementation of the procurement standards. And while we remain aware of legislative efforts to influence how the micro-purchase threshold should be set as it applies to grants, we viewed the March meeting with OMB as one of the last, best chances to influence the implementation of the procurement standards before the FY2018 go-live date.

We provided a recap of the March meeting with OMB, and the ensuing events, in an email to the COGR membership on April 14th. In summary, representatives from COGR and AIRI met with OMB and COFAR representatives on Thursday, March 24th. Four university representatives and one AIRI representative each presented an institutional perspective on the impact of a $3,000 micropurchase threshold. It was a compelling meeting and opened the eyes of many around the table. However, no definitive commitments were made at that meeting. COGR and AIRI

followed up with a post-meeting letter on Tuesday, March 29th to reemphasize the sense of urgency. Karen Lee from OMB immediately responded to the letter and personally met with COGR staff on Friday, April 1st. The meeting with Karen Lee was followed by a call with David Mader and the next steps were confirmed in a letter from David Mader to COGR and AIRI on Tuesday, April 12th.

In short, the next steps, included a request by OMB for a new survey, with an emphasis on the administrative and cost burden that would be created with the introduction of a $3,500 micropurchase threshold (note, the original $3,000 micropurchase threshold, tied to the FAR, has been adjusted to $3,500). In a May 4th email to the COGR membership, we attached the COGR survey and asked you to participate if you felt you could provide high quality data by May 19th. As we finish compiling the data, we are confident that the results are compelling. The final results will be given to OMB on May 31st.

Our understanding of the next steps is as follows:

1) In June, OMB will review the data submitted by COGR. If the data supports the same conclusions made by the 5 institutions at the March 24th meeting, OMB has indicated that an extension of the grace period to FY 2019 (i.e., July 1, 2018 for most institutions) would be appropriate.

2) Furthermore, if the data supports the same conclusions made by the 5 institutions at the March 24th meeting, OMB would plan to formally reopen the Rulemaking process. As such, we would expect a Federal Register notice in the September / October 2016 timeframe.

3) Over the remainder of 2016 and into the first-half of 2017, the Rulemaking process would unfold. As warranted and as supported by the data, COGR will remain cautiously optimistic that 2 CFR 200.317-326, Procurement Standards, will be modified. NOTE: Under this timeline and due to an extension of the grace period, our expectation would be that regardless of any modifications, new procurement standards would become effective in FY 2019 (i.e., July 1, 2018 for most institutions).

These developments are contingent on the objective conclusions drawn by OMB and the COFAR as derived from the results of the COGR Survey. While OMB cannot promise the exact outcome, we can state that David Mader, Karen Lee, and the entire staff at the OMB Office of Federal Financial Management are committed to dialoguing with our community in the spirit of good faith and under the auspices of open and transparent communication. COGR takes OMB at its word and we look forward to working closely with OMB and the COFAR to bring positive closure to the implementation of procurement standards.

We will provide a recap of the COGR Survey, as well as any other updates specific to the procurement standards, at the June COGR meeting.

Uniform Guidance: Open Items beyond Procurement

The February 25th presentation and Q&A session with David Mader extended beyond procurement. An important take-away from the session was Mr. Mader's invitation for COGR to

share with OMB additional areas of concern related to the Uniform Guidance implementation. Consequently, COGR wrote a letter to Mr. Mader, dated March 16, 2016, titled "*Open Items per 2 CFR Part 200*." OMB responded to the COGR letter on May 16, 2016. Copies of both letters are available here.

In a May 17th meeting, COGR staff met with OMB staff to review the OMB response. Based on this meeting, the following summarizes next steps on each item.

1) Procurement. Ongoing and separate initiative (see prior section).

2) Conflict of Interest. OMB is interested in reviewing a COGR analysis of this issue. Some solutions discussed included "harmonizing definitions" and other basic clarifications.

