COGR
Council On Governmental Relations
An Association of Research Institutions

November 20, 2017

October 26-27, 2017 COGR Meeting Report

GENERAL DEVELOPMENTS

Tax Reform Impacting Universities and Nonprofits

On November 16 The House approved its tax reform bill, the *Tax Cuts and Jobs Act* (H.R. 1) by a vote of 227-205, with 13 Republicans opposed. Ahead of the vote, ACE, on behalf of COGR and 45 other higher education associations, sent a letter to House Speaker Paul Ryan (R-WI) and Minority Leader Nancy Pelosi (D-CA) reiterating strong opposition to the concerning provisions noted in the November 6 community letter.

Status of Continuing Resolution

On November 14, House of Representatives Speaker Ryan said Congress may need to adopt a short-term spending bill to prevent a December 9 government shutdown, noting, "We might need a little more time to let the appropriators write their bill." Congressional leaders reportedly continue to negotiate potential changes to the Budget Control Act (BCA) caps.

COSTING POLICIES

Committee: Cindy Hope, University of Alabama (Chair) , Joseph Gindhart, Washington University-St. Louis, Lynn McGinley, University of Maryland-Baltimore, Jeffrey Silber, Cornell University, Cathy Snyder, Vanderbilt University, Michael Daniels, Northwestern University, Amanda Dotson, Texas A&M University, Michael Legrand, University of California-Davis, James Fortner, Georgia Institute of Technology, Sarah Axelrod, Harvard University, Nate Martinez-Wayman, Duke University, Marcia Smith, University of California – Los Angeles

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The Administration's Efforts to Cut F&A: UPDATE

The September 2017 COGR Update included an update, as of the end of the Summer, on the Administration's efforts to cut F&A. At the COGR meeting on Thursday, October 26th, COGR staff and Dr. Kelvin Droegemeier, Vice President for Research at the University of Oklahoma, provided additional insight.

Of particular interest was Kelvin's perspective on the hearing in which he participated as a witness on October 24th: Oversight Hearing - The Role of Facilities and Administrative Costs in Supporting NIH-Funded Research**.** We encourage you to follow the link above to view a video recording of the hearing, and to read Kelvin's Written Testimony**,** which includes an extensive history of F&A reimbursement by the Federal government. It also includes advocacy points on how the current system for F&A reimbursement is necessary to ensure that the United States remains the world leader in producing state-of-the-art, cutting-edge research and outcomes.

Chairman Tom Cole (R-Oklahoma) and Ranking Member, Rosa DeLauro (D-Connecticut) presided over this hearing held by the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies – House Committee on Appropriations. Kelvin, along with Dr. Gary Gilliland, President and Director of the Fred Hutchinson Cancer Research Center; Dr. Bruce T. Liang; Dean at the University of Connecticut School of Medicine; and Dr. Keith Yamamoto, Vice Chancellor for Science Policy and Strategy at the University of California, San Francisco testified as witnesses.

Kelvin's perspective, along with COGR's analysis, is that the hearing was "friendly" and that Chairman Cole is satisfied that the existing system for F&A reimbursement is fair and adequate; and that the Administration's efforts to cut F&A are inappropriate. However, the work on this issue is not complete and it is likely that the Administration will revisit this issue.

The Associations F&A Working Group comprised of COGR, the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), the Association of Public Land-grant Universities (APLU), the Association of Independent Research Institutes (AIRI), the National Association of College and University Business Officers (NACUBO), and other partners, will continue to be focused on this issue, as we have been since March. The COGR website contains resources developed by the Working Group, which help to explain the role of F&A costs in the research enterprise; we will add to this library, as appropriate. In addition, your institutions have been key in writing letters and engaging government leaders to explain the importance of F&A and other infrastructure costs.

Our community's combined efforts have had a significant impact and we are cautiously optimistic that we will be successful. Still, while we have been successful stemming the tide, to-date, we expect to be engaged in more work around this issue. **The COGR Costing Committee is evaluating its role in further advocacy around the politics of F&A, including exploration of themes such as transparency, alternative models, education and myths.** We will keep the Membership updated on all developments.

Alternatives to Effort Reporting: Thursday Afternoon Session at the COGR Meeting

This panel session provided the COGR Membership with an update by the "National Cohort for Alternatives to Effort Reporting" organization (i.e., the Cohort) on their recent activities and next steps. The PPT for the session is available on the COGR website (www.cogr.edu). The panelists included:

- Lisa Mosley, Yale University (National Cohort Leader)
- Jeremy Forsberg, University of Texas at Arlington (National Cohort Leader)
- David Ngo, The New School (National Cohort Leader)
- Paul Coleman, Former NSF Fraud Investigator (Consultant to the Panel)
- Susan Zaffers, SUNY Research Foundation (Cohort Member and Case Study Expert)

The National Cohort history dates back to January of 2016 when the National Council of University Research Administrators (NCURA) funded a research project to establish a nationally recognized cohort of institutions to develop efficient and effective model policies, procedures, and practices designed to reduce administrative burden for both faculty and the institution, minimize audit risk, and most importantly, facilitate research within an ethical and compliant framework for 2 CFR 200.430

(Compensation – personal services). Today, the Cohort has 90 member institutions that span the spectrum of large to small, public and private, some with medical schools, etc. All of the Cohort documents (available on their website), with the exception of the Internal Control Framework and Policy Matrix, are publicly available.

As the panelists shared, the Internal Control Framework is the foundational cornerstone to the work of the Cohort and the institutions that have transitioned to new systems, with risk assessment and identifying audit vulnerability being a key step in the transition process. To date, at least 25 institutions from the Cohort have transitioned or are in various stages of transition to new systems. While explicitly endorsing alternative systems is not the role of auditors, single audit results have demonstrated that alternative systems implemented by Cohort members are acceptable. There is a perspective by Cohort leaders that over prescribing policies and procedures, or making policies too complex, may actually create more audit risk by setting unrealistic institutional standards that are not required under 2 CFR 200.430. Instead, following the Internal Control Framework provides more assurance through balanced compliance efforts, while at the same time, creating systems that are user-friendly and more intuitive for faculty and university staff who process payroll.

To date, federal leaders and agencies have not specifically endorsed alternative systems, though the general consensus is that the FDP Payroll Certification model is a strong alternative, despite noncommittal acceptance by the IG Community (see June 21st NSF OIG Memorandum from Mark Bell, Assistant IG, addressed to OMB). Also, a recent National Institute of Food and Agriculture (NIFA) Fact Sheet, published in September 2017, is problematic (and inaccurate) on several fronts. However, Cohort leaders are in contact with NIFA, and COGR will engage, if necessary. Still, OMB and leaders from several federal research agencies continue to encourage alternative systems with an emphasis on reducing administrative burden.

