COGR
Council On Governmental Relations
An Association of Research Institutions

May 1, 2018

TO: COGR Membership

FROM: COGR Staff

SUBJECT: May 2018 Update

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The President's Management Agenda (PMA)

The Trump Administration released the President's Management Agenda in April. COGR views this as an invitation from OMB to actively re-engage with OMB and other stakeholders on important grants administration issues. As described by a representative from the OMB Office of Federal Financial Management (OFFM):

> *The PMA lays out a long-term vision for modernizing the Federal Government in key areas, improving agencies' ability to deliver mission outcomes, provide excellent service, and effectively steward taxpayer dollars on behalf of the American people. For while the Federal Government's business is to serve the American people in core mission areas, it has become too bureaucratic and complex to seamlessly meet the needs of the 21st century.*
>
> *The Administration will advance progress not through isolated efforts, but at the junctions where three key drivers of change intersect:*
>
> - *Modern information technology (IT) will serve as the core function for Government to meet the needs and expectations of Americans while keeping sensitive data secure.*
> - *Data, accountability, and transparency will provide the framework and data to deliver better outcomes to the public and hold agencies accountable to taxpayers.*
> - *A modern workforce will drive needed civil service reforms to empower everyone from senior leaders to front-line managers to better align staff skills with evolving mission needs.*
>
> *To drive implementation of the PMA, Cross-Agency Priority (CAP) Goals have been established to tackle critical government-wide challenges that cut across agencies. I'm writing to inform you of a specific CAP Goal, Results-Oriented Accountability for Grants, to tackle many of the long-standing challenges we face in the grants management community. This vision was informed by your feedback as a grants management stakeholder and builds on the ongoing efforts of the grants management community to improve the way we deliver results to the American taxpayer.*
>
> *For details on the Results-Oriented Accountability for Grants CAP Goal, please visit: https://www.performance.gov/CAP/CAP_goal_8.html*
>
> *For more details on all the CAP Goals and the PMA, please visit omb.gov and performance.gov/PMA*
>
> *You can also view the launch of the PMA at https://youtu.be/51TPpZChiIQ*
>
> *The PMA reflects an important collaboration between OMB, agencies, and non-Federal community. The Office of Federal Financial Management (OFFM) is fully committed to working with you as we continue to make strides that modernize government and meet the changing demands of the American public.*

In early May, COGR staff will meet with representatives from the OMB Office of Federal Financial Management and our understanding is that OFFM also will do PMA presentations at various venues over the upcoming months. Some of the advocacy COGR will do is related to ongoing issues (e.g., see Procurement below), though the bigger picture is to address new opportunities with a fresh lens of perspective. We encourage the COGR Membership to share ideas that could be advocated for in the context of the PMA and we will keep the Membership updated on all developments.

Procurement and the Micropurchase Threshold (MPT): Approval Status

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.

In the February Meeting Report we provided Observations on Implementation of the MPT and an assessment on Other Procurement Issues. As we engage OMB on the President's Management Agenda (see above), we hope to raise the importance of establishing a simplified process, which allows institutions that currently have an MPT greater than $10,000 to continue using that threshold.

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 National Defense Authorization Act is met: "*clean audit findings under chapter 75 of title 31, internal institutional risk assessment, or State law*." In this scenario, an approach would be to notify OMB, your Cognizant Agency for Indirect Cost (i.e., CAS-HHS or ONR), and possibly the HHS Office of Grants and Acquisition Policy and Accountability (OGAPA). In your correspondence, you could indicate that "*to be in compliance with the National Defense Authorization Act, our institution is notifying you that we will continue to use an MPT of $25,000*."

While we recognize this approach requires an audit risk analysis, it may be reasonable. Still, COGR recommends that prior to taking any position, consult with your Auditors and/or General Counsel at your institution. In the meantime, COGR will continue to actively pursue a resolution to this issue and will keep the Membership updated.

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.

F&A Update. While it appears as though F&A no longer is being specifically targeted by the Administration, COGR continues its participation in 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 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. We are making significant process on the White Paper 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) increases from $187,000 to $189,600. The most recent NIH guidance is dated March 7, 2018), NIH Notice Number: NOT-OD-18-137, Guidance on Salary Limitation for Grants and Cooperative Agreements FY2018. We expect NIH soon will release its

annual guidance on legislative mandates, consistent with the final Department of Health and Human Services Appropriation for FY 2018.

