June 2015 COGR Meeting Report

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COUNCIL ON GOVERNMENTAL RELATIONS

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June 19, 2015

June 4 and 5, 2015 Meeting Report

GENERAL DEVELOPMENTS

Dr. Sally Rockey to Step Down as the NIH Deputy Director for Extramural Research

NIH has announced that Dr. Sally Rockey will step down as the NIH Deputy Director for Extramural Research in mid-September. Sally will take on a new role as the Director of the non-profit Foundation for Food and Agriculture Research.

Audit

The NSF and HHS Seminannual reports to Congress for the period Oct. 1- March 31 were published online June 1. The NSF report includes a number of areas of interest to our membership. Among them, the report highlights over $4.6 million in questioned costs at four member institutions with a focus on costs related to senior personnel salary that exceeded two-months. The report indicates that "*institutions stated that they relied on NSF's 'Frequently Asked Questions' document*" and that they "*generally agreed with the recommendations pertaining to questioned costs with the exception of those relating to senior personnel salaries' costs.*"

The report includes a summary of findings from Single Audit reports related to NSF awards. Findings included "*untimely or inaccurate submission of financial and/or progress reports; untimely and/or incorrect reporting of time and effort; failure to ensure that property purchased with federal funds was adequately tracked and safeguarded; failure to ensure that the procurement process included verification that vendors had not been suspended or debarred; and inadequate monitoring of subrecipients*."

On the topic of research misconduct, the NSF OIG reported analyzing over 8,000 proposals awarded in FY11 for evidence of plagiarism (using commercial plagiarism software) and opened 34 plagiarism investigations, ten of which resulted in findings of research misconduct with $357,602 in federal funds recovered. The report notes that "*less than one half of one percent of the funded proposals contained enough plagiarism to constitute research misconduct*." The report includes several pages of descriptions of misconduct and actions taken by NSF management.

The HHS Semiannual report to Congress notes that the HHS OIG "*could not determine whether the University of California—Irvine's pilot payroll certification system provided data that supported labor charges that it made to its Federal awards because it could not reconcile its accounting records to its Federal financial reports (FFRs)*" and also that UC Irvine did not concur.

COGR regularly checks the HHS (NIH) and NSF OIG websites, which provide access to published audit reports, and the NSF website for management decisions on audits of external awardees. In addition to HHS and NSF OIG initiatives, we are interested in activity related to the

OIGs at other agencies. Please do not hesitate to contact us on audit issues or developments at your institution.

Enhancing Reproducibility through Rigor and Transparency

NIH released NOT-OD-15-103 on June 9th. The Notice indicates NIH's intent to "*revise application instructions and review criteria to enhance reproducibility of research findings through increased scientific rigor and transparency*." This initiative is in response to concerns about reproducibility and inability to extend research findings reported in peer-reviewed literature. The new instructions and revised review criteria will focus on four areas: 1) the scientific premise of the proposed research, 2) rigorous experimental design, 3) consideration of relevant biological variables, and 4) authentication of key biological and/or chemical resources.

Per the notice, NIH will expect applicants to describe the strengths and weaknesses of the prior research they are citing in support of their application and to "*describe how they will achieve robust and unbiased results when describing the experimental design and proposed methods."* As previously indicated, NIH "expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies (and other biological variables considered) and that "*key biological and/or chemical resources will be regularly authenticated to ensure their identity and validity for use in the proposed studies*."

The revised instructions will be incorporated into the SF424 Application Guide and funding opportunity announcements in Fall of 2015, for application submission for the January 25, 2016 due date and beyond. Applicants will be instructed to include their consideration of scientific premise, rigorous experimental design, and consideration of sex and other relevant biological variables in the Research Strategy section and page limits for this section will not change. Evaluation of these areas will be included in the assessment of overall impact. Authentication of Key Resources will be incorporated as a new attachment under the Other Research Plan Sections and reviewers asked to comment but not consider it when scoring overall impact.

Assessing Regulatory Compliance Costs

The June COGR Meeting included a session on assessing regulatory compliance costs. Panelists provided an overview of recent efforts to assess the cost to research universities of complying with Federal regulations. Andy Rudczynski, Associate Vice President for Research Administration, Yale University, presented findings from the recent AAU/COGR/APLU survey to assess the impact and cost of regulations among member institutions in six key areas, including subrecipient monitoring, PHS FCOI, effort reporting, human and animal research and financial and other reporting.

Brett Sweet, Vice Chancellor for Finance and CFO, Vanderbilt University, Tejus Kothari, Principal, The Boston Consulting Group (BCG), and David Sadoff, BCG Partner and Managing Director, presented findings from Phase I and II of their effort to assess the cost of regulatory compliance at Vanderbilt and other research universities. The presentation included background information on regulatory burden and reform efforts and estimated compliance costs at 13 diverse institutions, with specific details on cost of compliance at Vanderbilt. Cost of compliance as a percentage of FY2014 operating expenses ranged from about 3-11%. The presentation

included a breakdown of compliance costs by area. For research compliance, grants and contracts (including pre-award management, effort reporting, subrecipient monitoring, and post-award accounting and management) were the primary source of compliance costs followed by human research, environmental health and safety and animal research. For higher education compliance, accreditation represented the largest compliance cost. Estimated sector-wide federal regulatory compliance cost was $27 billion.

