

COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 460, Washington, D.C. 20005

(202) 289-6655/(202) 289-6698 (FAX)

November 6, 2015

October 22-23, 2015 COGR Meeting Report

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RESEARCH & REGULATORY REFORM

Committee: Sara Bible, Chair, Stanford University, Cindy Kiel, University of California-Davis, Kerry Peluso, Emory University, Lois Brako, University of Michigan, John Ritter, Princeton University, Suzanne Rivera, Case Western Reserve University, Ara Tahmassian, Harvard University, Daniel Shapiro, University of Southern California, Robin Cyr, University of North Carolina-Chapel Hill, Lynette Arias, University of Washington, Naomi Schrag, Columbia University

Common Rule Notice of Proposed Rulemaking (NPRM)

The deadline for submitting comments on the Common Rule [NPRM](#) is Dec. 7 with no word on an extension. As we mentioned in the [October report](#), COGR and many of its members have submitted requests for an extension ranging from 30-90 days. The Secretary's Advisory Committee on Human Research Protections (SACHRP) has recommended a 60 day extension. SACHRP met on October 21-22. Archived webinars for [Day 1](#) and [Day 2](#) of the meeting are available online. The focus of the meeting was the Common Rule NPRM. SACHRP will approve recommendations on the NPRM at a December 3-4 meeting. Among the possible recommendations are support for electronic notification about the range of research uses of biospecimens and data collected for non-research purposes, and the opportunity to opt-out of secondary research use resulting in the need to track consent. The proposed recommendation was said to run counter what the subcommittees proposed, which was that biospecimens and data should be treated the same. Consistent with recommendations on the draft NIH single IRB policy, SACHRP is expected to support the concept of a single IRB, but not a mandate. Members of COGR's Common Rule working group presented an overview of COGR's initial response to the NPRM at the October meeting. Slides are available on the COGR website. We anticipate distributing a draft of the COGR response to the NPRM sometime during the week of November 9. As a reminder, the OHRP Website includes links to a [webinar series on the Common Rule](#) as well as the [archived Public Town Hall Meeting](#).

FDA/OHRP Joint Guidance on IRB Minutes

The FDA and OHRP have issued draft guidance titled, "Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs" which is available on the [FDA](#) and [OHRP](#) websites. The joint draft guidance is intended to assist institutions and IRBs with preparing and maintaining minutes of IRB meetings. It describes requirements for minutes and provides recommendations for meeting them. Comments are due by January 4.

FDA Guidance on Informed Consent for Device Studies Using Deidentified Biospecimens

The FDA released a [notice](#) on October 23 requesting comment on a proposed extension of guidance on informed consent for in vitro diagnostic device studies using leftover human specimens that are not individually identifiable. The notice indicates that *under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations* and that *FDA*

regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens. The [guidance](#) has been in place since 2006 and aligns with proposed revisions to the Common Rule. Comments are due Dec. 22.

NIH Proposal to Amend Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

NIH released a [notice](#) on October 16 seeking public comment on its proposal to amend the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules to incorporate the [recommendations of the Institute of Medicine](#) (IOM) regarding human gene transfer clinical research protocols. The notice indicates the IOM recommended that the NIH maintain its protocol submission and safety reporting requirements, but restrict individual gene transfer protocol reviews to exceptional cases that meet specified criteria. NIH is proposing to amend the guidelines for the criteria and process for selecting protocols for NIH Recombinant DNA Advisory Committee review and the process by which human gene transfer protocols are registered with NIH, and to streamline the submission requirements for protocol registration. Comments are due November 30.

NIH Notice on the FY 2016 NIH Grants Policy Statement (NIHGPS)

NIH published a Notice ([NOT-OD-16-017](#)) on October 27 to inform grant applicants and recipients of the “[significant changes](#)” that will be incorporated into the revised FY 2016 NIHGPS. The FY16 NIHGPS incorporates new and modified requirements, clarifies policies, and implements changes in statutes, regulations, and policies implemented since the publication of the March 31, 2015 version. It will be available in November and changes and clarifications effective at the time of publication.

DATA Act Section 5 Pilot

DHHS released a notice on November 2 of an [Information Collection Request](#) for a DATA Act Sec. 5. “Simplifying Federal Award Reporting” Grants Pilot. Clearance is being requested to conduct tests under the pilot program. The notice indicates that the DATA Act Program Management Office within HHS has developed test models to determine whether new technology, data standards, processes, and forms aid in reducing recipient burden and to increase the accuracy and quality of the data submitted. Topic areas may include, but would not be limited to, Standard Form (SF) 424, the Consolidated Federal Financial Reports, and the expanded Single Audit form (SF-SAC).