HHS/NIH Policy Update: Financial Reporting. In the February Meeting Report we shared a summary of COGR's meeting 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. We believe there is an opportunity to pursue issues including: Facilitating and/or eliminating the quarterly Federal Cash Transactions Report (FCTR, SF-272); consistent grantee close-out requirement of 120 days applicable to all HHS operating divisions; and addressing weaknesses in the Payment Management System (PMS). We will keep the Membership posted on all developments.

NIH pooled accounts in the Payment Management System. As the conversion to subaccounting almost is complete, some institutions are sharing with COGR discrepancies between the amount that PMS indicates as available in the pooled account versus the remaining awarded/authorized funds recorded in the institution's financial system. It is not clear how these discrepancies are to be resolved, but as appropriate, COGR will engage with federal officials.

2018 "Skinny" Compliance Supplement. OMB is working on the 2018 Compliance Supplement (CS) in the context of a "skinny" CS. This will includes only significant updates to a few sections and programs and auditors will use the 2017 CS and the 2018 CS together to guide their audits. We believe Procurement may be addressed, Payment and Reimbursement under 2 CFR 200.305 (see below) may not be, and Securing Student Information (see below) will be delayed until 2019. COGR hopes to engage with OMB before the release of the 2018 CS and to provide feedback on all areas of concern.

Payment and Reimbursement under 2 CFR 200.305. 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. As indicated above, we are learning this issue might not be addressed in the 2018 CS, which would be of concern. We will keep the Membership posted on this development and possible next steps.

Securing Student Information, Department of Education (ED). COGR has worked with several of our Association partners to raise concerns as to how ED has proposed audit objectives related to safeguarding data specific to an institution's information security program (i.e., Safeguards Rule). ED withdrew their initial inclusion of overly-complex audit guidance from the 2017 Compliance Supplement. COGR's position has been that the Compliance Supplement is not the correct vehicle for this guidance. We now understand that the guidance will not be included in the 2018 Compliance Supplement, but will be revisited in the 2019 Compliance Supplement. We will continue to track this issue.

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.

American Association for the Advancement of Science (AAAS) Research Budget Website, https://www.aaas.org/program/rd-budget-and-policy-program. As presented at the February COGR Meeting, 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 at the February COGR Meeting, 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.

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.

NIST Issues Revised Bayh-Dole Regulations

On April 13 NIST issued revised implementing regulations for the Bayh-Dole Act. The changes initially were proposed in November of 2016. COGR has been in close touch with NIST during the 18-month process that led to publication of the final revised regulations (see e.g. COGR October 2017 Meeting Report). The changes for the most part are consistent with what we expected.

Perhaps the most important change is a new requirement in the regulations for employees to assign by written agreement invention rights to the contractor. COGR supported this change, which should help institutions still dealing with the aftermath of the Supreme Court's *Stanford v. Roche* decision several years ago. Previously there was no specific regulatory requirement for such assignments. Institutions vary in their compliance practices but written assignments need to be in place before federal awards.

Several of the changes involve various time limits in the regulations. We had opposed a proposed change that would have allowed funding agencies to shorten the two-year period for contractor election of title. It has been removed. However, the proposal to remove the 60-day limit for agencies to request title upon learning of a contractor's failure to disclose an invention or elect title was retained. We also had opposed this change. A third change would have extended the required notification period for contractor decisions not to continue patent prosecution from 30 days to 120 days. Our view was that 120 days was too long. NIST somewhat split the difference. The new requirement lengthens the notification period to 60 days.

A new change is a requirement for a contractor to file a non-provisional patent application 10 mos. after filing a provisional. This was not included in the original proposal. Concerns have been expressed about this change by COGR members. We plan to discuss further with NIST. However there is an automatic one-year extension if requested, unless the agency notifies the contractor within 60 days of the request.

There are a variety of other changes, including new detailed provisions dealing with federal co-inventor situations. We did not favor some of these changes, such as requiring notification to funding agencies rather than the Commerce Department about small business preference concerns. However they do not appear to be of major concern. COGR will participate in a free AUTM webinar on the changes, scheduled for May 8.

