COGR
Council On Governmental Relations
An Association of Research Institutions

March 12, 2018

February 22-23, 2018 COGR Meeting Report

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

Procurement and the Micropurchase Threshold (MPT)

COGR members are preparing for implementation of the Uniform Guidance Procurement Standards, 2 CFR 200.317-326, to become effective on the first day of your new fiscal year. For many, this is July 1, 2018. For several, however, the effective date was January 1, 2018.

COGR will continue to pursue clarification around implementation of the MPT and we encourage you to contact COGR staff as your institutions strategize on how to address concerns on implementing the MPT, as well as sharing feedback you receive from federal agencies. Below are several observations related to the current status of the MPT. Following these observations, we share a summary of other procurement issues raised by a Procurement Director from a COGR member institution.

Observations on Implementation of the MPT

- COGR maintains that language in the National Defense Authorization Act (NDAA) is definitive and that the $10,000 MPT is the "law of the land." Some commentators have raised doubts because the NDAA has not been implemented into the Uniform Guidance. While COGR has passionately advocated that the NDAA language be incorporated into the Uniform Guidance, we still await action by OMB. Until then, we rely on this authoritative language from the Uniform Guidance: 2 CFR 200.101(b)(3) *"… in any circumstance where the provisions of Federal statutes or regulations differ from the provisions of this part, the provision of the Federal statutes or regulations govern."*

- A process for confirming an MPT greater than $10,000 still is not clear. At issue is what entity is empowered as the "*relevant executive agency*" per the NDAA. OMB continues to work on a solution and is aware that there is a sense of urgency and that several COGR members have a fiscal year that began on January 1, 2018. It appears as though OMB will not be the "*relevant executive agency*" to approve an MPT greater than $10,000. This suggests it will be either the institution's Cognizant Agency for Indirect Cost (i.e., CAS-HHS or ONR), the institution's Cognizant Agency for Audit, or even an entity such as the HHS Office of Grants and Acquisition Policy and Accountability (OGAPA), which has experience in approving "direct cost" requests (i.e., effort reporting / payroll charging).

- COGR is aware of institutions with a January 1, 2018 fiscal year start date that continue to use, for example, a $25,000 MPT. In these situations, COGR believes a strong case can be made for continuing use of a $25,000 MPT if one of the three criteria per the NDAA is met: "*clean audit findings under chapter 75 of title 31, internal institutional risk assessment, or State law*." However, COGR also recommends that prior to taking this position, consult with your Auditors and/or General Counsel at your institution.

- NSF Research Terms & Conditions Agency Specific Requirements Effective March 1, 2018. Article 34 is helpful by designating the $10,000 MPT, though is specific to NSF. In addition, per Article 34, "*NSF is in the process of developing procedures for submission of grantee requests for higher micro-purchase thresholds as specified in AICA Section § 207 (a)(2).*" Note, however, NSF has implemented Article 34 to be in compliance with the American Innovation and Competitiveness Act (AICA), which is limited to NSF and several other agencies. Ultimately, agency-by-agency implementation is not the preferred solution; rather, the more universal NDAA language must be leveraged.

- The General Services Administration (GSA) published a Memorandum for Civilian Agencies, dated February 16, 2018, "Class Deviation from the Federal Acquisition Regulation (FAR) increasing the micro-purchase threshold and the simplified acquisition threshold." The change pertains to GSA-funded acquisitions (GSA schedule contracts, purchase cards, etc.). Changes to the FAR are pending (FAR Case 2018-004). The changes implement Sections 805 and 806 of the FY 2018 NDAA. This, too, is helpful, but is limited to contracts.

- If your institution will continue to use, for example, a $25,000 MPT, COGR recommends you notify OMB, your Cognizant Agency for Indirect Cost (i.e., CAS-HHS or ONR), and possibly OGAPA (see above) and indicate that "to be in compliance with the NDAA, our institution is notifying you that we will continue to use an MPT of $25,000." At OMB, contact:

  Rhea Hubbard at: Rhea_A_Hubbard@omb.eop.gov
  Gilbert Tran at: hai_m._tran@omb.eop.gov

Other Procurement Issues

- 200.320(c) & (d) - Publication of RFPs: Concerns with logistics, costs and resources needed to implement this new requirement.

- 200.323(b) - Negotiation of Profit: Concerns with the practicality and logistics of negotiating profit for all non-competitive procurements and items above the SAT.

- 200.323(a) - Independent Estimates: Concerns with practicality, logistics and resources needed to ensure development of independent estimates before receiving bids or proposals.

- 200.305(b)(3) - Payment: Requires institutions to pay their sub-recipients and contractors within 30 days. A number of schools have longer standard payment terms. Practicality and cost concerns with managing shorter payment terms based upon funding source.

- 200.319(b) - Geographic Preferences: Some concern over the interpretation of "preferences." Many institutions have initiatives and programs in place to encourage development of relationships with local based suppliers for a variety of reasons (service, sustainability, economic development, etc.). Could be a minor issue as some are interpreting that this item is simply prohibiting inclusion of a scoring based preference around geography, but language is not entirely clear.

- 200.320(f)(4) - Sole Source Requirements: Some concern over interpretation of "solicitation". Appears to be a minor issue as most are interpreting "solicitation" as encompassing both formal and informal efforts to evaluate the competitive landscape. All schools have sole source documentation procedures in place to document the marketplace evaluation efforts.

- Dual Procurement Policies: An overriding concern at some institutions is the moving away from a "one-policy" environment, and consequently, being compelled to manage federal funds separately. This is an unfortunate repercussion of 2 CFR 200.317-326, but will need to be considered given some of the above constraints.

As our community moves toward implementation of the full suite of the Uniform Guidance Procurement Standards in 2018, COGR will continue to be available to address concerns and raise these concerns with the appropriate federal officials.