Costing Committee Update: Thursday Morning Session at the COGR Meeting

This session presented an update on issues in which the Costing Committee currently is engaged, as well as an introduction to the members on the Committee. The PPT for the session is available on the COGR website (www.cogr.edu). The roster for the Committee is below and many of the issues discussed during this session are addressed below.

Board Members:	At-Large Members:
Cindy Hope (Chair), Alabama	Sarah Axelrod, Harvard
Mike Daniels, Northwestern	Amanda Dotson (ACUA liaison), Texas A&M
Joe Gindhart, Washington U	Jim Fortner, Georgia Tech
Lynn McGinley, Maryland, Baltimore	Mike Legrand, UC Davis
Jeff Silber, Cornell	Nate Martinez-Wayman, Duke
Cathy Snyder, Vanderbilt	Marcia Smith, UCLA

Procurement and the Micropurchase Threshold (MPT)

Joe Gindhart from Washington University in St. Louis led this discussion. First, the May 17, 2017 Federal Register Notice confirms a one-year grace period for implementation of 2 CFR 200.317-326 (Procurement Standards). For most COGR members, this means that 2 CFR 200.317-326 must be

implemented on July 1, 2018. Though note, several COGR members have a fiscal year start date of January 1, which means implementation for these institutions is less than two months away. **In addition, during the session, several COGR members shared a concern that at least one single audit firm (Ernst & Young) is questioning the validity of a $10,000 MPT.** The Ernst & Young perspective seems to be that because OMB has not updated 2 CFR Part 200.317-326 to reflect the new MPT, the allowable MPT is $3,500, as currently reflected in section 200.320(a).

COGR disagrees with this interpretation as the statutory language in the National Defense Authorization Act (NDAA) is definitive, and further, supersedes the language in 2 CFR 200.317-326. **COGR is in conversation with OMB requesting that OMB confirm the standing of the NDAA and we expect a statement of support from OMB soon.**

The MPT you are using now (e.g., $5,000, $10,000, $25,000, etc.) remains effective through the end of the one-year grace period. For those institutions that exceed $10,000, the one-year extension gives you cover to continue following your policies implemented under OMB Circular A-110. However, COGR recommends documenting your justification for exceeding $10,000 so that you are in compliance with the NDAA; i.e., *(A) $10,000; or (B) such higher threshold as determined by the head of the relevant executive agency and consistent with clean audit findings under chapter 75 of title 31, internal institutional risk assessment, or State law*). As necessary, COGR recommends you consult with your Single Auditors and/or General Counsel for your institution.

COGR also is in conversation with OMB regarding approvals of an MPT greater than $10,000 after the grace period expires. Gilbert Tran (Office of Federal Financial Management, Office of Management and Budget-OMB), spoke at the National Conference on College Cost Accounting (NACCA), held in Bethesda, Maryland, October 2-5. Mr. Tran commented on the process for approval of an MPT that exceeds $10,000. While his comments are not available as official, written policy, they are informative. According to Mr. Tran, OMB may be the entity that approves an MPT greater than $10,000, and this may be coordinated with the institution's Cognizant Agency for Indirect Cost (i.e., CAS-HHS, ONR-DOD). If your institution will need this approval, we encourage you to contact Mr. Tran at: hai_m._tran@omb.eop.gov. COGR is following this development closely. Please contact COGR if there are questions or concerns and we will continue to advance this discussion, as appropriate.

Application of the F&A Rate and "Equity": Cloud Computing Case Study

Cindy Hope from The University of Alabama led this discussion. This is a long-term, ongoing discussion about perceived inequities when applying an F&A rate to certain types of bulk and/or "low overhead" purchases. While we know the averaging concept behind the F&A rate is fair, we also know that maintaining healthy relationships with faculty and investigators, who often perceive the F&A charge on large expenditures as inequitable, requires our institutions to look closely at their concerns.

Application of the full F&A rate to Cloud Computing, Genomic Arrays (see 2010 NIH policy), Microelectric Chips, and some types of bulk purchases were raised in this session. The application (or waiving) of F&A on Cloud Computing services was a timely discussion as more institutions are facing this issue. One participant suggested that Cloud Computing is similar to the rental of space (which normally is excluded from the application of F&A), and could be treated as renting space on a server.

While COGR currently is not addressing this issue in an active manner, we are paying attention and will engage more, when appropriate.

Direct Charging and Service Centers: Technology Infrastructure

Sarah Axelrod from Harvard University led this discussion, which delved into the equity issue of certain categories of charges being relevant to a subset of awards, therefore direct charging may be more appropriate when the costs can be directly attributed to specific awards. Some prominent items of cost where direct charging may be appropriate are technology infrastructure (including data storage, research computing, data security, and other computing related costs) and IRB-related costs (see Single IRB and Direct Charging later in this report). As direct charging of these types of costs is considered, closely related issues are the use of service centers and compliance with allowability and consistency requirements in the Uniform Guidance.

This discussion is even more timely in the context of the Costing Committee's role in further advocacy around the F&A issue (see previous section) and the possible themes such as transparency, alternative models, education and myths. We will keep the Membership updated as the Costing Committee engages further on direct charging issues within the bigger picture of the politics of F&A.

Recent F&A Rate Negotiations

Jeff Silber from Cornell University led this discussion. Of particular interest was the question of whether there has been any sense of change in negotiation approach by Federal negotiators (HHS-CAS and ONR) under the new Administration. The answer to that question appears to be: No, the negotiation model has not changed under the new Administration. A number of institutions shared anecdotes of relatively positive rate negotiation experiences and reasonable rate increases.

In addition, requests for extensions of an institution's current F&A rate (for up to four additional years) under the extension provision specified in 2 CFR 200.414(g) were said to be favorably addressed by HHS-CAS and ONR. Backlog appears to be an issue at both agencies and has resulted in long timeframes between F&A rate proposal submission and issuance of a signed rate agreement (e.g., greater than one-year seems to be the norm); and in the case of ONR, the role of the Defense Contract Audit Agency (DCAA) has contributed to the long timeframe. Finally, the status of the DS-2 remains "no change"; i.e., schools are updating as each school deems appropriate, and the approval process, while inconsistent, has not been problematic.

FAQs to the Uniform Guidance: Software Capitalization Threshold

We updated the Membership on the positive resolution to this issue in the Thursday morning session. OMB released updates to the Frequently Asked Questions for the Uniform Guidance (2 CFR Part 200) in July 2017, and they included 24 new FAQS and 4 revised FAQs. COGR did an assessment of those FAQs in the September 2017 COGR Update. Since then, at the NACCA meeting held in Bethesda, Maryland, October 2-5, one update of note was made. A representative from Cost Allocation Services (CAS-HHS) clarified the intent of FAQ .33-1 Capitalization Level for Software to mean that the $5,000 software capitalization threshold is applicable only to situations where the software is attached to the hardware.

