COGR
Council On Governmental Relations
An Association of Research Institutions

December 20, 2018

TO: COGR Membership

FROM: COGR Staff

SUBJECT: December 2018 Update

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Farewell and Good Luck Tony!

This is the last COGR Update produced under the leadership of Tony DeCrappeo. Tony joined COGR in 1995 as a staff associate, leading both the RCA and Costing Committees at different times during his COGR tenure, and became COGR President in August of 2005. From a COGR staff perspective, he has provided wise counsel and guidance throughout his term as President of COGR. The recognition and respect that COGR receives among the higher education associations in Washington is due in no small part to Tony's influence and leadership. This has allowed COGR to be an important organization with an esteemed voice in the research world. While we are looking forward to Wendy Streitz serving as our President, we will miss Tony both as a friend and mentor. We wish him nothing but the best as he embarks on his new life on the "Other Coast" and a well-earned retirement.

The COGR F&A White Paper To Be Released in January

The COGR F&A White Paper will be released in January. The stated goal of the paper is to provide a basis for productive discussion so that research funding debates are no longer diverted by nonproductive disagreements over caps on F&A cost reimbursement and misunderstandings about what is covered in the F&A cost rate. The paper addresses equitable reimbursement of F&A costs, how the F&A cost rate works, misunderstandings and myths, and other related topics. The paper is clear about the importance of how a reliable F&A reimbursement policy is critical to the continued success of the research enterprise of the United States, while also providing a strong educational foundation for understanding how the current system works and exploring potential improvements.

The following chapters underpin the paper:

Chapter 1. BRIEF HISTORY
Chapter 2. F&A FOR "NON-ACCOUNTANTS"
Chapter 3. F&A "NUTS AND BOLTS"
Chapter 4. OVERSIGHT AND AUDIT
Chapter 5. POLICY & SPECIAL TOPICS
Chapter 6. FACTS AND MYTHS
Chapter 7. THE CAP AND BURDEN
Chapter 8. WHY THE SYSTEM WORKS
Chapter 9. ALTERNATIVE SYSTEMS
Chapter 10: IMPROVING THE SYSTEM

The paper will be a memorial to a wide variety of F&A issues; with the hope that it will be a longstanding resource to the research community, as well as an advocacy-piece that can be used when F&A (inevitably) comes under scrutiny (again) in the future. We will keep the Membership updated on the release date and how to obtain the paper.

Blockchain Technology

As we shared in the October Meeting Report, COGR is listening to the growing buzz around "Blockchain Technology." The Federal Government is taking notice, as well. While COGR still is learning details about the practical application of this technology, in its simplest form it is described as the "next internet." The promise of

blockchain technology is in its facilitating of financial transactions, plus the enhanced security behind these transactions, via a peer-to-peer paradigm that effectively eliminates the third party entity. In fact, practical applications already exist in fields such as the music industry, which introduces a stronger model of intellectual property protection. At the invitation to COGR by at least one federal agency, COGR expects to start engaging with federal leaders and "getting smarter" in this area. Several interesting TED Talks are available on the Blockchain Revolution website, sponsored by Don Tapscott & Alex Tapscott, and we encourage you to contact COGR staff if you have experience in Blockchain Technology.

Cloud Computing and F&A

In 2015, COGR for the first time reported that the treatment of cloud computing costs and application of F&A to these costs was of concern to select federal agencies, as well as to investigators at our institutions. At the time, it seemed an isolated discussion. Rather than opening the discussion to a broader discussion around the definition of Modified Total Direct Costs (MTDC) and the corresponding applicability of F&A, COGR leadership concluded the best strategy was to "pay attention." The issue recently was raised again, this time in the form of an NSF Program solicitation, NSF 19-510, which prohibits the application of F&A to cloud computing costs. As these costs normally are included in our MTDC research bases, prohibiting the application of F&A to these costs prompts the concern. We encourage the Membership to share any experience or concerns related to this topic, and as appropriate, COGR will engage further.

OMB Compliance Supplement for 2019

The 2018 Compliance Supplement (CS) was released as a "skinny" CS (251 pages) and included only significant updates to applicable sections. Early in 2019, we expect OMB to share with COGR a draft version of the 2019 Compliance Supplement, which should be a return to the full and complete version of the CS. We will keep the Membership posted on all developments.

NSF Sexual Harassment Frequently Asked Questions (FAQs)

COGR has been working closely with NSF to communicate questions of concern and/or clarity regarding NSF's new reporting term and condition on Sexual Harassment that became effective October 21, 2018. On December 4th, NSF disseminated a revised set of Frequently Asked Questions (FAQs) regarding NSF's Award Term and Condition Entitled, "*Notification Requirements Regarding Sexual Harassment, Other Forms of Harassment, or Sexual Assault*". The revised set included the addition of sixteen (16) additional FAQs. The COGR membership was immediately alerted of new FAQs via the COGR listserv. Several of you wrote to say that you felt that FAQ #21 and FAQ#26 \ seemed to contradict one another.