This is a final rule, with no further opportunity to comment. It is effective May 14, 2018.

NIST Holds Symposium to Kickoff ROI Initiative

On April 19 NIST hosted a symposium in Washington on "Unleashing American Innovation." It served as the formal kick off the NIST Return on Investment (ROI) Initiative. The COGR CIP Committee met with the NIST Director in February to discuss this initiative (see February Meeting Report). The symposium was attended by 120 people.

The Symposium featured introductory remarks by the NIST Director, the Secretary of Commerce, the Deputy Director for Management of OMB, and the Deputy Chief Technology Officer from OSTP. 3 panels followed: one on federal perspectives (including NSF and NIH participation), one on university perspectives (including an AUTM representative) and industry perspectives. The event was characterized by very positive remarks from the participants on university technology transfer. Commerce Secretary Ross noted that universities are much more effective than federal labs at tech transfer, and the labs need to learn best practices from universities. The 2011 NAS report on *Managing University Intellectual Property in the Public Interest* was discussed in some detail. It was noted that the report had emphatically rejected the faculty "free agency" concept for managing intellectual property (the report was discussed in COGR updates and reports at the time, e.g. see the Fall 2010 Update).

Other main themes at the symposium were the need to maximize ROI, the importance of intellectual property protection, the effectiveness of Bayh-Dole, and the need to consider both universities and the federal labs in the overall ecosystem for university tech transfer. Concerns about IP protection and China also were mentioned. The agenda was controlled, with no outside speakers. However NIST plans to convene four public "listening sessions" over the next couple of months, tentatively scheduled for the San Jose, Denver and Chicago areas as well as one hosted by NIST which is to be webcasted.

While the tone was very positive, it was noted that the relevant statutes (Bayh-Dole Act; Federal Technology Transfer Act) now are 40 years old and should be reviewed, with a view to whether all the statutory authorities are being properly exercised. Concerns also were expressed about licensing technology to "fragile" startups. We understand NIST plans to post the symposium webcast on the ROI website.

The RFI that we discussed in February will be released soon, with a 90-day response deadline. We will discuss a joint response with the other higher ed. associations once the RFI is released. (An advance copy is available on the ROI website here.

Supreme Court Decides Two Important Cases on IPRs

On April 24 the U.S. Supreme Court decided two important cases related to the *inter partes review* (IPR) procedure established by the America Invents Act (AIA). A number of university patents have been invalidated as a result of IPR challenges.

> *Oil States Energy Services v. Greene's Energy Group.* By a 7—2 majority the Court upheld the IPR process on constitutional grounds. It held that patents are a public, not a private right. Private rights, such as real property, can only be adjudicated by courts, but public rights can be adjudicated by

executive agencies. IRP is simply a reconsideration by the Patent Office of the decision to grant a patent. This is a matter of public rights, involving the grant of a public franchise. The dissenting judges viewed patents as personal property rights that only can be adjudicated by courts.

There has been considerable negative commentary on the Court's decision, although the majority decision indicated it was only ruling narrowly on the constitutionality of IPRs. If patents are public rights that can be challenged and revoked at any time, they are not vested property rights, as previous Court precedents have indicated. PhRMA and others have stated that the decision heightens the need for IPR reform. There also could be implications for issues such as sovereign immunity in IPRs, licensing of patents, etc.

SAS Institute v. Iancu. This case dealt the practices of the Patent Trail and Appeal Board (PTAB) in considering IPRs. The PTAB had followed the practice of "partial institution." Following this practice it could institute IPRs against some but not all of the claims challenged in IPR petitions, based on its determination as to on which claims the petitioner was likely to prevail. The Court in a 5—4 decision held that under the text of the AIA a final written decision by the PTAB on all challenged claims was required. The court likened IPRs to civil litigation where the scope is defined by the complaint. The dissenters supported the ability of the PTAB to screen out frivolous challenged claims as consistent with the AIA.

While not a constitutional decision like *Oil States*, IPR petitioners will need to assure that IPR petitions are well-targeted to challenging claims where there is a reasonable likelihood of a finding of unpatentability. Otherwise they run the risk of being estopped from raising issues related to the challenged claims in subsequent court actions. PTO has issued guidance on the impact of *SAS* here.