3) 1.3% UCA and REUI weighting factor. CAS and ONR have stated they do not have the engineering background to review the REUI weighting factor. Hence, OMB will work with the Department of Energy to address. If/when a change is approved, OMB will post the new REUI on their web site.

4) DS-2. OMB is interested in the COGR proposed language in the March 16 letter (i.e., eliminate the 6 month approval process). OMB and the COFAR are committed to work with the Federal community, including CAS, ONR, and the IGs, to gauge support for such a change.

5) Subrecipient Monitoring and Safe Harbor. OMB is open to technical corrections and/or FAQs to clarify subrecipient monitoring responsibilities. We need to be very specific as to what our concerns and recommendations are with 200.331(d) prior to sharing with OMB.

6) For-Profits/10% deminimus and Foreign Entity Subrecipients. OMB is open to technical corrections and/or FAQs. They understand the challenge to a for-profit to accept 10% and the challenge to our institutions of having to do rate negotiations. They will take this issue to the COFAR. As to foreign entities and monitoring responsibilities and the expectation of foreign entity compliance with the UG, they are willing to help clarify if we can be very specific as to what our concerns and recommendations are prior to sharing with OMB.

7) Research Terms and Conditions (RTCs) and Uniformity. OMB is not responsible for implementing RTCs, but they are supportive and will promote uniformity when possible. Though OMB stated the a uniform 120-day grant close-out model currently is not being considered, we suggested that this could be an ideal Data Act pilot and could demonstrate that closeout accuracy and timeliness would improve.

8) Codification of the Preamble and FAQs. OMB provided a detailed explanation in their May 16 letter. They reiterated in the letter that the FAQs would continue to be incorporated in the annual Single Audit Compliance Supplement.

9) Cost Share and F&A deviations. We emphasized the real problem is when deviations show up in funding announcements and it is difficult to address these in a timely manner. We used this example to segue to the Ombudsman discussion (see next).

10) OMB Ombudsman. While the establishment of a specific position is not possible at this time, OMB is committed to being informed of agency deviations. We suggested that OMB establish a "process" where we share specific situations with OMB, OMB follows up with the agency, and then we reconnect at a later date to monitor/confirm action.

The COGR RCA and Costing Committees are coordinating action plans on each of the above. We will provide further insights and updates on these items at the June COGR meeting.

Single Audit Update: Student Financial Aid and the Compliance Supplement

A new development related to the scope of the single audit has been raised by the Department of Education. Specifically, this relates to whether the Student Financial Aid program is required to be audited on an annual basis, or if it can be rotated with the Research and Development cluster. This relates specifically to 2 CFR 200.518, Major program determination, and more broadly to the implementation of 2 CFR Part 200, Subpart F – Audit Requirements.

At the February 25th COGR meeting, Mandy Nelson, Partner at KPMG and a National Expert on the Single Audit, provided an update during one of the Thursday morning sessions. At the time, Ms. Nelson identified the issue as potentially problematic, though the Department of Education had not yet raised this issue. Now, however, it has become a concern. OMB is reviewing this and we expect to get more clarification soon.

Also note, OMB continues its work on the 2016 Compliance Supplement. At this stage, OMB expects to release it in late June. We will be sure to keep the Membership updated on all developments.

Affordable Care Act (ACA) Compliance and Graduate Students

The February Meeting Report (dated March 14, 2016) provided the most recent COGR update on several issues applicable to ACA compliance. The American Council on Education 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.

The American Council on Education (ACE) recently posted a Webinar titled "*Learn About Providing Subsidized Student Health Insurance to Graduate Students Under the Affordable Care Act*". Per the ACE description of the webinar, the focus is to provide information to a wide range of campus professionals about whether helping graduate students pay for student health insurance could trigger penalties under the ACA. Last year, the IRS raised questions as to whether institutions providing subsidized student health insurance to their graduate students are in violation of the ACA. On February 5, 2016, the IRS and several other agencies issued an IRS Notice which provides temporary transition relief for institutions that provide such subsidies. The webinar elaborates more about the IRS Notice and its implications for student health plans.