The Administration's Efforts to Cut F&A: WHAT'S NEXT?

We reported on this topic, extensively, in 2017, as prompted by the Administration's 2018 budget proposal to cap F&A costs on NIH awards. The Administration's 2019 budget proposal was released on February 12th and it appears as though F&A no longer is being specifically targeted. Still, 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 American Council on Education (ACE), the National Association of College and University Business Officers (NACUBO), and other partners, will remain diligent around this issue.

In addition, and as we have previously reported, the COGR Costing Committee, with assistance from the RCA Committee, has organized around the development of an F&A White Paper to address many of the themes related to transparency, alternative models, education and myths. While this may not be a "hot issue" in the Administration's 2019 budget proposal, development of the White Paper remains a COGR priority. The focus of the paper will be to advocate, with an educational component, for fair F&A reimbursement policies across many stakeholder groups, including Federal agency leaders, Federal policymakers, our own Faculty, and even the Media. The White Paper also will attempt to memorialize key discussions and perspectives and talking points so that we can use it as resource when/if F&A comes under attack next time.

We expect to make significant process on the White Paper throughout the Spring and will provide an update to the Membership at the June COGR Meeting.

NIH Salary Cap for 2018

As published on the website of the Office of Personnel Management (OPM), Salary Table No. 2018-EX shows the Executive Schedule salary rates, effective January 2018. Per the Executive Schedule, the NIH salary cap (Executive Level II) will increase from $187,000 to $189,600. The authority for implementation of the salary cap falls under the Labor-HHS Appropriations bill, which ties the salary cap to the Executive Level II salary level.

However, as noted in the March 7, 2018 NIH Notice Number: NOT-OD-18-136, NIH Operates Under a Continuing Resolution Through March 23, 2018: "*All legislative mandates that were in effect in FY 2017 (see NOT-OD-17-075) remain in effect under this CR, as well as the salary limitation set at Executive Level II of the Federal Pay Scale*." As such, the March 7, 2018 NIH Notice does not permit institutions to implement the new NIH salary cap level ($189,600).

A second March 7, 2018 NIH Notice Number: NOT-OD-18-137, Guidance on Salary Limitation for Grants and Cooperative Agreements FY2018, provides additional clarity on when the new NIH salary cap level ($189,600) can be implemented: "*Once the Department of Health and Human Services Appropriation for FY 2018 is enacted, NIH will publish the annual Notice of legislative mandates to provide information on any statutory provisions that limit the use of NIH grant funds in FY 2018*."

The Bipartisan Budget Act of 2018, signed into law on February 9, 2018, allows the federal government to operate under the CR through March 23rd, after which, the expectation is all FY 2018 agency appropriations, including HHS, will be finalized. Soon after the HHS appropriation is finalized for FY2018, NIH will publish the annual Notice of legislative mandates and the new NIH salary cap level will be implemented. COGR will keep the membership posted of any updates.

HHS/NIH Policy Update: Financial Reporting

This COGR Meeting Report includes several sections related to potential HHS/NIH policy updates. The Costing, RCA, and RRR committees met with Andrea Brandon, Deputy Assistant Secretary from the Office of the Assistant Secretary for Financial Resources (ASFR), Department of Health and Human Services (HHS), and with Michelle Bulls, Director of the Office of Policy for Extramural Research Administration (OPERA), NIH.

COGR has been active in its advocacy for Financial Reporting reforms since 2014. On several occasions, progress seemed to be made, only to be halted due to HHS staffing changes or other circumstances. The meeting with Ms. Brandon and Ms. Bulls provided cautious optimism that Financial Reporting reforms now could be addressed under the auspices of reforms mandated under the 21st Century Cures Act. These reforms include:

- Facilitating and/or eliminating the quarterly Federal Cash Transactions Report (FCTR, SF-272). The report became redundant after HHS and NIH implemented subaccounting. With real time cash balances available under subaccounting, the financial reconciliation embedded in the FCTR no longer provides the same value.

- Consistent grantee close-out requirement of 120 days applicable to all HHS operating divisions. NIH uses a 120 day closeout requirement. If HHS were to implement 2 CFR 200.343(g), Closeouts (*The Federal awarding agency or pass-through entity should complete all closeout actions for Federal awards no later than one year after receipt and acceptance of all required final reports*), rather than the HHS self-imposed 270 days, all HHS operating divisions could be empowered to convert from a 90 day to a 120 grantee close-out requirement.

- Improve/Replace the Payment Management System (PMS). While needed, this action is a "hope" rather than a short-term initiative. Still, Ms. Brandon raised this and we will provide feedback to her, when requested.

COGR expects to work closely with HHS and NIH to address all reform opportunities and we will keep the Membership posted on all developments.

NIH Notice NOT-OD-18-107 – NIH Enforcement of Closeout Policies: RESOLUTION

As we reported in the February 2018 Update, NIH Notice NOT-OD-18-107, published on November 30, 2017, was clarified. In numerous forums over the past year, NIH has been adamant about the importance of timely closeout and its statutory mandate to be in compliance with the Grants Oversight and New Efficiency (GONE) Act. COGR supports NIH efforts to be in compliance with the GONE Act, though several concerns related to the framing of NOT-OD-18-107 were raised, including: 1) timing for initiating unilateral closeout (the Notice states: *Without prior approval from the awarding IC, NIH will initiate unilateral closeout for all awards that fail to meet closeout requirements within 120 days as required by the NIH Grants Policy Statement (NIH GPS) Section 8.6*), 2) better leveraging of 2 CFR 200.343(g) (see above), which allows agencies to complete agency closeout actions within one year of the acceptance of all reports, and 3) utilizing the most user-friendly approach to reminder letters.

