COUNCIL ON GOVERNMENTAL RELATIONS
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February 14, 2017

TO: COGR Membership

FROM: COGR Staff

SUBJECT: February 2017 Update

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

Mandy Nelson, Partner at KPMG; Ralph DeAcetis, Managing Director at PwC; and Mary Foelster, Director, Governmental Auditing and Accounting at the AICPA, will participate in a panel session to discuss topics related to the Single Audit and the Uniform Guidance. We will address issues, such as: How have single audits changed under the Uniform Guidance (2 CFR Part 200 Subpart F - Audit Requirements)? What might be coming under the 2017 Compliance Supplement? And specifics related to testing Internal Controls (e.g., Subrecipient monitoring, Key personnel and effort, PI disengagement, Pre-award spending, Late spending, etc.). We encourage you to raise your questions and concerns relevant to your institution.

COGR F&A Survey: Results Available at the February COGR Meeting

We will present the 2017 "Executive Summary" during a Thursday afternoon session at the February COGR Meeting. The Executive Summary provides a primer on F&A (i.e., Research Operating Costs) and the F&A reimbursement process, including a high-level analysis of F&A rates and trends. The Executive Summary also includes the Appendix: Results of the Questionnaire portion of the Survey, which captures selected results of the survey summarized in tables and graphs. The Executive Summary and Reports will be available by accessing the COGR website (www.cogr.edu, see Policy Issues / Financial Management) the week following the COGR Meeting. Historical F&A Rates by Institution, Negotiation Experiences (de-identified), and other reports will be available to **COGR Members Only.**

Procurement Standards: Current Status, Next Steps

COGR continues its work toward a resolution on the Micro-Purchase Threshold (MPT) issue. The MPT, as specified in 2 CFR 200.67, defines the threshold to be consistent with the FAR (currently set at $3,500). Furthermore, 2 CFR 200.320(a), describes "*Procurement by micro-purchases*" as one of the five methods that can be used for procurement actions. While we successfully have delayed implementation of the MPT (and the entire suite of Procurement Standards) by obtaining grace period extensions, eliminating the MPT has been an ultimate goal.

Our focus remains on the highly anticipated Federal Register Notice, which should include a new procurement rule, via modifications to 2 CFR 200.67 and/or 2 CFR 200.320(a). More on that below. Concurrently, over the course of the past six months, legislative solutions were pursued in coordination with Lewis-Burke Associates and the Association of Independent Research Institutes (AIRI). Late last year, both the National Defense Authorization Act (NDAA) and the American Innovation and Competitive Act (AICA) were passed by Congress, and signed into law by President Obama before he left office. Both established a $10,000 MPT, with flexibility to use a higher threshold, albeit with slight differences:

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

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

COGR's assessment is that OMB will be the "relevant executive agency" responsible for implementation and incorporating the NDAA and the AICA language into the Uniform Guidance (2 CFR 200). **Both the NDAA and the AICA are effective now, so the $10,000 MPT (with provisions for a higher threshold) is applicable.** However, we still await release of the Federal Register Notice, which will provide a forum to clarify the slight differences and to provide possible other updates to the Uniform Guidance. COGR is in regular contact with OMB, and as of the writing of this COGR Update, the following can be noted:

Federal Register Notice/Uniform Guidance Update:

- The Federal Register Notice (as well as updated OMB/COFAR FAQs) are being held under President's governmentwide freeze on new or pending regulations.
- OMB asks for patience as they meet with their General Counsel and new Senior Leadership; the hope/expectation is that non-controversial "grants administration" guidance will be released soon.
- OMB fully understands that the NDAA and AICA statutory language needs to be clarified in the Uniform Guidance; this adds credence to the hope/expectation that the Federal Register Notice will be released soon.
- A one-year extension to the procurement grace period will be included in the Federal Register Notice. However, we need official confirmation of the extension soon. OMB understands our growing sense of urgency and is working towards solutions.

Patience continues to be the operative word. If there is no movement by March, we will strategize on how best to elevate concerns. We have invited OMB to speak during the Friday morning session at the COGR Meeting, though at this time they cannot confirm. We appreciate your patience and we will provide updates at the February COGR Meeting.

Costing Policies Committee: Other Issues

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

Student Financial Aid (SFA) Cluster and the Single Audit. The four Associations, the National Association of State Auditors, Comptrollers and Treasurers (NASACT), the American Institute of Certified Public Accountants (AICPA), the National Association of College and University Business Officers (NACUBO), and COGR, continue to monitor this issue (see November 4th Letter to OMB). We were concerned that the Department of Education (ED) position (requirement for a separate annual compliance audit of Title IV Student Aid Programs) might be included in the 2017 Compliance Supplement. However, in the DRAFT version provided to COGR, it is not included. **This is good news.** Still, we will continue to monitor this issue as ED continues to support an annual audit.

2017 Single Audit Compliance Supplement. OMB has circulated a DRAFT version of the 2017 Compliance Supplement. If interested in reviewing, contact David Kennedy at COGR at dkennedy@cogr.edu.