ACE and CUPA-HR will continue to pursue issues related to ACA compliance. If you have questions, COGR can connect you with contacts at ACE and/or CUPA-HR.

COGR Analysis: Equitable Treatment of Off-Campus Research Centers in RFAs

COGR, with significant help from several COGR member institutions, completed an analysis and forwarded it to representatives from NIH. The emphasis of the analysis is to devise a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. Specifically, at issue is the treatment of "space and facility-related costs" when a Research Funding Announcement (RFA) or policy regarding Investigator initiated proposals limits maximum costs in terms of maximum Direct Cost.

In the case of an off-campus research center, space/lease costs and other facility-related costs are considered a direct cost, which means that the off-campus research center will disproportionately have to propose these types of costs in comparison to an on-campus research center. In effect, the off-campus research center is at a competitive disadvantage because fewer costs can be proposed for research staff and other direct research-related costs. The inequity is compounded when a proposed collaborator is associated with an off-campus research center; in this situation, the potential subrecipient would include space and facility-related costs in the proposed budget.

Several options to restore equity that have been discussed are: 1) Allow the off-campus research center to exclude space and facility-related costs when the RFA includes a maximum Direct Cost limitation, or 2) Allow the off-campus research center to state maximum costs in terms of Total Cost instead of Direct Cost when the RFA includes a maximum Direct Cost limitation. If interested in receiving a copy of the analysis, please contact David Kennedy at dkennedy@cogr.edu. We will keep the Membership updated on all developments.

Final FAR Rule Published on Basic Safeguarding of Contractor Information Systems

On May 16 the final FAR rule on Basic Safeguarding of Contractor Information Systems was published. COGR/AAU had commented on this rule when it was proposed in 2012 (see October 2012 COGR Update). Our main concern was the broad scope of information potentially subject to the requirements. (Note: this rule does not involve Controlled Unclassified Information (CUI). Those safeguarding requirements will be the subject of a different pending rule, as discussed in the panel session at the COGR February meeting).

The main change in the final rule is to switch the emphasis from safeguarding information to safeguarding contractor information systems that involve federal contract information. However, the scope remains intentionally very broad. It applies to any contractor information system that processes, stores, or transmits such information. Federal contract information is defined as information not intended for public release that is provided by or generated for the government under a contract to develop or deliver a product or service to the government.

In our comments we had expressed concerns about the effect on contracts for fundamental research, and urged that such contracts be exempted from the requirements. The FAR Councils declined to do so, asserting that the since the focus is on information systems rather than specific types of information there should be no effect on fundamental research. We also suggested that "generated for" the government be changed to "delivered to." The response was that since the

focus is on safeguarding information systems rather than specific information, "it is not necessary to draw a fine line as to what information was "generated for the government." "
The rule has been streamlined from what was originally proposed, and certain vague terms have been dropped (e.g. "best level" of security; "reasonable assurance" of limited access). Most COGR member institutions probably have first level information system security requirements already in place that meet most of the basic safeguarding requirements in the FAR clause (52.204-21). Examples are limiting access to authorized users, identity authentication, sanitizing information system media before disposal, protection from malicious code, etc. However, the rule potentially could extend to data exchanged among researchers working on federal contracts through desktop or personal electronic devices. Institutions receiving contracts containing the new FAR clause will have to assess whether they are in compliance with the safeguarding requirements. The requirements also flow down to subcontractors at all tiers.

The basic safeguarding requirements do not specifically reference FISMA or NIST standards, although the requirements follow NIST SP 800-171 guidelines. Systems that contain CUI require more than this basic protection. We expect the pending CUI rule will specifically incorporate the NIST requirements.

COGR Discusses Revised Export Control Definitions with OMB/OIRA

The Reginfo.gov website indicated last month that OMB/OIRA was reviewing the final rules submitted by Commerce/BIS and State/DDTC containing revised EAR/ITAR definitions of concern to the COGR membership, including "public domain" and "results or products of fundamental research." COGR joined AAU and APLU in submitting comments on these definitions when proposed last June (see COGR August 2015 Update). We requested a meeting with OIRA to discuss our serious concerns with the rules as proposed.