> "*21. If a PI/co-PI receives a new NSF award after a final determination of a finding of harassment (determination made after 10/22/18 but prior to award) and remains at the institution, are there any NSF notification requirements? Yes. If the PI/co-PI had a final determination of a finding of harassment, or if there has been any imposition of administrative leave/administrative action made after 10/22/18 but prior to the new award, NSF should be notified within 10 days of the receipt of the new award."*

> *"26. Title IX officers were given instructions that for new awards there should be a look back for one year to report any administrative actions or findings from before the award period began. In the Federal Register the only reporting trigger is a new action or finding. Please clarify. The reporting requirement covers conduct of a PI or co-PI that occurred prior to the effective date of October 22, 2018 of the new notification term and condition, if the finding/determination or imposition of administrative leave/administrative action occurs after the term and condition became effective and if the award on which the individual is the PI or a co-PI is subject to the term and condition. The new notification term and condition will apply to new awards and any funding amendments made on or after the effective date of the term and condition."*

RCA reached out to NSF, citing our understanding that **we only need to report harassment findings/interim actions that are issued on or after we receive a new award containing the new Sexual Harassment term and condition. Specifically, there is no obligation to "look back" at findings/interim actions previously issued.** NSF subsequently removed the above-listed FAQ #21 and has replaced it with a placeholder that promises a future update. Stay tuned for additional updates. Any additional questions regarding the term and condition should be submitted to sexualharassmenttandc@nsf.gov or contact Jackie Bendall at jbendall@cogr.edu.

Reminder on Prior Approval Requirement for change in Principal Investigator (PI)/Project Director (PD)

We have been alerted by NSF that there has been an uptick with some COGR member institutions mistakenly believing they can unilaterally substitute/replace a PI without first obtaining written NSF approval, and that they are authorized to take unilateral action under the sexual harassment policy requirements. As a courtesy to NSF, COGR sends this message as a reminder that the prior approval requirement for a change in PI/PD as cited in the Prior Approval Matrix, Appendix A to the Research Terms and Conditions remains unchanged.

Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH, NOT-OD-19-020 ("Guide Notice")

As reported in our previous update, COGR is aware that many members are concerned about the October 17 Guide Notice (NOT-OD-19-020), Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH (the "Guide Notice"). The Guide Notice, requires reporting to NIH when the institution "suspects" research misconduct that "might impact the conduct of an NIH-supported project," or "suspects" that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research. In response to your concerns, COGR, along with Association of American Medical Colleges (AAMC), and the Association of Research Integrity Officers (ARIO) submitted a joint response to Dr. Michael Lauer, Deputy Director of the Office of Extramural Research at the National Institutes of Health (NIH). The authors convey concerns of reporting mere "suspicion" of research misconduct citing the likely potential of litigation related to irreparable reputational damage to institutions, students, postdocs, investigator(s), etc., including the protection of confidentiality and due process under the law. Click here to read more on this subject. Updates will be furnished to the membership once they become available.

Request for Information (RFI) on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research

On October 10, 2018, the National Institutes of Health (NIH) issued a Request for Information (RFI) NOT-OD-19-014 in the NIH Guide to Grants and Contracts to solicit public input on proposed key provisions that could serve as the foundation for a future NIH policy for data management and sharing. The feedback received will be considered for use in the development of a new draft data sharing policy replacing the current NIH policy. In response to the RFI, COGR signed onto a joint memo with the Association of American Universities (AAU), and the Association of Public Land Grant Universities (APLU) that expands on information obtained from the November 2017 AAU and APLU report and a recent NSF-funded workshop in October 2018 on Accelerating Public Access to Research Data. The recommendations in the memo make mention of the need for additional NIH funded workshops or venues for agencies and institutions to discuss better and new ways to collaborate, building upon the current momentum generated to date, the need for NIH to provide standards for data and metadata to ensure data is reproducible and user-friendly, the need for clarity when a researcher or university is responsible for compliance with the data management plan *after the grant has ended,* additional clarity associated with budgeting "reasonable costs" in proposal applications to make data publicly accessible, and finally the need for federal-wide agency harmonization of data elements and plans. To read more about the memo and our request for a two-year implementation period for new policy changes, click here.