Securing Student Information, Student Financial Aid (SFA) Cluster. This is new section that has been added to the DRAFT version of the 2017 Compliance Supplement (Section N.

Special Tests and Provisions, pages 5-3-52 through 5-3-55). **NASACT, the AICPA, and leaders from the Single Audit firms have raised significant concerns** as this could be a complex and expensive audit activity. We are monitoring this issue, as well.

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

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

F&A Rates and Nonprofit Research and Disease Foundations. COGR participated in a meeting in November, led by FasterCures, a DC-based center of the Milken Institute. The meeting included a diverse workgroup of representatives from nonprofit research and disease foundations, and research universities, to address issues of common ground. Issues related to data sharing, intellectual property and licensing previously were addressed by this workgroup, and the current initiative being explored is to develop better methodologies for recovering F&A-related costs. More to come on this initiative this year.

HHS Office of Grants Policy Update. Outstanding issues that we have raised with the HHS Office of Grants Policy include: 120-day grant closeout model across all HHS ODs, functionality of the Payment Management System (PMS), the prospects for other HHS ODs to join the Research Terms and Conditions. Issues related to grant closeouts are being addressed internally by the HHS Office of Grants Policy and their "Closeout Workgroup". Finally, the HHS Grants Policy Statement (last updated in 2007) is being revised and we hope to engage with the HHS Office of Grants Policy as this gets closer to completion.

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

Equitable Treatment of Off-Campus Research Centers in NIH RFAs. A COGR Workgroup continues its work with NIH to devise a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. At issue is the treatment of lease costs when a Request for Application (RFA) or policy regarding Investigator initiated proposals limits costs in terms of maximum direct cost. COGR's

position is that off-campus research centers are at a competitive disadvantage; i.e., by including the lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. NIH is reviewing our request to address this issue.

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

Dept. of Education Issues Final Open Licensing Rule

On January 19 the Department of Education (Ed.) published a final rule requiring open licenses to the public of copyrightable grant deliverables created with Department competitive grant funds. Our understanding is that it currently is subject to the Regulatory Freeze announced in the White House Memorandum of January 20.

COGR joined other higher education associations in commenting on this rule when proposed (See COGR December 2015 Update). We expressed support for the NPRM objectives to stimulate wide dissemination to the public of educational materials created under Ed. grants and to broaden the impact of the public investments. We noted that our member institutions already routinely use open licenses to make available educational and other materials and technologies that they create. However we expressed concern that the Department's "one size fit all" approach would frustrate our ability to commercialize these technologies to encourage entrepreneurism and startup formation and public—private partnerships.

Ed. has been fairly responsive to our concerns in the final rule. It narrows the scope somewhat and clarifies the rights of various parties, including third parties whose materials may be incorporated in the grant deliverables. It also adds two broad exemptions (in addition to individual programmatic exemptions). One is based on dissemination plans approved by the Secretary upon a determination that the grantee's dissemination plan would likely achieve meaningful dissemination equivalent to or greater than open licensing or that compliance would impede the grantee's ability to form necessary partnerships. The other is where compliance would conflict with or materially undermine the ability to protect or enforce other intellectual property rights or obligations of the grantee.

Our concern with the dissemination plan exemption is that it is likely to result in possibly lengthy delays and uncertainties in implementation. It is not clear how the Secretary will make the determinations or on what criteria they will be based or who in the Department will be responsible for advising the Secretary as the effectiveness of the submitted dissemination plans. Much more specificity is needed as to the submission and approval process. The experience of COGR member institutions with the process for review and approval of dissemination and commercialization plans by other federal agencies has not necessarily been positive. With regard to the other exemption for compromise of intellectual property rights, the broad nature of the exemption may be helpful but we also are concerned about the process and who makes the determination. While examples are provided in the rule (i.e. computer software with elements that may be protected under copyright laws, patent laws, and trade secret laws), they may raise more questions than answers.

Another area of major concern is quality control. The validation of educational technologies is extremely important, especially when developed with government funding. There is a critical need for evidence based assessments that are peer reviewed and published (e.g. "What Works Clearinghouse"). Open licensing could result in modifications without the necessary follow-on review and validation by the original developers, which could lead to undesirable and possibly dangerous outcomes.

The implementation of the rule if not rescinded has been postponed until March 21. We are working with the other higher ed. associations on draft comments to the new leadership at Ed. We want to acknowledge the responsiveness of Ed. staff to the concerns, but stress our belief that that an open licensing requirement should not be the default in all cases unless they fall under specific exemptions. Grantees should propose dissemination appropriate for the particular grant objectives or nature of the materials. In some cases this might well include open licensing, as is now the case. If individual Department programs believe open licensing will best achieve their goals, this should be stated in solicitation documents with the ability of grantees to propose alternative approaches.

NIST Revised Bayh-Dole Regulations On Hold

We've discussed in the past few COGR Updates and Meeting Reports the proposed changes to the Bayh Dole Act implementing regulations (37 CFR 401); see December 2016 Update). On December 9 COGR joined with four other higher ed. associations in submitting comments to NIST.