Heather Pierce, Senior Director, Science Policy, and Regulatory Counsel, Scientific Affairs, Association of American Medical Colleges, presented results from the AAMC Conflict-of-Interest Metrics Project. 74 AAMC member institutions are providing data on the cost and effect of the revised PHS FCOI regulations. Among the findings, 71 institutions spent $23 million in one-time costs to implement the rule and personnel administering the program increased from 1.9 to 2.7 FTEs. The session will help inform future efforts to assess the impact and cost of regulatory compliance. The presentation on the initial results of the AAU-COGR-APLU survey and the AAMC Conflict-of-Interest Metrics Project are posted on the COGR website.

COSTING POLICIES

Committee: James Luther, Chair, Duke University; Sara Bible, Stanford University; Kelvin Droegemeier, University of Oklahoma; Joseph Gindhart, Washington University in St. Louis; Cynthia Hope, University of Alabama; Lynn McGinley, University of Maryland, Baltimore; Kim Moreland, University of Wisconsin – Madison; Mary Lee Brown, University of Pennsylvania, ACUA Liaison; Michael Daniels, Northwestern University; Dan Evon, Michigan State University; Michael LeGrand, University of California, Davis; Cathy Snyder, Vanderbilt University

Uniform Guidance Update: Friday Morning Session at the June Meeting

The Friday morning session at the June 4-5 COGR Meeting, Midterm Report Card on the Uniform Guidance Implementation, was led by: Mary Beth Rudofski (Executive Director, Sponsored Award Accounting - University of Chicago), Sara Bible (Associate Vice Provost for Research - Stanford University), Jackie Bendall (COGR staff), and David Kennedy (COGR staff). The PPT Presentations are available at www.cogr.edu (see Meetings/June 2015 Meeting Presentations). Below is a summary of issues covered and corresponding next steps:

- **Procurement.** COGR is crystalizing the following position: "*Institutions are permitted to set a Micropurchase Threshold (MPT), not to exceed $10,000, based on the Institution's internal risk assessment and other factors that are in accordance with established IHE policies and practices. Institutions may apply for a higher MPT*." In addition, COGR will expand its advocacy beyond the MPT to propose a solution to OMB/COFAR that addresses broader concerns with implementation of the new Procurement Standards. We will provide an update to the Membership later this month.

- **Compensation and Documentation; Alternatives to Effort Reporting.** Some research institutions have begun designing alternative systems, which effectively would eliminate the concept of effort reporting at these institutions. The premise is that effective alternatives exist, which deemphasize the effort report as the primary internal control, and instead focus on those controls that comply with and reinforce the Standards for Documentation specified in section 200.430(i). COGR will provide regular updates on this topic, including release of the COGR Guide to 2 CFR 200.430 (see subsequent section).

- **Conflict of Interest.** New agency policies (e.g., EPA, DOJ, Commerce, NEA) being released to address agency compliance with section 200.112 of 2 CFR Part 200 continue to create angst for COGR member institutions. COGR is engaging with agencies and OMB to advocate for either clarifying FAQs to section 200.112 and/or to request that new agency policies be "stayed" until more clarity and consistency is offered. We will provide an update to the Membership later this month.

- **Agency Deviations.** Deviations that the Membership has shared include: inappropriate references to A-21/A-110, less than 60 days to respond to a funding announcement, F&A Caps, and Cost Sharing not required, but encouraged. As a way to inventory and more effectively follow up with the agencies, is proposing a 4-Step approach to urge agency accountability. The 4-Step approach is described in the next section and we encourage all COGR members to take this approach when you experience examples of agency deviations to 2 CFR Part 200.

- **Research Terms and Conditions, applicable to NIH, NSF, and others.** These may be published in the Federal Register, for public comment, this Summer. The exact timing remains uncertain.

- **DOD Terms and Conditions.** These are under final review at DOD; next they will be sent to OMB for OMB clearance and then published in the Federal Register, for public comment.

The above is not the complete list of issues. For example, an audit/management decision "Safe Harbor" and a "uniform" 120-day closeout model for all agencies continue to be pursued. In addition, more issues related to Compensation & Documentation and F&A are discussed later in this report.

As you know, COGR submitted its comments to the December 19, 2014 Federal Register Notice on February 13th. The COGR letter is available at www.cogr.edu on the homepage (see Latest News, February 13, 2015). In the letter, we addressed those topics COGR leaders considered the most pressing and critical issues. On March 20th, COGR staff and leaders from the RCA and Costing Committees conferenced with OMB and COFAR to discuss the status of the COGR Comment Letter submitted on February 13th. We summarized the conference call in a March 27th email to the COGR ListServe. OMB and COFAR have indicated a willingness to address these issues of concern and we remain engaged in ongoing communication with them. We will keep the Membership posted on all developments.

Recommended 4-Step Approach for Responding to Agency Deviations

During the Friday morning session, Midterm Report Card on the Uniform Guidance Implementation, we included a recommended approach for you to follow when your institution is presented with an agency deviation to 2 CFR Part 200 (or for that matter, deviations in general). Below is an example of the 4-step approach in response to an AHRQ funding announcement that did not require cost sharing, but encouraged cost sharing to be included. We expect the 4-step approach to be an email correspondence with the agency; initially, we recommend you work one-on-one with the agency and forward us the correspondence, as appropriate. COGR's engagement can be determined on case-by-case basis, which might include forwarding the situation to OMB.