Human Subjects Research

HHS Review of Fetal Tissue Research and NIH Funding for Alternatives

The Department of Health and Human Services (HHS) issued a statement on September 24, 2018 indicating that HHS will conduct a comprehensive review of federally funded fetal tissue research following concerns about a recent FDA contract involving fetal tissue. Per the statement "HHS is now conducting an audit of all acquisitions involving human fetal tissue to ensure conformity with procurement and human fetal tissue research laws and regulations. In addition, HHS has initiated a comprehensive review of all research involving fetal tissue to ensure consistency with statutes and regulations governing such research, and to ensure the adequacy of procedures and oversight of this research in light of the serious regulatory, moral, and ethical considerations involved. Finally, HHS is continuing to review whether adequate alternatives exist to the use of human fetal tissue in HHS funded research and will ensure that efforts to develop such alternatives are funded and accelerated."

As part of its review, HHS began holding listening sessions to hear from the community on the topic of research involving fetal tissue. A meeting held on November 16, 2018 included the American Society for Cell Biology, the Federation of American Societies for Experimental Biology, the Society for Neuroscience, and the International Society for Stem Cell Research. COGR participated in a November 30, 2018 meeting involving higher education associations, including AAU, APLU, and AAMC. Representatives from the associations and scientists from member institutions highlighted the continued need for this research and the lack of viable alternatives for some research. Groups opposed are pushing HHS to end the roughly $100 million in NIH funding used for research involving fetal tissue.

On December 10, 2018 NIH released a Notice of Intent to Publish Funding Opportunity Announcements for Research to Develop, Demonstrate, and Validate Experimental Human Tissue Models that Do Not Rely on Human Fetal Tissue (NOT-OD-19-042) which would fund $20 million in research on alternatives over the next two years. The House Oversight Committee's Subcommittees on Healthcare, Benefits and Administrative Rules, and Government Operations held a hearing on December 13, 2018 on Exploring Alternatives to Fetal Tissue Research. The hearing included testimony both for and against the use of, and need for, fetal tissue research. Finally, HHS conducted a workshop at NIH on Recent Advances and Opportunities in the Development and Use of Humanized Immune System Mouse Models on December 18, 2018. The workshop agenda included models using fetal and non-fetal tissue and challenges, limitations and optimization of current models.

Research Regulatory Reform

NIH OLAW Draft Report on Reducing Administrative Burden in Animal Care and Use

In a Federal Register Notice and blog dated December 7, 2018, NIH requested comment on a draft report by the "21st Century Cures Act Working Group on Reducing Administrative Burden to Researchers for Animal Care and Use in Research." The working group includes representatives from NIH, USDA, and FDA.

The draft report is the result of a review by federal agencies to ensure that regulations and policies associated with research with laboratory animals are not inconsistent, overlapping, or unnecessarily duplicative and to improve the coordination of regulations and policies as directed by the 21st Century Cures Act. Agency representatives conducted a series of listening sessions and published a request for information in March 2018. Agencies also reviewed related publications. Among the work cited is the October 2017 report by COGR, the Federation of American Societies for Experimental Biology (FASEB), the Association of American Medical Colleges (AAMC), and the National Association for Biomedical Research (NABR), *Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden*. The draft federal report, *Reducing Administrative Burden for Researchers: Animal Care and Use in Research*, addresses a number of recommendations from the COGR-FASEB-AAMC-NABR report and submitted in response to the RFI, among them:

Protocol Review. NIH "plans to review and update the guidance on non-pharmaceutical grade compounds to further clarify the options for IACUC review." Further, "USDA will propose, through notice and comment rulemaking, a regulatory change to "remove the requirement that IACUCs conduct 'continuing reviews of activities covered by [the Animal Welfare Act] at appropriate intervals . . . but not less than annually,' and, instead, insert a requirement that IACUCs conduct a three-year de novo review of activities."

Reporting. "NIH OLAW and USDA plan to allow annual reporting to both agencies on the same reporting schedule. The agencies will explore the development of a single reporting portal." Further, "NIH OLAW plans to review the guidance in NIH Guide Notice NOT-OD-05-034 on reporting requirements to refine and update examples of reportable situations, examples of situations not normally reported, the timeframe for reporting, and the information to be reported. Provision of the grant number in the noncompliance report will also be reevaluated."

Guidance on Federal Standards. "NIH OLAW plans to provide a minimum of 60 days for comments regarding significant policy guidance" and "plans to review its disclaimer concerning current guidance to emphasize that 'unless specific statutory or regulatory requirements are cited, the guidance should be viewed as recommendations in that an institution may use an alternative approach if the approach satisfies the requirements of the PHS Policy.'" Similarly, USDA will "include a statement in its policy manual to explain that such policies are clarifications or interpretations of the AWA and Animal Welfare Regulations, which are the only legally binding requirements."