After conversations with NIH policy leaders in early January; it was made clear that the intent of the Notice was to emphasize the NIH requirement for grantees to meet all closeout requirements within 120 days, and not to suggest that unilateral closeout actions would begin on day 121 if closeout requirements were not met. The NIH position is that NIH will initiate unilateral closeout within 180 days for all awards that fail to meet closeout requirements within 120 days. NIH will use FAQs to clarify NOT-OD-18-107.

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. For example, one 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 (dated October 20, 2017) to OMB, Gilbert Tran. Some of your institutions also sent letters, either documenting your unique circumstances or simply supporting the COGR letter. Our understanding is that OMB is reviewing the comment letters. A possible outcome is that this issue will be addressed in the 2018 Compliance Supplement. Interestingly, OMB is contemplating a "skinny" version of the 2018 Compliance Supplement (see below), which would focus only on the significant changes between 2017 and 2018. We will keep the Membership posted on all developments.

Costing Policies Committee: Other Issues and Areas of Interest

Below is a summary of other issues in which the Costing Policies Committee is engaged, and/or topics that might be of interest. As appropriate, we will continue to follow each throughout 2018.

NRSA Stipend Levels and Regional Cost of Living Differences. Stipend levels under the Ruth L. Kirschstein National Research Service Awards (NRSA) program are published annually by NIH. While the level may increase on an annual basis, there is no recognition of regional cost of living differences. COGR informally is surveying the Membership to determine if this is an issue of broad concern.

Army Corps of Engineers and DCAA Audit Scrutiny. COGR is engaged with several institutions that have been challenged by the Defense Contract Audit Agency (DCAA) on the management of Cooperative Agreement awards issued by the Army Corps of Engineers. COGR informally is surveying the Membership to determine if this is an issue of broad concern.

Dickey Amendment: Gun Violence and Safety Research. As raised Thursday morning during the plenary session, the impact of the Dickey Amendment on federal funding for gun violence and safety research remains unclear. The amendment, first inserted into the 1996 federal omnibus spending bill, mandated that "*none of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention (CDC) may be used to advocate or promote gun control*." While this language did not seem to preclude "conducting research", that has been the ongoing interpretation by Congress. The recent shooting at Parkland High School has prompted a new discussion on the Dickey Amendment, and Senator Patty Murray (D-WA) recently sent a letter to HHS Secretary Alex Azar asking the Secretary to elaborate on his plans to make gun violence research a "priority" for the Department. COGR will continue to follow this development.

American Association for the Advancement of Science (AAAS) Research Budget Website, https://www.aaas.org/program/rd-budget-and-policy-program. As presented Thursday morning during the plenary session, this website is recommended as a resource for institutions interested in tracking the status of the Federal research budget.

Federal IG Audit Website, https://www.oversight.gov. As presented Thursday afternoon during Committee Reports, this website is recommended as a resource for institutions interested in mining pubic reports from Federal Inspectors General who are members of the Council of the Inspectors General on Integrity and Efficiency (CIGIE). Note, DOJ settlements, including a recent DOJ settlement related to time and effort reporting, are not captured on this website.

2018 "Skinny" Compliance Supplement. As mentioned previously in this report, OMB is contemplating a "skinny" version of the 2018 Compliance Supplement. This would focus only on the significant changes between 2017 and 2018 with the intent of making for a more efficient update to the Compliance Supplement. Under this model, we would expect a return to the full version in 2019. We are in communication with OMB to determine the status of the Compliance Supplement.

Securing Student Information, Department of Education (ED). We have reported on this for issue regularly over the past year. 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 overly-complex 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 manageable guidance in a possible release of a 2018 "Skinny" Compliance Supplement.

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, Florida State 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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Human Subjects Research

Common Rule Delay

Health and Human Services (HHS) Office for Human Research Protections (OHRP) Director Dr. Jerry Menikoff joined us at the February 2018 COGR meeting for a discussion on the Common Rule, including the recent delay in the effective date and anticipated notice of proposed rulemaking (NPRM). On January 22, 2018, 16 federal departments and agencies filed an Interim Final Rule (IFR) titled "Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects". The IFR delays both the effective and compliance dates of the

revised rule to July 19, 2018 for these agencies and for the Consumer Product Safety Commission which adopted the rule on September 18, 2017. The notice cites a request from AAMC, AAU, APLU, and COGR, as well as a request from SACHRP a number of months ago to delay the rule. The request from COGR and the other higher education associations sent in June of this year was for a one-year delay in the compliance date, with no delay in the effective date. A one-year delay of the compliance date alone would have allowed institutions to move forward with implementation of certain provisions of the revised final rule and to delay implementation where additional guidance and education is needed.

Among the questions we asked during the discussion was why a delay in the compliance date was not implemented via the IFR. Our understanding from the discussion is that there was concern that institutions could not properly implement the final rule absent necessary guidance. Guidance was not previously issued due to an administrative review of the rule, which was implemented on the last day of the Obama administration. Priority went to rules with effective dates in the near term. Guidance is now in the works, in parallel with efforts to establish whether another delay is necessary and what that delay might encompass.

As indicated in the IFR, "…the federal departments and agencies named in this interim final rule are developing a notice of proposed rulemaking in order to fully engage regulated entities and the public regarding further delay of the 2018 Requirements until January 21, 2019." Stakeholders may comment on the IFR by March 19, 2018, however, the focus will be the NPRM and comments on specific proposals with respect to an additional delay. The NPRM is expected to seek feedback on a delay, but not the content of the rule. COGR may comment on both the IFR and the anticipated NPRM.

