COUNCIL ON GOVERNMENTAL RELATIONS

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June 26, 2017

June 8-9, 2017 COGR Meeting Report

GENERAL DEVELOPMENTS

Dramatic Reductions in the President's FY 2018 Proposed Budget for Research

At the recent COGR meeting Matt Hourihan, Director of the AAAS Research and Development Budget and Policy Program, provided details for all the Federal science departments and agencies in the President's FY 2018 budget request. Virtually every agency's research budget would be reduced, including a 21% reduction for NIH and a 11% reduction for NSF. However, as Mr. Hourihan and others remind us, Congress takes very seriously its constitutional responsibility for federal agency appropriations. During recent Congressional hearings many key members of Congress from both parties expressed their dismay at the proposed cuts to research at NIH and NSF and strongly imply they will take a different approach when the final appropriations are completed. Mr. Hourihan's presentation can be found here on the COGR website.

Appropriations Hearings

Senate HHS Appropriations Hearing

The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies held a hearing on June 15, 2017 on the HHS FY18 budget request. HHS Secretary Tom Price testified.

Senators expressed concern about efforts to replace the Affordable Care Act, and proposed cuts to NIH, CDC, Medicaid and other programs. Chairman Roy Blunt expressed concern with the proposed $15.1 billion budget reduction for HHS including a $7.5 billion (21%) cut to the NIH budget and a $1.2 billion (17%) cut to the CDC. Price suggested that programs shouldn't be measured on how much money is appropriated to them but whether they are effective. Price and others within HHS are discussing opportunities to "Reimagine HHS." While indicating that he hoped the Senate could work with Secretary Price to identify ineffective programs, the Chairman also noted that given the bipartisan Senate support for research funding it would be difficult to imagine the committee making these cuts. Blunt suggested that he wouldn't be part of reducing funding for NIH. Senator Moran indicated opposition to proposed cuts to NIH funding but suggested that with respect to indirect costs, if money is being improperly used or used inefficiently there is support to ensure appropriate use without reducing the budget overall. Moran also suggested that universities should be paying the salaries of researchers. Senator Durbin asked Price whether given the proposed cuts to NIH Price has concluded that NIH research is a failure. Price suggested that he supports NIH but believes there are savings to be garnered that don't affect the number of grantees or amount of moneys; that the same or more could be given to research if changes are made to indirect costs. Durbin suggested that reform in the way the federal government pays for competitive research grants should not be part of the appropriations discussion.

Senate NIH Appropriations Hearing

The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies held a hearing on June 22, 2017 on the NIH FY18 budget request. NIH Director Dr. Francis Collins testified along with several institute directors. Dr. Collins was recently asked to stay on as NIH Director during the Trump Administration.

Chairman Roy Blunt (R-MO) indicated that the President's proposed budget includes a 21% cut to the NIH budget that the committee would find unacceptable, citing the loss of 90,000 jobs nationwide, including 1,700 jobs and $292 million in economic activity in MO. The Chairman indicated that there is a long history of congress asserting itself on issues of allocating money and noted that nine committee members had been out to visit NIH recently. The important role of the Fogarty International Center was highlighted, including combating Zika, HIV and other infectious diseases. There was discussion about AHRQ, and the possibility that the agency's portfolio could be distributed among existing NIH institutes. There was also a focus throughout the hearing on the impact of NIH research on a broad spectrum of diseases and disorders, from Cancer to Lupus to Cystic Fibrosis and Alzheimer's disease, as well as discussion of new models for evaluation and treatment of opioid addiction. The hearing was lightly attended as a result of the release of the Senate's health care bill.

A number of Senators spoke out on the topic of indirect costs. Senator Leahy mentioned the University of Vermont's letter to OMB Director Mulvaney and HHS Director Price and noted that under a 10% capped rate the university would be forced to dramatically scale-back biomedical research and opportunities to develop cures. Senator Murray indicated that there is tremendous concern about HHS leadership's proposed plans to replace negotiated indirect cost rates with a flat 10% rate. Collins indicated that IDC reimbursement averages 28% at NIH and discussed what this covers - buildings, utilities, operations, human and animal care oversight, etc. – noting that they are all necessary for the institution to conduct research. Senator Murray asked what similar costs were for intramural and what would happen to intramural if costs were capped at 10%. Collins indicated that the rate would similarly be about 30% for the intramural program and that with no other potential source of funds they don't know what they would do if it dropped to 10%. Senator Murray suggested that the budget proposal assumes states would pick up this federal responsibility which is dubious and that many places such as the Fred Hutchinson Cancer Research Center are private and don't have other funding sources. Dr. Collins and others indicated that the work of these centers is central to NIH's efforts to cure cancer. Senator Moran asked if some research institutions make the salaries of their researchers, as much as 80%, contingent upon receiving an NIH grant, and whether there has been any thought about trying to focus the grant dollars "on the research" instead of the salaries of the scientists. He suggested that universities should be supporting more of the salaries. Collins indicated that the government contracts with universities to provide the full costs of the research including the percentage of an investigators time devoted to federal research projects. Where scientists are primarily conducting research the percentage could be 50-80% but in reality it is much less than that and the government doesn't pay for other activities conducted. Collins indicated that 5-10% of the NIH budget funds faculty salaries and that there is a cap on salaries. Efforts to reduce the percentage of salaries have not been attempted. Dr. Collins also noted that 35-45% of the NIH budget is spent on salaries where including trainees but that this is the most critical part of the research as they are making these discoveries, and is consistent with the federal-university partnership created after WWII.

Senator Alexander noted the complexes of industry that grow up around research institutions and both the role of universities and related industry in fostering jobs and a healthy economy. The Senator asked about China's investment in research relative to the U.S. Dr. Collins indicated that China is investing heavily in academic research, that scholars are being attracted to work back home, and that China is on track to surpass the U.S. in research spending in the next few years. Senator Alexander indicated that the proposed cuts to indirect costs from 28% to 10% are "harebrained" ideas that would result in fewer jobs

and less research and noted that universities are already subsidizing research and can't make up the difference. Senator Alexander indicated that if HHS is planning to pursue this, Congress and the Senator plan to get involved. He asked that Dr. Collins assess and report to HHS how much state universities would lose in funding, how much they already contribute to F&A, and whether there would be more or less research as a result of any reduction in indirect cost rates. He indicated that he hoped we can nip this idea in the bud – that it is a thoroughly awful idea and bad policy when the administration is looking to create more jobs and research not fewer and less. Senator Alexander suggested that if NIH wants a constructive way to get more for less they should look at the two National Academies reports on reducing regulatory burden – reduce regulations and free up investigators time for research. Senator Lankford echoed these concerns.