Agency Harmonization. The report indicates that NIH and USDA plan to engage with DOD and the VA about options for harmonizing requirements to reduce administrative burden. Regarding training and resources, NIH "in coordination with USDA will support the continued development of industry-led training and resources"; "continue to support the efforts of the IAA to create a repository of IACUC best practices"; and "continue to support the efforts of the FDP members to create CUSP as a repository of best practices for standard procedures used for research with animals." NIH will also "consider updates to simplify its sample animal study protocol form." Regarding inspection, no changes were proposed. The report suggests that the both the PHS policy and the USDA allow "flexibility in how and by whom the inspections are conducted" and that the agencies "plan to develop guidance to address existing flexibilities."

Appendix 1 of the draft report offers an analysis of findings from reports, communications and surveys, as well as proposed actions that are not included in the main report. As indicated in the appendix, NIH and USDA "plan to review and develop resources to support IACUCs' use of existing options that streamline protocol review and significant changes to approved protocols without compromising animal welfare." Regarding recommendations that USDA amend the language of Policy #12 for literature searches to be consistent with the AWA and Animal Welfare Regulations and that Policy #14 be modified to allow multiple operative procedures at the discretion of the IACUC, the report indicates that "The policy manual was removed from the USDA website in July 2018, and the policies are inoperative, while USDA conducts a review to ensure conformity with the AWA and Animal Welfare Regulations; harmonize with NIH OLAW guidance; and reduce investigator burden where possible. USDA will make any revised and future policies involving the use of animals in research, teaching, testing, experiments, or surgery available for public comment using regulations.gov or a similar service." Appendix 2 notes that multiple survival surgeries are already allowed under certain conditions.

The report indicates that "NIH and USDA agree that review of a research project or evaluation of a program or facility by more than one recognized IACUC is not a federal requirement. IACUCs may choose which IACUC will review protocols for the animal activities being conducted. NIH Grants Policy Statement on Written Agreements (NIH GPS, chapter 15.2.1) requires that awardees have a formal written agreement with consortium participants that addresses the negotiated scientific, administrative, financial, and reporting requirements of the grant." Additional details of interest are included in the appendix 1. Appendix 2, provides an analysis of RFI comments that agree or disagree with what was proposed along with proposed actions that are largely described in the body of the draft report and appendix 1.

Among the approaches not adopted were proposals to consolidate agency oversight into a single agency, and a single set of guidelines such as the Common Rule for research with human participants. NIH also rejected the recommendation that the agency eliminate the PHS requirement for compliance with the National Academies

Guide to the Care and Use of Animals and instead use it as a best practices document, and to not enforce "Should" statements in the *Guide* as "must" statements. NIH OLAW suggested that such a change would negatively impact animal welfare and that the burden is due to risk aversion on the part of institutions. Per NIH OLAW, "There is flexibility with the use of performance standards, and NIH OLAW's guidance offers flexibility for professional judgment at the institution for "should" statements in the *Guide*." NIH OLAW also did not agree with the recommendation to eliminate the requirement for protocol and grant congruency, a change that NIH is making with respect to research with human participants in compliance with the implementation of the revised Common Rule.

Comments on the draft report are due on February 5, 2018 and must be entered into a text box (it does not provide for document uploads). COGR will be submitting comments and will distribute them to members in advance of the deadline. COGR and other associations will also ask NIH to increase the current 900-word limit on comments.

National Science Board November 28-29 Meeting - Update on NSF Efforts to Reduce Burden

The National Science Board (NSB) met on November 28-29, 2018. The meeting agenda and links to the archived webcasts can be found here. The NSB oversight committee reported on a number of topics including the NSF OIG Semiannual Report to Congress (see the section of this COGR update on audit) and NSF management's response.

Also discussed were the NSF OIG's report on Management Challenges for the National Science Foundation in Fiscal Year 2019. Among the challenges are Ensuring the Ethical Conduct of Research. Fae Korsmo, a Senior

Advisor in the Office of the Director, and Fleming Crim, Chief Operating Officer, NSF, joined the committee to discuss actions that NSF has taken to address this challenge. The discussion was framed in terms of facilitating the responsible conduct of research while not taking such an expansive view of the issue that the agency creates significant administrative burden. Dr. Crim mentioned that the agency, though the latest version of the PAPPG, is encouraging, not requiring, RCR training for faculty. The agency will also hold a promising practices summit next year. One board member called for agreement on where there can be common policies and practices which should be led by OSTP.