Dr. Menikoff indicated that OHRP would like to see the NPRM published, and the process finalized, as quickly as possible. Proposed rulemaking is yet to be published however, and given the need for agreement by all Common Rule agencies and Office of Information and Regulatory Affairs review, a comment period, review and consideration of comments, and review of any final regulatory action, the timeline for another delay is likely to stretch on for several months, and the uncertainty to continue close to the time of the next effective date of July 19. At the meeting, COGR members noted the inability to properly plan out a transition given the late date of the IFR and any forthcoming rulemaking with some suggesting that decoupling the effective and compliance dates would be optimal.

A question that will go unanswered is whether appropriate guidance will be in place prior to July 19 that would allow for implementation of some or all of the provisions of the final rule. When asked whether there would be an opportunity to comment on guidance, Dr. Menikoff suggested that he would expect that there would be.

In issuing the NPRM, OHRP would presumably expect to have guidance in place to allow for implementation of at least some of the provisions of the final rule, possibly the three "burden-reducing provisions" noted in the title of a previously proposed NPRM that was not issued. Implementation of the rule may only be partial, with a full effective date of January 21, 2019. COGR will comment on the

NPRM once issued, and on needed and proposed guidance. We will continue to update members on the status of forthcoming rules and guidance as information becomes available.

HHS Secretary's Advisory Committee for Human Research Protections (SACHRP) Meeting

SACRHP will meet next Tuesday and Wednesday, March 13-14. The meeting will be webcast and links are available for Day 1 and Day 2. The agenda includes secondary use of biospecimens and data and broad consent; Single IRB; the impact of the EU's General Data Protection Regulation on HHS Human Subjects Research; and the role of "key information" in informed consent.

European Union General Data Protection Regulation

Mark Barnes, a Partner with Ropes and Gray, LLP, joined us at the COGR Board meeting on February 21 to discuss the EU General Data Protection Regulation (GDPR) which becomes effective May 25, 2018. Slides are available on the COGR website. As indicated in the slides, the GDPR may apply extraterritorially to U.S. universities and academic medical centers through online education programs; sites and study abroad sites in members states; maintaining alumni clubs and recruiting students in members states; offering telemedicine services and sponsoring clinical research in members states; and other scenarios.

GDPR will supersede the current EU Data Protection Directive in the European Economic Area and will also be implemented by the United Kingdom. Jurisdiction covers: Businesses established in the EU; Marketing or promotion of services in the EU; Real-time monitoring of behavior of EU citizens as well as transfer of data. Under the GDPR, "Personal Data" including what is "identifiable" and "sensitive" is much broader than under U.S. regulations. Per the slides, "Data subjects must be provided a notice at the time their data are collected setting forth several details not typically found in a HIPAA notice of privacy practices or a HIPAA-compliant research authorization." If institutions have activities subject to the GDPR, they will have to "Determine legal bases for processing personal data and special categories of personal data (e.g., consent, vital interest)." More detailed information on the scope and applicability of the GDPR and recommended steps that institutions might take can be found in the slides. COGR will continue to monitor this topic.

Research Regulatory Reform

Update on 21st Century Cures Act Regulatory Reform Provisions

In spring of 2017, COGR provided NIH and HHS leadership with a set of detailed recommendations related to the implementation of section 2034 of the 21st Century Cures Act, *Reducing Administrative Burden for Researchers*. The Cures Act, and the recommendations, address regulatory burden and reform in the areas of financial conflict of interest, subrecipient monitoring, financial reporting, animal care and use, documentation of personnel expenses and the Research Policy Board recommended in the 2016 National Academies report *Optimizing the Nation's Investment in Academic Research*. The

following are updates on progress in these areas in follow-up to recent conversations with HHS, NIH and other federal staff.

In the area of financial conflict of interest, the Cures Act requires that the HHS Secretary "lead a review by research funding agencies of all regulations and policies related to the disclosure of financial conflicts of interest, including the minimum threshold for reporting financial conflicts of interest; and make revisions, as appropriate, to harmonize existing policies and reduce administrative burden on researchers while maintaining the integrity and credibility of research findings and protections of human participants." We understand from recent conversations that NIH is providing HHS with data, including data put forward by outside organizations such as AAU, AAMC, COGR and others, regarding the effectiveness and efficiency of the Public Health Services FCOI regulations which were revised in August 2011. We are not aware of any further action with respect to a federal-wide review.

Regarding documentation of personnel expenses, the Cures Act requires the HHS Secretary to "clarify the applicability of the requirements under the OMB Uniform Guidance for management and certification systems adopted by entities receiving Federal research grants…regarding documentation of personnel expenses, including clarification of the extent to which any flexibility…applies" to entities receiving HHS grants. In NOT-OD-18-108, Standards for Documentation of Personnel Expenses, released on November 30, 2017, NIH indicates that the agency "is clarifying the applicability and flexibility of the requirements for documentation of personnel expenses for its grants and cooperative agreements." Per the notice, "NIH supports recipients' systems that document personnel expenses charged to NIH grants and cooperative agreements that are consistent with the regulatory flexibilities" provided by the Uniform Guidance and 45 CFR 75.430(i) as detailed in the notice.

Section 2034 (d) of the 21st Century Cures Act, Animal Care and Use in Research, requires the NIH, USDA and FDA to conduct a review of regulations and policies involving research with laboratory animals within two years of enactment, with the goal of reducing burden while maintaining research integrity and protecting research animals. As reported previously, this review is underway. The agencies have conducted listening sessions and are expected to issue a request for information (RFI) sometime this month. FASEB, AAMC, COGR and NABR previously submitted the report *Reforming Animal Research Regulations: Workshop recommendations to Reduce Regulatory Burden* and will respond to the RFI once published.

With respect to the Research Policy Board (Board) proposed in the 2016 National Academies report Optimizing the Nation's Investment in Academic Research and required under Section 2034(f) of the 21st Century Cures Act within one year of enactment (December 2017) we understand that progress in standing up the board has slowed significantly. The Board, which would include both federal and non-federal members (representatives of academic research institutions, other private, nonprofit research institutions, or nonprofit organizations with relevant expertise) and is being led by the Office of Information and Regulatory Affairs, is tasked with reducing administrative burden on federally funded research. COGR will continue to follow and advocate for the establishment of the Board.