1) Identify language in Funding Announcement:

This FOA does not require cost sharing. While there is no cost sharing requirement included in this FOA, AHRQ welcomes applicant institutions, including any collaborating

institutions, to devote resources to this effort. An indication of institutional support from the applicant and its collaborators indicates a greater potential of success and sustainability of the project ...

2) Provide UG Citation(s):

§200.306 Cost sharing or matching.

(a) Under Federal research proposals, voluntary committed cost sharing is not expected ...

Appendix I to Part 200—Full Text of Notice of Funding Opportunity
E. Application Review Information

... If cost sharing will not be considered in the evaluation, the announcement should say so, so that there is no ambiguity for potential applicants. Vague statements that cost sharing is encouraged, without clarification as to what that means, are unhelpful to applicants ...

3) Statement to Agency:

Per 1) and 2) above, *"I have asked COGR, an association of 200 research institutions, to review this language in light of the newly implemented 2 CFR Part 200 that became effective on December 26, 2014. We are concerned that the vague request for cost sharing may inappropriately compel institutions to commit voluntary cost sharing in the budget proposal ..."*

4) Request to Agency:

"At your convenience, please provide: a) the basis or justification for the language included in the FOA, and b) a Policy Official point of contact at the agency who is responsible for approving the language. We look forward to working with you and COGR to resolve any discrepancies with 2 CFR Part 200 ..."

While we do not expect the 4-step approach to rectify agency deviations, we believe it provides a systematic mechanism to notify the agency of a deviation and make the agency aware that we are paying attention. In addition, we are accumulating these situations and will document them in an anticipated year-end report on COGR's perspective on the implementation of the Uniform Guidance. Jackie Bendall at jbendall@cogr.edu and/or David Kennedy at dkennedy@cogr.edu are the points of contact for these situations, and will follow up, accordingly.

Costing Policies Update: Thursday Morning Session at the June Meeting

One of the Thursday morning sessions at the June 4-5 COGR Meeting, Costing Policies Update, was led by: Kelvin Droegemeier (VP for Research - University of Oklahoma), Randy Bryant (Assistant Director for Information Technology R&D - OSTP), Cathy Snyder (Director, C&G Accounting - Vanderbilt University), Jim Luther (Associate VP, Research Financial Compliance - Duke University), Kim Moreland (Associate VC - University of Wisconsin), and Lisa Nichols

(COGR staff). The PPT Presentations are available at www.cogr.edu (see Meetings | June 2015 Meeting Presentations). Below is a summary of issues covered and corresponding next steps:

- **Cloud Computing.** This began percolating two years ago at a National Science Board retreat. The Federal Office of Science and Technology Policy (OSTP) became involved soon after and COGR was approached this past March. As this resource becomes a more feasible option for researchers, at issue is the applicability of F&A. Kelvin and Randy are developing a survey to be shared with Senior Research Officers, which will be designed to better understand the magnitude of cloud computing and related operational issues. COGR will stay connected to progress on the survey, the discussions that follow, and any applicable policy recommendations.

- **NIH Subaccounting, 120-day Grant Closeout, and the Payment Management System (PMS).** There seems to be a relative sense of readiness across the COGR Membership for the final transition to NIH Subaccounting starting on October 1, 2015. However, COGR will continue to work with FDP and NIH to address potential issues. Also, implementation of the 120-day grant closeout model at NIH has raised some concerns; mainly, lack of complete alignment with PMS. COGR is actively engaged with PMS administrators and NIH to confirm that open issues are being addressed. A more complete discussion is included in the following section of the Meeting Report.

- **F&A and the Uniform Guidance.** Implementation of 2 CFR Part 200 could have significant impact on F&A rate development and negotiation. In the COGR May 2015 Update (dated May 21, 2015), COGR provided a detailed update on the 1.3% UCA implementation, the DS-2 status, and treatment of tuition benefits for employees. In addition to covering these topics, the session covered: the upcoming COGR initiative to tackle the potentially flawed 2.0 UCA research space weighting factor, a recap on the to-date and favorable enactment of the 4-year rate extension, and development of a "negotiation experiences" template that will allow COGR and the Membership to track issues arising in F&A rate negotiations. A mechanism for sharing negotiation experiences is of particular interest as we begin to observe the approaches of CAS/HHS and ONR to rate negotiations under 2 CFR Part 200.

- **Compensation & Documentation and the COGR Guide to 2 CFR 200.430.** The past three COGR meetings have included sessions related to Compensation & Documentation and the Uniform Guidance. Each discussion seems to help us drill closer to the core issues and concerns. A clear and concise institutional definition of Institutional Base Salary, in connection with developing further clarity and examples of the different types of pay defined in section 200.430(h), appear to be helpful discussion topics. The Standards for Documentation described in section 200.430(i) also is an important discussion; this was elaborated in more detail in the Friday morning session and is summarized in a previous section of this report. COGR will provide regular updates on all facets of Compensation & Documentation, including release of the COGR Guide to 2 CFR 200.430 (see subsequent section).