House NSF Appropriations Hearing

NSF Director Dr. France Cordova testified before the House Appropriations Subcommittee on Commerce, Justice, Science and Related Agencies in a hearing on the NSF FY18 budget on June 7, 2017. The President's budget proposes cutting NSF spending by approximately $820 million, an 11% cut from FY17. Both the Chair and ranking member expressed their overwhelming support for NSF funding and research and their commitment to ensuring that NSF and NASA are appropriately funded and that the Nation's leadership in fundamental research and security are preserved. It was noted that other countries such as China are not compromising research funding. Dr. Cordova indicated that $4 billion in high quality proposals already can't be funded under the current budget, with an 11% cut NSF would potentially be looking at $5 billion in outstanding proposals that cannot be funded. Concerns were expressed about the Nation's ability to retain its best scientists. Dr. Cordova suggested that the accelerated pace of investment of other countries is a concern as well as the ability to maintain our global standing if we don't support scientific research.

Latest Developments on Proposal to Restrict F&A Payments

As you know, the President's proposed budget for NIH for FY 2018 includes a provision to limit Facilities and Administrative cost payments to 10% of the total amount awarded. COGR is working with our colleagues in Washington and at our member institutions across the country to inform members of Congress, the Administration, Foundations, patient advocacy groups, and industry of the devastating impact such a cut in funding would have on research, jobs, the pipeline of young investigators, and State and local economies. Some of you have responded to our call for letters to DHHS Secretary Price and OMB Director Mulvaney to highlight the specific impact at your institution. We urge those of you who have not yet done so, to submit such a letter as soon as possible. While we think we are making good progress with key members of Congress who oppose any cut to NIH, and in fact want to increase the NIH budget for next year, we cannot assume anything until we see what Congress actually ends up appropriating for NIH. Statements like the one here below will continue to come, and we must be prepared to respond appropriately.

The COGR letter is posted to the COGR web site, but please personalize your letter for the specific impacts – funding amount lost, labs closed or research cut short, jobs lost, etc.

For Director Mulvaney, letters can be sent to ombdirector@omb.eop.gov
For Secretary Price, it is secretary@hhs.gov

Please copy the COGR office at dkennedy@cogr.edu, and also the AAU at FandAcomments@aau.edu

F&A Advocacy and Engagement with the Private Research and Disease Foundations

The role of Foundations, and the low F&A rates included in their awards, has played a prominent role in the Trump Administration's FY2018 budget proposal and a proposed 10% F&A cap on NIH awards. The Administration's budget proposal for NIH states: "*The Budget includes an indirect cost rate for NIH grants that will be capped at 10 percent of total research … It would also bring NIH's reimbursement rate for indirect costs more in line with the reimbursement rate used by private foundations, such as the Gates Foundation, for biomedical research conducted at U.S. universities*."

The comparison to the Gates Foundation is problematic. In fact, the Gates Foundation Indirect Cost Policy (effective February 1, 2017) includes the following statement: "*While the maximum indirect cost rate percentages have not changed, we have adjusted the costs that can be considered direct to better reflect the cost of achieving project outcomes, specifically in the areas of facilities and project support*." Allowable direct costs per the Gates Foundation policy include: "*Allocable facilities, utilities and communications expenses that are required to execute the project, such as field clinics, laboratories, project office costs*." And as stated by a Gates Foundation spokesperson in a recent Science Insider article: The Trump proposal "*does not reflect [the foundation's] process for determining direct or indirect costs*."

While many other Foundations do not have the robust indirect cost policy of the Gates Foundation, their historical role within the research ecosystem is unique. Foundations play a critical role in the discovery of new treatments and cures for serious and often fatal diseases by providing supplemental funding for federally funded research conducted at research universities and nonprofit research institutions. Foundations often fund higher risk / higher reward research, as well providing an important funding source for early career scientists. According to NSF data, private foundation funding represents 6% of academic research and development (R&D) funding in the U.S., while the Federal government and research institutions account for 55% and 24%, respectively.

As such, the partnership agreement that has been in place for over five decades is that the Federal government assumes the primary responsibility for funding the F&A support and research infrastructure (e.g., state-of-the-art building and labs, utilities and lab maintenance, hazardous waste disposal, etc.), while universities and research institutions provide significant cost-sharing in support of the infrastructure.

Unfortunately, the longstanding agreement is under attack. In response to questionable assumptions in the Trump Administration's FY2018 budget proposal, one of several initiatives COGR is now actively engaged includes reengagement with our colleagues from FasterCures and the Milken Institute. Last November, COGR participated in a meeting led by Faster Cures and the Milken Institute, which included a diverse workgroup of representatives from Foundations and research universities. Previous meetings of the workgroup focused on issues related to data sharing, intellectual property and licensing, and the November meeting discussion focused on F&A rates and reimbursement. While at the

conclusion of the November meeting it was clear there were still areas of disagreement, the workgroup remained committed to ongoing dialogue and transparency in solutions.

Now, in light of the Trump Administration's FY2018 budget proposal and the threat of 10% F&A limitation on NIH awards, the reengagement of the workgroup is focused on the common interest of ensuring that the Federal government not abandon its historical role as being the primary funder of F&A support and research infrastructure. Engagement with the Foundations is one of several outreaches in which COGR continues to pursue as we work to reject the proposed 10% F&A cap on NIH awards.

RESEARCH & REGULATORY REFORM

Committee: Sara Bible, Chair, Stanford University, Cindy Kiel, University of California-Davis, Kerry Peluso, Emory University, Lois Brako, University of Michigan, Suzanne Rivera, Case Western Reserve University, Ara Tahmassian, Harvard University, Daniel Shapiro, University of Southern California, Robin Cyr, University of North Carolina-Chapel Hill, Lynette Arias, University of Washington, Naomi Schrag, Columbia University, Marti Dunne, New York University, Martha Jones, Washington University – St. Louis, Charles Greer, University of California-Riverside

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Regulatory Reform

Federal Agency Efforts to Reduce Regulatory Burden

Federal agencies are seeking comments on regulations, paperwork requirements and other obligations that can be modified or repealed to reduce administrative burden as part of the implementation of Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs," issued on January 30, 2017 and Executive Order 13777, "Enforcing the Regulatory Reform Agenda", of February 24, 2017. Notices of interest include the Department of Energy (comments due July 14), Department of Education (due August 21), the Defense Federal Acquisition Regulation Supplement (August 21), and the National Oceanic and Atmospheric Administration (comments due July 7). COGR is currently drafting a response to the DOE notice and may submit comments on other notices. If you have comments on requirements that should be modified or repealed in relation to these notices that you would like COGR to consider for submission please send them to Lisa Nichols.