NIST has advised us that the revised regulations now are subject to the regulatory freeze. NIST is optimistic that they eventually will be released. They were a product of the Obama Administration's Lab to Market Initiative. It is not clear if that will be viewed negatively by the new leadership at Commerce. Since they are technical in nature, it appears unlikely they would raise major policy concerns. However, the possible effect of the recent "two-for-one" Executive Order on Reducing Regulation is unclear.

While our comments identified 10 categories of concerns with the proposed changes, we expressed particular concern about the proposal to require 120 days' notice to agencies if a contractor decides not to continue to prosecute applications or to abandon patents. In addition to raising technical issues about the deadlines for this purpose, the comment letter expressed concerns about the ability to properly assess technologies for patenting and licensing purposes. Informal discussions with NIST indicated understanding of the concerns about this requirement. There also apparently was interagency discussion of all the comments received.

We have invited NIST representatives to meet with the COGR CIP Committee this month. We hope to be able to obtain some further indications of the status of the proposed changes and likely responses to some of the concerns raised. We will keep the COGR membership informed.

PTAB Holds State Universities Are Immune from IPR Proceedings

On January 25 the Patent Trial and Appeal Board (PTAB) held that state universities and their research foundations are entitled to assert sovereign immunity as a defense to the institution of *inter partes review* (IPR) proceedings against their patents (IPR2016-01274, Paper 21 (PTAB Jan. 25, 2017).

In deciding the case the PTAB relied heavily on the Supreme Court decision in *Fed. Mar. Comm'n v South Carolina State Ports Auth* (FMC), 535 U.S. 743, 753–761 (2002). In that case the Supreme Court held that while state sovereign immunity is meant to cover judicial proceedings, it also applies to adjudicary administrative proceedings that have many common features with litigation. The PTAB characterized *inter partes reviews* as similar in nature to the FMC case. They are basically directed against private patent owners, with similar adversarial rules as lawsuits. The PTAB also found that the University of Florida Research Foundation was an arm of the state, based on its functions to commercialize University intellectual property, state law, the degree of control exercised by the University, and the financial relationship with the University. As such, it was entitled to assert sovereign immunity.

The debate over state sovereign immunity is longstanding. Critics have pointed to the "uneven playing field" between public and private institutions with regard to patent litigation.
Legislation to address this issue has been proposed previously, such as conditioning the ability to enforce patents on waivers of sovereign immunity. It is not clear whether the PTAB decision is appealable. A related case in the Federal District Court for a declaratory judgment claim of non-infringement which also found sovereign immunity is under appeal to the Federal Circuit. Regardless of the ultimate outcome, this case may reignite the sovereign immunity debate, which has been divisive among universities.

Attention Continues to Focus on Drug Pricing and Federally-Funded Patents

Knowledge Ecology International (KEI based) has requested the HHS Inspector General to investigate the alleged failure of Cold Spring Harbor and its licensee (Ionis) to disclose federal funding of inventions leading to the development of Nusenersin, a drug for spinal muscular atrophy. Ionis now allegedly is charging $750k for the first year and $375k after for maintenance doses of the drug. The situation is particularly troubling because NIH allegedly has provided at least $17.5M in funding, some directly to Ionis (formerly Isis). In the letter to the IG, KEI provided a scientific analysis of the grants that appear related to the Nusenersin patents.

The Bayh-Dole Act requires disclosure to funding agencies of inventions. Failure to disclose can lead to forfeiture of title to the government (37 CFR 401.14(d)(1)), which was upheld by the Federal Circuit in the *Campbell Plastics* case (289 F.3d.1243; Fed. Cir. 2004; the case was discussed in a panel session at a COGR meeting shortly after the decision, COGR February 2005 Meeting Report). In the letter KEI asks the IG to "explore relevant remedies" in light of the alleged failure to disclose as well as to investigate whether NIH conducted proper oversight.
The required government support statements apparently were lacking from some of the patents involved in Nusenersin development. Cold Spring Harbor informally has advised COGR that the invention was disclosed to NIH (pre-iEdison). It should be pointed out that lack of disclosure triggers the government's forfeiture right, not lack of a government support statement in a patent. Certificates of correction frequently are issued to add or correct government support statements. However, regardless of the outcome of this case, we have become increasingly concerned about compliance with invention reporting requirements (see COGR June 2016 Meeting Report).

AUTM shares the concern, and NIH repeatedly has expressed concerns to GOGR. One recent study claimed that under reporting of inventions might be as high as 50%, although there is some controversy about that figure. Regardless, we believe institutions need to pay attention to this issue especially given the heightened political visibility of drug pricing concerns. There are

obvious resource implications to increased staff investment in compliance and reporting particularly if it requires is a shift away from commercialization and partnering activities. But it may be a necessary investment in the current political climate. We also plan to discuss invention reporting issues with NIST (our comments on the NIST NPRM included discussion of the issues).