Progress in the areas of financial reporting (Section 2034c) and subrecipient monitoring (2034b) can be found in the Costing and RCA sections of this update respectively.

Efforts to Improve the Rigor and Reproducibility of Research

At the October 2017 COGR meeting we held a session on research quality and reproducibility and efforts by NIH and organizations and societies, such as the American Physiological Society, to improve rigor and reproducibility in the wake of unreliable pre-clinical findings and failed clinical trials. These efforts include improving experimental design, ensuring appropriate statistical power, attentiveness to bias, and transparency in reporting of methods, materials and results. Beginning with a 2011 NINDS notice, NIH has made a concerted effort to ensure the rigor and reproducibility of the research the agency funds, including improving the review and evaluation of grant applications, and requiring a description of the research that was used to develop the proposed research question. Further, we reported in the February 2018 COGR update that NSF has established an agreement with the National Academies to conduct a study to assess reproducibility and replicability in science. A committee held its first meeting in December and more recently on February 22-23. Three additional meetings will be held in 2018.

In support of these efforts, COGR has developed a survey to assess the resources institutions' are providing to foster rigor and reproducibility, including computing, biostatistical/statistical, data analysis, data management, mentoring, training, and other resources. **We encourage, and would greatly appreciate, your institution's participation in the survey. Responses would be appreciated by COB Friday, April 6.** If you have questions about the survey please contact Lisa Nichols.

AAAS Report on Perceptions of Science in America

The American Academy of Arts and Sciences recently published the report Perceptions of Science in America to identify, and increase awareness of, nuances in the public's perception of science. The report is the first in a series from the Academy's "Public Face of Science Initiative". The "Top Three Takeaways" indicate that: (1) Confidence in science leaders has remained stable over 30 years with American's expressing strong support for public investment in research (71% indicated that government investments in basic scientific research pay off in the long run) and the majority viewing scientific research as beneficial.; (2) Confidence varies based on age, race, educational attainment, region, political ideology, and other characteristics. Those without a high-school diploma are less likely than those with a college degree to view science as beneficial (52% versus 84%, and 94% for those with a graduate degree) and confidence is greater among younger age groups, Democrats and Independents, and those living in the Northeast. (3) There is no single anti-science population. Attitudes vary based on the specific scientific issue.

The report and data highlight "the need to consider the audience when communicating science" and "support the perception that there is not one general 'public' but rather many publics who consume information based on a range of underlying factors." With respect to controversial scientific issues, data indicate that ideology/party and age are strong factors in views of the role of human activity in global

warming, while race/ethnicity are strong factors in views on the safety of childhood vaccines, and education on views of the safety of genetically modified foods.

National Science Board

Science and Engineering Indicators 2018

On January 18, 2018, the National Science Board issued its biennial Science and Engineering Indicators Report for 2018. The report includes U.S. and international R&D trends and data on academic R&D among other areas. On February 1, the Board released a companion policy statement to indicators *Our nation's future competitiveness relies on building a STEM-capable U.S. workforce* and accompanying press release.

National Science Board member Diane Souvaine of Tufts University, and National Center for Science and Engineering Statistics staff members Beethika Khan and Carol Robbins presented SEI data at the February 22-23 COGR meeting. The presentation focused largely on international trends in science education and R&D investments, with China demonstrating rapid growth in science and engineering bachelor's degrees awarded, far surpassing other countries, and R&D investment where they have passed the EU, and are second only to the U.S. At current trajectories China is expected to surpass the U.S. in gross expenditures on R&D sometime this year. China also now has more peer-reviewed science and education publications than the U.S.

Other indicators data of interest includes spending for Academic R&D. The report indicates that, "In 2016, U.S. academic institutions spent $72 billion on research and development" and "basic research constituted just under two-thirds of academic R&D spending". Data indicate that the federal government provided 54% of academic R&D funds in 2016 but that its share declined for the fifth year in a row. "By contrast, universities' share of academic R&D spending has grown in recent years and reached its highest level ever in 2016 (25%)." The report also includes data and trends relating to infrastructure for academic R&D. Per the report, "In 2016, universities spent just over $2.1 billion on movable capitalized research equipment, an increase of 3% from the amount spent in 2015. The 2016 federal support share remained below 50% for the third consecutive year, reaching 45%. This share reached 63% as recently as 2011." The report also includes data and information on publications; Public Attitudes and Understanding about S&T, including use of stem cells and animal testing; and Invention, Knowledge Transfer, and Innovation. The report indicates that "In the higher education sector, invention disclosures filed through university technology management and transfer offices totaled 22,507 in 2015, up from 13,718 in 2003" and that "University applications for U.S. patents also increased over time: 13,389 in 2015, nearly doubling from 7,203 in 2003."

National Science Board February 2018 Meeting

The National Science Board met February 21-22. The meeting agenda and session webcasts are available on the NSB website. During the NSB's Oversight meeting the committee discussed taking a deeper look at the merit review data. NSF reports a 21% success rate overall with a range of 12%-38% across divisions. On a recent call, the committee raised several questions: How has the variability of the success rate evolved over time as an agency and by division and is the variability the result of NSF's strategic plan? How does it affect NSF's reputation among its stakeholders? Is the high number of

proposals a burden on personnel workloads? Is there a success rate so low that it constrains the progress of science? It was suggested that a year over year comparison for individual directorates would be helpful. Members suggested that it is important to determine the questions that the committee wants to answer. For example, what is the experience of trying to get funding (e.g., NSF reports a 50% success rate over 5 years). How many proposals did it take? The experience of the PI might be more relevant. What is a better way of reporting success rates?