COGR, AAU, APLU, and university representatives met with representatives from OIRA, Commerce and State to discuss our concerns on May 5. We expressed serious concerns about two issues. The first was the provision in the proposed ITAR rule that sponsor proprietary review would take a research project out of fundamental research status. This was the biggest concern expressed in our comment letters. We stated that if this requirement was unchanged it would have a chilling effect on university—industry research collaborations. We pointed out that this would conflict with the Administration's initiative to increase such collaborations leading to greater commercialization of university research. It also contradicts the harmonization objective of the export control reform initiative, since the EAR (presumably) still explicitly allows such review. We pointed out that government policymakers at all levels are seeking to encourage more university-industry partnerships, and provided examples. We also discussed the real world compliance implications of such a requirement.

The second issue was the inconsistent treatment of software as a result or product of fundamental research in both the proposed EAR and ITAR rules. The Definitions sections of the proposed rule treat software similarly as technology or technical data, but the sections on Fundamental Research conspicuously mention only technology or technical data as results or products of fundamental research. We expressed the view there should be no difference between natural language and computer language research results for these purposes. We also pointed out a potential conflict with another Administration initiative, the open source software policy (see #3 below). We also mentioned some concern about the somewhat limited nature of the educational exclusion in the proposed rules.

The rules for these meetings do not allow the government representatives to discuss the content of the rules under review. However, they asked a number of questions about the nature of university-industry collaborations and the process for determinations of fundamental research on campus. We asked about the timing of the issuance of the final rules. There was not a clear answer; however, subsequently on May 9 the website indicated that OIRA review was concluded.

While we at least had the opportunity to make our points with OIRA, we do not know if our comments had any impact on the content of the rules. There is no indication as to when the rules will be published, but we expect this might happen at any time.

COGR Comments on Open Source Software Policy

The February Meeting Report discussed the Department of Education's recent proposal to require open licensing of all grand-funded products and the related panel discussion at the February COGR meeting. In mid-March OMB released a draft policy requiring that a portion of custom software code developed with Federal funding be released as Open Source Software (OSS). A pilot program was proposed for participating agencies to release at least 20% of newly-developed custom code each year for 3 years as OSS. Unlimited government rights to the source code and documentation would be required in contracts. Comments were due April 11 (subsequently extended to April 18). The Administration also is launching Project Open Source, an online repository of tools and best practices to help agencies with implementation. For more information see https://sourcecode.cio.gov.

COGR and AAU submitted comments on the draft policy on April 11. While we expressed support for increasing access to custom software developed for the government, we also expressed concerns about the increased administrative burdens and loss of commercialization opportunities. We pointed out that the draft policy is inconsistent with the FAR's prescription (27.409(b)(5)) for use of the Alternative IV to the basic FAR data rights clause for research contracts with universities. We also pointed out that the FAR clause (52.227-14) already gives the government unlimited rights in software first produced in the performance of a government contract where Alternative IV is not applicable. This would allow for the reuse and sharing of such software by other agencies; one of the principal objectives of the draft policy. The policy also is ambiguous as to what open source license language would govern release of particular custom code.

We expressed the view that the 20% minimum requirement could negatively impact commercialization and innovation without consideration of the nature of individual custom code on a case-by-case basis. Finally, we strongly objected to including grants and cooperative agreements in the policy (a question on which comments were sought). We pointed out that grants and cooperative agreements are used for financial assistance, not to procure products for government use. Mandating release of custom code could have a negative impact on research, since the required use of OSS might guide research decisions. The comments are posted on the COGR website.

The Administration is strongly committed to an Open Source approach to government data and government-funded outputs such as software. We are likely to see similar initiatives to the draft OSS policy and the Ed. proposed requirement.