Controlled Unclassified Information (CUI) Developments

Discussions Continue with NARA on Development of FAR CUI Clause

We mentioned in the October Update that NARA was developing a FAR rule to implement compliance requirements based on NIST SP 800-171 for Controlled Unclassified Information (CUI) for non-federal entities including contractors. The FAR rule will apply government-wide and is supposed to supersede individual agency clauses (Among other things the FAR rule will address situations where a contractor has outsourced part of the CUI processing to an external Cloud Service Provider (FedRAMP protections may apply in such cases)). NARA has discussed both with COGR and FDP input for the planned FAR rule.

On January 5 the Chair of the FDP Contracts Working Group (also Chair of the COGR CIP Committee) sent a letter to NARA discussing the contractor environment for purposes of the FAR clause. The letter discussed the importance of clear identification of CUI with proper markings by agencies, the need to exempt fundamental research, and the need for flexibility in compliance, with full certifications or project-specific plans and self-monitoring as options. It also discussed alternate clauses for various scenarios and performers, including flowdown situations.

NARA subsequently contacted COGR and expressed a desire for further discussions. NARA does not expect the regulatory freeze to have much effect on this activity. We plan to meet again with NARA, in conjunction with FDP and university representatives.

DHS Issues Safeguarding Requirements for Contractor CUI

On a related matter, on January 19 DHS issued a new clause for the HSAR on CUI. A footnote at the end states that the rule applies to contractor information systems operated on behalf of the agency (NIST SP 800-53 and FISMA apply to systems operated on behalf of agencies, whereas NIST SP 800-171 requirements apply to non-federal entities that handle, process, use, share or receive CUI). There is also a statement in the rule that "Neither the basic clause or its alternates should ordinarily be used in contracts with educational institutions" (3004-470-4(a)).

While the proposed DHS rule does not appear inconsistent with the NARA CUI rule and is not expected to have much effect on COGR member institutions, there are confusing statements in the rule stating that it applies to "any situation where contractor employees may have access to CUI (e.g. 3004-470-3(a))." The Background statement in the proposed rule also talks about the need to "ensure adequate security for CUI that is accessed by contractors." Also the DHS policies linked in the rule contain many terms such as "For Official Use Only" which supposedly have been superseded by CUI. We may suggest to DHS the need to clarify upfront the scope of the rule, since it is not immediately apparent. Comments are due March 20.

DOE Revises Order Pertaining to Foreign Nationals Performing DOE-Funded Research

For the past several years we have reported on discussions with DOE about the requirement of the DOE National Energy Technology Lab (NETL) in Morgantown that all foreign nationals performing research on NETL-funded work must be submitted to DOE for approval. The requirement has been applied to fundamental research projects performed on campus even where the foreign nationals have no access to NETL-provided information or DOE facilities. It is based on DOE Order No. 142.3A ("Unclassified Foreign Visits and Assignment Program").

In October the CIP and RCA Committees met with Adam Cohen, DOE Under Secretary for Science and Engineering (see October Meeting Report). He informed us that NETL's interpretation of the DOE Order was based on the view that all information pertaining to DOE-funded projects is protected DOE information. The Secretary of Energy had issued a letter approving a waiver process for accredited institutions of higher education for fundamental research projects where the information generated will be published and the results will not be export controlled. While the waiver process has been helpful, it was clear that some clarification was needed in the DOE policy which Dr. Cohen acknowledged at our meeting.

On January 18 DOE issued an amendment to DOE Order 142.3a, which provides for an exemption from the Foreign Nationals prior approval requirements for universities conducting fundamental research. The exemption reads:

> "Portions of this Order relating to approval for foreign national access to DOE information do not apply to research conducted under grants and funding opportunities sponsored by the program offices that report to the Under Secretary for Science and Energy, performed at institutions of higher education, and for which results will be published for access by the general public. Performance of this research is not considered access to DOE sites, information, technologies, equipment, programs, or personnel for purposes of this Order. The work products of this research are not considered DOE information during the performance of the research and after completion of the research. However, the Order does apply to visits by any foreign nationals to DOE sites and any access to DOE information, equipment or personnel not exempted in this paragraph."

The exemption only applies to programs that report to the Under Secretary of Science and Energy. The Order specifically lists NETL as among those.
On February 1 COGR sent a letter of appreciation to Dr. Cohen. The letter cited the reduced administrative burdens of having to obtain foreign approval for foreign nationals. We believe AAU has sent a similar letter.

Department of Labor Overtime Rule

In December's update COGR mentioned the November 2016 preliminary injunction filed by a Texas Federal judge blocking the Obama administration's overtime rule and the DOL appeal to the injunction that would delay the decision into the new administration. On January 25, 2017 the Department of Justice requested that a Louisiana federal appeals court delay case, Nevada v. DOL, 5th Circuit for 30 days in order to allow the Trump Administration to file its brief to defend or kill the rule. Critics of the rule have stated that the duties test should be the determining factor of who receives overtime. If the extension is approved, the due date of the brief will be March 2nd. COGR will update the membership as information becomes available.