Patent and Tech-Transfer Legislation Advances

STRONGER Patents Act. We reported previously on this Act (S. 1390), introduced by Sen. Coons (see December 2017 Update). A house version (H.R. 5340) was introduced in March by Reps. Stivers (R—OH) and Foster (D—IL), with 15 co-sponsors. The legislation is aimed mostly at the IPR process. It would conform PTAB practices more closely to standards used in district courts. It also would eliminate USPTO fee diversion and clarify the micro entity status of institutions of higher education (this has been a source of confusion since passage of the AIA—see COGR June 2012 Meeting Report). Another section of the bill addresses bad faith demand letters sent by patent trolls. The bills also declare that patents are property rights, which may be of some importance given the *Oil States* decision.
A hearing was held on the Senate bill by the Senate Judiciary Committee on April 18. Currently that bill has 3 co-sponsors; we understand additional co-sponsors are being sought. The bills are not expected to pass in this Congress, but clearly send a message of concern about the IPR process. This may be heightened by the recent Supreme Court decisions.

PTO Director Testifies on IPRs and Other Matters. At a Senate oversight committee hearing on April 18 new USPTO Director Andrei Iancu testified on changes in PTAB practices designed to address some of the concerns that have been raised by stakeholders. He also discussed the need for greater clarity on subject matter eligibility and the need to better understand IP protection in China. Higher ed. association representatives including COGR will be meeting with Mr. Iancu on May 15.

***Innovation to Entrepreneurs Act* Passes House**. The February Update and Meeting Report discussed COGR endorsement of this bill (H.R. 5086), introduced by Rep. Lipinski (D—IL). The bill passed the House on April 24. It would expand the eligibility for the I-Corps program to SBIR grantees and enable SBIR funds to be used for program participation. It also directs NSF to develop a course to teach I-Corps participants and other entrepreneurs how to start and grow a company, and authorizes $5M for this purpose. Finally it directs GAO to evaluate the program within the next 2 years to assess the effects on commercialization and regional economies. We understand Sen. Coons is working on a companion Senate bill including securing co-sponsors.

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Bills Target Foreign Threats to U.S. Institutions of Higher Education

Legislation has been introduced or drafted in both the House and Senate targeting foreign threats to U.S. higher education. A bill (H.R. 5336), introduced in the House by Rep. Wilson (R—SC) and in the Senate by Sen. Rubio (S. 2583), would broaden existing institution disclosure requirements (20 USC 1011(f)), to require disclosures of gifts or contracts of $50k or more from a foreign source, or $250k in the aggregate (the existing requirement). The contents of contracts also would need to be disclosed. A Senate bill drafted by Sen. Cruz (R—TX) would require designation of foreign actors as foreign intelligence threats to higher education if the FBI finds them to have committed one or more of ten different types of activities (e.g. theft of trade secrets, economic espionage, etc.) in connection with an institution. It also contains similar disclosure requirements to the other bills, and requires an FBI assessment of the impact.

A hearing was held on April 11 by the House Science Committee on "Scholars or Spies: Foreign Plots Targeting America's Research and Development." The witnesses did not include any university representatives. However, COGR joined the other higher ed. associations in submitting a statement to the Committee. The statement cited past efforts by the government to work with the higher ed. community on security issues. In particular it mentioned the former FBI National Security Higher Education Board (NSHEB) as a useful forum for joint discussion of these issues. It expressed disappointment at the decision to disband the NSHEB, and the desirability of an alternative forum for future high level discussions. (A copy of the statement is posted on the COGR website). In addition, on April 25 ACE formally wrote to the FBI to request a meeting to discuss national security issues, citing the importance of the NSHEB. The letter also cited the April 11 hearing, and concerns about Chinese students at U.S. universities.

Updates

Export Controls. On February 15 Congressman Royce introduced a bill (H.R. 5040) titled the "Export Control Reform Act of 2018." It repeals and replaces the (expired) 1979 Export Administration Act (the Export Administration Regulations (EAR) have remained in effect pursuant to annual proclamations by the President under the International Emergency Economic Powers Act). The bill provides that the

EAR will remain in effect. While there are some concerns about the definitions, we have not identified any particular issues for COGR member institutions in the bill.