Each of the above is a priority issue on the agenda for the Costing Policies Committee. We will provide regular status updates and keep the Membership posted on all developments.

NIH Subaccounting, Grant Closeout, and the Payment Management System (PMS)

COGR has reported and advocated on various threads of these topics for two years. The Costing Committee Update on Thursday morning at the June 4-5 COGR Meeting included an update and further elaboration on where each stands and how they tie together. In summary:

- **NIH Subaccounting and Final Transition starts on October 1, 2015.** The final transition is almost upon us. The final version of the NIH subaccounting policy can be found in NIH Notice Number: NOT-OD-14-103 (July 11, 2014); *Revised Timeline for Administrative Changes to NIH Domestic Awards to Transition to Payment Management System Subaccounts*. In addition, the recent 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*, reinforces the October 1 final transition date and addresses some of the operational procedures that will be in place. Institutions should be focused on understanding what needs done to prepare for October 1st, and, as applicable, revamping systems and business processes to make for a smooth transition. Additionally, institutions should be considering how to support the additional work and financial risk associated with NIH subaccounting.

- **Grant Closeout and 120-day Closeout Model.** Under NIH subaccounting, award-by-award financial management and closeout is the new standard. In the 2015 NIH Grants Policy Statement, section 8.6 CLOSEOUT states: *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 we are thankful for the new NIH 120-day closeout model, NIH-specific operational issues, as well as internal institutional management issues will provide unique challenges. Further note, the 120-day closeout model transcends NIH; as other funding agencies consider implementing similar models, institutions must be aware of those challenges created by potential inconsistencies across agencies.

- **PMS Consistency with the 120-day Closeout Model.** Consistency in the configuration and functionality of PMS with the NIH 120-day closeout model is integral to successful implementation of the NIH 120-day closeout model. PMS is managed by the Division of Payment Management Services (DPM), which organizationally falls under the Program Support Center (PSC) and the Department of Health and Human Services (HHS). COGR is engaged in active dialogue with staff from DPM and is working closely with DPM, NIH, and HHS to work toward PMS consistency with the 120-day closeout model.

As summarized earlier, COGR will continue to work with the FDP and NIH to address potential issues associated with the final transition to subaccounting and we will engage actively with PMS administrators and NIH to confirm that open issues associated with PMS and the 120-day grant closeout model are being addressed. We will keep the Membership posted on all developments.

COGR Guide to Compensation and Documentation (2 CFR 200.430)

Compensation and Documentation requirements from the Uniform Guidance (2 CFR 200.430) were addressed in several sessions at the June COGR Meeting (see previous sections of this report). COGR has developed a Guide to 2 CFR 200.430 that is intended to serve as a resource to assist member institutions as they assess the alignment of their written policies and procedures and internal controls with this section of the OMB Uniform Guidance. The Guide should be viewed as a *first assessment*, which is based on our initial understanding of this section. As we learn more with regard to auditor perspective and interpretation from Federal and Higher Education leaders, this could inform updates. Version 1 of the Guide will be available early this Summer.

Equitable Treatment of Off-Campus Research Centers in RFAs

As we shared Friday morning, COGR is working with several of our members and the NIH to devise a more equitable mechanism for comparing proposed costs between on-campus and off-campus research centers. Specifically, at issue is the treatment of "space and facility-related costs" when a Research Funding Announcement (RFA) or policy regarding Investigator initiated proposals limits maximum costs in terms of maximum Direct Cost. In the case of an off-campus research center, space/lease costs and other facility-related costs are considered a direct cost, which means that the off-campus research center will disproportionately have to propose these types of costs in comparison to an on-campus research center. In effect, the off-campus research center is at a competitive disadvantage because fewer costs can be proposed for research staff and other direct research-related costs. The inequity is compounded when a proposed collaborator is associated with an off-campus research center; in this situation, the potential subrecipient would include space and facility-related costs in the proposed budget.

Several options to restore equity, which have been discussed with NIH are: 1) Allow the off-campus research center to exclude space and facility-related costs when the RFA includes a maximum Direct Cost limitation, or 2) Allow the off-campus research center to state maximum costs in terms of Total Cost instead of Direct Cost when the RFA includes a maximum Direct Cost limitation.

Please contact Jackie Bendall at jbendall@cogr.edu and/or David Kennedy at dkennecy@cogr.edu if your institution has an off-campus research center that has been adversely impacted by RFAs or policies that include a Direct Cost maximum. NIH is interested in addressing this inequity in a fair and constructive manner. By quantifying a critical mass of institutions that have been affected will help demonstrate to NIH that this is a significant issue that requires immediate attention.

2015 Compliance Supplement: Draft Available

A draft version of the 2015 Compliance Supplement (CS) is available for internal planning purposes at the link below. A final version should be available soon. You can download individual sections, Parts, Appendices or the entire CS.

http://www.aicpa.org/InterestAreas/GovernmentalAuditQuality/Resources/OMBCircularA133/Pages/2015DraftOMBComplianceSupplement.aspx

Part 3, Compliance Requirements, and Part 5, Clusters of Programs, Research & Development may be of special interest. Page 3-1 describes the implementation of the 2015 CS as a "Transition Supplement" and page 3-3 includes a cross-reference to the FAQs from the Uniform Guidance.