National Academies Dual Use Research of Concern (DURC) Workshop

Since the release of the USG's policy on Institutional Oversight of Life Sciences Dual Use of Research Concern (September 2014), institutions and faculty performing such research have a shared responsibility to promote responsible conduct and communication of DURC. On January 4, 2017, the National Academies hosted a "Dual Use Research of Concern: Option for Future Management" workshop. The agenda of the workshop included options for communicating the results of dual use research of concern while protecting certain information. The workshop reviewed existing mechanisms for control of information sharing such as retraction, FOIA, classification, and export controls, as well as First Amendment issues and the applicability of free speech to a scientist's right to publish research results. Papers at the workshop were commissioned for the purposes of offering options for dissemination of dual use research results that could be adopted.. The deliverable from the workshop will be a report that assesses the various options presented from the commissioned papers discussed during the workshop. For additional information on the workshop and the webcast, click here.

NIH RFI on Data Sharing and Management

As mentioned in the "upcoming notices" section of the December update, the NIH sought comments to its RFI: "Strategies for NIH Data Management, Sharing and Citation." Specifically, NIH requested information on the types of data to be shared ranked by highest priority and the value of each, how long the data should be made available, questions of maintenance, sustainability and storage implications and finally barriers in terms of costs and mechanisms to overcome the costs. COGR, AAU and APLU filed a joint response that can be found here for additional information.

The Research Compliance and Administration (RCA) Committee will be hosting Carrie Wolinetz, Associate Director for Science Policy, and Dina Paltoo, Director, Division of Scientific Data Sharing Policy, Office of Science Policy at its upcoming meeting on February 22nd. The NIH will share feedback from the comments received to the RFI and update the Committee regarding the current and future expectations of the NIH Public Access Policy. The Committee will share this information with the membership during the Public Access Panel presentation Thursday, February 23, at 4:15 p.m.

Department of Defense NPRMs

COGR recently responded in its comment letter to DoDs first series of six (6) NPRMs revising its interim implementation of Government-wide Guidance on administrative requirements, cost principles and audit requirements for Federal Awards. Although not a departure specifically from the OMB Guidance, COGR did call attention to a change from the previous prior approval matrix where the participating DoD Components waived prior approval for re-budgeting among budget categories. In this revised interim guidance, noted in Appendix D, Section B.1.h, page 78403, DoD incorporates 200.308(e), requiring prior approval for budget transfers exceeding 10% of the total award, if the award is above the simplified acquisition threshold. COGR explained that the new requirement is a deviation from what other major federal agencies have implemented regarding re-budgeting and has asked that the previous DoD guidance be reinstated. Moreover, since DoD allows components to pre-approve a 30 day extension to performance reports, COGR asked that DoD consider a change in due dates for final progress reports from 90 days 120 days to be consistent with the due date for final financial reports.

COGR stressed that a change in the due date would help alleviate potential inconsistencies across all DoD components. For other comments click here.

RCA will be hosting Dr. Lawrence C. Schuette, Director of Research, Office of Naval Research at its February committee meeting and will raise these issues along with others mentioned in COGR's recent letter to DoD on proposal deadlines. Stay tuned for additional information in the next post meeting update.

Background:

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

National Policy Requirements General Award Terms
https://www.federalregister.gov/documents/2016/11/07/2016-25700/national-policy-requirements-general-award-terms-and-conditions

DoD Grant and Agreement Regulations
https://www.federalregister.gov/documents/2016/11/07/2016-25717/dod-grant-and-agreement-regulations

Format for DoD Grant and Cooperative Agreement Awards
https://www.federalregister.gov/documents/2016/11/07/2016-25699/format-for-dod-grant-and-cooperative-agreement-awards

Administrative Requirements Terms and Conditions for Cost Type Awards to Non Profit and Governmental Entities
https://www.federalregister.gov/documents/2016/11/07/2016-25701/administrative-requirements-terms-and-conditions-for-cost-type-awards-to-nonprofit-and-governmental

Definitions for DoD Grant and Agreement Regulations in Subchapters A-F.
https://www.federalregister.gov/documents/2016/11/07/2016-25698/definitions-for-dod-grant-and-agreement-regulations-in-subchapters-a-through-f

NIH Salary Cap, Executive Level II 2017

COGR has received several inquiries regarding whether the Trump administration plans to revoke, modify or supersede the current Executive Order and Executive Level II Salary cap effective January 1, 2017. Although we note that the NIH has not updated their website with the current 2017 pay scale, institutions should budget according to the rate table posted on the Office of Personnel Management website found here.

DoD Proposal Deadlines

In our previous update we urged the membership to share email correspondence and agency examples of funding opportunities showing time variances in proposal deadline dates beyond 5:00 p.m. local submitter's time. As a result of your effort and willingness to participate, COGR has submitted its letter to the DOD urging that funding opportunities specifying 11:59 p.m. proposal deadlines be uniformly changed across all DoD components to 5 p.m. local submitter's time. COGR highlighted a number of factors that result from imposing such deadlines including but not limited to the significant burden such deadlines have on research staff, the need to pay overtime for proposal staff and other office personnel, (e.g., COI, IRB, IACUC) whose signatures are necessary for review of protocols and conflict of interest requirements beyond 5:00 p.m. For more information about COGR's letter, click here.