Section 5 of the [DATA Act](#) requires the Director of OMB to work with federal agencies and award recipients to identify common reporting elements, unnecessary duplication in financial reporting, and unnecessarily burdensome reporting requirements and to conduct a pilot program to include 12 months of data collection. The notice indicates that there will be 300 respondents and that the collection will require roughly 56 hours per response. If your institution is interested in participating in the pilot please contact [Lisa Nichols](#). Additional information is expected to be made available in an upcoming national webinar on this topic scheduled for Wednesday,

November 18, from 2:00 – 3:00 p.m. Eastern Time. The Speakers will be Karen Lee of OMB and Mike Peckham of HHS. For details and to view the webinar, [register here](#).

Audit Update

HHS OIG

The HHS OIG released its [FY2016 Work Plan](#) on November 2. The work plan includes audits proposed in previous fiscal year work plans as well as new proposed audits. Areas of interest that have been added to the FY16 plan include: A possible audit of the Center for Disease Controls (CDCs) oversight of the Select Agent Program (pg. 52) including the number, frequency, and results of inspections, as well as CDC's response to noncompliance; An assessment of colleges' and universities' controls over the subcontracting of NIH grant and contract work (pg. 56) including whether the services subcontracted to other organizations are effectively monitored and Federal funds are spent on allowable goods and services in compliance with cost principles and the terms and conditions of the grants and subcontracts. Reviews will be based on the dollar value of Federal grants received and input from NIH.; and, A review of OHRPs process for reviewing violations of HHS regulations protecting human research subjects (pg. 57), including the extent and scope of OHRPs' compliance evaluations from 2000 to 2014, how OHRP works with government entities and IRBs during its evaluations, and how OHRP's work with these entities enhances or constrains its capacity to conduct evaluations.

NSF OIG

The NSF OIG released its [FY2016 Audit Work Plan](#) on October 29. A message from Brett Baker, the Assistant Inspector General for Audit, indicates that the OIG will continue to perform data analytics on NSF, awardee, and other external databases and sources to identify higher-risk awardees to audit. The plan includes audits of universities, non-profits, and for-profit entities to determine whether costs charged to NSF awards are allowable, allocable, and reasonable; assessing the adequacy of awardees' internal controls over the administration of NSF funds in compliance with federal and NSF requirements and recipient financial information; and incurred cost audits of NSF awardees. No additional details are provided. The plan indicates that the OIG may also utilize desk reviews to examine costs claimed by NSF awardees.

COSTING POLICIES

Committee: Kim Moreland, Chair, University of Wisconsin, Joseph Gindhart, Washington University-St. Louis, Cindy Hope, University of Alabama, Lynn McGinley, University of Maryland-Baltimore, Jeffrey Silber, Cornell University, Cathy Snyder, Vanderbilt University, Michael Daniels, Northwestern University, Dan Evon, Michigan State University, Charles HrnCir, Texas A&M University, Michael Legrand, University of California-Davis, James Fortner, Georgia Institute of Technology, Vivian Holmes, Broad Institute

FDP Payroll Certification Pilots: Thursday PM Session at the October COGR Meeting

A Thursday afternoon session at the October 22-23 COGR Meeting, The FDP Payroll Certification Audit Results and their Impact on the Future of Effort Reporting, included presentations by:

David Reed, Vice President for Research, Michigan Technological University
Michael Laskofski, Associate VP for Research Operations, George Mason University
Debbie Rafi, Director University Business Affairs, Office of Naval Research

The PPT presentations by David Reed and Michael Laskofski are available at www.cogr.edu (see Meetings tab on home page). Also, Debbie Rafi spoke from her notes and did have a PPT presentation.

This session was inspired by the release of the Michigan Technological University ([MTU Pay Cert audit](#)) and the George Mason University ([GMU Pay Cert audit](#)). Both were conducted by the NSF OIG and COGR has summarized both audits in recent COGR Updates. Note, the HHS OIG also has conducted two Pay Cert audits; the [University of California, Irvine audit](#) was the first Pay Cert audit to be released, though the HHS OIG did not render an opinion due to their concerns with reconciling University accounting data to Federal Financial Reports. The University of California, Riverside audit is expected to be released soon.

COGR's analysis of the session, including take-aways and next steps include:

- GMU and MTU developed and implemented high-quality Payroll Certification systems and processes. Under the auspices of the FDP pilot, the systems at both institutions have been operational and effective for over three years. Furthermore, both system implementations have resulted in a dramatic decrease in the number of reports produced, an equally dramatic increase in faculty acceptance and goodwill, a significant reduction in training costs and effort (which allow resources to be shifted to more high-risk compliance areas), and ultimately, more robust and intuitive systems that result in effective, efficient, and compliant accounting for payroll charges made to Federal awards.
- The audit results, while containing several findings generally not originating from the pilot at each institution, affirmed the validity of the design and controls inherent to the

Payroll Certification systems at GMU and MTU. The most important statement in both audit reports (slightly modified in each) is: “*We concluded that these problems occurred because [GMU / Michigan Tech] did not follow its internal policies and procedures, and not as a result of inadequate design of pilot system controls.*” Affirmation by the NSF OIG that the design and controls are acceptable is a positive and significant finding.