Pages 5-2-1 through 5-2-9 (Part 5) incorporate selected revisions proposed by COGR. For example, pages 5-2-2 and 5-2-3 describe the audit procedures applicable to reviewing Compensation and include provisions for institutions that have transitioned to 2 CFR part 200 and those that have not. This seems to confirm COGR's position that institutions should work with their auditors to determine an institution-defined transition date for implementing section 200.430, Compensation - personal services.

As this draft proceeds through OMB clearance, there may be an opportunity to share final concerns with OMB. If you have concerns, you can contact Gilbert Tran at OMB at hai_m._tran@omb.eop.gov or David Kennedy at dkennedy@cogr.edu.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: David Winwood, Chair, Louisiana State University; Cindy Kiel, University of California, Davis; Alexandra McKeown, The Johns Hopkins University; Cordell Overby, University of Delaware; Patrick Schlesinger, University of California, Berkeley; Kevin Wozniak, Georgia Institute of Technology; Catherine Innes, North Carolina State University; Fred Reinhart, University of Massachusetts; John Ritter, Princeton University; Wendy Streitz, University of California

New "Harmonized Definitions" for Export Controls Proposed

On June 3 the Commerce Bureau of Industry and Security (BIS) and the State Department Directorate of Defense Trade Controls (DDTC) issued a set of proposed revisions to definitions in the Export Administration Regulations (EAR) and International Traffic in Arm Regulations (ITAR). The definitions directly impact university research. The proposed EAR revisions are at https://www.federalregister.gov/articles/2015/06/03/2015-12843/revisions-to-definitions-in-the-export-administration-regulations; the ITAR revisions are at https://www.federalregister.gov/articles/2015/06/03/2015-12844/international-traffic-in-arms-revisions-to-definitions-of-defense-services-technical-data-and-public.

The proposed revisions to the definitions were expected and are in some respects the culmination of the export controls reform initiative that we have followed and reported on for the past several years. We previously commented on some earlier versions of the proposed definitions (e.g. see COGR August 2013 Update). The migration of items from ITAR to EAR control also was discussed by a panel of senior government officials at the October 2014 COGR meeting.

With one major exception, the proposed revised definitions appear largely positive for COGR member institutions. This is especially true of the EAR revisions, which with the migration of items to EAR control may have greater impact for most COGR members. Our preliminary analysis does not indicate any particular concerns with the proposed EAR changes. Technology that arises during, or results from, fundamental research and is "intended to be published" remains not subject to the EAR (734.8). Prepublication review to ensure that publication would not compromise patent rights or inadvertently divulge proprietary information is specifically allowed. USG-funded research covered by contract controls on publication or participation of non-U.S. citizens continues not to be considered as "fundamental research" (734.11). There are other changes in definition of "export," "reexport," and "release," but none appear problematic.

Unfortunately, while many of the proposed ITAR changes also appear positive, there is a major issue with regard to prepublication review. The good news is that the ITAR now recognizes that information arising during, or resulting from fundamental research that is intended to be

published is not technical data subject to the ITAR (120.49). Previously the ITAR was ambiguous on this point. However, a note states that "intended to be published" does not apply to research sponsor proprietary information review. The researchers must be free to publish the information without any restriction or delay. This is a marked contrast from the EAR. All agreements with research sponsors subject to proprietary information review that touch on ITAR controlled technology would not be considered fundamental research under this definition. Control plans and licenses for any foreign nationals involved in such activities would be required.

We plan to challenge this definition in comments on the proposed changes. It contradicts the intent of the reform initiative to harmonize the EAR and ITAR. More importantly, it will have a chilling effect on university-industry collaborations, almost all of which include provisions for proprietary information review. It also raises serious legal issues relating to government prior restraint on dissemination of information.

A positive ITAR change is the revised "defense services" definition (120.9). We had commented favorably on the change previously proposed to the definition which would have required use of other than public domain information. The proposed new definition eliminates all mention of public domain information. Instead the performance of assistance to a foreign person by a U.S. person who has knowledge of U.S.-origin technical data directly related to the defense article that is the subject of the assistance now is a "defense service." This appears to be an even narrower definition. Also there is no change in the "bona-fide" employee exemption (125.4(10)) for disclosures of unclassified technical data in the U.S. by U.S. institutions of higher learning to foreign persons who are bona fide and full time regular employees. DDTC does not perceive that normal duties of university employees would be encompassed by the revised definition, which relates to assistance in production, assembly, testing, etc. of defense articles.

There are many other changes in definitions, some of which now are more harmonized between the EAR and ITAR (e.g. the EAR has adopted the ITAR "general scientific, mathematical, or engineering principles" language for the education exemption (734.3), the ITAR has adopted the EAR concept of "release"). There is a helpful side-by-side "harmonization chart" on the BIS website (http://www.bis.doc.gov/index.php/regulations/federal-register-notices#FR31505). In addition to the prepublication review, another clear difference of relevance to universities is with regard to deemed exports. Both the EAR and ITAR maintain the current distinctions where the EAR considers only a foreign national's most recent country of citizenship or permanent residency (734.13) while the ITAR deems exports to a foreign person in the U.S. as an export to all countries in which the foreign person has held citizenship or permanent residency.