Human Subjects Research

Associations Request a Delay of the Common Rule Compliance Date

COGR, AAMC, AAU and APLU sent a letter to Dr. Jerry Menikoff, Director, HHS Office for Human Research Protections, on June 21, requesting a one year delay in the compliance date of the Federal Policy for the Protection of Human Subjects (Common Rule). The letter notes that it is typical for a major rule affecting institutional research practices to be issued with a compliance date that is at least 6 to 12 months later than the effective date. The revised rule has both an effective and compliance date of January 19, 2018. The letter also highlights the uncertainty surrounding the rule, including recent public presentations from OHRP staff indicating that the rule is currently under administrative review. As

indicated in the letter, a delay in the compliance date would allow institutions adequate time to come into compliance with all provisions of the revised rule while also allowing the regulated community to move forward with those provisions that would reduce administrative burden for investigators. The associations have requested that OHRP allow institutions to implement these measures on or before the effective date.

NIH Delays Implementation of the Policy on the Use of a Single IRB for Multisite Research

NIH released a notice on June 16 indicating that the agency is extending the effective date for the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research to January 25, 2018. COGR and other associations had previously requested a one year delay in the effective date and NIH had previously extended the effective date to September 25, 2017. The new date corresponds with an NIH policy requiring all applications involving one or more clinical trials to be submitted through a Funding Opportunity Announcement specifically designed for clinical trials effective January 25, 2018.

June 2017 COGR Meeting

Meeting and Session on Animal Research Regulatory Reform

The Research and Regulatory Reform (RRR) Committee met with Dr. Kathryn Bayne, Chief Executive Officer of the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). Dr. Bayne participated in a recent FASEB-AAMC-COGR workshop on animal research regulatory reform and the committee discussed how AAALAC might assist institutions in identifying and reducing institutional administrative burden associated with animal research and regulations. Dr. Bayne reviewed the COGR checklist for reducing administrative burden, indicating that the suggested actions were consistent with AAALACs thinking and not in conflict with accreditation. We discussed how AAALAC might communicate this on a number of topics. Dr. Bayne indicated that institutions should contact AAALAC if they are unsure if something is a requirement. There was discussion about the benefit of having concise institutional policies and procedures to ensure adherence with an institution's own standards; that more is not better.

RRR committee member Ara Tahmassian, J.R. Haywood, Assistant Vice President, Regulatory Affairs, Michigan State University (MSU); Molly Greene, Advisor, Institutional Animal Care and Use Committee, MSU; and Matt Bailey, President, National Association for Biomedical Research, discussed animal research regulatory reform and a pending FASEB-AAMC-COGR report in a June 8 session. Slides from this session are available on the COGR website.

Meeting and Session on ClinicalTrials.gov

The RRR committee met with Dr. Deborah Zarin, Director of ClinicalTrials.gov at NIH, on the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information and Clinicaltrials.gov. Discussion included the difficulties that investigators have entering data into ClinicalTrials.gov and the challenges for institutions in assisting them which can sometimes lead to a mismatch in what is registered and what is reported. Dr. Zarin suggested that this is sometimes due to an administrator registering information from what may be a poorly written protocol. Dr. Zarin suggested that universities need to take on a larger role in ensuring that their investigator's protocols are scientifically

sound. She also offered that 12 Ph.D. level ClinicalTrials.gov staff are available for one-on-one conversations about how registration and reporting should be structured and that both sides are happier when this resource is utilized. We talked about this policy being more broadly applicable than the regulations in that it incorporates pilot and phase 1 studies and social and behavioral research. Dr. Zarin suggested that one third of studies weren't being reported and that if an intervention isn't being reported it wastes participant's time and federal funding. She suggested that CT.gov is getting a lot of use by journals, IRBs, industry and others and that they are studying the impact of CT.gov registration and results reporting. Dr. Zarin and Diane Wilson Regulatory Specialist, University of Michigan, presented on this topic in a session on June 8. Diane discussed a number of challenges that institutions face when entering data into ClinicalTrials.gov. Slides from this session are available on the COGR website.

NIH Efforts to Stabilize the Biomedical Research Enterprise

Several COGR committees met with NIH Deputy Director for Extramural Research Dr. Mike Lauer on June 7 to discuss the proposed Grant Support Index detailed in the May 2017 COGR Update. Mike discussed NIH plans to take a different approach to addressing funding challenges for early stage and mid-career investigators. As part of the Next Generation Researchers Initiative NIH plans to further extend the payline for R01 equivalent applications from early stage investigators by funding most applications that score in the top 25 percentile. For mid-career investigators who are within 10 years of receiving their first NIH R01 equivalent award whose applications score in the top 25 percentile, extending the payline for those about to lose all NIH funding and "Prioritizing funding of an additional concurrent research project grant award for particularly promising mid-career investigators currently supported by a single ongoing award." The cost of this effort is estimated to be $210 million the first year and approximately $1.1 billion annually at year five and thereafter. The change in approach addresses concerns about the possible impact of capping the number of grants on science and collaboration.

Audit

NSF OIG Semiannual Report to Congress

The NSF OIG has published its Spring Semiannual Report to Congress. The report begins by highlighting the impact the OIG has had over the course of the last six months including changes to large facilities management, inspiring language in the American Innovation and Competitiveness Act that requires NSF to cut costs associated with employing individuals under the Intergovernmental Personnel Act (IPA), and highlighting the questioned but not resolved costs of five institutions. The report notes that $1.9 million of the questioned costs involved salaries and associated costs for senior research personnel "in excess of NSF limits" and that "similar charges have been questioned in several prior audits, but NSF has not sustained the questioned costs, even when the awardee agreed to repay the disputed amount." The report indicates that the NSF OIG's "opinion remains that the costs were in violation of NSF policy in effect at the time the claims were made."