- Based on the audit results, FDP’s assessment of the pilots it that “*the pilots were a success*” and that Payroll Certification is a viable methodology to use for confirming payroll charges to Federal awards.
- Payroll Certification is project-centric and puts the focus, more intuitively, on the PI’s active Federal project(s) and those individuals charged to the project. By excluding all other activity, it raises discussions regarding: treatment of non-sponsored activities (mentoring students, proposal writing, service, etc.) and IT system capabilities to ensure that payroll cannot exceed 100%. However, as institutions are able to demonstrate that strong internal controls exist to address such issues, any potential risks are mitigated.
- Officials from the Office of Management and Budget (OMB), Office of Federal Financial Management, have been strong in their encouragement for universities to explore and implement new systems, such as Payroll Certification and other alternatives to effort reporting, as long as the system complies with the nine requirements listed in section 200.430(i) – Standards for Documentation of Personnel Expenses. The FDP Payroll Certification pilots are a helpful start and will serve as a “green light” to some institutions to consider alternatives.
- Acknowledgement by Federal officials that a system, such as Payroll Certification, is acceptable will be helpful to institutions that are contemplating alternatives to effort reporting. However, more important may be working with your institution’s internal audit and compliance offices, along with your A-133/Single auditors to assess an alternative system’s compliance with the principles and internal control standards defined in 2 CFR Part 200.430 – Compensation and documentation. When compliance is demonstrated, an alternative to an effort reporting should be considered acceptable.
- The approval process in the form of a DS-2 amendment to implement a new system still is murky. For institutions that are proposing a new system, COGR’s suggestion is to contact your cognizant agency for indirect cost (HHS/CAS or ONR), notify that the institution is considering a change, and confirm what needs to be submitted (e.g., a notification letter) to proceed with the change. Note, if the approval process becomes burdensome or uncertain in any manner, we encourage you to contact COGR.
- Federal OIG audit and acceptance of alternative systems is an unknown, and could be an unknown for several years. However, and COGR reiterates, the most important consideration when implementing a new system may be working with your institution’s internal audit and compliance offices, along with your A-133/Single auditors to assess compliance. When compliance is demonstrated, audit risk should be minimal.

COGR will continue to follow developments on the FDP Payroll Certification Pilots and all issues related to alternatives to effort reporting and implementation of 2 CFR Part 200.430 – Compensation and documentation.

Costing Policies Committee Update: Thursday AM Session at the October COGR Meeting

COGR recently has welcomed new leaders and members to the Costing Policies Committee. This session included an introduction to the members of the Costing Policies Committee and an issues update. Presenters, and the topics addressed by each panelist, included:

Dan Evon (Financial Closeouts and Procurement), Michigan State University
Cathy Snyder (Utility Cost Allowance), Vanderbilt University
David Kennedy (DS-2, NIH Salary over Cap/Research base, UG Report Card), COGR
Steven Bloom (ACA), American Council on Education

Below is a summary of the presentations from this session, as well as other items that are on the agenda for the Costing Policies Committee. *Note, many of the sections below were reported in the October 2015 COGR Update. Significant updates and next steps, since then, have been highlighted in bold-italic.* Also note, the PPT presentations are available at www.cogr.edu (see Meetings tab on home page).

Financial Closeouts: Next Steps for COGR Engagement

The interrelated topics of the transition to NIH subaccounting (i.e., award-by-award accounting), the new 120-day grant closeout model at NIH (as well as the implementation of 120 days at other agencies), and the functionality of the Payment Management System (PMS) have been significant COGR agenda items for the past two years. The final transition to NIH subaccounting is underway (see [NIH Notice Number: NOT-OD-15-105](#) (May 28, 2015); *Reminder of Timeline for Administrative Changes to NIH Domestic Awards to Transition to Payment Management System Subaccounts*). COGR leaders, who also are active in the FDP, have been instrumental in tracking issues related to the transition to subaccounting. We encourage COGR members to contact COGR staff if/when concerns and/or operational issues arise.

The two primary focuses for COGR going forward are: 1) 120-day consistency across all agencies (ongoing focus), and 2) 120-day functionality in PMS (immediate focus). First, 120-day consistency across all agencies will require continuing engagement with each Federal agency, as well as OMB and other Federal leaders. While NIH, NSF, and DOD have implemented favorable 120-day policies, standardization across all Federal agencies will require ongoing work and advocacy. While achieving results could be a longer term activity, COGR will continue to raise this issue.

Second, and of more immediate concern, is the challenge to implement the 120-day functionality in PMS so that it is consistent with the new NIH policy described in section 8.6 CLOSEOUT of the [2015 NIH Grants Policy Statement](#) (*Recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 120 calendar days of the end of the period of performance (project period). The reports become overdue the day after the 120 calendar day period ends.*) While the 120-day functionality has been implemented in PMS, unease exists. ***This topic was addressed in detail during the Thursday morning session.***

At issue is the complex reconciliation between the Federal Financial Report (expenditures report) that is submitted to NIH and the Federal Cash Transaction Report (cash report) that is submitted into PMS. The reconciliation is challenging and has compromised a seamless transition to the 120-day closeout model at NIH. However, COGR's understanding is that *in most situations (e.g., NIH awards) the Federal Cash Transaction Report (FCTR) becomes obsolete* as each NIH award is converted into a subaccount. The function of the FCTR is to verify the cash balance of each NIH award; however, under subaccounting, the cash balance automatically is maintained in PMS, in which case, the FCTR would appear to no longer be necessary.