With respect to the quality of proposals, the chair indicated that a principle of the merit review process is that the primary consideration is the intellectual quality and scientific/engineering importance of the work and not the reputation of the institution. What data should be examined to ensure that this is the case? How can NSF reduce the chance of unintentional bias on the part of the reviewer? Regarding geographical distribution: What is the distribution of awards to states over time with and without EPSCOR? The number of awards per faculty member, stem researcher, or submissions to NSF in a state? Is there a better way to look at this rather than per capita? The committee will continue to discuss the data and develop appropriate questions.

Mark Bell, Assistant Inspector General for Audit, provided the NSF OIG update on management challenges. Among the three areas Mark focused on were major multi-user facilities, where Mark suggested that the agency has made great efforts in improving its oversight, and grants administration, where he suggested there wasn't always clear guidance. New IT systems will help with management, policies continue to be updated, and the stewardship collaborative between the agency and the OIG has been effective. Mark suggested that going forward the OIG/agency will need to balance stewardship and oversight with allowing grantees to do their work. He indicated that the OIG hears a lot about all of the audits, Single Audit and agency audit, and that it is their responsibility to ensure that their work is not impeding the work and objectives of the award. The third area discussed was the management of IPAs. Mark noted that the agency has established a performance rating system, steering committee and pilot cost sharing program. Going forward the agency will need to continue to control costs without impeding the NSF's ability to draw in quality IPAs, and continue to manage conflict of interest. Dr. Cordova noted the importance of the IPA program and asked how the agency might retire that risk. When does the OIG think controls are sufficient? The OIG will continue to look at this and recognizes that the program is really important to the agency.

In the final few minutes of the meeting NSF staff indicated that the agency has implemented the new term and condition to raise the micropurchase threshold to $10,000 in accordance with the American Innovation and Competitiveness Act requirement.

Audit

NSF Office of Inspector General Session at the February 2018 COGR Meeting

National Science Foundation Assistant Inspector General for Audit Mark Bell, and Deputy Assistant Marie Maguire, spoke at the February 22-23 meeting about recent and upcoming changes to the NSF OIG audit process, including ongoing changes to how the OIG assesses risk (e.g., risk score and awardee type) and conducts audits. This includes updates to the OIG's risk matrix, greater use of internal auditors, enhanced flexibility with external audit contracts, addressing issues consistently identified in

audit, and early communication with NSF staff on the merit of potential findings. Also discussed were common external audit findings and current and planned audits, including NSF's oversight of its foreign awardees. The presentation is available on the COGR website.

NSF Audit Resolution Report

An audit resolution report dated February 9, 2018 and recently published by NSF's Division of Institution and Award Support allowed $755,858 of $794,221 in questioned costs. The institution is required to remit $38,363 of the questioned costs related to supplies, recharge center costs, general expenses, foreign travel and clerical and administrative costs. Regarding $660,699 in questioned costs on supplies, the agency found that all but $573 was allowable. Auditors had suggested that the costs should have been treated as F&A. The agency disagreed with the premise "that costs normally treated as F&A cannot qualify as direct costs" and found the costs to be "reasonable, necessary, allocable and allowable as charges to the applicable NSF awards".

Nonprofit Funder – Research Institution May 16 Meeting

COGR, the Health Research Alliance, and FasterCures are leading a workshop for stakeholders to consider guiding principles and beneficial practices to build and foster effective relationships between research-funding organizations and research-performing institutions. The day-long workshop, convened by the Government-University-Industry Research Roundtable of the National Academies of Sciences, Engineering, and Medicine, will be held on May 16 at the Academies Keck Center in Washington, DC.

The workshop is intended to facilitate discussions on the need for ongoing efforts to enhance nonprofit funder and research institution relations, and on four key elements of the partnership: (1) Administrative requirements; (2) Indirect costs/research operating costs; (3) IP and tech transfer issues; and (4) Overall principles for successful partnerships between non-profit funders and research institutions. View additional details about this event.

Space is limited. If you would like to attend the workshop in person, please contact Lisa Nichols. Register for a webcast of the event here.

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

CIP Committee Meets with NIST Director

The CIP Committee met with recently-appointed NIST Director Dr. Walter Copan at the February meeting. Representatives of AAU, APLU, AUTM and AAMC also attended. The main topic of discussion was the NIST Return on Investment (ROI) Initiative (see February Update). Dr. Copan emphasized NIST's convenor and stewardship roles for federal technology transfer. The review will seek to draw on the collective experience of stakeholders to identify what's working and should be protected, what needs to be fixed, and what additions or changes would increase the effectiveness. As mentioned in the Update, an RFI will be issued shortly along these lines. It will be followed by public discussion forums, perhaps hosted by the PTO regional offices. The goal is to complete the activity by the end of this fiscal year.

Dr. Copan noted that the findings and recommendations of earlier studies such as those of the NAS will be considered (see COGR Fall 2010 Update). He indicated that one goal is to raise the profile of the benefits from federally funded research, given the huge federal investment in R&D. He discussed the many challenges in the federal laboratory system, which is not as effective as university tech transfer. Ways to simplify and streamline the federal system are sought. He also discussed the increasingly global context of tech transfer. There is greater competition, particularly with other countries emulating Bayh-Dole. As an example, Dr. Copan mentioned that China was benchmarking NIST. One important aspect of the ROI assessment is to identify ways to strengthen U.S. competitiveness. He affirmed that the ROI is viewed by the Administration as its current initiative in tech transfer. NIST has the lead role, working with OSTP and the NSTC.