The OIG report addresses Single Audit. The report suggests that the percentage of audits that fully meet federal requirements decreased from 83% to 58% in one year. Per the report, quality issues identified "included 18 reports in which the Schedule of Expenditures of Federal Awards did not include required information to allow for identification of awards received from or passed-through to other non-federal entities and/or did not adequately describe the significant accounting policies used to prepare the

schedule. In addition, 7 reports were not submitted to the Federal Audit Clearinghouse in a timely manner; 5 reports included incomplete presentations of the audit findings; 3 reports contained incomplete Corrective Action Plans to address the audit recommendations; 10 reports were submitted to the Federal Audit Clearinghouse with an inaccurate Data Collection Form (Form SF-SAC); and 1 report failed to include all of the required report elements."

Program integrity investigations included a $1.2 million settlement on falsification of time and effort reports. The report also includes a number of cases of research misconduct, OIG congressional testimony, and statistical data such as aging of open recommendations and research misconduct statistics. NSF management's response to the OIG Semiannual Report focused on three areas: the FY16 financial statement audit, the conference spending audit and the review of the project baseline schedule for NSF's relocation.

OIG Report on NSF Controls to Mitigate IPA Conflicts of Interest

The NSF OIG published a report titled "NSF Controls to Mitigate IPA Conflicts of Interest on June 8. The OIG found that "NSF has implemented internal controls to identify and mitigate IPA conflicts of interest" but also identified areas that could be strengthened. The OIG recommends that NSF "reassess controls to ensure staff do not have access to awards and proposals for which they are conflicted; ensure that staff obtain exit interviews; and clarify and enforce its rules on the submission of preliminary proposals by current employees and IPAs."

HHS OIG Semiannual Report to Congress and Updated Work Plan

The HHS OIG published its Semiannual Report to Congress on June 1. The report is primarily focused on Medicare, Medicaid and other healthcare related fraud. The HHS OIG also announced that it will update its work plan webpage monthly. Recently added items include a proposed audit of NIH compliance with federal requirements for indirect cost rate setting. Per the work plan, the NIH Division of Financial Advisory Services "is the cognizant Federal agency responsible for negotiating and establishing indirect cost rates for commercial organizations that receive the preponderance of their Federal contract awards from HHS. We will determine whether DFAS established indirect cost rates for applicable commercial organizations in accordance with Federal requirements."

COSTING POLICIES

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

Management, Compliance and the Cost of the Data/IT Enterprise: Thursday Morning Session on June 8th

An expert and diverse panel led a Thursday morning discussion on the growing challenges of managing the Data/IT enterprise and how institutions are balancing compliance and cost in light of federal compliance requirements associated with Controlled Unclassified Information (CUI) and other related mandates. The session was organized by COGR and EDUCAUSE, and the PPT presentations are available on the COGR website. The panelists included:

- Missy Peloso, Assoc. Vice President/Assoc. Vice Provost, Research Services, University of Pennsylvania (COGR Board Member)
- Jack Suess, Vice President for IT and Chief Information Officer, University of Maryland, Baltimore County
- Brian Markham, Assistant Vice President, Information Security and Compliance Services, George Washington University
- Doug Backman, Director, Compliance, Office of Research and Commercialization, University of Central Florida

The discussion was robust and deep, and take-aways included:

- Complexity of the Data/IT portfolio; which includes managing protected versus unprotected data (regardless of federal mandates), managing data subject to federal mandates versus data not subject to these, as well appreciation of the "mixed use city" (Markham) that requires solid controls over email, web browsing, research data, and other data applications.

- Diversity of the Stakeholder Community; i.e., recognizing the unique perspectives of IT professionals, research and compliance administrators, financial and budget managers, and not least, faculty and investigators.

- Challenges of Federal Compliance; CUI, FISMA, and Public Access top the list, while other trials loom. And when compounded with unique expectations (e.g., Public Access plans) from 26 different federal research funding agencies, federal compliance poses potentially overwhelming challenges requiring shared responses both within and between institutions.

- Cost is Real, but Recovery is Uncertain; in the case of CUI compliance, certain Data/IT security costs can be directly attributed to a grant or contract, though charging the award may be unacceptable for a variety of reasons. And broadly speaking, as the Data/IT infrastructure inevitably grows, the role of direct charging through a core facility model versus that of the F&A recovery mechanism must be considered.

The session advanced the discussion and reinforced the importance of continued dialogue across all stakeholders at an institution. Institutional strategies and effective practices to address the challenges described above can be promoted through articles, policy and advocacy papers, panel discussions at other venues, and a commitment by the community to openly discuss challenges and solutions. COGR will continue to take an active role in this forum by working with EDUCAUSE, other leaders in the community, and engaging with federal officials when appropriate.

Procurement Standards: Grace Period Extended for One Additional Year

A May 17, 2017 Federal Register Notice confirmed a one-year grace period for implementation of 2 CFR 200.317-326 (Procurement Standards) has been approved. For most COGR members, this means that the 2 CFR 200.317-326 must be implemented on July 1, 2018. Per the Federal Register Notice:

> *For all non-Federal entities, there is an additional one-year grace period for implementation of the procurement standards in 2 CFR 200.317 through 200.326. This means the grace period for non-Federal entities extends through December 25, 2017, and the implementation date for the procurement standards will start for fiscal years beginning on or after December 26, 2017.*

Below are several observations and recommendations published in the May 30, 2017 COGR Update. The first point is directly from OMB and the points that follow are COGR-specific understandings/interpretations. Also note, item 6) below represents an addendum to the May 30, 2017 COGR Update:

1) Per OMB: *As many of you are aware, OMB in partnership with the COFAR was considering proposed changes to 2 CFR last Summer and Fall that have since been held up due to the ongoing government and regulatory reform efforts, therefore, we are granting one final grace period for non-Federal entities who choose not to implement the Uniform Guidance procurement standards. Non-federal entities who wish to take advantage of this grace period must document this internally, continue to follow the standards in prior OMB guidance, and begin preparing for implementation of the procurement standards prior to the end of this third and final extension.*

2) The procurement standards that you historically have used (premised on OMB Circular A-110) can continue to be used until the new implementation date.

3) The micro-purchase threshold that you are using (e.g., $5,000, $10,000, $25,000, etc.) remains effective until the new implementation date, though note the next point below.