DoD has expressed interest in pursuing future discussions with Grants.gov personnel so that these revisions can be made possible without manual rejections. Stay tuned for more information.

Select Agents and Toxins NPRM

On January 19, 2017, one year later from HHS NPRM 1/19/16 seeking comments to the HHS list of select agents and toxins, the Centers for Disease Control and Prevention (CDC) releases its final rule effective February 21, 2017. At this time NO proposed changes to the list of select agents and toxins or provisions addressing permissible toxin limits and inactivation of select agents are set to take place. The rule also specifies no change or further clarifications as previously proposed to biosafety or regulatory language regarding security, training, incident response, and records.

The final rule does however make changes to the **current regulations** as follows:

1) Adds new provisions regarding the inactivation of select agents, specific biosafety requirements, and toxin requirements;
2) Clarifies regulatory language regarding security, training, and records;
3) Adds the name of agent B. cereus Biovar anthracis for Tier 1 agents in sections 5 and 9 of the regulations previously left off in error from interim rule.

The U.S. Department of Agriculture (USDA) has made parallel regulatory changes.

Human Subjects Research

Final Revised Federal Policy for the Protection of Human Subjects (Common Rule)

HHS released a much anticipated final revised Common Rule on January 19, 2017. The effective date for most provisions of the rule is January 19, 2018. The effective date for mandated use of a single IRB for multisite research is January 20, 2020. Proposed changes to the Common Rule were initially published for comment as an advanced notice in July 2011. That notice contained a number of very controversial provisions, including a proposal to expand the definition of "human subject" to include non-identified biospecimens; to require broad consent for secondary research use of biospecimens collected in research and clinical care settings; and to make IRB waiver of consent for secondary research use of biospecimens "very rare." A notice of proposed

rulemaking (NPRM) released in September 2015 retained many of the same provisions. Other controversial proposals included extending the Common Rule to non-federally funded clinical trials at institutions that receive federal funding for non-exempt, non-excluded human subject research; mandated use of a single IRB for all multisite studies; and privacy and security standards that were not defined in the proposed rule. The NPRM drew over 2,100 comments. A COGR-APLU analysis of the comments found significant opposition to most major proposals, in particular with respect to proposed changes involving non-identified biospecimens. The findings were consistent with those of an HHS Office for Human Research Protections (OHRP) review. COGR staff met with OMB Office of Information and Regulatory Affairs and HHS OHRP staff on January 12, prior to the release of the final rule, to restate university concerns with the proposed changes.

Many of the controversial changes proposed in the NPRM have been removed from the final Common Rule. The revised rule does not expand the definition of "human subject" to include non-identified biospecimens; broad consent for secondary research use of identifiable biospecimens and identifiable private information is optional; and IRBs' ability to waive consent for secondary research use of non-identified biospecimens is unchanged. The Common Rule was not extended to non-federally funded trials, and proposed privacy and security standards were not included in the final rule and will be addressed in guidance. The rule does not include the proposed concept of "excluded" activities. It indicates activities not considered research and adds to and modifies existing exemptions. An exempt decision tool, if created, will be addressed outside of the rule and publicly vetted.

The final rule does include the proposed requirement for use of a single IRB for U.S. multisite research conducted or supported by Common Rule agencies. The final rule does allow agencies to exempt broad categories of research, and potentially all research funded by an agency. The rule requires that informed consent forms include key information up front, adds additional elements of consent, and requires that any version of an IRB approved consent form for clinical trials conducted or supported by a Common Rule department or agency be posted on a publicly available federal website. Continuing review is eliminated for many minimal risk studies and the final rule eliminates the requirement that grant applications undergo IRB review and approval. The final rule does alter the definition of "human subject" which now includes identifiable biospecimens. This definition and the definition of "identifiable private information" will be re-examined within one year of publication and every four years thereafter. The Secretary's list of categories of research eligible for expedited review will be evaluated at least every 8 years. Additional details on the content of the final revised rule are available on the COGR website as an overview and one-page summary table.

Animal Research

USDA Animal and Plant Health Inspection Service (APHIS) Website

The USDA APHIS announced on February 3 that following a "comprehensive review" of the information it posts on its website, "inspection reports, regulatory correspondence, research facility annual reports, and enforcement records that have not received final adjudication" related to the Animal Welfare and Horse Protection Acts will no longer be posted to the agency's website. Those seeking this information are instructed to submit a Freedom of Information Act (FOIA) request. Reasons cited for the removal include evolving court decisions and Federal guidance. The notice also indicates that "consistent with recent amendments to the FOIA, if the

same records are frequently requested records under the FOIA, and are subject to release under the FOIA and Privacy Act, APHIS will post the appropriately redacted versions to its website."

Regulatory Reform

Legislative Efforts to Reduce Research Regulatory Burden

A number of bills recently signed into law include provisions aimed at reducing research regulatory burden. These include the 21st Century Cures Act, the American Innovation and Competitiveness Act and a provision of the National Defense Authorization Act. An updated matrix that relates provisions of each of the bills to recommendations made by the National Academies, National Science Board and Government Accountability Office for reducing research regulatory burden is available on the COGR website. A session at the February COGR meeting will focus on all aspects of the legislation with implications for research institutions, how the new laws are being implemented, and COGR's engagement in the implementation process.