While the easy fix seems to be to eliminate the FCTR (and in turn, eliminate the need to reconcile the Federal Financial Report with the FCTR), PMS and HHS leaders may be reluctant to eliminate this report. *Their concern is that cash payments for awards from other HHS Operating Divisions (e.g., HRSA, Indian Health Service, etc.) are considered "Cash Advances" rather than "Cost-Reimbursements", in which case, the FCTR remains necessary to reconcile cash payments to expenditures. So, while elimination of the FCTR as it relates to NIH awards would be a helpful, it will be difficult to fully eliminate the FCTR for awards from other HHS Operating Divisions.*

An important backdrop to this is the ongoing pressure on NIH, and more broadly, on HHS, to address concerns related to unspent balances, timely reporting, and other grants administration and oversight issues. The May 2012 GAO report ([GAO-12-360](#), *Action Needed to Improve the Timeliness of Grant Closeouts by Federal Agencies*) and the recent August 2015 report by the HHS Inspector General ([OEI-07-11-00190](#), *NIH Postaward Grant Administration and Oversight Could be Improved*) put a spotlight on these concerns and, to some extent, distract from more rational and obvious solutions.

COGR will continue its work addressing issues related to Financial Closeouts. *First and foremost is to work with NIH, PMS, and HHS to resolve the FFR/FCTR disconnect. There are several solutions being pursued, including reassessing the timing for when the FFR/FCTR reconciliation has to be completed, and consequently, what triggers the HHS self-imposed 180-day unilateral closeout process.* Also, we will continue to advance consistency across agencies and develop solutions that will minimize administrative burden, while at the same time, maintaining the highest standards of oversight and stewardship over Federal funds. We will keep the Membership posted on all developments.

Procurement: Next Steps for COGR Engagement

In a COGR letter to OMB, dated June 30, 2015, we requested that 2 CFR 200.112 (Conflict of interest) and 2 CFR 200.317-326 (Procurement Standards) be suspended immediately and subject to an extended grace period (see www.cogr.edu homepage, Latest News, for a copy of the letter).

COGR's request specific to 2 CFR 200.317-326 (Procurement Standards) was granted (note, the request specific to 200.112 was not) as part of the [Technical Corrections](#) released in the Federal Register on September 10, 2015. For most research institutions, this means the effective date will be July 1, 2017 (i.e., FY2018). The extra year will allow the community to engage with OMB to address issues such as the micropurchase threshold and other related issues.

COGR plans to draft a position paper / letter and consolidate a number of recommendations and solutions, which we would share with Federal officials. We expect to develop this during November and December, and will provide regular updates to the COGR Membership.

F&A: Next Steps for COGR Engagement

The Costing Policies Committee is spending significant time tracking F&A related issues within the context of the Uniform Guidance implementation. This includes:

- **1.3% UCA and 2.0 research weighting factor.** COGR has completed an analysis, in partnership with Attain, to address the flawed 2.0 factor. ***A more accurate REUI (relative energy use index) for research, and supported by data, is closer to 4.0. We will present the COGR analysis to Federal officials in November with the goal of working with OMB and the Cognizant Agencies for Indirect Cost to update the REUI for research as soon as possible.*** The analysis also will be available to the COGR Membership.
- **DS-2 Approvals.** COGR will continue engaging with OMB for a technical correction, clarification or FAQ that is crystal clear: “if allowable per the UG, a DS-2 approval is not required.” While there are some schools of thought that this already is the OMB expectation, additional confirmation would be helpful.
- **NIH Salary over the Cap and F&A Research Base.** A UG FAQ (Appendix III – 3) states that salary costs above the NIH salary limitation must be included in the appropriate MTDC cost base. COGR’s position is that the appropriate MTDC base is Instruction and Departmental Research and believes this treatment would be consistent with Appendix III – A.1.a(3) and would be the most fair and equitable approach to all stakeholders. However, this is a “hot-topic” with the Cognizant Agencies and we recommend IHEs approach this discussion cautiously. COGR has shared its position with OMB and the Cognizant Agencies, and will continue to do so. ***However, our immediate focus is on the REUI for research and the DS-2. As such, we will revisit this issue in 2016, as appropriate.***
- **Employee Tuition Remission (200.431j).** A UG technical correction resolved this issue by confirming the allowability of employee tuition benefits applicable to undergraduate and graduate work completed at other institutions.
- **1.3% UCA application.** A UG FAQ (Appendix III – 2) has clarified application of the UCA: 1) IHEs currently receiving the 1.3% UCA under OMB Circular A-21: for FY2014 and FY2015 F&A rate proposals, they will retain the 1.3% UCA; and for F&A rate proposals for FY2016 and forward, they must propose the UCA using the new methodology, and 2) IHEs not currently receiving the UCA: they may begin proposing the UCA for F&A rate proposals beginning with FY2014, and going forward.
- **Negotiation Experiences.** We want to hear about the results of your F&A rate negotiations. In addition to the results of the actual rate negotiation, this includes issues that were raised. If your institution has requested the 4-year rate extension, we also are interested in these results. This will allow COGR and the Membership to track issues and