4) 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, we recommend

documenting your justification for exceeding $10,000 so that you are in compliance with the National Defense Authorization Act (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.

5) Update from the May 16th email to the COGR ListServe: Section 1902 of Title 41 of the United States Code codifies the NDAA language specific to: INCREASED MICRO-PURCHASE THRESHOLD FOR UNIVERSITIES, INDEPENDENT RESEARCH INSTITUTES, AND NONPROFIT RESEARCH ORGANIZATIONS. As such, the increase in the micropurchase threshold should be considered permanent, unless there is deliberate action by Congress to repeal this provision.

6) The NDAA is applicable to grants and contracts. As it relates to contracts, the FAR should be updated. Currently, there is an open FAR case (2017-012) that would raise the threshold to $10,000 for institutions of higher education and nonprofit research organizations. A report was due back to the FAR Council last month, but the due date was extended to June 21. There is a parallel DFARS case (2017-D027). The final DFARS rule has been under review since April. For other types of entities, the base FAR $3,500 micropurchase level is not scheduled to be adjusted until 2020; however, for DOD it will be raised to $5,000 in the pending DFARS rule. Note that there are various higher micropurchase thresholds in the FAR for different types of contracts that presumably won't be affected by the changes.

Also, per OMB: "*Any future changes to 2 CFR will be considered as part of the larger government and regulatory reform efforts and the final President's Management Agenda*." COGR anticipates there will be no revisions to 2 CFR Part 200, nor any new FAQs, in the near future. Therefore, COGR recommends that you start preparing for a July 1, 2018 implementation of the new procurement standards with the expectation that OMB may not be providing any implementing guidance. This will be especially important for those institutions that exceed the $10,000 micropurchase threshold per the NDAA.

Going forward, OMB will be focused on the President's Management Agenda. COGR will share its voice and hopes to work with the new Administration on these efforts. However, it is fair to say that the vehicle to affect change may not be 2 CFR Part 200. We will keep you posted on all developments.

Council on Financial Assistance Reform (COFAR) is Disbanded

In an OMB Memorandum (M-17-26) dated June 15, 2017, OMB announced the elimination, modification, or pause of selected OMB memorandums and other OMB activities. On pages 4-5 of the OMB Memorandum, it is states: "… *the COFAR … is disbanded*." While this should have no impact on current federal grants administration rules, we will pay close attention to how this may affect the Uniform Guidance FAQs and other initiatives in which the COFAR was engaged.

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 2017 engagement.

2017 Compliance Supplement: DRAFT COPY AVAILABLE. Per a "Dear Single Audit Stakeholders" letter from OMB to the community: "*While the 2017 Compliance Supplement is in OMB Clearance, we have provided a Draft copy to AICPA to make it available on the AICPA website to all Single Auditors for audit planning purpose only. Once the document cleared OMB, we will publish a Federal Register notice to announce its availability on the OMB website.*" The DRAFT copy is available here.

SINGLE AUDIT: Reimbursement/Advance Payment Methodology. Recently, several auditors have challenged COGR member institutions by suggesting that grants and cooperative agreements should be subject to a strict interpretation of the reimbursement methodology. 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 the normal practice where reimbursement is requested after a vendor has been billed and the transaction has been posted in the Accounts Payable system. The source of this new audit approach seems to have been generated by the IG community. COGR is working with Federal government representatives, and representatives from KPMG and PwC, to address this issue.

SINGLE AUDIT: Securing Student Information, Student Financial Aid (SFA) Cluster. This was the new section proposed by the Department of Education in the original draft version of the 2017 Compliance Supplement. COGR has worked with association partners to raise our objections to OMB and the Department of Education. Included in the coalition are NACUBO, EDUCAUSE, the National Association of Student Financial Aid Administrators (NASFAA), the National Association of State Auditors, Comptrollers, and Treasurers (NASACT), the AICPA, and leaders from the Single Audit firms. In April, we received notification from OMB, based on the recommendations of our coalition: the Department of Education has agreed to delay new requirements for "Securing Student Information" in the SFA cluster until the 2018 Compliance Supplement. According to OMB, the delay will avoid confusion for this year's audit and allow for better planning and execution on future year audits. We expect to re-engage on this issue later in the year once the 2018 Compliance Supplement begins to be vetted.

SINGLE AUDIT: Annual Compliance Audit, Student Financial Aid (SFA) Cluster. The four Associations, the National Association of State Auditors, Comptrollers and Treasurers (NASACT), the American Institute of Certified Public Accountants (AICPA), the National Association of College and University Business Officers (NACUBO), and COGR, continue to monitor this issue. The Department of Education appears to continue using its *Dear Colleague Letter* from last August as the basis for their position that an annual compliance audit is required. However, we have been notified that in at least one state, the State Auditor's Office (SAO) indicated the Participation Division of the Department of Education has decided that all higher education institutions covered by the statewide single audit for fiscal year 2017 will be considered compliant with the Title 34 CFR 668.23 annual compliance audit requirement for HEA Title IV programs, even if the

institution has not been selected to have their specific federal student aid programs audited by the SAO. Prior to this development, schools covered by the SAO for their single audit would have been required to contact their Participation Division for further guidance. This is a positive development, though at this stage we are uncertain if this is an isolated case.

Equitable Treatment of Off-Campus Research Centers in NIH RFAs. A COGR Workgroup has worked closely with NIH for over a year with the goal devising a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. At issue is the treatment of lease costs when a Request for Application (RFA) or policy regarding Investigator initiated proposals limits costs in terms of maximum direct cost. Off-campus research centers are at a competitive disadvantage; i.e., by including the lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. Since this impacts only several COGR institutions, the new solution being considered by NIH is to note this situation in the "Special Remarks" section of the F&A Rate Agreement and to cross-reference this to section 2.3.7.1 (Applications That Include Consortium/Contractual F&A Costs) of the NIH Grants Policy Statement. 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.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Alexandra McKeown, Chair, The Johns Hopkins University, Elizabeth Peloso, University of Pennsylvania, Patrick Schlesinger, University of California-Berkeley, 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, Wendy Montgomery, University of Maryland, Melanie Roewe, Washington University – St. Louis; Michael Moore, University of North Dakota

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Ed. Implements Open Licensing Requirement

On May 22 the Department of Education (Ed.) informed us that its requirement for open licensing of competitive grant products had become effective the previous day. This requirement is likely to have little or no impact on many COGR institutions, but the impact will be significant for some. It applies to all Ed. grant programs in FY'18 unless specifically excepted.