OIRA Releases Interim Guidance on Reducing Regulations and Controlling Regulatory Costs

OIRA has issued interim guidance to Federal departments and agencies on implementing section 2 of the January 30, 2017 Executive Order "Reducing Regulation and Controlling Regulatory Costs" titled "Regulatory Cap for Fiscal Year 2017" with respect to significant regulatory actions issued between January 20 and September 30, 2017. The order indicates that when an executive department or agency proposes a new rule it must identify at least two existing regulations to repeal as a means to fully offset the costs of the new regulation. The guidance instructs that the total incremental cost of all new regulations, including those repealed, must not be greater than zero. The guidance indicates that "new significant guidance or interpretive documents will be addressed on a case-by-case basis" and instructs agencies to consult with OIRA before issuing new significant guidance or regulatory interpretations and ensure that it is clear that such guidance is voluntary. "Meaningful burden reduction through the repeal or streamlining of mandatory reporting, recordkeeping or disclosure requirements may also qualify." The guidance encourages agencies to "determine the actual cost and other effects of eliminating regulatory actions" rather than relying on the original regulatory impact analyses and indicates that "To the extent feasible, regulatory actions should be eliminated before or on the same schedule as the new regulatory action they offset." Per the notice, "All requirements under other Executive Orders and implementing guidance (e.g., EO 12866 and OMB Circular A-4) remain applicable." Public Citizen, the Natural Resources Defense Council and the Communications Workers of America are suing over the Executive Order on the grounds that it violates the Constitution and the Administrative Procedures Act.

Audit

HHS Office of Inspector General (OIG) Reports on Payroll Certification

The HHS OIG released its report on the payroll certification pilot at the University of California, Riverside. This is the final of four audit reports on the Federal Demonstration Partnership pilot by the HHS and NSF OIGs and the first complete report by the HHS OIG. An audit of UC Irvine provided no conclusions or recommendations.

In the UC Riverside report, the HHS OIG suggests that there was no suitable means of verification that charges were reasonable in relation to work performed. A key concern expressed is that budget estimates became actuals as the payroll system automatically charged the project account. The OIG suggests that while investigators could review charges and make changes to the account on a monthly basis, there was "no evidence that such changes had ever been made other than cost transfers." The report notes that interviews with investigators suggested that some carefully reviewed the monthly reports and others did not and that the review was not mandatory at the time of audit. Investigators did perform annual certification for each award. The university indicated that "suitable means exist to document that salary charges represent the actual work performed on a grant and not just budget estimates" and provided details in its response included in the report. The OIG also found that "PIs adjusted the amounts charged to Federal awards after Payroll Certification forms had been certified without (1) prior supervisory approval, (2) documented justification, or (3) amending the Payroll Certification forms."

The OIG also expressed concern that the "university did not provide the PI with a full salary distribution that could assist in determining the reasonableness of the salary charges made to the PI's project." The report suggests that "having a transparent view of each employee's full payroll allocation, including percentage allocations assigned to other awards or projects, *is necessary* [emphasis added] for a PI to ensure the salary charged to his or her project is reasonable in relation to the work performed." In contrast, the NSF OIG report on the audit of payroll certification at George Mason University notes that making full payroll allocations available to PIs would "be useful" and "is important" in assuring that charges to federal awards are accurate and that it could be an important control to help ensure that overcharges and inaccurate charges do not occur. The report does note that "78% of GMU employees charged salaries to a single NSF grant and that the full allocation remains recorded and available within GMU's systems." Similar statements are made in the Michigan Tech report where 73% of employees in the sample allocated full salaries to a single NSF grant.

The HHS OIG report noted variations in implementation across institutions and also differences in NSF and NIH policy guidance that have implications for the outcomes of the various audits. Per the report, "Although the audit plan and methodology were consistent across all pilot institutions, the results differ depending on each institution's implementation of its respective pilot system and the nature of the grants and related guidance from the awarding agency (HHS/NIH or NSF). The report notes that NSF limits an investigator's salary charged to an award to 2 months of their annual base salary; that graduate students typically do not charge their time to more than one NSF grant and that faculty rarely charge administrative staff time directly to NSF grants. This is in contrast with HHS awards where "faculty and graduate students often work on multiple HHS grants and… administrative labor costs can also be charged to HHS grants." The report suggests that a payroll certification system "needs the functionality to track and report salary information that provides an audit trail for determining:" the reasonableness of costs charged and transfers; that pay charged is no more than 100 percent of total pay; and "the appropriateness of reclassifying administrative costs as direct costs."