Changes common to both include distinguishing software from "technology" (EAR) or "technical data" (ITAR), provisions that submission of written manuscripts to editors or reviewers of journals or publications with the intent they will be made publicly available as constituting published or public domain information (EAR 734.7; ITAR 120.11), and provisions that sending technology, software or technical data secured with end-to-end encryption are not considered "exports" (to address cloud computing situations, whose export status has been of considerable uncertainty under the current regulations). However, the ITAR requires compliance with NIST FIPS 140—2 controls, while the EAR allows "other similarly effective cryptographic means" (EAR 734.18(4); ITAR 120.52(4)).

Both BIS and DDTC invite public comment with regard to a number of questions, including the effective date of the proposed revisions. Of particular relevance to COGR, BIS asks for comments on a proposed streamlined alternative definition of fundamental research based on NSDD-189. The EAR changes also include definitions of "basic research" (734.8, currently found at EAR 772.1) and "applied research" (taken from the DFARS; the ITAR (120.49) also includes these definitions). In addition, BIS asks a number of other questions, including whether the Q's and A's should be removed from the existing Supplement No. 1 to EAR Part 734 and instead included on the BIS website (while helpful, COGR members also have found the Q's and A's may raise more questions than they answer), and questions involving the proposed encryption standards and definitions such as "peculiarly responsible and "specially designed." DDTC asks for comments on the technical aspects of the proposed data transmission requirements (the proposed EAR and ITAR definitions also differ somewhat in this area and BIS also asks for comments on these differences).

We are still analyzing the proposed changes and their implications. There may be further aspects to some of the proposed definitions such as "peculiarly responsible" or in the case of the ITAR, "integration" which are not immediately apparent. We encourage COGR member institutions to submit comments on the proposed changes, and expect to have suggested bullet points available by early July that may facilitate that process. Comments are due August 3.

COGR Comments on Proposed NARA CUI Rule

As discussed in the May Update, on May 8 the National Archives and Records Administration (NARA) published a proposed rule for federal agencies on Controlled Unclassified Information (CUI): (http://www.gpo.gov/fdsys/pkg/FR-2015-05-08/pdf/2015-10260.pdf

This is the second of the three-part federal implementation of EO 13556 on CUI, along with the NIST security standards and a pending FAR rule also discussed in the Update. The purpose is to establish uniform policies and practices across the federal government with regard to CUI.

While the proposed rule is primarily directed to federal agencies, it includes provisions directed to contractors and vendors. There also is a lengthy discussion in the rule Preamble of the application to federal contractors. This raises a question as to the interaction of the proposed rule with the NIST standards and the upcoming FAR rule. While it cites NARA partnering with NIST to develop the draft NIST 800-171 standards (see COGR May Update), it is unclear whether the proposed rule requires agencies to impose the NIST requirements. It also discusses the need for agencies to enter into formal information-sharing agreements regarding CUI with non-executive branch entities including contractors, but provides no guidance as to the nature or content of these agreements.

Further confusion results from the references to the NARA CUI registry. All information designated as CUI must be included in categories approved by NARA and published in a publicly accessible CUI registry maintained by NARA. NARA previously defined 23 main

categories of potential CUI information, some of which include subcategories (http://www.archives.gov/cui/registry/category-list.html). Some include "CUI Specified" security requirements. "CUI Basic" standards are the default in the absence of CUI specified standards. However, the nexus is unclear between the 30 Basic Security Requirements in the draft NIST 800-171 and the CUI Basic in the proposed NARA rule. It is unclear whether the NARA CUI Basic also may include the 79 Derived Security Requirements in the NIST draft. (The CUI registry includes both copyrights and patents as categories, which seems rather strange in a CUI context).

The FAR rule may resolve some of the confusion when it is issued. However, there is CUI maintained by institutions that may not be covered by the FAR (e.g. SEVIS data under the registry Immigration category). Also the NARA rule may be effective prior to issuance of the FAR rule.

We plan to submit comments to NARA on the proposed rule in which we will raise these questions. We will also cite the timing issue; the various implementations of EO 13556 need to be coordinated, at least as regards their application to outside entities. Comments are due July 7.

Patent Troll Legislation Advances in Congress

Past COGR Updates and Meeting Reports have discussed the anti-patent troll legislation pending in Congress, and the concerns of the university community. The status of the legislation and the issues also were discussed in a session at the COGR June meeting.

The Senate Judiciary Committee on June 4 approved the PATENT Act by a vote of 16 to 4, with only Senators Durbin (D-IL), Coons (D-DE), Vitter (R-LA), and Cruz (R-TX) voting against it. During consideration of the bill, the Committee approved an amendment offered by Sen. Cornyn (R-TX) that alters the definition of micro-entity status in a way that is potentially helpful to universities, technology transfer organizations, and research foundations. The panel also approved the manager's amendment, which among other changes, clarifies that the burden is on the prevailing party to demonstrate that it is entitled to fee shifting, a provision which universities support. (See http://www.grassley.senate.gov/news/news-releases/patent-act-clears-committee-overwhelming-vote-support for a copy of the Committee news release).