The discussion on RCR and efforts to avoid increasing administrative burden to the extent possible, led into a discussion on NSF's efforts to reduce administrative burden in response to the 2014 NSB report, *Reducing Investigators' Administrative Workload for Federally Funded Research*, and related efforts including Renewing NSF, NSF's work with the Federal Demonstration Partnership, and the efforts of the Research Business Models subcommittee of the National Science and Technology Council for which NSF is a co-chair. The May 25, 2018 RBM report was mentioned, including a central certification and assurance repository that is nearing completion. On subrecipient monitoring, it was suggested that it is a risk-based approach left to the institutions but that there are still a lot of questions. The NSTC/RBM will look at the Uniform Guidance again and make sure it is clear; that there are no questions or that institutions are doing things wildly differently. Specific to NSF, preproposal pilots and no deadline pilots for proposal submission continue as does automated checking of applications. A simplified proposal submission process via Research.gov is underway.

Updated COGR Research Regulatory Reform Matrix

COGR had previously published a matrix highlighting sections of the 21st Century Cures Act, the American Innovation and Competitiveness Act, and the FY17 National Defense Authorization Act, that address research regulatory reform. We have recently posted an updated matrix to the COGR website. The matrix includes areas targeted for reform, statutory requirements, and subsequent actions by executive branch agencies and offices to address the requirements. COGR will continue to expand and update the matrix as new information becomes available.

NIH Advisory Committee to the Director Meeting Sessions on Foreign Influence and NGRI

Foreign Influences on Research Integrity Working Group Report

The NIH Advisory Committee to the Director (ACD) met on December 13-14. The meeting agenda, archived video casts, and meeting presentations are available here. Among the items on the agenda were the Foreign Influences on Research Integrity Working Group Report. We previously reported that Dr. Collins announced the working group at a Senate hearing in August. The working group's charge and roster, consisting largely of university presidents and NIH personnel, can be found here.

Roy Wilson, co-chair of the working group, identified three broad themes that have emerged, undisclosed foreign financial conflicts/conflicts of commitment, peer review violations, and diversion of intellectual property. Dr. Wilson stressed the importance of foreign nationals to the U.S. scientific enterprise. In terms of failure to disclose, breaches of peer-review, and diversion of IP, he suggested that while there have been a relatively small number of occurrences when considering the context of the larger research ecosystem, they are nevertheless systematic and significant and need to be addressed. The working group presentation and report are available on the ACD webpage. Recommendations were made both with respect to NIH and recipient organizations.

Recommendations for NIH:

- "Conduct a broad education campaign to raise awareness about the need to disclose other foreign support, international affiliations, international collaborations, and financial interests";
- "Re-evaluate existing policies and forms and to expand the requirements and make the requirements explicit as to what must be reported as other support";
- "Expand current regulatory approach concerning conflicts of interest to expressly account for interest in which no financial remuneration is indicated but which overlaps with scope of NIH award";
- "Collaborate with the Office of Research Integrity or appropriate oversight authority to determine if and when material nondisclosures to the NIH regarding funding (and overlap in effort) should be considered as research misconduct";
- "Reexamine and consider clarifying the ownership of NIH grant-funded research data, to make clear that these non-commercialized data, resources, and tools are the property of the recipient organization"; and to make changes to mitigate risk in peer-review.

Recommendations for Recipients:

- "Implement a broad education campaign about the needs to disclose other foreign support as part of disclosure processes for NIH, and international affiliations, international collaborations, and financial interests to home recipient organization";
- "Discuss how to safely host laboratory and VIP medical visits which can be potential entry points for unwanted information gathering";
- "Initiate pre-travel 'safety briefings' to educate investigators and encourage precautions for international travel";
- "Assess the physical, technical, and administrative controls frameworks employed by Recipient Organizations that host foreign scientists for the risk of data misappropriation and exfiltration";
- "Examine the robustness of their internal processes to identify potential breaches";
- "Vet potential employees prior to hiring through unclassified searches, review of any agreements they have with businesses, organizations, and institutions; check their FCOI and conflicts of commitment";
- "Develop review and adjudication processes that are appropriate for examining potential misconduct related to foreign influences";
- "Implement systematic audits to ensure FCOIs and conflicting commitments are accurately reported";
- "Develop a list of 'flags' that may trigger a university to conduct an audit, particularly if inconsistent with funding";
- That institutions should "Always proactively notify NIH about peer review violations and inaccurate or undisclosed foreign support or affiliations with outside organization."

See the report and presentation for full recommendations. COGR will continue to engage with NIH on this issue and with respect to the working groups recommendations.