new practices that may be introduced by the Cognizant Agencies. This is of particular interest as we begin to observe the approaches of CAS/HHS and ONR to rate negotiations covered under 2 CFR Part 200.

Contact David Kennedy at dkennedy@cogr.edu on any of the items listed above. In addition, Cathy Snyder from Vanderbilt University and recently selected to the COGR Board also is a point of contact. Cathy can be contacted at cathy.snyder@vanderbilt.edu.

Year-One Report Card for the Uniform Guidance

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

In January 2016, COGR will begin analyzing metrics related to the implementation of the Uniform Guidance. We believe OMB and the COFAR will be doing the same. As appropriate, COGR will formalize an analysis that can be shared with various stakeholders and officials in the research community. *We encourage you to share your institutional perspectives and experiences with COGR staff, which we can include in our analysis.* Send comments to David Kennedy at dkennedy@cogr.edu.

Uniform Guidance: September 10, 2015 Technical Corrections and Updated FAQs

As we reported in the October 2015 COGR Update, a “Dear Colleagues” letter from the Council on Financial Assistance Reform (COFAR), dated September 11, 2015, formally announced the release of technical corrections to the Uniform Guidance (2 CFR Part 200). Per the “Dear Colleagues” letter, corrections were included only where it came to the attention of the COFAR that particular language in the final guidance did not match with the COFAR’s intent and would result in an erroneous implementation of the guidance. Technical corrections also were made to 2 CFR Part 25 to remove references to the “System of Award Management” and replace them with the correct term “System for Award Management”.

The electronic version of [2 CFR Part 200 \(per the eCFR\)](#) has since been updated to incorporate the technical corrections. In addition to the extension of the grace period to the Procurement Standards (see previous section), COGR had requested that section 200.431(j) be corrected to confirm the allowability of employee tuition benefits applicable to undergraduate and graduate work completed at other institutions. This technical correction was made. In addition, FAQs were updated and posted to the [COFAR website](#). The direct link to the [updated FAQs](#) is available on the website.

Affordable Care Act (ACA) Compliance and Graduate Research Assistants

As we have reported in COGR updates since the summer, COGR was contacted by the American Council on Education (ACE) and the College and University Professional Association for Human Resources (CUPA-HR) to help them craft policy proposals concerning the management

of graduate student employees consistent with the ACA's employer mandate. A summary of the issues and concerns were included in the October 2015 COGR Update.

Steven Bloom, Director of Federal Relations, American Council on Education (ACE) provided an update on this topic during the Thursday morning session at the October COGR Meeting. ACE and CUPA-HR are the lead Higher Ed associations on ACA-related issues and are working closely with the IRS and the Department of Treasury. Currently, universities are required to be at 70% compliance with the employer mandate (i.e., 70% of employees must be offered an ACA compliant health plan). That threshold is scheduled to be phased to 95% compliance in 2016.

Consequently, in order to establish compliance, a university must demonstrate the appropriate thresholds of employees are being offered an ACA compliant health plan. Use of "safe harbors" can be helpful in demonstrating compliance for non-traditional employees. For example, ACE and CUPA-HR have successfully worked the IRS and Treasury to establish "safe harbors" for Adjunct Professors and Work-study Students, which allows more intuitive standards to establish ACA compliance. ACE and CUPA-HR are working to establish a similar "safe harbor" for Graduate Research Assistants (GRAs). As we have described in previous COGR Updates, we have provided ACE and CUPA-HR support on this issue, and we will continue to do so.

We also are paying close attention as ACE and CUPA-HR address other ACA-related issues, including advocacy for the acceptance of student health insurance plans (SHIP) as a compliant alternative to an employer provided plan. ACE and CUPA-HR are seeking a clarification from Treasury that would permit schools to continue providing SHIP subsidies to graduate students, or, at a minimum, provide schools with permission to continue this practice during the 2015-16 academic year while Treasury further examines the issue.

There are many moving pieces with 2016 being an important marker for universities to demonstrate compliance with the ACA's employer mandate. ***Steven Bloom welcomes feedback from the COGR Membership*** and if your institution has specific questions or comments, contact David Kennedy at dkennedy@cogr.edu and he will connect you, accordingly.