Therefore, the $5,000 software capitalization threshold is not applicable to internally developed software and is not applicable to stand-alone software acquisitions; **and institutions are not expected to change their software capitalization if they are in compliance with GAAP.** For those institutions that initially were questioned by CAS-HHS, or for those that recently have had similar issues raised, this should resolve any uncertainty. If this issue is raised at your institution, please contact COGR.

Payment and Reimbursement under 2 CFR 200.305 and the Compliance Supplement

As COGR has reported, auditors have challenged COGR member institutions by suggesting that grants and cooperative agreements should be subject to a strict interpretation of what constitutes payment/disbursement to a vendor. Specifically, the auditor position is that prior to billing a federal sponsor for reimbursement, the institution must have evidence that the institution's payment to the vendor has been cleared. This is in conflict with existing policy per 2 CFR Part 200.305(b): … *payments methods must minimize the time elapsing between the transfer of funds from the United States Treasury or the pass-through entity and the disbursement by the non-Federal entity.*

Predicating a request for reimbursement on when a payment to a vendor has cleared will make timely reimbursement inefficient, and in many cases, impossible. Furthermore, this discards longstanding, effective, and common-sense disbursement practices typically employed at research institutions where reimbursement is requested after an invoice from a vendor has been approved, identified for payment in the accounts payable system, and posted in the institution's official accounting records.

In response to a request for Public Comments to the 2017 Compliance Supplement, COGR sent a Comment Letter to OMB, Gilbert Tran. We are aware of at least another half-dozen institutions that have sent comment letters. This is an important issue with significant systems and administrative burden implications and we will keep the Membership posted as we further engage.

Costing Policies Committee: Other Issues

The Costing Policies Committee is working on a wide range of other issues. Some of these are ongoing and have been covered in past COGR updates. As appropriate, each one will remain on our list for the remainder of 2017, and into 2018.

Securing Student Information, Department of Education (ED). COGR has worked with several of our Association partners to raise concerns as to how ED has proposed audit objectives related to safeguarding data specific to an institution's information security program (i.e., Safeguards Rule). ED withdrew their initial inclusion of audit guidance from the 2017 Compliance Supplement. While COGR's position is that the Compliance Supplement is not the correct vehicle for this guidance, ED is now working with the community to include more reasonable language in the 2018 Compliance Supplement, or possibly through some other forum.

GAO-17-721, National Science Foundation: Actions Needed to Improve Oversight of Indirect Costs for Research. The GAO report, GAO-17-721, reviewed the amount of NSF funding for indirect costs and NSF's negotiation of Indirect Cost Rates (ICRs). NSF has cognizance for about 110 organizations, mostly nonprofit and professional societies, museums, and operators of large

shared-use facilities (such as accelerators, telescopes, and research vessels. The GAO recommended NSF take three actions to improve its guidance for setting ICRs, including adding certain details and procedures. NSF concurred with GAO's recommendations and described plans to address them. While COGR's perspective is that the GAO report is neutral to our community, the fact that F&A rates are being closely scrutinized at the federal level suggests that we should pay attention to other perspectives and reactions to this report.

Single IRB and Direct Charging. The Research and Regulatory Reform (RRR) Committee continues to follow this topic, including developments related to the new January 25, 2018 implementation date. From a costing perspective, the primary focus has been on the costing FAQs. The most recent version of FAQs for the NIH Policy on the Use of a Single IRB for Multi-Site Research Costs is available at the NIH Office of Science website.

Equitable Treatment of Off-Campus Research Centers in NIH RFAs. This has been an ongoing "niche" issue to encourage NIH to devise a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. Off-campus research centers are at a competitive disadvantage; i.e., by being required to include lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. We hope to resolve this longstanding issue soon.

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

RESEARCH & REGULATORY REFORM

Committee: Lois Brako, University of Michigan (Chair), Kerry Peluso, Emory University, Suzanne Rivera, Case Western Reserve University, Ara Tahmassian, Harvard University, Robin Cyr, University of North Carolina-Chapel Hill, Lynette Arias, University of Washington, Naomi Schrag, Columbia University, Marti Dunne, New York University, Martha Jones, Washington University – St. Louis, Charles Greer, University of California-Riverside, Mary Mitchell, Partners, J.R. Haywood, Michigan State University

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Research and Regulatory Reform Committee

COGR's Research and Regulatory Reform committee, Chaired by Lois Brako of the University of Michigan, introduced two new members at the October meeting, JR Haywood of Michigan State University and Mary Mitchell of Partners Healthcare. They join current members Sue Rivera of Case Western Reserve University, Kerry Peluso of Emory University, Marti Dunne of New York University, Lynette Arias of the University of Washington, Charles Greer of the University of California Riverside, Ara Tahmassian of Harvard University, Martha Jones of Washington University, St. Louis, Naomi Schrag of Columbia University, and Robin Cyr of the University of North Carolina Chapel Hill.

Regulatory Reform

USDA and FDA Seek Comments on Regulatory Reform Opportunities

We previously reported that USDA is requesting comment on regulations, policies and guidance documents in need of reform pursuant to Executive Orders 13771 and 13777. Comments will be reviewed at four time points. COGR, AAU and APLU submitted comments as well as a copy of a recent report by COGR-FASEB-AAMC and NABR on animal research regulatory reform prior to the deadline for the second review, November 14, 2017. Subsequent cut-off dates include February 12, 2018 and July 17, 2018.

FDA is also seeking comments on opportunities for regulatory reform, both general and specific to the Center for Biologics Evaluation and Research. Comments are due December 7.

Joint Association Working Group Report on Animal Research Regulatory Reform

COGR, the Federation of American Societies for Experimental Biology (FASEB), the Association of American Medical Colleges (AAMC), and the National Association for Biomedical Research (NABR), released the report *Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden* on October 24, 2017.

Section 2034 of the 21st Century Cures Act, signed into law on December 13, 2016, directs leadership of NIH, USDA, and the FDA to "complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals." On April 17, 2017, the associations convened a workshop on reforming animal research regulations. The goal of the workshop and report was to provide actionable recommendations from the research community for promoting regulatory efficiency, animal welfare, and sound science that might inform the federal agency review mandated by the Cures Act. Workshop participants were university investigators, laboratory animal veterinarians, and administrators engaged in animal research or oversight; chairs and administrators of Institutional Animal Care and Use Committees; directors of university animal welfare programs; accreditors; and representatives of associations with members who are engaged in animal research and oversight. The report was distributed to federal agency and congressional staff. Association staff will meet with USDA officials this month to discuss the report and recommendations.