Next Generation Researcher Initiative Working Group Report

The ACD meeting also included recommendations from the NextGen Working Group. The working group charge and roster can be found here. The working group made a number of recommendations, most prominently, maintaining the current early stage investigator (ESI) length at 10 years; discontinuing the "Early Established Investigator (EEI)" term and introducing the definition of "at-risk" applicants. The working group recommended expanding pathways for funding ESIs through programs that do not require preliminary data; "Separate review, comparison and scoring/percent ling of ESI applications, grouped during the initial discussion in Study Section"; "Funding ESI investigators on R01-equivalent applications for at least 5 years"; "Increasing the gradient of post-doctoral support levels after 5 years"; ensuring diversity in all funding opportunity announcements; "Requiring institutions to provide professional development and training plans for mentors and trainees"; "establishing a formal analysis plan for evaluating the impact of NGRI and early-career investigator programs," and for assessing disparities across ICs. The presentation and report also include recommendations for the broader biomedical research community.

One recommendation that resulted in a lot of discussion at the end of the meeting was that NIH "conduct, within one year, a detailed analysis of salary support derived from NIH grants, updating the 2007 study on this topic." There was a lot of discussion on the reliance of NIH funds for salary and about NIH limiting the amount of

salary support provided, but also some concern expressed about unintended consequences (e.g., fewer investigators).

NIH Financial Conflict of Interest (FCOI) Training

NIH announced the release of a new Financial Conflict of Interest Training Module on December 3, 2018 that institutions can use to satisfy FCOI training requirements. Information and a link to the training module can be found here.

Audit

HHS OIG Audit Report on Subrecipient Monitoring

The HHS OIG recently published an audit report on subrecipient monitoring at a COGR member institution. The report suggests that the institution "did not always conduct a risk assessment on its affiliates and FDP member organizations." The report indicates that in fiscal years 2015 and 2016, the institution "categorized the affiliates and FDP member organizations as low risk solely because…institutional experience with these organizations was positive, and Federal awarding agencies had made awards to the organizations. Additionally, although required under 45 CFR part 75, [the institution] did not always perform risk assessments of subrecipients that were issued initial subawards before December 26, 2014, but received incremental funding after December 26, 2014." Per the report "Neither Federal statutes, regulations, nor the terms and conditions of subawards permit prime Federal award recipients to exempt affiliates, FDP members, or subrecipients from a risk assessment." The institution concurred with the recommendations.

HHS and NSF OIG Semiannual Report to Congress

The fall 2018 HHS OIG Semiannual Report to Congress, under NIH, includes overstated chilled water costs in an institution's facilities and administrative cost proposal. The OIG suggests that the costs were not in accordance with federal requirements and that the negotiate rate was therefore inflated by 1% for a three-year period and that the institution received as much as $5.9 million in overpayments. The institution acknowledged the overstated costs but disputed the amount. The report also notes that NIH's Division of Financial Advisory Services "did not always establish final indirect cost rates for applicable organizations in accordance with Federal requirements during our audit period." NIH disagreed with the OIG's recommendations.

Under fraud investigations, the report includes $1.32 million in recovered costs at one institution. The report indicates that an Institute improperly applied the institution's indirect cost rate and that the institution improperly retained and used program income generated from a Center on an NIH grant. The report also indicates that the institution "mischaracterized costs related to equipment and depreciation resulting in the calculation of an erroneous indirect cost rate which was applied to certain Federal awards."

The NSF OIG Semiannual Report to Congress was submitted in follow-up to the November 28-29 National Science Board meeting. The report includes awardee audits, primarily of institutions, with $908,000 in questioned costs. The report also includes audit resolutions but reports only the sustained (not questioned) costs.

Regarding desk reviews of 47 single audit packages, the report indicates that 37 (79 percent) fully met Federal reporting requirements. Those that did not meet requirements were not submitted timely; contained omissions

from the Schedules of Expenditures of Federal Awards; inaccurate data collection forms; and incomplete corrective action plans or omissions of required language.

Investigations reported include a university that agreed to settle (False Claims Act) "allegations that it failed to maintain a time and effort system capable of ensuring that salary costs were charged correctly and appropriately to various grants." "The settlement with DOJ required the university to pay more than $1.7 million." A university research foundation also settled with DOJ and "agreed to pay more than $700,000 to resolve allegations of misuse of funds in awards from several Federal agencies." Per the report "The matter originated as a qui tam legal proceeding against the research foundation alleging: improper supplemental salary payments to researchers; violation of salary caps; violations of NSF's 2-month summer salary rule; improper charging of administrative salaries; inadequate time and effort compliance; internal cost sharing noncompliance; and other miscellaneous issues."

The report also includes an investigation of concurrent overseas employment that was not disclosed. The report indicates that an investigator took two extended overseas absences "without providing the required advanced notice to NSF." The investigator "was on unpaid leave from the university but held concurrent employment overseas, the latter of which was not disclosed to NSF." The award was voluntarily suspended by the institution and more than $50,000 was returned. Per the report, the investigator is no longer employed with the institution.