Federal Government Funded through December 11, 2015: Stay-tuned

The Fiscal Year 2016 Continuing Appropriations Act, 2016 (H.R. 719), signed by President Obama on September 30, 2015, allows government operations to continue under a Continuing Resolution (CR) through December 11, 2015. However, what will transpire as we approach December 11th remains uncertain. The "good news" is agency plans that were implemented during the Federal Government shutdown in October 2013 remain fresh, so in the event of a shutdown, agencies are relatively well-prepared to respond. In the event of a worst-case scenario shutdown, COGR will engage with the Membership and the Federal agencies, accordingly.

Under the current CR, agencies are operating under their agency-specific plans. In the case of NIH, Notice Number: [NOT-OD-16-002](#) describes the NIH plan for operating under the CR: *Continuing the procedures identified under NOT-OD-15-050 and consistent with NIH practices during the CRs of FY 2006 - 2015, the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments to awarded levels will be considered after FY 2016 appropriations are enacted, but NIH expects institutions to monitor their expenditures*

carefully during this period. All legislative mandates that were in effect in FY 2015 (see NOT-OD-15-054 and NOT-OD-15-048) remain in effect under this CR, including the salary limitation set at Executive Level II of the Federal Pay Scale as described in NOT-OD-15-049.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Alexandra McKeown, Chair, The Johns Hopkins University, Cindy Kiel, University of California-Davis, Elizabeth Peloso, University of Pennsylvania, Patrick Schlesinger, University of California-Berkeley, Kevin Wozniak, Georgia Tech Research Corporation, David Winwood, Louisiana State University, Cathy Innes, North Carolina State University, Fred Reinhart, University of Massachusetts-Amherst, John Ritter, Princeton University, Wendy Streitz, University of California, Wendy Montgomery, University of Maryland, Melanie Roewe, Washington University – St. Louis

COGR Comments on New DOD Information Security Rules

The [October Update](#) summarized the new DOD requirements for cyber incident reporting and information system safeguarding. It noted that DOD has issued two interim final rules: an August 26 DFARS rule (80FR51739), and an October 2 rule mandating cyber incident reporting requirements for DOD contracts (research contracts are specifically included), cooperative agreements and other transactions (80FR59581).

COGR and AAU [submitted a joint comment letter](#) on the DFARS rule on October 30 (the comment period was extended until November 20; 80FR63928; 10/22/15. **We encourage COGR institutions to consider submitting their own comments**).

In the letter we noted two principal concerns:

1. The substantial compliance burdens incurred by our member institutions who handle controlled defense information and will be subject to the new safeguarding and reporting requirements; and
2. The lack of a clear exemption for DOD-funded fundamental research.

For those institutions that have controlled defense information, COGR has received estimates of up to \$10M in compliance costs for the new safeguarding and reporting requirements. The DOD rules adopt the [NIST SP 800-171 security standards](#) as compliance requirements for DOD. This is exactly what we feared and expressed in our comments to NIST on the draft requirements (see [COGR May 2015 Update](#)). While there is a provision that alternative but equally effective security measures may be used, it requires that the equivalent measures be approved in writing by an authorized representative of the DOD CIO prior to contract award. The letter questioned on what basis the CIO will make this determination or what information will be deemed sufficient to compensate for the inability to satisfy a particular requirement.

The letter also noted that the requirements went beyond the statutory provisions cited by DOD as authority. They also seem premature in that the FAR rule which is to extend security requirements for controlled unclassified information government wide has not yet been issued (see below). The letter also mentioned some definitional issues with the new rule, and discussed

the need for DOD to provide funding for the added costs of compliance in contracts and other awards involving covered defense information subject to the cybersecurity requirements. With the interim rule it becomes even more critical to ensure that our member institutions who solely conduct fundamental research with DOD funding do not become inadvertently subject to the new requirements. We urged DOD to include a provision referencing projects determined to be fundamental research as not involving covered defense information subject to the reporting and safeguarding requirements. Institutions must not accept restrictions on disclosure or dissemination of research findings or information to avoid having “covered defense information.”

We also urged DOD to clarify the relationship between the DFARS rule and the subsequent broader rule, for which comments are due December 2 (we expect to submit similar comments on that rule).

A copy of the [comment letter is posted](#) on the COGR website.

COGR CIP Committee Discusses Information Security Issues With NARA

The COGR Contracts and Intellectual Property Committee (CIP) met with Patrick Viscuso, Associate Director for Controlled Unclassified Information, Information Security Oversight Office, National Archives and Records Administration (NARA). Mr. Viscuso discussed the responsibilities of his office, which includes implementation of Executive Order (EO) 13556 on Controlled Unclassified Information (CUI). Designating NARA as the Executive Agent for implementation of the EO rather than the defense or intelligence agencies was a deliberate choice. NARA is charged with developing consistent standards for designating, marking and protecting CUI, and brings a civil agency perspective to this mission.

NARA published a proposed rule in May which establishes policies for agencies and a [CUI Registry](#) (COGR commented on this rule; [see August Update](#)). The next step is to develop a FAR rule for nonfederal CUI. The NIST SP 800-171 security requirements require protection at the moderate confidentiality level, which was adopted in the DFARS. In response to concerns expressed by CIP members about the new DFARS clause, Mr. Viscuso indicated these will be interim requirements which will be superseded by the FAR rule. The FAR rule will clarify the marking requirements for CUI and provide a taxonomy (presumably based on the CUI Registry). It also may allow for self-certification.