Controlled Unclassified Information

New DOD Guidance. On April 24 DOD issued draft guidance on the implementation of the NIST SP 800-171 security requirements. It provides a "DOD value" to assess the degree of risk of each unimplemented security requirement. A priority is assigned to each requirement and the value to DOD. The highest priority is "P1" and the highest value to DOD of a control is a "5." Perhaps not surprisingly, the overwhelming majority of controls are "P1s" with a value of "5."Supporting documents for assessments of contractor information systems are included in the regulation docket.

Comments are due May 31. At this time we are not anticipating submitting COGR comments. However we understand that the Association of University Export Control Officers may be considering submitting comments. The docket (DARS-2018-0023) may be found here.

FAR Clause. The due date for submission of the draft FAR clause (Case 2017-016) to the FAR Civilian Agency Acquisition Council (CAAC) for review has been extended again, until May 9. This is almost a year from the original due date. We have been in contact with NARA, who has the lead responsibility, and have asked to be updated as to any change in status.

Human Subjects Research

Common Rule Proposed Delay

On April 20, the Department of Health and Human Services and 16 other federal departments and agencies published a Proposed Six Month Delay of the general compliance date of the Federal Policy for the Protection of Human Subjects, or Common Rule, while allowing the use of three burden-reducing provisions during the delay period. **The proposed effective date in the notice is July 19, 2018, however, regulated entities would not be allowed to implement the 2018 requirements prior to the January 21, 2019 compliance date with the exception of the following three burden reducing provisions**:

- The revised definition of "research," which deems four categories of activities not to be research;
- The elimination of the requirement that IRBs review grant applications or other funding proposals related to the research; and,
- The allowance for no annual continuing review of certain categories of research.

In the notice, agencies suggest that implementation of these particular provisions would minimize burden without creating significant complexities. **It is important to note that if any of these provisions are implemented prior to the January 21, 2019 general compliance date, all of the 2018 requirements must be implemented for those studies on January 21, 2019.** The NPRM indicates that "An institution's decision about whether to transition a study to the 2018 requirements to take advantage of the three burden-reducing provisions might vary depending on the nature and progress of the study, including any elements of the study to be conducted on or after January 21, 2019. For example, studies planning to recruit some subjects on or after

January 21, 2019 would have to meet the new requirements for obtaining the informed consent of those subjects. In contrast, for studies whose remaining activities consist only of completing data analyses, the new requirements for informed consent generally would not be applicable." At the same time, research that is not deemed research (e.g., scholarly and journalistic activities) would still not be subject to the 2018 requirements so this provision would allow that change to be implemented six months earlier.

COGR, in response to the interim final rule published on January 19, 2018, had requested that OHRP maintain the current effective date of July 19, 2018 while allowing institutions an additional year to come into full compliance. This would have allowed institutions to voluntarily move forward with implementation of the revised final rule while also providing the flexibility to delay implementation of certain provisions until anticipated guidance was published. The NPRM suggests that this approach could have resulted in confusion in the absence of agency guidance. Per the notice, "The 2018 requirements include new exemptions, new IRB review procedures, and new provisions pertaining to informed consent, among other revisions, and guidance would be helpful to the regulated community in understanding and complying with these requirements." To date, guidance has not been issued.

To the extent agencies would not permit voluntary compliance for the full 2018 requirements as requested, we support the flexibility provided by the proposed option to implement three burden reducing provisions. Institutions will have to determine whether to implement these provisions with consideration of further changes to their IT systems and whether to subject research that precedes the January 21, 2019 compliance date to the full 2018 requirements beginning January 21. Comments on the proposed delay are due May 18. COGR will make comments available to the membership in advance of the deadline.