Discussions with Federal Agency Officials on Research Regulatory Reform

The Research and Regulatory Reform Committee met with senior staff from the OMB Office of Information and Regulatory Affairs and other federal agency officials during the October COGR meeting. OIRA is standing up the Research Policy Board mandated by the 21st Century Cures Act. The Board, which will review federal regulations and identify opportunities to reduce regulatory burden and cost, includes 10 federal members and 9-12 non-federal members. Among the federal members are OIRA, OSTP, HHS and NSF as well as six additional agencies that support or regulate scientific research which may possibly include DOD, DOE, NASA, ED, Commerce and USDA. To our knowledge, non-federal appointments have not been formalized. Statute requires that the Board be stood up in December. In addition to the Research Policy Board, section 201 of the American Innovation and Competitiveness Act calls for an interagency working group on research regulations. A similar group

currently exists, the Research Business Models Subcommittee of the National Science and Technology Council, and this group may serve to fulfill that role.

Also discussed in the meetings was growing regulatory and sub-regulatory burden, including the increase in policies and guidance created in the absence of statute and regulation and the lack of research regulatory reform to date, despite numerous reports and recommendations. OIRA staff indicated in response to questions, that federal agencies can and should seek stakeholder feedback early on in the development of regulations, policies, and guidance, and that this can be conducted through informal communications.

Evaluation of NSF's Use of Preliminary Proposal Review

NSF has posted the results of an evaluation of the piloted use of preliminary proposal review in the Biological Sciences Directorate (BIO). The report notes that in 2012 the Divisions of Environmental Biology (DEB) and Integrative Organismal Systems (IOS) made three changes to the review of proposals, including limiting the number an investigator could submit per cycle to two proposals, requiring a four-page preliminary proposal, and switching from a semi-annual to an annual submission deadline. The intent was to "reduce researcher and NSF staff workload, increase funding rates for full proposals, and improve the quality of reviews."

A review of the effect of the changes, conducted three years later, found no effect on portfolio diversity, and significant improvement in funding rates for full proposals (from 15-17% to 28-34%) because approximately 75% of proposals did not proceed to full proposal stage. The quality of full proposals was thought to have improved. However, applicants were dissatisfied with the switch to annual submission. There was also preference for slightly longer preliminary proposals and shorter full proposals.
Per the report, the most common change proposed by reviewers and applicants was to return to at least two deadlines per year and the second most common to eliminate the preliminary proposal. Funded applicants in the comparison group were much happier with the submission process than funded applicants in DEB and IOS. DEB and IOS concluded that the proposals created additional burden and they have been discontinued. Other NSF directorates are finding that the elimination of grant deadlines has helped to reduce administrative burden.

Human Subjects and Health Research

Status of the Common Rule

We previously reported that a proposed delay to the implementation of the Common Rule was posted to the White House Office of Information and Regulatory Affairs website on October 7. The proposed action pending review is entitled "Federal Policy for the Protection of Human Subjects: Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year." To date, an NPRM has not been published. Until a final revised rule and revised effective or compliance date is published (in follow-up to a proposed rule) the current date (January 19, 2018) remains in effect. This has been an area of concern as the NPRM has not yet been published for comment.

In a letter to Dr. Jerry Menikoff, Director of the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP), dated June 21, 2017, COGR, AAMC, AAU and APLU requested a one year delay in the compliance date with an effective date for most provisions [those other than cooperative research] remaining January 19, 2018. This would allow the regulated community to move forward with any or all provisions of the rule, including those that would reduce administrative burden for investigators (e.g., certain exclusions and exemptions, elimination of the continuing review requirement for certain types of research, and IRB review of grant applications) while allowing institutions more time to come into full compliance given the uncertainty and lack of guidance and templates that has resulted from an administrative review of the rule.

Update on NIH Clinical Trial Case Studies

As previously reported, COGR, AAMC, AAU and APLU sent a letter to Dr. Michael Lauer, NIH Deputy Director for Extramural Research, on September 17, 2017, expressing concern that NIH's definition of "clinical trial" has been significantly expanded through the set of case studies published by the agency in late spring/early summer. Associations had a call with Dr. Lauer in follow-up to the letter on October 16 and other stakeholder groups also continue to engage NIH staff, however, no significant progress has been made on this issue to date. As a result, several organizations representing investigators whose fundamental health research has been designated a clinical trial have approached congressional staff on this matter.

On October 25, NIH published Plans for Clinical Trial Specific Parent R01 and R21 FOAs (NOT-OD-18-010). That notice seems to reinforce NIH's position on classifying fundamental research as clinical trials. The notice indicates that:

> "NIH not only supports trials of safety and efficacy, it also supports mechanistic exploratory studies that meet the definition of a clinical trial and are designed to explore or understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention. These studies may focus on basic and/or translational discovery research in healthy human subjects and in human subjects who are affected by the pathophysiology of diseases and disorders. By addressing basic questions and concepts in biology, behavior, and pathophysiology, these studies may provide insight into understanding human diseases and disorders along with potential treatments or preventive strategies. NIH also supports biomarker studies that meet the definition of a clinical trial and that may provide information about physiological function, target engagement of novel therapeutics, and/or the impact of therapeutics on treatment response. NIH thus supports studies that meet the definition of clinical trials (as noted above) but do not seek to establish safety, clinical efficacy, effectiveness, clinical management, and/or implementation of preventive, therapeutic, and services interventions."

The notice also includes examples of "mechanistic clinical trials" including "Studies that use a manipulation (physiological or behavioral) to answer basic science questions about normal functions." And "Studies that use an experimental manipulation in order to understand normal functioning or the pathophysiology of a disease or disorder, but do not aim to demonstrate clinical improvement" among other examples.

On a related note, we previously reported that NIH issued a notice on September 21, 2017, announcing "new and more rigorous" review criteria that the agency will apply to clinical trial applications submitted on or after January 25, 2018. The additional review criteria relate to the significance of the proposed work; the expertise and experience of the personnel; whether the research plan includes innovative elements; the approach in terms of study design and data management and statistical analysis; whether the environment is appropriate for conducting the proposed research; and the study timeline. On October 6, NIH announced additional review criteria for Career Development Awards in NOT-OD-17-121 related to the candidate, research plans, mentors and collaborators, and the environment and institutional commitment to the candidate. Detailed information is included in the notice.

New NIH Guidance on Clinical Trials and Single IRB

NIH has released additional guidance in relation to its Single IRB Policy which goes into effect on January 25, 2018. Guidance on Exceptions to the NIH Single IRB Policy (NOT-OD-18-003) and Guidance on Implementation of the NIH Policy on the Use of a Single IRB for Multi-Site Research (NOT-OD-18-004) were published on October 11. With respect to exceptions, applicants need to contact their program officer and identify the request in the sIRB plan. Requests must demonstrate a compelling justification and rationale for "why the single IRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s)." The implementation guidance includes options for meeting the policy requirements, expectations for proposals, and links to resources.