Ed. invited COGR, AAU and APLU to discuss further our concerns with them, particularly with regard to the exception process. We are discussing appropriate responses. One possibility is to convene a meeting with appropriate Ed. staff later this summer, which would include the participation of representatives from heavily impacted COGR institutions.

Ed. also indicated they will be reviewing the regulation again later this year consistent with the April 26, 2017 Executive Order. Given that we twice urged Ed. to review and reconsider the open licensing requirement, there does not appear any reason to expect that the requirement now will be revised or rescinded.

For a discussion of our concerns with the requirement see the COGR December 2015 and September 2016 Updates.

NIH Issues Reminder of Approval Requirement for Invention Disclosure Extensions

On May 11 NIH issued a notice (NOT-OD-17-065) reminding awardee institutions that NIH approval is required for extensions of time for invention disclosures, including election of title and filing of patent applications. Enhancements have been made to iEdison to ease compliance with the requirement. Requests must be submitted at least 60 days in advance of the deadlines.

We asked NIH about the reason for the notice. They indicated that they had received several comments/suggestions from grantees that the process for extensions of time was unclear e.g. how much time could be extended, when, and how. On the federal agency side, a similar set of questions surfaced as to how to accommodate extensions and record them in iEdison. Over the past couple of years these questions increased. Hence the changes were made in iEdison to accommodate both awardees and agencies.

Discussions Continue with DOD on Covered Defense Information and Fundamental Research

The May Update and February Meeting Report discussed concerns raised by the October 2016 amendment to the DFARS 252.204—7000 clause. The clause was amended to provide that fundamental research "by definition cannot involve any covered defense information" (7000(a)(3)). The discussion in the final rule states "A contract or project that is appropriately scoped as fundamental research will not contain any covered defense information."

We previously discussed concerns raised by COGR members about the revised clause, and examples of situations where fundamental research could involve covered defense information. We invited the representative of the DOD Defense Procurement and Acquisition Policy (DPAP) Directorate who spoke at the COGR meeting in February 2016 on this topic to meet with the COGR CIP Committee at the June meeting for further discussion. However, we were informed that his responsibilities within DPAP had changed.

We have reached out to the office of the DOD Director for Basic Research for assistance. They have promised to get back to us with the appropriate contact(s) in DPAP. Depending on further developments, we may invite DOD representatives to the COGR October meeting for more discussion.

Important Patent Law Developments Affecting COGR Institutions

PTAB Holds that Sovereign Immunity Applies to IPR Challenges

In two recent cases the Patent Trial and Appeal Board (PTAB) held that state sovereign immunity applies to *Inter Partes Review* (IPR) proceedings filed against patents held by public universities or a related research foundation. This means that IPR cannot be used to challenge the validity of patents held by state institutions.

IPR was created by the American Invents Act (AIA) in 2012. Since then over 80 IPRs have been filed against patents owned by universities, divided fairly evenly between publics and privates. IPRs have been controversial in the patent community, since the PTAB has invalidated many patents challenged in IPR reviews.

A 1999 Supreme Court case established that states cannot be sued in federal courts for patent infringement without their consent. Two different PTAB panels have found that IPR is an adversarial litigation-like proceeding and that sovereign immunity under the 11th Amendment to the Constitution applies to IPRs that challenge patents held by state institutions. (Sovereign immunity would not apply to IPRs brought in situations where a state institution already has sued an alleged infringer. Asserting a patent in litigation waives sovereign immunity).

In one of these cases the IPR was brought against a state university research foundation. The PTAB found that sovereign immunity still applied. The function of the foundation was to license patents on behalf of the university, it was a direct support organization of the university which controlled its budget and personnel, and its assets and liabilities were considered part of the university's finances.
There are a number of unanswered questions. One is whether an appeal of these holdings is possible. The AIA is unclear on this point. There also may be issues of consistency with the WHO TRIPS Agreement (i.e. the effect is to provide more favorable protection of IP to certain of one's own nationals). There also are business implications, such as licensing vs. assigning patents to university startups and joint ownership considerations. It also is unclear whether the same rationale would apply to AIA Post-Grant Review (PGR) proceedings. PGRs can be brought only against more recently-issued patents, so experience with them is much more limited. The finding that university foundations essentially are arms of the university also seems to undercut some of the rationale for establishing foundations.

Perhaps most importantly, the PTAB holdings raise again the specter of an uneven playing field as between public and private universities with regard to IP. Legislation was introduced years ago that would have required public universities to waive sovereign immunity with regard to IP protection in order to sue to enforce their copyrights, patents and trademarks. The legislation to some extent divided the higher education community. Ultimately it was strongly opposed both by state governments and higher ed., and did not pass. The PTAB decisions may refocus Congressional attention on these matters. (Pending legislation from Sen. Coons would require petitioners to have business or financial reasons for standing to bring PTAB actions. It is aimed at reducing incentives to seek to extort nuisance settlements. See 6.b. below for further discussion).

The cases are *Covidien LP v. Univ. of Fla. Res. Found. Inc.*, IPR2016-01274 (PTAB Jan. 25, 2017), and *NeoChord, Inc. v. University of Maryland, Baltimore*, IPR2016-00208 (PTAB May 23, 2017).

Supreme Court Restricts Venue in Patent Infringement Cases

On May 22 the Supreme Court held that a company can be sued for patent infringement only where it is incorporated or has a regular and established place of business. The decision turned on the Court's finding that the patent venue statute (28 USC 1400(b)) takes precedence over the general venue statute (28 USC 1391(c)) that allows a corporation to be sued in any federal judicial district where it might be subject to personal jurisdiction.

The practical effect of the decision is to remove a large number of patent infringement suits from the Eastern District of Texas, which is reputed to be friendly to plaintiffs in infringement actions. It may lead to more infringement suits being filed in Delaware, where many companies are incorporated, or California, home of many IT companies that are frequent targets of such suits. It has been widely viewed as an anti-patent "troll" decision which may forestall further Congressional action.

To our knowledge COGR member institutions have not often been subject to patent infringement suits brought by so-called trolls in the Eastern District of Texas. Nevertheless the decision appears positive for all patent owners including universities. The case is *TC Heartland v. Kraft Foods* (SCOTUS No. 16-341; 581 U.S. ___ (2017)).