NIH Clinical Trial Case Studies

Report language in the Consolidated Appropriations Act of 2018 directs NIH to "delay enforcement of the new policy published in the Federal Register on September 21, 2017-including NIH' s more expansive interpretation of 'interventions'-in relation to fundamental research projects involving humans." NIH released New Review Criteria for Research Project Applications Involving Clinical Trials on September 21, 2017. The review criteria and the NIH Policy on Funding Opportunity Announcements [FOA] for Clinical Trials became effective January 25, 2018. Per the language, "This delay is intended to provide NIH sufficient time to consult with the basic research community to determine the reporting standards best suited to this kind of research. The agreement directs NIH to provide the Committees on Appropriations of the House of Representatives and the Senate a plan and schedule for soliciting comments and input from the research community within 30 days of enactment of this act, and brief the Committees on the results of these consultations and next steps by June 22, 2018." To date there has been no change in practice or indication of how NIH plans to address the language. COGR will keep members updated on any developments.

Animal Research and Regulatory Reform

NIH OLAW Request for Comments

NIH published a request for comments, Laboratory Animal Welfare: Coordination and Harmonization of Regulations and Policies, in the Federal Register on March 14. Per the notice the agency is "seeking information to improve the coordination of regulations and policies with respect to research with laboratory animals as required by the 21st Century Cures Act" in coordination with USDA and FDA to reduce administrative burden. The notice indicates that NIH, USDA and FDA are currently reviewing the recent FASEB-AAMC-COGR-NABR report *Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden*; the National Academies report *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*; and the National Science Board report *Reducing Investigators' Administrative Workload for Federally Funded Research* among others. The notice seeks input on proposed actions and resources, including approaches not specifically mentioned. There is a 90 day comment period. COGR plans to comment and will distribute comments to member institutions once available.

COGR Checklist for Reducing Institutional Administrative Burden

An ad hoc subcommittee of the Association of American Medical Colleges Group on Research Advancement and Development has been charged with identifying "best practices" for meeting animal research regulatory requirements while minimizing the time and effort spent by investigators, IACUCs, and staff and insuring the humane treatment of animals. As part of its review and report, the subcommittee has asked to include data from the COGR checklist on actions that institutions have taken to reduce administrative burden associated with the conduct of animal research. COGR is asking members to consider taking the time to complete a brief survey on current practice and actions taken by Friday, May 4. Data made available to COGR members and to AAMC would be aggregated and not identify individual institutional responses.

Recent Hearings

NIH FY19 Budget Hearing

The House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies held a hearing on the NIH fiscal year 2019 budget on April 11. NIH Director Dr. Francis Collins testified along with the directors of NIAID, NCI, NICHD, and NIDA. Chairman Cole highlighted the $3 billion increase in FY18 funding for NIH, the second highest in the agency's history. Ranking Member DeLauro noted the total budget increase of $7 billion over the last three years and expressed concern about the administration's FY19 budget proposal which would take NIH back to FY17 levels. She also expressed concern about discussions on rescission and noted that members of Congress would fight to preserve NIH's FY18 funding if targeted. Congresswoman DeLauro spoke in terms of "restoring" NIH's budget, noting that it is still $5 billion below 2003 levels when adjusted for inflation. She also raised concern about the administration's proposal to cap the percentage of an investigators salary that can be charged to an award at 90% and also to limit salary from grant funds to $154,000. Dr. Collins suggested that universities have opportunities to support

investigators and do so but that under the current circumstances, if an investigator doesn't have the grant funding they likely could not continue with their research because universities can't pick up the difference.

Representative Harris mentioned the age at which investigators get their first R01 and expressed concern that despite increased focus on this issue and increased funding, the situation has worsened, not improved. The current average is 43 years of age and Harris noted that for MDs it is 45. Dr. Collins expressed concern about the issue and indicated that NIH is working to reverse this trend. He indicated that NIH needed help from research institutions and noted that the next generation researchers report on the topic, highlighted in this update, would be released later the same week.

There were questions about reports of NIAAA's solicitation of funds from the alcohol industry and possible bias in research funding. Dr. Collins indicated that NIH is aggressively looking into the situation and will have an Advisory Committee to the Director Working Group evaluate the scientific merit of the study and that the HHS inspector general would be engaged as appropriate. Representative Harris noted that public-private partnerships can be appropriate and beneficial and that care should be taken to ensure that there isn't an overzealous and counterproductive response.