NSF Audit Resolution

Audit resolution for an institution with questioned costs of $111,516 resulted in $15,634 being allowed. The institution was required to pay the remaining $95,882 in questioned costs on equipment and materials purchased near award expiration, indirect costs, participant support, and "unallocable transactions."

Commerce/BIS Issues APRM on Emerging Technologies Controls

On November 19 the Commerce Bureau of Industry and Security (BIS) issued an Advanced Notice of Proposed Rulemaking (ANPRM) on *The Review of Controls on Certain Emerging Technologies* (83 FR 58201; https://www.gpo.gov/fdsys/pkg/FR-2018-11-19/pdf/2018-25221.pdf).

The notice is pursuant to the Export Control Reform Act (ECRA) of 2018 included in the FY'19 NDAA (see COGR September Update). That Act (Sec. 1758) called for an interagency process to identify and regulate emerging critical technologies. The process is to be informed by a number of sources, including public comments which are sought in the ANPRM and the Emerging Technology Advisory Committee. The process is to consider a number of factors such as the development of these technologies in foreign countries and the effect export controls may have on their development in the U.S. as well as the effectiveness of export controls in limiting proliferation. Once the technologies are identified, BIS will propose specific controls. A separate ANPRM on identification of "foundational" technologies is planned.

The ANPRM describes representative technology categories from which BIS will determine more specific technologies warranting controls. The technology categories represented in the ANPRM are very broad (e.g. biotechnology such as nanobiology, synthetic biology, genomic engineering; artificial intelligence and machine learning such as neural networks, computer vision, speech and audio processing, etc.). The ANPRM asks for public comments on seven subjects: 1) how to define emerging technologies for these purposes, 2) criteria to

determine specific technologies important to U.S. national security, 3) sources for identification, 4) other general technology categories warranting review, 5) status of development of these technologies, 6) impact of controls on U.S. technological leadership, and 7) other approaches to identifying technologies. Comments were due December 19.

The ANPRM states that Commerce is not seeking to expand jurisdiction over technologies not subject to controls, such as fundamental research. However, the technology categories listed in the ANPRM potentially could encompass much if not most of the research conducted at our member institutions. Because of the complex and very technical nature of this topic, COGR joined with other higher education associations in requesting an extension of the comment deadline (memo posted on COGR website). Industry groups also requested an extension. On December 14, BIS extended the comment period until January 10, 2019 (83 FR 64299).

COGR is discussing possible comments with other higher ed. associations including AAAS and the Association of University Export Control Officers (AUECO). While some of the questions for which BIS is seeking involve policy considerations, others require highly technical responses. AUECO is planning to submit substantive comments. AUECO has not finalized their comments, but they may express concerns about the potential impact on the ability of universities to conduct cutting edge research on early stage technologies, and the importance of maintaining the existing definition of "fundamental research." We share these concerns and may join in or endorse the AUECO comments.

Due to the substantial potential impact of increased controls in these technology areas, **we highly encourage COGR member institutions to submit their own individual comments**.

NIST Issues Draft ROI "Green Paper"

On December 6 NIST released a draft "Green Paper" report on the Administration's Return on Investment Initiative (ROI) that was announced earlier this year. COGR submitted extensive comments and recommendations jointly with other higher ed. associations in response to the ROI RFI. The comments are posted on our website, and were summarized in the September Update.

We are very pleased to report that in the draft "Green Paper" (NIST SP 1234) NIST has responded positively to many of our comments and recommendations. The Intended Actions in the Green Paper include many that we had recommended. These include defining the scope of the government use license and clarifying the proper statutory uses of the "march-in" rights provided by the Bayh-Dole Act; streamlining the waiver process for the U.S. manufacturing requirement and providing a single government-wide point of application; allowing for the limited use of federal research funds for intellectual property protection; implementing harmonized government-wide requirements for managing conflicts of interest involving recipients of federal R&D funding; and establishing a modernized platform for reporting data on intellectual property resulting from federal R&D funding with consistent government-wide reporting requirements. These actions address serious concerns in the current system. If implemented, they would have a direct positive impact on technology transfer at our institutions.

Certain other matters we had raised also are the subject of Intended Actions. These include establishing and expanding government-wide technology entrepreneurship programs, such as the highly successful NSF I-Corps

program, and streamlining partnership agreements for collaborations with federal laboratories. In a number of cases NIST plans to refer our recommendations to other agencies. These include concerns with the America Invents Act, including Patent Trial and Appeals Board Proceedings, the grace period, and the scope of patent eligible subject matter, which NIST will refer to the U.S. Patent and Trademark Office. NIST will refer the issue of the need for more flexibility in the use of SBIR/STTR funds to the Small Business Administration. Finally NIST will refer the suggestions received from us and others to appropriate policy-making bodies with regard to changes in the tax code and tax incentives.