Controversy Continues Over March-in Rights and Drug Pricing

The February Meeting Report and Update discussed developments related to the Congressional request to NIH to exercise march-in rights under the Bayh-Dole Act to address drug pricing issues. NIH still has taken no formal action that we know of on the January march-in petition regarding the prostate cancer drug Xtandi. However the petitioners in that case recently have suggested that NIH instead use the royalty-free government use license to inventions subject to Bayh-Dole to produce generic versions of Xtandi for Medicare patients. A Canadian company has offered to produce generic versions of Xtandi under the government license.

The Bayh-Dole Act gives the government the right "to practice or have practiced (a subject invention) for or on behalf of the United States." The scope of this license has never been clearly defined. In a 2003 report GAO suggested that these rights should be used only to meet needs reasonably related to the requirements of federal programs. NIH expressed concern at the time that GAO may have taken too limited a view of the scope of the government's rights. Conflicting views have been expressed by others in the legal literature. There is no case law on the issue that we have been able to find.

In some ways use of the government license for this purpose might be "cleaner" from a legal standpoint than use of march-in rights. It also might be consistent with GAO's view of the proper scope of the license. However there are substantial policy and practical implications associated with such use. Broadening the scope of the government license for Xtandi as suggested could have a chilling effect on the ability of universities to license inventions in biomedical areas. There also is an issue as to what government agency might have authority to exercise the license to produce and distribute drugs. NIH has stated in its responses to various march-in requests that it does not have such authority. Nevertheless pressures on NIH to address this issue for inventions subject to Bayh-Dole are likely to continue. (In a related development, the petitioners in the Xtandi case also have filed objections to a number of recent NIH exclusive license announcements.

In another related development, a recent article and related op-ed in the May 13 Washington Post proposed that the government use its authority under 28 USC 1498 as a mechanism to address high drug prices. This provision basically gives the government eminent domain-like authority to use or manufacture any patented invention without permission but requires payment of "reasonable and entire compensation" to the patent owner. This provision has been used by agencies such as DOD (e.g.to produce night vision goggles), but it's only use with regard to drugs occurred 15 years ago in response to the anthrax scare. At that time HHS threatened to use the authority to import generic versions of Cipro to establish a stockpile for treatment purposes unless the manufacturer of Cipro agreed to provide the drug at a reasonable price. The manufacturer agreed, and actual use of the provision was averted. It should be noted that the government's authority under this provision extends to all patents, not just those that result from federal research support. It may be unlikely that the government actually would use the 1498 authority against drug patents, given the substantial repercussions. However, it does not involve Bayh-Dole and could be less immediately damaging to the ability of universities to license inventions.

We understand that an upcoming Report of the UN Secretary General's High Level Panel on Access to Medicines will contain findings and recommendations that cite the role of patents in

preventing access. A number of policy papers were submitted to the UN panel. Some of them were critical of the Bayh-Dole Act and U.S. university licensing practices. We understand the draft report may signal out the Bayh-Dole Act for specific criticism. The USG did not participate in this panel and recently submitted highly critical comments. We are reaching out to the appropriate USG agencies to discuss our concerns with the draft report. We also are working with AUTM and other higher ed. associations to prepare materials and information for use in responding to the report. The draft is expected to be available next month.

Neither the UN Report nor these other developments themselves may result in specific adverse actions. However, the ferment and controversy over drug pricing clearly is not going away, and appears to be increasing. The university community needs to be vigilant in seeking to provide accurate information and challenging misrepresentations of university tech transfer practices. We will keep the COGR membership informed of events.

Bayh-Dole NPRM Expected in June

The February 2016 Update discussed a pending NIST NPRM that will contain a number of proposed changes to the Bayh-Dole Act regulations (37 CFR 400). These mostly involve technical changes or issues that primarily involve federal agency implementation. We had expressed concerns to NIST about the timing of the NPRM, given the current controversy over march-in rights and drug pricing.