New HHS Secretary Nominated

The Administration has announced the nomination of Alex Azar as Secretary of the Department of Health and Human Services. If confirmed, Azar would step into the role vacated by Tom Price and currently held by Acting Secretary Eric Hargan. As reported by the NY Times, Washington Post and other news outlets, Azar is a lawyer that has previously served at HHS in the role of General Counsel and Deputy Secretary under George W. Bush, and more recently served as a senior executive at Eli Lilly. He is described as a conservative who is very knowledgeable of the department, health policy, and the regulatory process.

NIH Genomic Data Sharing (GDS) Policy: Access Model for Genomic Summary Results

We previously noted that NIH had published a request for comment on proposed updates to its GDS Access Model for Genomic Summary Results, or aggregate genomic data, that the agency suggests would provide access that is proportional to risks and benefits posed. Per the notice, "access to this information is currently only available through controlled access. NIH is proposing to allow broader access to genomic summary results from most studies subject to the NIH GDS Policy." The notice indicates that public data resources to share genomic summary results have not resulted in "individuals being matched to participation in a research study." NIH is proposing to "promote broad sharing of genomic summary results from most research studies with data held in an NIH-designated data repository through a new 'rapid access' tier". COGR, AAU and APLU submitted joint comments in support of the proposed updates on October 20.

OHRP Releases the 2018 Edition of the International Compilation of Human Research Standards

OHRP has released the 2018 edition of the International Compilation of Human Research Standards. The compilation includes listings and hyperlinks to "over 1,000 laws, regulations, and guidelines on human subject protections in 130 countries, as well as standards issued by a number of international and regional organizations." The 2018 edition also includes a new section on Social-Behavioral Research.

Audit

Audit Reports

Agency Inspectors General have been auditing agencies on implementation of the Digital Accountability and Transparency Act of 2014. A recent report published on the Department of Defense's implementation of the Act found that the DoD Senior Accountable Official (SAO) had not complied with the Act. The report found that the SAO "did not certify and submit complete award data, timely award data, accurate financial and award data, and quality financial and award data for publication on USASpending.gov" in part because the SAO lacked adequate internal controls.
The NSF OIG has published findings from an audit of incurred costs at a university research center. Auditors questioned $329,049 of costs, including $172,030 in equipment expenditures; $91,484 in travel expenditures; $42,054 related to "inadequate" documentation; and $13,047 related to an Award Cash Management $ervice (ACM$) reimbursement request.

National Science Board Oversight Meeting

The National Science Board met November 8-9, 2017. The Board agenda and link to the webcast are available on the NSB website. The Oversight Committee noted that the OIG semiannual report and any management response will be transmitted to Congress. There was a question about trends with integrity investigations, including those specific to SBIR, but no further discussion on report.
NSF IG Allison Lerner noted that the IG community unveiled a new website, Oversight.gov, on October 1. The website offers one place to locate final reports from all of the 67 federal IG offices that publish public reports. Reports can be viewed by release date, filtered by type, agency OIG, and other factors, and located by state, agency or key word. The site also tracks "potential savings" identified in reports. Ms. Lerner suggested that the website will assist IGs in identifying cross-cutting opportunities for oversight, and that it had been demonstrated for OMB and on the Hill.

NSF Assistant IG Mark Bell presented on the FY18 OIG Audit Work Plan. The OIG will focus on testing new policies and processes with respect to major facilities, including whether grantees are applying the policies, and whether there are weaknesses such that policies or processes should be changed or adjusted. The OIG is also looking to do more varied work, not just incurred cost audit, for example, focusing on a grantee's accounting system and other areas that are most useful for a particular institution. Mr. Bell indicated that he would like OIG staff to be more familiar with not just the internal performance work but the external work at an institution, so OIG staff are doing more of the external audit work. The OIG is also letting the agency know earlier on of potential findings and recommendations to ensure that they are on the right track and making the right recommendation. If corrective action is taken during audit, the OIG will note that in the report.

Mark noted that 21% of the OIG portfolio is required by Congress or others and 77% is OIG initiated. There was a question about the process that the OIG uses to select universities for audit. He indicated that they have a structured process for assessing risk that involves 25 risk factors. This includes the number of dollars received, but also other factors such as whether an institution has received funds before, their single audit findings, and any ongoing investigations. The OIG may also receive complaints or other information that something is amiss at a particular university. The OIG is currently reassessing how risk is allocated and updating the matrix. Mr. Bell noted that large universities generally have robust grant offices and capabilities but middle- size and smaller colleges often don't and that they are factoring this into their update.

Acting CFO Teresa Grancorvitz discussed the agency's implementation of the GONE Act. The agency has to report awards that have expired but haven't closed out in over two years. NSF addressed approximately 840 issues and closed over 300 awards. The grants typically have no remaining funding, only outstanding progress reports. Maria Zuber indicated that MIT had a few of these grants and that the institution froze the expenditures of those investigators until the outstanding reports were completed. NSF staff indicated that the agency benefited from the process in terms of identifying opportunities to streamline the close-out process.

NSB External Engagement Committee Meeting

The NSB External Engagement Committee discussed two concurrent listening sessions with educators, students, industry representatives and policy makers in Louisiana that are part of an NSB effort to hear from constituents and partners about their views on discovery and education. Representatives from a number of universities and colleges in Louisiana participated. NSB members provided an overview and discussion of the sessions and suggested that there will be a summary report. The committee intends to identify additional opportunities to engage with stakeholders in the coming months.
The committee also discussed a new initiative for NSB members to host a member of their congressional delegation at their institution. This initiative will initially be piloted at the University of Florida which will host Congressman Ted Yoho for a breakfast meeting with NSF graduate research fellows, a roundtable discussion with NSF-funded faculty members and a tour of the National Hazards Engineering Research Facility supported by NSF. The committee also discussed plans for the roll-out of Science and Engineering Indicators in January 2018.

October COGR Meeting

Research Quality and Reproducibility

COGR's Research and Regulatory Reform committee held a session on research quality and reproducibility on October 26. Bob Finkelstein, Director, Division of Extramural Research, National Institute for Neurological Disorders and Stroke, discussed concerns about rigor and reproducibility with respect to animal research in particular, and the steps that NIH has taken to address these concerns. NIH held a meeting in 2012 with editors, investigators, funders and reviewers to discuss this issue and has generally sought to raise awareness on the need for transparency in reporting and a focus on good experimental design. The agency has made training materials available and is increasingly focused on rigor and transparency in the review of grant applications, including providing a scientific premise for

the proposed work, authentication of key biological or chemical resources and consideration of sex and other biological variables.