Mr. Viscuso stated that a primary objective is to assure that federally-funded fundamental research is not adversely affected by the new rules. He would like to partner further with COGR as the FAR implementation proceeds. We indicated we would welcome this partnership. NARA worked closely with NIST in developing the SP 800-171 requirements. They tried to allow for equivalent protections; however, we pointed out that the DFARS requires DOD approval in an unclear process. Mr. Viscuso acknowledged the difficulties of applying the requirements to CUI in the absence of defined categories.

While the DFARS supposedly will be phased out, institutions receiving the new requirements will have compliance obligations in the interim. This will require investments in new business systems, etc. While hopefully the situation will improve with issuance of the FAR rule

(expected next March), this will not resolve the current problems with the new DOD requirements.

DOE Adds Export Control Compliance Clauses to Contracts

On October 23, [DOE amended its Acquisition Regulations \(DEAR\)](#) to add export control compliance clauses (80FR64361). The new rule is at DEAR 925.71. The clause responds to IG and GAO recommendations for DOE to provide export control guidance to contractors. The clauses are modeled on the DFARS clause (252.225-7048), which was added to the DFARS after a long development process in which COGR extensively participated (e.g. see COGR Fall 2008 [Update](#)). Similar to the DFARS, the new DEAR clause (952.225-71) states the contractor's responsibility to comply with all applicable export control laws and regulations. It contains a list of applicable laws and regulations, including NSDD-189. It notes that contracts for the performance of unclassified fundamental research generally do not involve export-controlled activities. However, it adds the caveat that export controls may apply to controlled items used to conduct research. This is not necessarily fully consistent with NSDD-189. A separate but similar clause applies to DOE management and operating contracts.

When first proposed, the DEAR clause included a provision that an Export Restriction Notice be included in all transfers or sales of unclassified information, materials, technology, equipment or software pursuant to a DOE contract. We had concerns about the scope of this notice requirement, particularly as applied to products of fundamental research (see COGR June 2013 [Meeting Report](#)). This requirement has been removed from the final DEAR clause. Given that all notification and reporting requirements have been removed (including a requirement proposed earlier for written assurances of compliance), the new clause does not appear problematic. It places responsibility for compliance on contractors. DOE contracting officers are only authorized to direct contractors to the agencies responsible for export controls. They are not to advise or make decisions on applicability. DOE explicitly followed the DFARS approach in the final rule (the FR notice even includes references to the DFARS PGI on release of fundamental research information). This responds to recommendations made by six respondents in comments on the rule when it was proposed in 2013 (78FR35195). We also clearly favor this approach.

Note that the DEAR compliance clause has a different scope and purpose from the DOE/NNSA rule on export of unclassified nuclear technologies (the 10 CFR Part 810 rule). COGR has had some concerns about that rule, particularly as to the consistency with EAR and ITAR terms and definitions. Most of our concerns were addressed in the final version of that rule published earlier this year (80FR9359; 2/23/15; see March [Meeting Report](#)).

UIDP Holds Meeting on Partnering with National Labs

The October UIDP meeting hosted by the University of Tennessee focused on increasing engagement between university/industry and the DOE national labs. The meeting was an outgrowth of the UIDP National Lab project, which was initiated two years ago to generate new models of collaboration to increase engagement and lower barriers among the sectors. The project currently is developing a national lab-specific supplement to the UIDP contract accords and using big data (in partnership with Elsevier) to analyze existing relationships.

Much information was presented at the meeting on university—lab relationships and efforts by the labs to increase collaborations. Interesting data was presented by Elsevier on mapping current collaborations. A follow-on workshop was held on ways to maximize university-industry engagement with the labs, with specific attention on partnering mechanisms.

On October 28 the final report of the Commission to Review the Effectiveness of the National Energy Laboratories (CRENEL) was released. The Commission was Congressionally established in 2014 (P.L. 113—76). It was charged with evaluating the Labs alignment with DOE’s strategic priorities, ability to meet future challenges, and efficiency and effectiveness. The plan was to present the CRENEL report at the UIDP meeting, but instead it was held for release at Congressional testimony the following week.

The report cites over 50 past reports on the national labs that show “a strikingly consistent pattern of criticism with a repeating set of recommendations for improvement.” It has six major theme areas: recognizing value, rebuilding trust, maintain alignment and quality, maximizing impact, managing effectiveness and efficiency, and ensuring lasting change. It is in two volumes, with Volume I the Executive Report and Volume 2 consisting of technical chapters and appendices. Both volumes discuss contracting issues. Of particular interest in Vol. 2 is a discussion (pp. 206-7) of barriers to partnerships, including contract terms, negotiation difficulties, and issues with technology transfer.