NIST plans to issue the NPRM next month. We understand that in response to our concerns, the NPRM will contain a specific statement that comments on drug pricing issues will be viewed as non-responsive to the NPRM, and will not be further considered. While this is positive, we still are concerned that the NPRM could become a vehicle for other more threatening changes to Bayh-Dole. There also could be unintended implications for COGR members in some of the proposed technical changes. We will closely review the NPRM when it is issued and comment accordingly.

Piecemeal Patent Troll Legislation Introduced

The comprehensive patent troll legislation (H.R. 9; S. 1137) introduced in Congress last year remains stalled. However, a number of bills have been introduced that address specific aspects of concerns about patent trolls. These include S. 632 (STRONG Act—addressing USPTO *inter partes* review procedures), S. 2733 (Venue Equity and Non-Uniformity Elimination Act of 2016), H.R. 1896 (Demand Letter Transparency Act), H.R. 2045 (Targeting Rogue and Opaque Letters (TROL) Act), and H.R. 4829 (Trade Protection Not Troll Protection Act). The higher ed. associations have not taken a position on any of these bills. None address the issues in the comprehensive legislation that are of greatest concern to us (e.g. fee shifting, joinder). However, should there be indications that any of these bills may advance, we will review and analyze the provisions more closely, and proceed accordingly.

PTO Publishes Additional Guidance on Subject Matter Eligibility

We have discussed in several COGR Updates and Meeting Reports the updated guidance issued by the U.S. Patent and Trademark Office (PTO) on patent subject matter eligibility (see August 2015 Update). PTO initially issued this guidance in December of 2014 and issued updated guidance last July.

On May 6 PTO issued further updated guidance. It includes a number of new life science examples. PTO is seeking public comments, but the comment period is open-ended.

Our preliminary review indicates that the updated guidance is helpful and more positive with regard to subject matter eligibility than the previous guidance. PTO continues to make a determined effort to rationalize a maze of recent contradictory court decisions in this area. The new guidance adds six additional examples to the 27 that were previously issued, including two directed to diagnostics, which has been of particular concern to patent practitioners.

PTO also specifically asks for comments on the quality of the correspondence concerning subject matter eligibility rejections. Hopefully the continued evolution of the guidance will help improve the quality both of the decisions and explanations. We do not intend to comment, but encourage comments and suggestions to PTO from COGR members.

New Effective Management Practices Guide

At the February meeting we advised the membership that the revised edition of COGR's "Managing Externally Funded Sponsored Programs: A Guide to Effective Management Practices" had been updated for the university community on effective financial, compliance, and administrative practices in research administration. The revised guide incorporates 2 CFR 200 (UG) and other updated regulations. Last revised July 2009, the new version is now available and posted on COGR's website with hyperlinks throughout to relevant information and cross cutting sections. The online version will be updated twice a year or as applicable when new regulations are effective. Click here to access the revised Guide. Hard copies are currently out for print and will be sent to each member institution over the summer. COGR will provide an overview of the changes made to the Guide in the Thursday morning session at the June meeting.

HHS, Office of Research Integrity (ORI)

At the February meeting, the RCA Committee met with Dr. Kathryn Partin, new Director of ORI to hear about her plans for developing strategic goals for ORI. During this meeting Dr. Partin asked for written suggestions and recommendations by early May on changes the grantee community would like to see implemented, examples of challenging issues with ORI, and what ORI data we would like to see published. COGR responded to her request on May 9th with nine recommendations. Click here to review the COGR letter. Dr. Partin thanks the membership for our feedback and hopes to have a document completed by the end of June incorporating all the feedback she received during her visits with the grantee community. COGR plans to have Dr. Partin present her strategic goals at the October 2016 meeting.

NSF PAPPG Guide and Large Facilities Manual

NSF published in the Federal Register for comment the draft *Proposal & Award Policies & Procedures Guide* (PAPPG). Comments are due **July 15, 2016**. A number of clarifications and additions including but not limited to the addition of two new proposal types, "Research Advanced by Interdisciplinary Research and Engineering" (RAISE) and "Grant Opportunities for Academic Liasson with Industry" (GOALI), additional information on automated compliance

checks, the addition and clarification of voluntary and uncommitted cost sharing, clarification of language regarding IRB documentation, etc. have been made. Click here for additional information: Draft PAPPG and Federal Register Notice.