There was note of a recently published paper indicating that 100% of FDA-approved drugs have benefited from NIH support at some point in the process and questions about how to promote NIH's support of drug discovery. There was also concern that tax-payer funds were being used to support drug development while drug prices are sometimes excessive. Dr. Collins indicated that NIH can't pull levers on the cost of drugs and influence licensing agreements, citing Bayh-Dole. He suggested that what NIH can do is speed up drug discovery and lower the cost of developing drugs that often leads companies to set high prices to recoup their investment in discovery.

House Hearing: Shining the Light on the Federal Regulatory Process

The House Oversight and Government Reform Committee held a hearing on March 12, 2018 to "assess federal agencies' processes for and compliance with rulemaking and guidance procedure requirements." In opening remarks Government Operations Subcommittee chair Mark Meadows noted that agencies cannot issue regulations unilaterally, but that in 2016 eighteen regulations were issued for each law passed by Congress. Meadows noted that 3,280 rules were issued last year, 9 rules per day, and 10.5 per day in 2016. He also noted that the while the number of federal guidance documents is not known, a request to 46 agencies to provide guidance documents has yielded 12,800 documents to date. There was discussion about the need for agency guidance but also concern that some agencies are using guidance, which is non-binding, in place of regulation and not following the 2007 OMB Bulletin for Agency Good Guidance Practices.

Kris Nguyen, Acting Director of the Government Accountability Office's Strategic Issues Division testified on recent GAO report, *OMB Should Work with Agencies to Improve Congressional Review Act Compliance during and at the end of Presidents' Terms*. The report found that the three previous presidential administrations published on average 2.5 times more economically significant regulations during transition periods, the period after an election until the start of the next administration. The report also found that "The most common CRA

deficiency was agencies' failure to provide Congress the required time to review and possibly disapprove regulations." This was particularly true for Economically significant regulations for which OMB completed its review within 3 months before the planned effective date.

Representative Carolyn Maloney and others highlighted the necessity of guidance and the importance of providing agencies with the flexibility to implement it. Amit Narang of Public Citizen expressed concern about what he described as the administration's "radical deregulatory agenda" including executive order 13771 which requires the elimination of two rules for every rule introduced, suggesting that this conflicts with multiple statutes. He also expressed concern about targeted outreach that does not include diverse views and about a lack of transparency, including failure to disclose the identity of agency regulatory reform officers.

National Science Board Meeting

The National Science Board will meet May 2-3. The meeting agenda is available here. NSB meetings are webcast live.

Academies Report: Next Generation of Biomedical and Behavioral Sciences Researchers

The National Academies released the report *The Next Generation of Biomedical and Behavioral Sciences Researchers: Breaking Through* on April 12. The report follows an 18 month study, the Next Generation Researchers Initiative, by an ad hoc committee overseen by the Board on Higher Education and Workforce.

The report calls for a number of reforms to strengthen the biomedical research system for early career scientists. Recommendations to Congress include increasing the NIH budget and working with the agency to promote pilot projects that accelerate transitions into independent careers. The report also recommends the establishment of a public-private research enterprise, the Biomedical Research Enterprise Council, to address ongoing challenges confronting these researchers and to help ensure that those engaged "including universities, play a shared role in developing and implementing solutions, rather than looking to NIH as the responsible party." The report recommends that NIH increase research fellowship and career awards for postdoctoral researchers fivefold by 2023; that the duration of R01 awards supporting early-stage investigators be no less than five years; and that following a pilot study, NIH phase in cap on salary support for postdoctoral researchers funded by NIH research project grants. The report also recommends that NIH require research institutions to "collect, analyze and disseminate comprehensive data on outcomes, demographics, and career aspirations of biomedical and behavioral science pre- and postdoctoral researchers."

Recommendations specific to research institutions include career guidance counseling for postdoctoral researchers; providing "evidence to NIH of formal training of faculty mentors of postdoctoral trainees"; that principal investigators provide a diversity and inclusion plan in grant proposals and updates in progress reports; and that institutions work with NIH to increase the number of individuals in staff scientist positions as a means of providing "more stable, non-faculty research opportunities." The committee was chaired by Ron Daniels, President of Johns Hopkins University. More information about the committee and its efforts can be found here.