The report suggests that the university's prior effort reporting system did not always provide the information to confirm payroll costs and that the pilot system provided less accountability than the prior system. With respect to the previous effort reporting system, the report indicates that the university did not separately identify non-sponsored activities into categories such as instruction, departmental administration, and departmental research and that investigators could therefore not determine if effort was greater than 100%. Per the report, "Even if the system could

provide assurances that salary charges did not exceed 100 percent, the PI would need more complete information, such as a certification form for all activities to which the employee was assigned, to make the appropriate certification." The OIG suggests that "The University's prior effort-reporting system often provided a clearer means of verifying direct salary charges made to HHS sponsored awards and that unallowable transactions under the prior effort-reporting system that could not have been identified under the pilot system.

The report indicates that "the pilot PCS did not comply with requirements of Circular A-21 and, as designed, limited the ability of the University and HHS to provide oversight of these funds." The OIG suggested that "we are unable to conclude that the University's payroll distribution reflected the principle of after-the-fact confirmation or determine that the salary expenses charged to HHS grants represented actual costs, in accordance with the requirements of Circular A-21" In contrast, the NSF OIG report of GMU found that "the certification meets the requirements of OMB Circular A-21 under which it was audited." A report of the Michigan Tech audit suggested that "Michigan Tech's system generally provided accountability over federal funds" and that issues identified "were not the result of inadequate controls over the pilot system."

The HHS OIG made 12 recommendations in the UC Riverside report, including several recommendations for strengthening general IT controls for systems used to support the pilot payroll certification system. UCR indicated that it does not agree with the recommendations or that "it is necessary to return to its prior effort-reporting system to comply with federal requirements." Per the report, "the University concurred with our fourth recommendation—requiring and documenting prior approval and justification for adjustments made after grant expenditures have been reported to the Federal Government—but did not concur with our other recommendations" The report indicates that UC Riverside did describe actions taken or planned actions to enhance internal controls. Per the report, the university plans to provide PIs the ability to "access an individual's full payroll distribution for the certification period" and "view payroll details including the payroll distribution percentage for each funding source used to pay the employee's salary;" among other changes.

HHS OIG Audit of Subrecipient Monitoring

The HHS OIG recently reported an audit of subrecipient monitoring at a large research university. The audit period was a little over a year and reviewed expenditures for which the university was both the prime (e.g., risk assessment, monitoring and F&A for the selected grants) and the subrecipient (e.g., costs claimed, including salary and wages, equipment, supplies, and travel). The report indicates that the OIG limited their review to "obtaining an understanding of [the institution's] policies and procedures for monitoring subrecipients and claiming costs as a subrecipient." And that "[the institution] monitored subrecipients and claimed costs as a subrecipient in accordance with NIH grant policies and Federal regulations." There were no negative findings or disallowed costs. We mentioned in the December COGR update that the HHS OIG was currently auditing one university on subrecipient monitoring with plans to audit additional universities this year. This report provides a sense for what universities might expect from an HHS OIG audit on subrecipient monitoring. NSF will also audit subrecipient monitoring at universities this year.

HHS OIG Audit of Direct Charging of Administrative and Clerical Costs

A recent report focuses on administrative and clerical costs charged directly to HHS Awards. The report suggests that the university "did not always claim selected costs charged directly to HHS awards in accordance with Federal regulations and NIH guidelines." Of 120 salary transactions in their sample, the OIG deemed 18 ($85,065) not allowable and of 100 nonsalary transactions in their sample, 39 ($104,302) were not allowable. The report indicates that "On the basis of our sample results, we estimated that the University charged at least $1,311,067 in unallowable transactions and related F&A costs to HHS awards during our audit period." "Fifteen transactions were for salary costs for administrative and clerical work such as ordering supplies, reconciling accounts, and caring for lab mice." The report suggests that "Salaries of administrative and clerical staff should normally be treated as F&A costs unless an unusual degree of administrative support is justified as necessary to perform the award (the Circular § F.6.b.(2))." Three salary transactions did not have a properly signed effort report. In terms of non-salary charges the report found that "Seven transactions were not supported with sufficient documentation; Eighteen transactions related to specialized service centers were not charged in accordance with Federal regulations; Four transactions were for general-purpose equipment and office supplies that should have been treated as F&A costs; and Ten transactions did not meet the Circular's criteria for allocable costs." The university suggests that "the vast majority of the costs questioned were reasonable, allowable, and allocable." Additional details are provided in the report.

The following excerpt from the report calls to mind concerns about the NIH sIRB policy in terms of tracking staff time to a project: "The employees' administrative duties benefited multiple activities and could not always be tied to an individual project. Because the administrative activities did not solely benefit the project to which the University charged the salary costs, we applied cost principles that state: "The apportionment of employees' salaries and wages which are chargeable to more than one sponsored agreement or other cost objective will be accomplished by methods which will ... (iii) distinguish the employees' direct activities from their F&A activities" (J.10.b (l)(b) of the Circular). In addition, we could not determine the percentage of effort these employees spent on administrative activities because the University's effort reports did not reflect time spent on administrative tasks."

DATA Act

HHS is concluding the DATA Act Section 5 Grant Pilot Test Models in preparation for a report to Congress. The agency is still accepting participants for the Single Audit Test Model. Those interested in participating should contact the DATA Act PMO at DATAActPMO@hhs.gov.