On May 9th, NSF published a notice in the Federal Register announcing the availability of a "For comment" draft of the NSF *Large Facilities Manual* (LFM). The Foundation is accepting comments from the external community until **COB July 8, 2016.** COGR will be responding to both notices. Please submit your comments to jbendall@cogr.edu.

Jean Feldman, Head Policy Office, NSF will be attending the June 9th Thursday p.m. session to provide an overview of the PAPPG and the LFM as well as provide status updates with Michelle Bulls, Director, Office of Policy for Extramural Research Administration, NIH on the Research Terms and Conditions and the Final Research Performance Progress Report (RPPR).

Department of Labor issues Final Rule on Overtime

On May 18, DOL released its **Final Rule** increasing the salary threshold from $23,660 to $47,476 with automatic increases every three years. See Final Rule for details and document specific to Higher Education. Institutions must be in compliance with the new rule by December 1, 2016.

COGR's comment letter stressed that the significant salary increase would have a substantial impact on postdocs and other research positions that are currently below the proposed salary threshold, raising important questions about the financial resources required to fund the increase, concerns regarding re-classification of exempt to non-exempt personnel, and increased administrative burden. To read COGR's comment letter to DOL, click here.

Acknowledging that more is needed to reflect the advanced education, the NIH will increase the awards for postdoctoral NRSA recipients to levels above the threshold qualifying postdoctoral research for exemption status. Click here for more information. More details regarding the implementation will be provided in the NIH Guide in the coming months.

Law makers from the House and Senate have issued a resolution to block the overtime rule stating that the new rule would raise costs for colleges and small businesses and lead to higher college tuition. The bill would require the Labor Department to conduct a new and comprehensive economic analysis on the impact of mandatory overtime expansion to small businesses, nonprofits and public employers as well as an analysis on the effect on employee flexibility before implementing a change to the exemptions. Click here for more information on the bill introducing the Protecting Workplace Advancement and Opportunity Act (S. 2707, H.R. 4773).

Josh Ulman, Chief Government Relations Officer, CUPA-HR will be attending the June 8th RCA Committee Meeting to discuss the Final Rule and efforts underway to block the rule. COGR will inform the membership of any new developments in this area and has partnered with CUPA-HR to provide the May 25th free webinar.

Analyses of Comments on the Common Rule Notice of Proposed Rulemaking

COGR, with support from member volunteers and the Association of Public and Land-grant Universities (APLU), released a comprehensive review and analysis of the 2,186 public

comments submitted in response to the 2015 Federal Policy for the Protection of Human Subjects (Common Rule) Notice of Proposed Rulemaking (NPRM). We reviewed three major proposals specific to biospecimens including the proposal to change the definition of "human subject" to include non-identified biospecimens, to mandate broad consent for secondary research use of biospecimens and to restrict IRB waiver of consent for secondary research use of biospecimens. We also reviewed responses on mandated use of a single IRB for multisite studies, extending the Common Rule to all clinical trials, proposed data security safeguards and the proposal to post clinical trial consent forms to a federal website.

The results of our analysis include a summary and table of all findings as well as over a dozen individual summaries by respondent category (e.g., patients, the general public, researchers, universities and medical centers and other stakeholder groups). Among the findings, we report that over 95 percent of patients and members of the research community opposed one or more of the proposed changes related to expanding the definition of "human subject" to include non-identified biospecimens. The findings were posted online and a joint association press release issued on Monday, May 9. The results of the review were reported by Bloomberg BNA, Inside Higher Ed, Politico and others. The findings were also discussed in a recent meeting with Howard Shelanski, Administrator of the Office of Information and Regulatory Affairs, and other OMB and White House staff.

The Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) presented its findings on the Common Rule comments at a meeting of the Secretary's Advisory Committee for Human Research Protections (SACHRP) on May 18. The results of the OHRP analysis were largely consistent with those of the COGR-APLU analysis. Regarding proposed changes involving non-identified biospecimens, OHRP reported that a "strong majority of commenters oppose these proposals" and that there was "opposition across all subgroups." OHRP similarly reported that responses on mandated use of a single IRB for all multisite studies and extending the Common Rule to all clinical trials regardless of funding source were mixed. A rationale that was not noted in the OHRP presentation is that universities already extend coverage but under the current rule can apply flexibility to reduce administrative burden while maintaining equal protections. The OHRP presentation suggested that responses were mixed on posting consent forms, where the COGR-APLU analysis found that 84% of responses opposed the proposed change.

Audit

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

The NSB held its A&O meeting on May 5. The NSF OIG Semiannual Report to Congress was briefly mentioned. NSF management has reviewed the report and is preparing its response. The response and report will be submitted to Congress this month. Allison Lerner, National Science Foundation (NSF) Inspector General, announced that Brett Baker has left the NSF Office of Inspector General (OIG). Brett is now the Head of Audits for the Department of Defense OIG. Marie Maguire will serve as Acting Head of Audits as the NSF OIG searches for a permanent replacement.

The National Academy of Public Administration (NAPA) report, *National Science Foundation: Use of Cooperative Agreements to Support Large-Scale Investment in Research* was discussed. A particular focus of the discussion was the use of management fees. There was also discussion on an NSF review of award titles and abstracts to assess for public accessibility. The review found that in 2015, 24% of titles were changed from the time of submission to award. Award

titles were found to be much clearer than submitted titles by NSF staff reviewing titles for accessibility. The review found that abstracts are still written at a level more appropriate for individuals with advanced degrees.

NSF Audit Resolution

The NSF Division of Institution and Award Support, Cost Analysis and Audit Resolution Branch completed its review and resolution of an audit report issued to a university. In a letter dated May 2, NSF did not sustain $108,819 in questioned costs related to NSF's two-month senior salary policy but did allow $40,853 in costs related to unallowable compensation, airfare expenses, and relocation costs.

NIH Single IRB Policy

We have been told to expect a final NIH policy mandating use of a single IRB for multisite studies in May with a June 2017 implementation date. In recent presentations on the policy, NIH has suggested that independent IRB fees for primary and secondary activities as well as fees for secondary activities performed by an institution as the IRB of record in a multi-site study could be charged as direct costs. COGR committee members will discuss the proposed policy, the feasibility of direct charging IRB costs and use of an independent versus institution-based IRB as the IRB of record for NIH multisite studies at a Thursday, June 9, morning session of the COGR meeting.

Research Regulatory Reform

Reports and Legislation

Two reports on research regulatory reform are anticipated in June. The National Academies Committee on Federal Research Regulations and Reporting Requirements is expected to release Part II of its report, *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*. Legislation aimed at implementing a number of the recommendations in the report, the *Promoting Biomedical Research and Public Health for Patients Act*, has been introduced by Senators Alexander and Murray and COGR and AAU have endorsed the legislation. Similar legislation has been drafted by Representative Lipinski but has not yet been introduced. A second report on research regulatory reform is expected to be published in June, this one from the Government Accountability Office (GAO) in response to a 2012 request from Representative Mo Brooks. The GAO report is expected to focus on finances, personnel, effort reporting, subawards, data sharing, and conflict of interest.

Department of Energy (DOE) Retrospective Review

The Department of Energy issued a Federal Register Notice on May 10 seeking comments on existing DOE regulations and reporting requirements consistent with Executive Order 13563 "Improving Regulation and Regulatory Review." The agency is interested in how DOE regulations could be modified, streamlined, expanded, or repealed to better achieve regulatory objectives and minimize burden. Comments are due July 11 and should be identified by "Regulatory Burden RFI." If you have comments on potential reforms to DOE regulations that you would like to discuss with COGR please contact Lisa Nichols.