“A few issues remain to be resolved before the bill proceeds to the Senate floor. As noted in the COGR May Update, the higher ed. associations including COGR are on record as stating that the Senate bill “is a substantial improvement over H.R. 9” (the companion House bill).

The House Judiciary Committee on June 11 marked up a modified version of Chairman Goodlatte's (R-VA) H.R. 9 (the Innovation Act). The bill was then reported out of committee by a vote of 24 to 8; Ranking Member Conyers (D-MI) led the opposition to the bill. A few amendments were offered that could have benefitted institutions of higher education and research foundations, but none were accepted.

“In advance of the House Judiciary Committee markup of H.R. 9, the group of six higher education associations that have been working together on patent reform, including COGR issued a statement that expressed opposition to both the underlying bill and the manager's amendment. The June 10 statement states, in part:

"We strongly support reducing abusive patent litigation practices, and prefer the direction of the Senate PATENT Act (S. 1137). H.R. 9 is not targeted to address the small minority of patent holders that are abusing the system. Rather the bill would weaken the entire patent system. H.R. 9 would make it far more difficult, risky, and costly for all patent holders to defend their rights in good faith, and thus seriously undermine the ability of universities to engage in technology transfer, the process by which universities make their research discoveries available to private sector enterprises for development into products." (For a copy of the full statement, see http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=16228).

“Prospects for final Congressional action on these bills are uncertain at this time. We understand that no House floor action on H.R. 9 is scheduled in July. We hope that should any of this legislation move forward, it will be along the lines of the Senate bill. As noted in the May Update, we also support related legislation including the TROL Act in the House and Sen. Coons’ STRONG Patents Act (S. 632).”

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Michael Ludwig, Chair, University of Chicago; Lois Brako, University of Michigan; Pamela Caudill, Harvard University; Kerry Peluso, Emory University; Suzanne Rivera, Case Western Reserve University; James Tracy, University of Kentucky; Pamela Webb, University of Minnesota; Walter Goldschmidts, Cold Spring Harbor Laboratory; Jennifer Lassner, University of Iowa; Steve Martin, Indiana University; Lisa Mosley, Arizona State University

Dual Use Research of Concern (DURC)

A representative from the White House Office of Science Technology Policy (OSTP) joined Thursday morning's session with members of the University of Pittsburgh to discuss Dual Use Research of Concern (DURC). Emphasis was made on the importance of having polices in place such as the recent U/S/\. Government Policy entitled, "Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern http://www.phe.gov/s3/dualuse/documents/durc-policy.pdf that allow critical life sciences research using select agents to take place while at the same time reliably identifying and mitigating risks to public health and national security where biosecurity is a global threat. The recent policy is the fifth released related to DURC since 2012 with future plans to introduce a policy related to Gain-of-function studies. The three areas discussed in the presentation include: 1) Traditional Adversaries 2) Asymmetric and 3) Proxy where controls can be put in place to limit the potential acquisition or misuse of select pathogens. The OSTP representative stated that despite the potential benefits derived from having policies, procedures and guidance related to select pathogens, the threats abroad will continue to be a major problem, and that U.S. allies must collaborate to develop criteria that can balance the growth of life sciences while protecting the public health and security.

COGR members Alan DiPalma, Director, Office of Export Control Services and Dr. Kelly Cole, University of Pittsburgh also presented on what their institution has done to meet the requirements of the USG Policy. Their presentation will be posted shortly to the COGR website.

The OSTP and the National Institutes of Health will co-host a public workshop on July 22, 2015, for interested stakeholders to discuss implementation of the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. The purpose of the meeting is to inform and engage stakeholders; collect feedback about resources needed to effectively implement the policy; and discuss stakeholder experiences, challenges, and innovative practices. For more information on the workshop, see: *http://www.phe.gov/about/OPP/DURCworkshop/Pages/default.aspx*

Public Policy and Animal Research in Academia

Matthew Bailey, Executive Vice President of the National Association for Biomedical Research (NABR) joined the COGR meeting Thursday morning to share his perspective and address

issues in animal research. Mr. Bailey stated that many new animal rights groups are collecting donations and creating coalitions attempting to ban the use of all animals in laboratories across the U.S. This movement to eliminate the use of animals in research is of great concern to the research community, and Mr. Bailey pointed to the recent petitions for the Animal Plant Health and Inspection Service to amend its regulations to further restrict use of animals in research and to increase the compliance burden in cases where animals are allowed to be used in research. For more information about this session, the presentation can be found on COGR's website.

America COMPETES Reauthorization Act of 2015

Matt Owens, Vice President for Federal Relations at the Association of American Universities (AAU), discussed the America COMPETES act, designed to invest in innovation through research and development, and to improve the competitiveness of the U.S. The previous 2007 and 2010 COMPETES acts received bi-partisan approval and were generally supported by the research community. However, the May 20th House approval of the America COMPETES Reauthorization Act of 2015 did in fact fall short of the first two COMPETES acts. Cuts are proposed in the social and behavioral sciences and geosciences directorates at the National Science Foundation. The Department of Energy would also receive cuts to their energy efficiency and renewable energy programs as well as ARPA-E, and bar the use of DOE-supported R&D activities for regulatory activities. Certain members of Congress believe that offsets in areas where research endeavors are advancing to commercialization stages should be left to the for-profit sectors, thereby allowing other areas of science to receive equal opportunity. The Senate has yet to draft its version of the COMPETES bill.