Rebecca Osthus, Senior Science Policy Analyst with the American Physiological Society, discussed efforts to raise awareness about reproducibility and to provide resources to the research community, including a reproducibility toolbox available on the APS website. Ross McKinney, Chief Scientific Officer, Association of American Medical Colleges, spoke about unconscious bias in research, skewing research results as a result of unconscious beliefs or motivations, and how to address it. This might include publishing negative results and primary outcome measures, controls and randomization, providing adequate biostatistical support, and other measures. Presentations, which include links to resources, are available on the COGR website.

Partnering with Foundations

Several COGR member representatives from the four COGR committees met on October 24 with a core group of foundations that fund research to discuss formalizing a partnership that began several years ago with engagement on intellectual property and technology transfer issues. It proceeded to a discussion on approaches to charging research operating costs to foundation awards and how to streamline administrative processes and requirements to reduce administrative work. Susan Sloan and Richard Bissell of the National Academies indicated the Academies support for convening a workshop meeting of a broader group of foundations and research institutions in late spring of next year to discuss possible establishment of a formal partnership modeled on the University Industry Demonstration Partnership and Federal Demonstration Partnership. Fred Reinhart, University of Massachusetts System, Sara Bible, Stanford University, Walter Goldschmidts, Cold Spring Harbor Laboratories, and Amy Laster, Foundation Fighting Blindness, discussed efforts to date and next steps in an October 26 presentation. Presentations are available on the COGR website. COGR will keep members apprised of ongoing developments with respect to the discussions and opportunities for engagement.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Patrick Schlesinger, University of California-Berkeley (Chair), Alexandra McKeown, The Johns Hopkins University, Elizabeth Peloso, University of Pennsylvania, Kevin Wozniak, Georgia Tech Research Corporation, David Winwood, Louisiana State University, Fred Reinhart, University of Massachusetts-Amherst, John Ritter, Princeton University, Wendy Streitz, University of California, Michael Moore, University of North Dakota, Elizabeth Ponting, Harvard University, Dan Nordquist, Washington State University, Cindy Kiel, University of California, Davis

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COGR CIP Committee Discusses "Covered Defense Information" and Fundamental Research Issue with DOD

Both in the September and October Updates we discussed the issue of "covered defense information" and fundamental research with regard to the DOD DFARS 252.204—7000 clause. The issue relates to the scope of "involve" in the clause provision that fundamental research "… by definition cannot involve any covered defense information…." We submitted comments to DOD in August on this issue, with examples of how we believe covered defense information (CDI) still could be "involved" in a fundamental research project.

The COGR/CIP Committee met with DOD representatives at the October meeting. The DOD representatives expressed understanding of our concern. In our comments we had suggested a change to the DFARS 7000 clause to address the concern. The DOD reps indicated that a change in the DFARS at this time was not possible. However, they are developing a FAQ to clarify the scope. They implied agreement with us on the example we had provided of a PI attending background meetings at a military facility but not otherwise disclosing CDI in the conduct or outputs of the research project. (In such cases at least one DOD agency has taken the position that CDI is "involved," and the project is not fundamental research).

The DOD reps indicated they would welcome inputs on the FAQ, particularly examples in addition to those discussed in our comments. We asked the membership at the COGR meeting for other examples, and very much like to hear further from COGR members. We may have the opportunity to help shape the FAQ in a way that is helpful.

Another item of discussion was the DFARS 7012 Safeguarding clause. The NIST SP 800-171 security requirements are required to by fully implemented by December 31 for contractor information systems that process, store or transmit CDI. The October Update mentioned new guidance from DOD. According to this guidance, the required System Security Plan (SSP) will be considered as implementing the NIST requirements for 7012 compliance purposes so long as the SSP accurately reflects compliance status, even if all 110 NIST requirements are not met. The DOD reps indicated that SSPs should document what contractors currently are doing and what they plan to do for compliance. They expect approved variances to be rare, given this interpretation of "implementation." They also confirmed that the 7012 requirements apply only when CDI is involved (i.e. it is "self deleting," as per the discussion in the panel session at the February 2016 COGR meeting). Any CDI received by contractors is supposed to be specifically marked. If there are questions about the applicability of the 7012 requirement, under paragraph (m) of the clause subcontractors can go directly to the DOD contracting officer, with notification to the prime contractor.

We also asked about the status of the FAR clause, and the effect on the DFARs once the FAR cybersecurity clause is issued. The DOD reps indicated that while the FAR clause may supersede the security requirements in 7012(b), the cyber incident reporting requirements in 7012(c) may remain in effect. They also made the somewhat puzzling statement that the FAR clause will be directed to information as opposed to information systems. Since the NIST requirements presumably still will apply, we are not sure what this distinction may mean operationally.

They also mentioned concerns about the distinction in DOD policy between 6.2-funded fundamental research conducted on campus, and similar 6.2-funded research conducted off campus, which is not viewed as fundamental. We responded that the particular DOD funding stream often is hard for universities to determine. They recognized this is more of an internal issue for DOD.
Overall it was a constructive discussion. We expect to continue the dialogue with DOD.

FAR CUI Clause Still Under Development

We met with NARA last February to discuss the pending FAR CUI clause (see February 2017 Meeting Report). Since the due date for the draft clause has been postponed several times. The most recent due date was November 8 (see https://www.acq.osd.mil/dpap/dars/opencases/farcasenum/far.pdf). We have tried several times recently to discuss the status with NARA but have been unsuccessful. As indicated above, the clause may have a different focus than the DFARS. We will continue to reach out to NARA. We may plan a session at the February COGR meeting on this topic, depending on developments.

Startup Act Introduced in Senate

In late September Sen. Moran (R—KS) with three co-sponsors introduced the Startup Act (S. 1877). The Act would tax agencies to fund a grant program at the Department of Commerce for improving commercialization and technology transfer, particularly proof of concept and translational initiatives. It also would fund a regional innovation program and research on best practices, metrics, etc. for regional innovation initiatives. The program would be funded through a 0.15% tax on the extramural budget of agencies with extramural research budgets over $100M over the next five years. The bill also contains provisions to encourage immigration of aliens in STEM fields and alien entrepreneurs.

The higher ed. associations are sympathetic with the goals of the legislation. However we do not support taxing other agency R&D budgets to fund the new Commerce grant program. It would be better to encourage agencies themselves to fund these types of initiatives.

House Judiciary Committee Holds Hearing on Sovereign Immunity

On November 7 the House Judiciary Subcommittee on Courts, Intellectual Property and the Internet held a hearing on *Sovereign Immunity and the Intellectual Property System.* The hearing was prompted by the recent transfer of rights to certain patents on the ophthalmic emulsion drug Restasis for dry eye disease from Allergan to a Native American tribe. The tribe granted an exclusive license back to Allergan for which it allegedly received $13.75M. Apparently Allergan had sued two generic drug manufacturers for infringement. The tribe would be able to claim sovereign immunity in any subsequent *interpartes review* (IPR) proceeding brought by the alleged infringers that sought to invalidate the patents.