In the group discussion it was noted that there is a larger context for "ROI" than simply dollars, which the review should not lost sight of. Dr. Copan agreed. On Bayh-Dole, data demonstrating its effectiveness would be useful. Problems with the PTAB were mentioned (see December 2017 Update). Dr. Copan indicated that he is aware of the problems and will be working with PTO. Concerns were expressed that the planned open forums could be "captured" by groups unfriendly to Bayh-Dole and federal technology transfer, such as march-in advocates. NIST will seek to organize the forums to focus on underlying drivers of innovation and economic value. The linkage of infrastructure and STEM issues as important drivers was mentioned. Differing agency requirements were raised as in issue, even within

agencies such as NIH. Dr. Copan indicated that data on this would be useful, especially given Commerce's oversight role. Finally there was discussion of appropriate metrics. The recent APLU and AAU metrics activities might be a useful source of information.

In summary Dr. Copan noted that the initial focus will be on recommendations for "low hanging fruit." An example might be where current authorities are not being exercised or exercised improperly. Then heavier lift items requiring legislative action will be addressed. He emphasized the critical importance of stakeholder engagement in the ROI Initiative.

We have invited Dr. Copan to be a plenary speaker at the June COGR meeting. At that time he hopefully will be able to provide an update on the status of the Initiative and perhaps preliminary findings and recommendations. We expect that COGR will join the other higher ed. associations in crafting a joint response to the RFI.

Revised Bayh-Dole Regulations Almost Ready for Release

At the meeting with the NIST Director NIST staff indicated that the revised Bayh-Dole regulations are in the final clearance stage with OMB. The sole issue appears to be quantifying the impact on agency regulatory budgets, rather than substantive issues with the regulations. This needs to be worked out among the agencies for purposes of the preamble to the rule. As we have reported previously, the regulations have been pending for a year. Hopefully we will be able to discuss them in the next COGR Update.

Update on SRC Contract Issues

The February Update discussed issues with the IP provisions in the Semiconductor Research Corporation (SRC) JUMP initiative contracts. When a few of the prospective university subcontractors were unwilling to accept funds under the terms negotiated by the prime awardees, SRC negotiated a slightly different approach to the background IP of non-contract performers for those institutions. Under this approach, the institutions consult with non-contract performers before licensing their IP, rather than obtaining the consent of the non-contract performers. The latter approach was preferred by many of the other institutions. SRC seems to be letting institutions choose which approach they would like to use. At the time of this writing, SRC was still tweaking agreement language with multiple institutions, in one instance including language that potentially extends background IP obligations past the term of the agreement. This raises very difficult compliance issues and is likely to be unacceptable to most universities. SRC is already requiring use of the JUMP terms outside its JUMP program, and individual SRC member companies have started using similar terms in their university contracts. The goal of SRC and its member companies is to guarantee their freedom to operate. DARPA, which has provided significant funding for the JUMP initiative, has been very concerned about SRC's approach. Discussions are continuing.

I-Corps Expansion Bill Introduced

The February Update mentioned COGR endorsement of the proposed *Innovators to Entrepreneurs Act of 2018,* which Rep .Lipinski (D—IL) planned to introduce.

The bill (H.R. 5086) was introduced on February 26, co-sponsored by Rep. Webster (R—FL). Rep. Lipinski's press release is at https://lipinski.house.gov/press-releases/lipinski-introduces-bill-to-boost-american-innovation-and-create-jobs/.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Pamela Webb, University of Minnesota (Chair); Michael Ludwig, University of Chicago; Jeffrey Friedland, University of Delaware, 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

COGR Panel on Cannabis Research – Legal and Policy Issues

As discussed in previous updates, COGR has established a new ad hoc committee on the barriers of conducting research for medical marijuana purposes. The committee of members from various institutions meets bi-weekly to discuss legal and policy related issues related to conducting this research. Thursday afternoon's session of the COGR meeting provided COGR members with an update on the current landscape of conducting medical research with cannabis. The power point for this session can be found here. Panelists for this session include:

Linda Schutjer, Senior Legal Counsel, Colorado State University System
Ellen R. Auriti, Senior Counsel, University of California
Dan Nordquist, Associate Vice President, Research Support & Operations, Washington State University

The takeaway from the presentation is as follows: that there are many unanswered questions in various areas of regulation and proposed legislation including but not limited to the area of derivatives and extracts, lack of clarity in what is authorized or unauthorized in the Farm Bill vs the Controlled Substances Act (CSA), lack of understanding regarding products that require a Schedule 1 license under the CSA, financial barriers, and the ability to obtain additional strains of THC from plant materials. The Cannabis Committee plans to address these gray areas over the next several months through correspondence and meetings with congressional staff and agency personnel. The addition of a Frequently Asked Questions (FAQs) document on the COGR website will be a living document and may be useful to our member institutions considering research in this area. In the immediate future, COGR plans to submit a letter to the Agriculture Committee, Department of Agriculture and the Drug Enforcement Agency to voice our concerns regarding the barriers of conducting research with industrial hemp. We anticipate that the Association of American Universities (AAU) and the Association of Public Land Grant Universities (APLU) will join COGR in signature. COGR will continue our focus on cannabis over the next several months and will provide updates as they become available. For additional information, please contact Jackie Bendall at @ jbendall@cogr.edu.

Fixed Amount Subawards

At the Wednesday Research Compliance and Administration (RCA) Committee Meeting, COGR had the pleasure of hosting Samuel Ashe, Director, Division of Grants Policy at the National Institutes of Health (NIH), Stephanie Scott, Columbia University and FDP Subaward Sub-Committee Co-Chair, Jennifer McAllister, Duke University and FDP Subaward Committee to discuss and propose recommendations for reducing burden related to fixed amount subawards. Specifically, the committee asked if the NIH Grants Policy Statement (GPS) could be amended to acknowledge that pass-through entities with awards that contain clinical trials are budgeted on a fixed rate per-patient, per-procedure, or protocol milestone basis and therefore (similar to capitation awards) require no prior approval. This would also include any subaward in this category that exceeds the Simplified Acquisition Threshold (SAT). COGR offered to draft language for the NIH to consider. If NIH approves this approach, Mr. Ashe indicated that the clarifying language would be added to the GPS and NIH would develop and issue staff guidance to the Institutes and Centers (ICs). Based on our discussion with Mr. Ashe, we feel confident that a solution to this problem will be solved in the near term. COGR will update the membership as more information becomes available. Please direct your questions to Jackie Bendall at jbendall@cogr.edu.