Many of the specific issues identified are similar to those we raised in comments to DOE in response to an RFI some years ago, as discussed in the October Update. From discussions at the UIDP meeting it appears industry has many of the same problems as universities in seeking to work with the national labs. The UIDP project is aimed at addressing some of these problems. COGR plans to stay engaged with UIDP as this project continues to unfold, and participate as appropriate. While the 50 past reports do not provide grounds for optimism, many of the labs were represented at the meeting. It is possible some incremental progress may be made. Also these issues and concerns appear to have the attention of policymakers.

The CRENEL report is available at http://energy.gov/labcommission/downloads/final-report-commission-review-effectiveness-national-energy-laboratories?et_rid=35380937&et_cid=66423

COGR Declines Further Comment On PTO Subject Matter Guidance

The October Update mentioned the continuing confusion over patent subject matter eligibility. In July PTO published updated guidance, which was discussed in our August Update. We noted that the updated guidance did not solve the basic problems.

Comments were due October 28. We did not choose to submit additional comments since the concerns remain similar to those identified in the comments we previously submitted. Other commenters have expressed the view that patent eligibility requires factual determinations and is not solely a matter of law as PTO asserts in the updated guidance. Concerns also have been expressed about procedural aspects of the guidance. We fully agree that more stable solutions are needed than the shifting guidance from PTO and the courts.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Michael Ludwig, Chair, University of Chicago; Jeffrey Friedland, Princeton University, Pamela Caudill, Harvard University, Walter Goldschmidts, Cold Spring Harbor Laboratory, David Norton, University of Florida, James Tracy, University of Kansas, Pamela Webb, University of Minnesota, Jennifer Lassner, University of Iowa, Steven Martin, Indiana University – Bloomington, Lisa Mosely, Arizona State University

Laboratory Safety

A Thursday morning session at the October 22-23 COGR Meeting included a presentation on the Laboratory Safety by Kacy Redd, Association of Public and Land-grant Universities (APLU). APLU in coordination with the Association of American Universities (AAU), American Chemical Society (ACS), and Council on Government Relations (COGR) created a Laboratory Safety Task Force, comprised of senior research officers, environmental and health safety officers, faculty, and industry and national lab representatives.

The task force was created to provide research universities with recommendations and guidance on the most appropriate strategies to enhance a culture of laboratory safety. The task force recommends that all universities embrace a renewed commitment to improve the safety culture for all academic research, scholarship, and teaching. During this presentation, Kacy presented twenty (20) recommendations from the draft task force report as well as a tool kit for implementing the recommendations. The recommendations were drawn from research and reports from the National Academies, ACS, OSHA, and the US Chemical Safety and Hazards Board's review of the Texas Tech accident in which a student was seriously injured. The final report is expected to be released soon. For more information, [click here](#).

Department of Labor

On July 6, 2015 the Department of Labor issued a Federal Register notice entitled, "[Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales and Computer Employees.](#)" DOL proposes to more than double the minimum exempt salary threshold from \$23,660 to \$50,440 per year with automatic annual salary updates. How does this impact IHE's? The federal agency supporting the largest number of postdocs is the National Institutes of Health (NIH); the current base standard for a NIH postdoctoral stipend is set at \$42,840. COGR's letter urged reconsideration of the proposed regulation and supported the three recommendations of the College and University Professional Association for Human Resources. See www.cogr.edu homepage, Latest News, for a copy of the letter.

Open Access

As a result of the February 22, 2013 Office of Science and Technology Policy (OSTP) [memo](#), "Increasing Access to the Results of Federally Funded Scientific Research" many federal agencies have and will continue to release their plans to promote transparency and open access to

the results of federally funded research. We suspect that the burden to comply with various agency requirements will be onerous over the next few years. Like the examples we've seen regarding various deviations against the Uniform Guidance, COGR would like to hear from the membership about specific challenges as a result of multiple access plans. We will be working with AAU and APLU collectively to develop relevant recommendations to the National Dialogue in an effort to improve the efficiency of compliance. Stay tuned!

Research Terms and Conditions (RTCs)

The National Science Foundation (NSF), on behalf of the Research Business Models (RBM) working group, has released for [public comment](#) updated [June 4, 2015 RTCs](#). While the companion resources (Appendix A, Prior Approval Matrix, Appendix B, Subawards Requirements Matrix, and agency specific terms) have yet to be released, at first read there are both 'wins' and issues that need further clarification. Of note, the RTCs provide clarification that unrecovered IDC as cost sharing/matching does not require prior approval, the 120 closeout requirement has been extended to all reports (i.e. financial, performance, and other reports, though what is included by 'other' needs to be specified), and the use of the RPPR report to measure performance outcomes. Initial issues that will likely need additional clarification include methods of procurement standards, fixed amount subawards (when issuance is appropriate and when prior approval is required), and the 10 day requirement on grantee approved extensions (to align with federal electronic reporting systems). COGR will respond to the RTC's as published by the December 14 deadline. Please submit your comments to jbendall@cogr.edu by December 1.