The focus of the hearing was on tribal sovereign immunity. There was general agreement that “rentals” of IP rights to avoid potential IPR patent invalidation was not in the best interests of the patent system or envisioned by the American Invents Act. While state and state university sovereign immunity was mentioned in some of the witness statements and by witnesses, it was not a strong focus. State sovereign immunity is derived from the Constitution (11th Amendment), but tribal immunity is subject to

Congressional restrictions. Sen. McCaskill has introduced a bill (S. 1948) that would abrogate tribal immunity for IPRs. https://www.congress.gov/bill/115th-congress/senate-bill/1948/text.

The higher ed. associations did not furnish statements or otherwise provide testimony for the hearing. Given the focus, we did not believe it was necessarily in our best interests to provide a high degree of visibility for universities. The witnesses and Congressional Representatives at the hearing clearly recognized distinctions between tribal immunity and state immunity. At the end Chairman Issa indicated that the Subcommittee would be developing legislation that would "treat both states and Native American tribes the same way." We understand that Chairman Issa elsewhere has asked for more input from stakeholders and stated the intent to develop bipartisan legislation.

The Patent Trial and Appeal Board (PTAB) has invited interested parties to submit *amicus* briefs on the tribal sovereign immunity issue. COGR is among those who have been requested by the attorneys representing the St. Regis Mohawk Tribe in the Allergan case to submit a brief in support of the Tribe and against administrative usurpation of sovereign immunity by the PTAB.. The COGR CIP Committee is reviewing the request. While the issues raised are important, the case is not focused on universities and is not likely to meet the COGR criteria for *amicus* brief participation.

We will follow developments closely. The House Subcommittee hearing webcast may be found at https://judiciary.house.gov/hearing/sovereign-immunity-intellectual-property-system/.

Updates

Revised Bayh-Dole Implementing Regulations

COGR has been informed that the revised Bayh-Dole implementing regulations (37 CFR 401) have been approved by the Department of Commerce. The regulations have been pending for nearly a year. We expect the content will be similar to the discussion of the CIP Committee with the NIST General Counsel last February (see February 2017 Meeting Report). Our understanding is that there will not be another round of public comments.

New iEdison Invention Reporting System Under Development

For some time we have discussed issues with the iEdison system in COGR Updates and Meeting Reports. We understand that NIST and NIH are working on a substantial revamping of the system. It will be rolled out over the next year.

NDAA Conference Report Fails to Address DOD Drug Pricing Mandate

The September Update discussed the mandate to DOD in the FY'18 National Defense Authorization Act (NDAA) Senate Committee Report to use march-in authority under the Bayh-Dole Act for compulsory licensing of inventions that benefitted from DOD funding when the price of the drug or medical technology in the U.S. is higher than the median price charged in other large economies. We had hoped that the House—Senate Conference Report on the NDAA might address or modify this language. However, the Conference Report released on November 9 is silent on the issue. The mandate raises a number of legal and jurisdictional issues as well as implementation concerns. DOD presumably will have to determine whether and how to comply. We will assess possible further options.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Pamela Webb, University of Minnesota (Chair); Michael Ludwig, University of Chicago; Jeffrey Friedland, Princeton University, Walter Goldschmidts, Cold Spring Harbor Laboratory, David Norton, University of Florida, Jennifer Lassner, University of Iowa, Steven Martin, Indiana University – Bloomington, Lisa Mosley, Yale University, Allen DiPalma, University of Pittsburgh; Jeremy Forsberg, University of Texas-Arlington, Stephanie Endy, Case Western Reserve University, Twila Reighley, Michigan State University

Research Compliance and Administration Current Issues and Priorities

Thursday morning's concurrent panel session provided COGR members with an update on public access initiatives, financial systems (i.e., PMS and ASAP), Subawards and Subaward Monitoring and an overview of concerns raised at the September Association of Research Integrity Officers (ARIO) conference held in San Diego, CA. The session kicked off with panelist and RCA Committee member Mike Ludwig, Director of University Research Administration at the University of Chicago who presented an overview of some concerns raised at the recent Association of Research Integrity Officers (ARIO) meeting and Hogan Lovell's webinar; Stephanie Endy, Associate Vice President for Research, Case Western Reserve University who gave a Public Access update; and Pamela Webb, RCA Chair and Associate Vice President for Research Administration, University of Minnesota; who presented on Open Issues in Federal Subawards and Subrecipient Monitoring.

- **ARIO overview**: Mike Ludwig gave a brief overview of hot topics that resulted from the recent ARIO Conference. The NIH Research Integrity Officer at the NIH told ARIO conference members the NIH is to be notified of any situation where Falsification and Fabrication had occurred on NIH funded grants as indicated in the Grants Policy Statement. Members of the conference took objection to this statement saying that RIOs follow the regulations stipulating that any reports of misconduct be reported to the HHS Office of Research Integrity. Further, the Grants Policy Statement has no such guidance specifying falsification and fabrication be reported to the NIH. Based on the fact that this was not included in the Guidance, it was recommended that members use their own discretion as whether to notify the NIH RIO.

  Mike also informed COGR participants about research misconduct intersecting with the False Claims Act. This was raised in a recent Hogan Lovells webcast, "Navigating the ins and outs of research misconduct-related litigation and enforcement: Emerging trends and hot topics". With Federal budgets becoming more and more scrutinized, public access trending in publications and data, the number of whistleblower or qui tam cases are on the rise for research fraud. Institutions should ensure their research integrity programs have accessible and diverse means for educating investigators, students, and research staff about research ethics and responsible conduct standards as delineated in the COGR's 2016 Guide to Effective Management Practices.

- **Public Access Update**: Stephanie Endy gave a Public Access update on the information presented by Community of Science (an interagency working group with NSF) members that attended the RCA Committee Meeting on Wednesday afternoon. The session focused on the scope, resources, mechanisms, issues, and next steps of the Open Science initiative. During this meeting, RCA members voiced concerns around the expectations of data curation and storage, i.e., all data versus data supporting research results/publications as indicated in the OSTP Holdren memo. Acknowledging that the Holdren memo encourages use of leveraging existing archives, members said these archives may not be sufficient to meet all requirements for all data and the costs to curate and store all data remain yet undefined. The issue of how to comply with the Data Management requirements was raised. RCA expressed that data exceeds the life of a project and with the notion that data management plans are subject to change throughout the course of the period of performance, the ability to properly manage these plans will be challenging. RCA recommended that the NIH consider making Data Management Plans part of the just-in-time process, which would eliminate burden on the front end of an application process allowing researchers more time to focus on the proposed science. Other issues such as costing data management in proposals, the increase and complexity of data use certifications for incoming data sets, etc. will be addressed when a draft policy or Notice of Proposed Rulemaking (NPRM) is released for comment. We should expect to see a notice and/or draft policy for comment in the coming months.