Public Health Concerns Raise New Challenges to Pharmaceutical Patents

The U.S. Army (Walter Reed Army Institute of Research) recently developed and filed provisional patent applications on a Zika vaccine, which it is planning to license exclusively to Sanofi Pasteur, Inc. to manufacture and sell. Governor Edwards of Louisiana in a May 10 letter to the Army as well as a number of public interest groups including Knowledge Ecology International (KEI) and Sen. Sanders (I—VT) have asked the Army to delay granting the exclusive license until Sanofi agrees to "reasonable pricing" terms. In a letter dated June 13, a number of Florida Congressional representatives asked the Army to hold a public hearing on the pricing issue and delay the exclusive license until after the hearing. Louisiana and Florida are two states that potentially may be particularly affected by Zika. There are concerns in particular about the ability of poorer populations in these states to afford the vaccine. Depending on the success of Phase I (funded by the Army), HHS is planning to provide Sanofi $43M for a Phase II clinical trial and if successful, $130M for Phase III.

Sanofi reportedly has rejected the Army's request for the license to include a fair pricing provision. It was the only pharmaceutical company that applied for the license. In addition to its own investment in the clinical trials, Sanofi has cited that it will pay royalties on the vaccine to Walter Reed, thus allowing the government to recoup its investment. (For further discussion see https://www.statnews.com/pharmalot/2017/05/17/sanofi-us-army-zika-vaccine/).

The Army has stated that it currently is negotiating the license terms, and has not made a final decision to grant Sanofi an exclusive license. It also is not certain that the vaccine will work, or whether other Zika vaccines currently under development may prove more effective. The controversy over the Zika vaccine is similar to that with the hepatitis C vaccine which was discussed in the May Update. In that

case the state of Louisiana asked HHS both to obtain voluntary licenses to drugs for treatment of hepatitis C that could make medications available at a deep discount to poorer populations, and to invoke 28 USC 1498, which provides for government use of any patented invention for "reasonable compensation."

KEI has filed a number of recent march-in petitions on the UCLA cancer drug Xtandi based on pricing grounds, as discussed in previous COGR Updates and Meeting Reports. While the Zika controversy does not involve a COGR institution, the issues raised are similar. We are concerned that pressure will continue to grow for pricing to be addressed in licenses for pharmaceuticals developed with government funding, either directly or to universities or other institutions. This could complicate the ability of universities to work with private sector partners to develop, manufacture and distribute vaccines and other pharmaceutical inventions.

Updated BIO/AUTM Report Shows Economic Impact of University Patents

On June 20 BIO/AUTM released an updated study on *The Economic Contributions of University/Nonprofit Inventions in the U.S. 1995—2015*. It shows that, during the 20-year period, academic patents and the subsequent licensing to industry bolstered US industry gross output by up to $1.33 trillion, US GDP by up to $591 billion, and supported up to 4,272,000 person years of employment.

The report is based on AUTM Licensing Survey Data. The impacts on gross industry output and GDP are up 14% while the number of U.S. jobs supported rose 12% since the previous report issued two years ago. These numbers are impressive given the stagnant nature of the U.S. economy during this period. This is the fourth in a series of reports produced by a team of senior economic consultants and technology transfer experts, including former senior officials at the Commerce Bureau of Economic Affairs and NSF. As noted by BIO, it provides evidence of the importance of academic-industry partnerships to the U.S. economy, and the importance of preserving the current system of technology commercialization.

For the report and accompanying BIO materials see https://www.bio.org/Patents.

Access to Research on the High Seas

A meeting was held at the State Department on June 13 to discuss a possible new international treaty on access and benefit sharing obligations for research on marine organisms that are outside the jurisdiction of any country. Ultimately, this negotiation may result in the creation of a new international agency that will regulate specimen collection and research activities in international waters, and administer the distribution of royalties or other benefits from research-intensive countries to select beneficiaries elsewhere.

COGR did not participate in this meeting. There is a long history of concerns about access to biospecimens and bioprospecting. A number of international agreements have been negotiated which address access and benefit sharing (e.g. Convention on Biological Diversity). There also have been a number of sessions on this topic at BIO/AUTM meetings over the years.

We will coordinate with BIO and other associations and organizations should this negotiation proceed.

Updates

Controlled Unclassified Information (CUI)

A FAR Case (2017-016) has been opened. A report was due to the FAR Councils on June 21. We will continue to follow the progress.

DFARS

DOD is seeking comments (82 FR 28041) on DFARS solicitation documents and contract clauses that may be appropriate for repeal, replacement or modification, in accordance with Executive Order 13777. Comments are due August 21. We will consider whether we may wish to submit any comments.

STRONGER Patents Act of 2017

On June 21 Sen. Coons (D—DE) introduced the STRONGER (Support Technology and Research for Our Nation's Growth) Patents Act, with three bipartisan co-sponsors. The bill updates the STRONG Patents Act introduced by Sen. Coons last year. It addresses a number of concerns about *Inter Partes* and Post Grant Reviews. It also restores the presumption of injunctive relief upon a finding that a patent is valid and infringed, eliminates USPTO fee diversion through establishment of a new Treasury revolving fund for USPTO, addresses certain concerns about infringement litigation, and clarifies that universities qualify as micro-entities under the AIA. In addition, it empowers the Federal Trade Commission to crack down on abusive demand letters sent by patent trolls (mirroring bipartisan legislation introduced in the last Congress). The higher education associations including COGR plan to endorse the bill.

USPTO Leadership Change

The May Update reported on a May 1 meeting of higher ed. representatives with Michelle Lee, U.S. Patent and Trademark Office (USPTO) Director. Ms. Lee abruptly resigned on June 6. The reasons for her resignation are unclear. Joseph Matal currently is performing the functions of Director. Prior to serving as Associate Solicitor in USPTO, he had served on the staff of the Senate Judiciary Committee, and was closely involved in drafting the AIA.