The Grant Reform and New Transparency (GRANT) Act

Thursday's session also included an update on the GRANT Act. The primary purpose of the GRANT Act, first introduced in 2011, is to provide greater transparency and accountability to federal grant programs through the creation of a new Office of Management and Budget (OMB) website. While the information to be housed on this website is still undetermined, efforts by AAU, APLU, and COGR have been fruitful in explaining the implications and burden of this bill on the research community. Two major modifications to the current version of the bill include an extension to the requirement to post full grant applications. Originally the bill would have required making full grant applications available when awarded. The current version of the bill now states that grant applications must be posted 3 months after the grant expires. While this is an improvement, it still does not negate the concerns with respect to intellectual property protection, and is inconsistent with public access polices agencies have and will be implementing in accordance with the current Administration's public access requirements. https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf. The second modification to the bill is that it no longer requires disclosure of detailed peer reviewer information, but instead requires an Inspector General review of each agencies' peer reviewer conflict of interest policies.

AAU and COGR will continue to work with Congressional staff to improve the bill, and we will update the membership on subsequent developments.

21st Century Cures Act

Lizbet Boroughs, Associate Vice President for Federal Relations at AAU, provided her perspective of the 21st Century Cures legislation. While the legislation is aimed mostly towards the Food and Drug Administration (FDA), her primary focus was to inform the membership on the National Institutes of Health (NIH) provisions, specifically Title 1 of the Act. She noted that the overall intent of the bill is positive, i.e., more money, more infrastructure, more transparency of data, and more patient access to medications in clinical trials. The bill supports growth of the NIH and adds new programs such as the Innovation Fund, and a new Institute/Center Director responsible for reviewing all R-series awards other than non-competing renewals. NIH Strategic Planning and increases to minority and general enrollment are also mentioned in the bill, although both seem duplicative of initiatives already in place. The bill would also require NIH to take action to reduce administrative burden on grant recipients and researchers. While the overall intent of the legislation is positive, particularly the potential of a $10B additional investment in NIH, similar action by the Senate is uncertain.

The Digital Accountability and Transparency Act (DATA) Implementation

During a session on legislation at the COGR meeting, Helena Sims, Director of Intergovernmental Relations with the Association of Government Accountant's https://www.agacgfm.org/home.aspx discussed the status of the DATA. This effort would reduce burden in terms of financial reporting and compliance costs and transform the way we currently view federal spending information. Recent initiatives during the pilot phase and released in May include the deployment of a blog-type dialogue to initiate a discussion among the grants community on opportunities to reduce burden and compliance costs for Federal award recipients. Development of a Common Data Element Repository Library (C-DER Library) and a Grants.gov re- launch that includes information on the lifecycle of grants were also made available. The DATA pilot timelines will continue through 2017, when all agencies will report under the standards. The OMB Guidance on Applicability to Recipients is set to be released in November 2018. More information can be found on USASpending.gov, and COGR will follow and report on developments and engage with DATA implementation when appropriate.

We noted in the May update that COGR has been participating in monthly calls with recipient organizations interested in the DATA, led by Helena Sims. Federal officials participated on the most recent call. Members interested in participating in future calls should contact Lisa Nichols at lnichols@cogr.edu.

Helena participated in the National Webinar on DATA Implementation hosted by OMB and Treasury in April and provided an update on DATA implementation at the June COGR meeting. AGA's Intergovernmental Partnership is hosting a DATA discussion session during their annual conference in Nashville, Tennessee on Sunday, July 12 from 10:15 a.m. to Noon. Amy Edwards of Treasury, Karen Lee of OMB and Christopher Zeleznik of HHS (which is leading the DATA pilot) will participate. COGR members are welcome to attend. Please contact Lisa Nichols for details.

NIH Office of Science Policy Launch of New Blog

Dr. Carrie Wolinetz, Associate Director of Science Policy, announced June 10, 2015 the launch of a new blog entitled, "Under the Poliscope: Bringing Science Policy Into Focus." "Under the Poliscope" aims to highlight the activities of the NIH Office of Science Policy focusing on science policy matters in general as well as emerging issues of interest to the life sciences community and public at large. The blog is meant to be an interactive experience by encouraging readers to provide their thoughts and ideas to stimulate dialogue between NIH and the stakeholder community. You can also keep current on the new Twitter Account found here: https://twitter.com/CWolinetzNIH

RCA Committee Discusses Genomic Data Sharing with NIH

The Research Compliance and Administration Committee was joined via teleconference during Wednesday's Committee meeting by NIH officials, Dr. Dina N. Paltoo, Director, Genetics, Health, and Society Program; Dr. Carrie Wolinetz, Office of Science Policy and Dr. Sarah Carr, Office of Clinical Research and Bioethics Policy. The discussion involved ongoing questions from the membership related to the Genomic Data Sharing Policy. The NIH was receptive to the questions and concerns and has asked for a follow-up in writing. COGR will summarize our comments and update the membership in the near future.