Alleged Fraudulent Activity in GSA's System for Award Management (SAM)

A recent update on the U.S. General Services Administration website indicates that an OIG investigation is under way into "alleged, third-party fraudulent activity in SAM." The notice suggests that a limited number of entities have been impacted, that these entities have been notified, and that steps are being taken to address the issue. This includes "requiring submission of an original, signed notarized letter identifying the authorized Entity Administrator for the entity associated with the Data Universal Numbering System (DUNS) number before the registration will be activated." This requirement "went into effect on March 22, 2018 for new entities registering in SAM and goes into effect on April 27, 2018 for existing registrations being updated or renewed." Additional information and instructions can be found here.

Nonprofit Funder- Research Institution Working Group May 16 Meeting and Webcast

We previously informed members that COGR, the Health Research Alliance, and Faster Cures are leading a workshop for stakeholders to consider guiding principles and beneficial practices to build and foster effective relationships between non-profit 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 from 8 am to 3 pm EDT on May 16 in Washington, DC.

The workshop is intended to facilitate discussions on the need for ongoing efforts to enhance nonprofit funder and research institution partnerships, and on four key elements: (1) Administrative requirements; (2) Indirect

costs/research operating costs; (3) IP and tech transfer issues; and (4) Overall principles for successful partnerships.

Registration for a live webcast of the meeting, including breakout sessions, can be found here and the workshop agenda here. There is no fee to register for the webcast. Questions about the webcast and event can be directed to Lisa Nichols.

NSF Federal Register Notice on Harassment

First reported on February 8th by the NSF Important Notice No. 144, NSF releases Federal Register notice seeking comment on its proposed new term and condition. The term and condition requires recipients of NSF grant awards to report findings/determinations of sexual harassment, other forms of harassment, or sexual assault, regarding an NSF funded PI, or any co-PI. In addition, the term also requires the awardee to notify NSF if it places the PI or any co-PI on administrative leave relating to a harassment finding or investigation. NSF has reserved their right to take unilateral action as necessary to protect the safety of all awardee personnel, to include requiring the substitution or removal of a PI, or any co-PI, suspension or termination of an award, or a reduction in the funding amount. The deadline for comments is May 4th. COGR, along with other associations will be submitting jointly in response to the notice. The letter will be posted to COGRs website. Contact jbendall@cogr.edu for additional information.

EPA Federal Register Notice, "Strengthening Transparency in Regulatory Science"

On April 30th, the EPA released a federal register notice seeking of plethora of public comments aimed to increase transparency of data and models in scientific research. Congruent with existing laws and regulations that govern federal agencies currently, EPA seeks comments on how to incorporate stronger data and model access requirements into the terms and conditions of cooperative agreements and grants and seeks to build upon other federal agencies' policies regarding grantee and cooperator requirements. EPA also seeks comment on platform suggestions and on methodologies and technologies to protect identifiable and sensitive data and copyrighted or confidential business information.

Comments are due May 30, 2018. COGR anticipates responding and would appreciate any feedback from your faculty and staff. Please submit your comments to jbendall@cogr.edu no later than May 25, 2018.

Department of Labor Fact Sheet

On April 12th, the Department of Labor posted updated guidance on application of overtime to white collar exemptions under FLSA. This guidance is similar to previous guidance issued when the Obama Administration's prior rule was struck down by a Texas district court. Click here for the March 2018 guidance.

COGR will continue to monitor this. If the Democrats win the presidency and if DOL fails to issue a new rule by 2020, we could expect the newly elected administration to defend the previous salary threshold of $913 per week ($47,476 annually).

COGR Submits Hemp Letter to Congress

As reported in previous updates, COGR has formed a working group to support, help identify and remove the barriers to conducting cannabis research for medical purposes. On April 19th COGR, AAU, and APLU submitted a joint letter to Congress in support of H.R.5485, the Hemp Farming Act of 2018. In this letter we point out the contradictory definitions of "marihuana" as defined under the Controlled Substances Act (CSA) with the provisions contained in the current Farm Bill. The intent is to support legislation that would remove industrial hemp from the CSA. This would not only provide Universities with the clarity needed to continue pursuit of current Department of State Agriculture pilot programs without fear of prosecution, but would open the doors to all research with industrial hemp. COGR will update the membership regarding the status of H.R. 5485 when the vote on the hill occurs. Contact Jackie Bendall at jbendall@cogr.edu for more information on this topic. To read COGR's letter, click here.