Associations Engage Outside Patent Counsel

COGR has joined AAU, APLU, AUTM and AAMC in jointly engaging Michael Best & Friedrich LLP as outside patent counsel. This addresses the need for advice and counsel on proposed patent legislation such as the STRONGER Patents Act, and related patent policy issues. A cost sharing agreement among the associations outlines and limits the financial commitment of each in terms of number of hours.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Pamela Webb, Chair, University of Minnesota; Michael Ludwig, University of Chicago; Jeffrey Friedland, Princeton University, Pamela Caudill, Yale University, Walter Goldschmidts, Cold Spring Harbor Laboratory, David Norton, University of Florida, James Tracy, University of Kansas, , Jennifer Lassner, University of Iowa, Steven Martin, Indiana University – Bloomington, Lisa Mosley, Arizona State University, Allen DiPalma, University of Pittsburgh; Jeremy Forsberg, University of Texas-Arlington

Research Misconduct: Expert Panel Discussion on Academies Report, "Fostering Integrity in Research"

COGR convened a panel Thursday afternoon to discuss the April release of the National Research Council's report on "Fostering Integrity in Research". Panelist included Dr. Robert Nerem, Committee Chair of the NRC's report and Professor Emeritus of Bioengineering, Georgia Institute of Technology, Sheila Garrity, JD, MPH, MBA, Associate VP, Research Integrity George Washington University and President, Association of Research Integrity Officers (ARIO), and Dr. Joan Ferrini-Mundy, Chief Operating Officer, National Science Foundation.

The report succeeds the previous report produced over two decades ago; emphasizing that factors such as societal changes, changes in technology and modern science, and a focus on more transparency and reproducibility has necessitated the need for an updated report.

Although the report continues to endorse the federal definition of scientific misconduct (fabrication, falsification and plagiarism in proposing, performing and reporting research), the report emphasizes the need to question other practices deemed "detrimental" research practices not only by individual researchers, but those of institutions and journal companies. Dr. Nerem explained that success in this area must start at the top of an institutions food chain and that the senior leadership must create a culture and actively engage the research community.

Several recommendations mentioned in the report and presented at COGR are as follows:

- Scientific societies and journals should develop clear disciplinary authorship standards;
- Ensure protection of good faith whistleblowers and address concerns in a fair, thorough, and timely manner;
- Ensure that results are made transparent at the time of publication or soon thereafter, including negative results of analyses conducted as a means to prevent bias;
- The need to establish an independent non-profit Research Integrity Advisory Board (RIAB) to advocate and facilitate information by various stakeholders in the area of research misconduct;
- The need to train faculty in mentoring and apply RCR training to a broader base

Dr. Ferrini-Mundy of the National Science Foundation (NSF) presented NSF's perspective focusing more on the Responsible Conduct in Research (RCR) training and educational components. Suggestions for improvement include but aren't limited to the need to cultivate ethics across curricula or memberships in organizations, the need to provide clarity on goals and objectives and to establish the goals with outcomes; the need to revisit delivery approaches to RCR training such as case studies, interactive formats, on-line tools and resources, mentoring programs and "live" presentations with research faculty.

Sheila Garrity, President and Founder of the Association of Research Integrity Officer's (ARIO) and Associate VP at the George Washington University also presented about the role of ARIO and the strategies taken at GW to improve education in this area.

Finally, although many of the suggestions and recommendations mentioned in the report are positive recommendations; lack of supporting data in this field and the lack of funding to perform and manage such tasks are critical factors to improving and reducing findings of scientific research misconduct. COGR will continue to follow closely any press associated with the report and update the membership as necessary.

COGR Starts New Ad Hoc Committee on Confidentiality in Research Misconduct

COGR will be leading a new hoc committee regarding confidentiality in Research Misconduct led by Ann Pollack (UCLA) Committee Chair and Sheila Garrity, President and Founder of the Association of Research Integrity Officers (ARIO).

The federal-wide definition of research misconduct adopted by Office of Science and Technology Policy (OSTP) requires that federal agencies that conduct or support research all have policies policy for assessing allegations that fall within the definition of research misconduct - fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Universities that receive federal research support must have policies in place for responding to allegations that fall within this definition. Those policies typically outline the institution's requirements for assessing research misconduct allegations, for sequestering evidence, for conducting formal inquiries and investigators, for reporting to sponsors, for making findings, correcting the research record, and to strive for confidentiality for all involved to the extent consistent with a fair and thorough process and as allowed by law.

A review of several federal agency policies - PHS, DOT, EPA and NSF, indicates that institutions are expected to maintain confidentiality during the process of responding to allegations. The question is what should be kept confidential and for how long. Based on discussions at national meetings and questions/comments raised after presentations made at several meetings where the Office of Research Integrity (ORI) was in attendance, it is clear that many in the research community believe that confidentiality provisions extend beyond the active assessment, inquiry, investigation and determination process. In declining to pursue cases, ORI staff has sometimes asked institutional officials to not share the nature of the communication citing confidentiality policies. Concerns have been raised about communication with journal editors and how much information can be shared when editors bring allegations to the institutions and then ask to be kept informed about the outcome. Institutional officials sometimes write to journal editors requesting that articles be corrected and/or retracted but refrain from

providing specific information because of confidentiality concerns. There are also questions about what if anything a Research Integrity Officer can say when asked about postings on PubPeer or RetractionWatch about faculty at their own institutions. Similarly there are questions about the appropriate application of the confidentiality provisions of the regulations/policies are complicated by issues of risk and caution exercised by institutional officials.

This committee will seek to further explore these challenges and to make recommendations for dealing with such challenges. The first meeting will be held mid-July. COGR will update the community through normal communication channels and provide updates to the membership at its meetings. For more information, please contact Jackie Bendall at jbendall@cogr.edu.

Other Committee News:

Federal Wide Research Terms and Conditions: The RCA Committee will continue to work with agency representatives who are not part of the Federal Wide Research Terms and Conditions (RTCs). Future meetings will include other HHS agencies such as the CDC, HRSA, FDA, and CMS, the Department of Defense, US Dept. of Agriculture, Department of Education and the Department of Justice. The Committee believes that more networking is necessary to promote the use of these terms as a means to reduce administrative burden on both the institutions and agencies and to further endorse the Cures law.

Department of Defense – Ongoing Dialogue to Improve Processes: RCA was joined by Debbie Rafi, Director of Contract, Grants and Acquisition at the Office of Naval Research. RCA expressed concern regarding issues surrounding the iRAPT invoicing system, inconsistent award notification process, delays in reporting no-cost extensions and other inefficiencies previously expressed in its letter to DoD. Systems adjustments with recent information technology upgrades have delayed progress and encourages the research community to cite and show examples in order to make progress improvements.