- **Open Issues with Federal Subawards and Subrecipient Monitoring:** Pamela Webb gave an overview of open issues that remain to be addressed with federal subawards and subrecipient monitoring in five (5) key areas as follows:

  De Minimus F&A Rate
  - Establishing Valid & Acceptable F&A Rates for For-profit entities
  - the use of De Minimus Rate for Entities with Expired F&A Rates

- ***Risk Assessments***
  - Timing of risk assessments
  - Reliance on Federal audit Clearinghouse (FAC) for audit findings
  - Safe Harbor
  - Lack of direct link to the FAC audit package

- ***Fixed Price Subawards***
  - Mechanisms for exceeding the simplified acquisition threshold
  - Burden and lack of standardization for prior approvals
  - Reducing burden of multiple fixed price subawards to same subrecipient for same project
  - Difficulty of managing Clinical Trial fixed price subawards with variable enrollment and costs
  - Adding fixed price subawards that involve cost-sharing.

- ***Foreign Subawards***
  - (See also Fixed Price Subawards, all items)
  - Lack of Clarity about whether SAM Registration is required or just a DUNS number

  - Establishing standards for appropriate foreign subrecipient risk assessment and monitoring
  - Developing and determining appropriate terms and conditions
- ***Other***
  - Federal Agency acceptance of negotiated F&A Rates
  - Pass-through Entity Acceptance of Negotiated F&A Rates

COGR will continue to work on these issues with FDP and federal agency representatives into the next year. Stay tuned for further updates in this area.

Research Compliance and Administration (RCA) Committee Updates

The RCA will continue to monitor existing projects and new developments including RCAs recent initiative to review and advocate the barriers of conducting marijuana and hemp research.

Stakeholder's Workshop on Dual Use Research of Concern

In the October update we wrote that the U.S. Government and the National Science Advisory Board for Biosecurity (NSABB) sponsored a workshop to engage with stakeholders and facilitate information sharing and best practices among research institutions regarding their approaches to, and experiences with, implementing the *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)*. COGR staff attended the workshop to determine if changes to the current policy were being considered. Primarily, the workshop focused on training and communication of DURC by various presenters. The Dual Use Research of Concern Companion Guide was quoted as being the go-to guide for training, development, review of risk mitigation plans, and other DURC related questions and scenarios. This Companion Guide has been recently updated in September 2017. Despite the recent GAO report on the Federal Select Agent Program of the Centers for Disease Control and Prevention and the Animal and Plant Inspection Service, COGR is unaware of any changes being considered to the current policy at this time.

NSF Science of Science Innovation Policy (SciSIP) Workshop on The Value of Data Sharing

As mentioned in our last update, the NIH Office of Science Policy and the NSF Science of Science Innovation Policy (SciSIP) program hosted a closed one-day workshop on October 13, 2017. The workshop entitled "The Value of Data Sharing" included participants with a wide array of expertise in data sharing who could make recommendations on how to improve the value of data sharing systems. NIH is interested in addressing both low hanging fruit for immediate consideration as well as recommendations for areas where additional research is necessary prior to any changes to policy. To address the later, NIH is considering the release of Funding Opportunity Announcements that would ultimately become the basis for the development of a White Paper. At Wednesday's RCA Committee Meeting, members of the Community of Open Science, Neil Thakur (NIH/OD) [E], Dina Paltoo (NIH/OD) [E], Jerry Sheehan (NIH/NLM) [E], Beth Plale (NSF/OAC) and Patricia Knezek (NSF/ODI) were invited to expand on the direction both agencies are heading in regard to any future policy

revisions. See Public Access Update above during the Thursday morning concurrent session for additional information obtained during this meeting.

Ad Hoc Committee on Confidentiality in Research Misconduct

In the June meeting report, COGR indicated that a new Ad hoc Committee on Confidentiality in Research Misconduct was being formed to address and seek solutions to issues related to confidentiality during and after the active assessment, inquiry, investigation, and determination process.
RCA hosted, Ann Pollack, UCLA and Chair of the Ad Hoc Confidential Committee to provide an update of issues/topics raised over the last several months. Initial Questions addressed by the committee include:

- How are the regulations/policies interpreted and how are they applied by institutions? How do institutions apply the regulations after research misconduct proceeding has been completed? Are communications different depending on whether there is a finding of research misconduct or not?
- Is communication from the federal Office of Research Integrity about maintaining confidentiality once an institution's process has ended consistent? If not and/or if not clearly understood, is there value in approaching ORI to seek clarification and/or change?
- Is there value in benchmarking the confidentiality provisions in the research misconduct policies of COGR member institutions? To what end?
- What are reasonable deliverables?

A key element of several Committee discussions has centered around the deliverable(s) and outcomes. Members expressed concerns about providing additional guidance without risking the loss of institutional flexibility in interpreting and implementing federal regulations and policy. The Committee's recommendation is that COGR and the Association of Research Integrity Officers (ARIO) prepare a guidance document that sets for various scenarios with which RIOs and their institutions struggle, addressing topics such as communicating with journals, maintaining confidentiality internally, handling media requests, notifying collaborators and co-authors, responding (or not) to "fans" of the respondent(s), etc..

The COGR 2002 brochure on "Recognizing and Managing Personal Financial Conflicts of Interest" was identified as a model for the kind of document that the Committee envision; something that would identify scenarios, highlight key issues, and then provide management strategies that might reflect various approaches.
RCA provided input on the deliverable and recommended that this be brought to the Board for approval to move forward. The Board approved during its October meeting and work on the deliverable has started. All deliverables produced by COGR go through Committee and Board review. Approval will also go through Board review at ARIO. COGR will continue to provide status updates as necessary. For questions, please contact Jackie Bendall at jbendall@cogr.edu.

Joint Association letter to Environmental Protection Agency (EPA) Administrator Scott Pruitt

As a result of EPA Administrator Scott Pruitt's directive on "Strengthening and Improving Membership on EPA Federal Advisory Committees", COGR and other Associations submitted a letter urging

Administrator Pruitt to withdraw the directive barring scientists who receive Environmental Protection Agency (EPA) grants from serving in advisory roles, due to a purported conflict of interest or lack of objectivity. COGR will continue to follow this issue and update the membership on any new developments.

New Work Group on the Barriers of Conducting Marijuana and Hemp Research

COGR is forming a new ad hoc working group to advocate its concerns regarding the barriers of conducting marijuana and hemp research on university campuses. H.R. 3391- Medical Marijuana Research Act of 2017 aims to amend the Controlled Substances Act to make marijuana accessible for use by researchers for medical and other purposes. COGR will review the bill and begin drafting its agenda for a meeting in December. If you have questions, please contact Jackie Bendall at jbendall@cogr.edu. Stay tuned for further updates.