Responsible Conduct of Research (RCR) Training

RCA also had the pleasure of hosting Jean Feldman, Head, Policy Office, Division of Institution and Award Support to discuss the NSF IG report and NSFs future plans related to RCR training. During this meeting, Jean indicated that **NSF does not envision any policy changes in RCR at this time.** NSF will continue to explore other opportunities such as workshop offerings and webcasts and expand marketing of their online ethics center. Recently the NSF has removed their old, outdated FAQs and had issued a new solicitation on RCR. If there are any changes in this area, the membership will be notified.

NSF Releases Important Notice No. 144 and Federal Register Notice on Harassment

On February 8, prior to the February COGR meeting, the NSF issued Important Notice No. 144: Harassment. Of particular interest for those who've voiced their concerns, was the lack of specificity in the notice. Since then, the NSF has released a Federal Register Notice that expands and clarifies a few areas of concern. Although, other questions will undoubtedly come up, COGR has provided a list of what was contained in the Federal Register notice not previously addressed in Notice 144 as follows:

1) Adds "on-line" to the list of locations where work must be performed responsibly.

2) Adds "sexual assault" to the list of reportable offenses

3) Clarifies that reporting includes "findings" and "determinations" by the awardee institution

4) Includes guidance re: subawards – the subrecipient must report to the pass-through entity, who must report to NSF.

5) Indicates that the "awardee code of conduct, policies, regulations, or statutes related to sexual harassment, other forms or harassment, or sexual assault" are to be used in terms of assessing misbehavior.

6) Indicates that awardee organizational processes and policies are expected to be in accordance with federal law and regulation (see, e.g., NSF Research Terms and Conditions, Appendix C.)

7) Defines "on administrative leave" to include any administrative action by the awardee that could impact the PI or Co-PIs ability to fulfill their responsibilities on the award. (Broader than just "administrative leave" per se.)

8) Defines time-frame (7 business days from the date of the finding/determination or the awardee's placement of the PI or co-PI on administrative leave) when report must be filed. The report must be filed by institutional authorized organizational representative to NSF's Office of Diversity and Inclusion at: harassmentnotifications@nsf.gov.

9) Report contents must include:

   a. NSF Award Number
   b. Name of PI or Co-PI being reported
   c. Identification of whether there is a reported violation or whether there is a placement of the reported individual on admin leave
   d. Description of the finding/determination and action taken, if any
   e. Reason(s) for, and conditions of, placement of the PI or any Co-PI on administrative leave
   f. Plan for continued oversight and implementation of the project during the administrative leave period of the reported PI or Co-PI.

10) Indicates the awardee may propose a substitute investigator if awardee determines the PI or a co-PI may not be able to carry out the project/activity or abide by award terms and conditions.

11) Clarifies that although reporting is not required for other personnel on the grant, the awardee must make appropriate arrangements to ensure the safety of other award personnel and the continued progress of the funded project.

12) Reminds us that NSF may take unilateral action, as appropriate, to require the substitution of the PI or any CO-PI, suspension or termination of the award, or a reduction in the award funding amount (new)

13) New award term will be applied to all new NSF awards and funding increments to existing awards made on or after the effective date.

On behalf of the membership, COGR will be submitting comments by the May 4th deadline. Please submit your comments to Jackie Bendall at jbendall@cogr.edu for inclusion in the letter.

NIH Releases Strategic Plan for Data Science

The NIH has released a Request for Information (RFI) seeking comments on the agency's Strategic Plan for Data Science. The NIH would like the research community to respond to the following items:

- The appropriateness of the goals of the plan and of the strategies and implementation tactics proposed to achieve them;
- Opportunities for NIH to partner in achieving these goals;
- Additional concepts that should be included in the plan;
- Performance measures and milestones that could be used to gauge the success of elements of the plan and inform course corrections;
- Any other topic the respondent feels is relevant for NIH to consider in developing this strategic plan.

The deadline for the comment period to the NIH is April 2nd . COGR will be responding. Please submit your comments to Jackie Bendall at jbendall@cogr.edu.

USDA Issues Records Freeze

At the recent COGR meeting and as previously reported on COGR's listserv, many of our members both shared concerns and confirmed that they had received the letter from USDA.

The letter notifies recipients of funds from ***certain*** USDA components Agricultural Research Service (ARS), Economic Research Service (ERS) and National Agricultural Statistics Service (NASS) and applies to all records generated from and/or pertaining to agency agreements. ***Awards from other USDA components do not appear to be subject to this freeze.***
COGR, with other DC-based organizations, will post an update as it continues to find the source of this records disposal freeze and its likely duration.
At the present time, COGR recommends that institutions consider the following actions:

- Notify impacted investigators to retain all research-related records on their primary awards or subawards from these USDA components, including data and biospecimens;
- Determine whether any institutional standardized records purging practices (electronic or manual) need to be adjusted;
- Ascertain what offices need to be notified, such as pre-award and post-award offices, effort reporting offices, departmental or collegiate offices (if responsible for official records such as invoices, receipts, purchase orders, hiring records, labor distribution records, etc.); human and animal subjects compliance offices, environmental health and safety, purchasing, IT systems groups, etc.

This is, of course, in addition to any local guidance offered by an Office of General Counsel or others involved in records retention practices.