We plan to provide feedback to NIST applauding these Intended Actions. However, we also plan to raise a few concerns related to the discussion of new partnership mechanisms in the Green Paper. Of particular concern is the recommendation that new Research Transaction Authority agreements be established modeled after Other Transaction Authority (OTA) agreements. The Paper makes a number of questionable assertions regarding the benefit of OTAs. COGR member institutions have found them somewhat troublesome and often requiring extensive negotiation.

The deadline for feedback is January 9, 2019.

Discussions on Drug Pricing Legislation Continue

We have discussed in recent COGR updates and meeting reports potential legislation that would address drug pricing concerns in ways that might threaten university intellectual property rights. The October Meeting Report discussed a House bill (H.R. 6505) introduced by Rep. Doggett (D—TX) with many Democratic co-sponsors that would provide for compulsory licensing of patented drugs when negotiations by HHS over the price under Medicare D are unsuccessful.

On November 28 COGR, AAU, APLU and AAMC representatives met with Rep. Doggett and his counsel. In the meeting we emphasized that our institutions are important stakeholders at both the upstream and downstream ends of the drug development process. Upstream we have an interest in assuring our discoveries and inventions achieve public use and benefit through licensing them to the private sector for further development. Intellectual property protection is essential in this process. However many of our institutions have medical schools and health science centers that are major consumers of prescription drugs. We thus have a shared interest in finding ways to reduce their price.

Rep. Doggett indicated his understanding of the need to protect innovation. He invited us to submit suggestions to improve the current bill. In further discussion with his counsel we pointed out some of the practical difficulties with the bill's approach. As an example university patent holders have no role in drug pricing and would have no involvement in the price negotiations with our licensees, but if unsuccessful our patents would be substantially devalued if subject to compulsory licensing. Another example is drugs with multiple patent holders.

Separate legislation was announced last month by Sen. Sanders (I—VT) and Rep. Khanna (D—CA) The Prescription Drug Price Relief Act of 2018 would require HHS to list annually "excessively priced" patented drugs that are sold in the U.S. at prices higher than the median price in several other Western countries. HHS also would be authorized to make an excessive pricing determination based on other factors. If an excessive price determination is made, HHS would be empowered to waive any exclusive rights granted to the manufacturer and grant compulsory licenses. Reasonable royalties would be paid to the original patent holder.

A common feature of both pieces of legislation is the patent-based remedy for pricing violations. Rep. Doggett indicated that it is not clear what exact legislation the incoming House Democratic majority would back, but

that it would be a major priority in the new Congress. From our discussions it is clear that a patent-based approach is likely to be the focus.

We have been extensively discussing this issue with the other associations. Clearly there is a risk to university patent rights. However this involves a highly sensitive political issue. We do not believe universities should have high visibility in this process. The Doggett bill does not involve Bayh-Dole march-in rights but rather is based on the patent "eminent domain" statute (28 USC 1498). It applies to all patents and does not constitute a unique risk to university patents. At this time we do not see a benefit in engaging in detailed discussions with Congressional staff on the text of specific bills. We plan to continue to closely monitor the situation and provide feedback if asked.

Science and Security Developments on Chinese Influence

Hoover Institution Offers Recommendations on Chinese Influence

A group of 32 well-known scholars produced a report that was released on November 29, 2018 on *Chinese Influence & American Interests: Promoting Constructive Vigilance*.

The report proposes three broad principles that should "serve as the basis for protecting the integrity of American institutions inside the United States while also protecting the basic core of American values, norms,

and laws." Embedded within the three principles of transparency, integrity, and reciprocity are a variety of reforms and actions for consideration by the U.S. government and various institutions like universities, think

tanks, and the media. A series of recommendations are addressed to universities (Sec. 4). They include promoting the transparency of Confucius Institutes, applying stricter due diligence procedures to gifts and contracts from China, defending academic freedom in transactions involving China, greater risk awareness of inappropriate influences and loss of intellectual property, and promoting reciprocity in U.S.—China academic exchanges.

The report has received some press attention.

Senate Judiciary Committee Holds Hearing on Chinese Influence

On December 12 the Senate Judiciary Committee held a hearing titled *China's Non-Traditional Espionage Against the United States: The Threat and Potential Policy Responses.*

Members and witnesses (the FBI, Department of Justice, Department of Homeland Security, and experts from various think tanks) outlined a variety of efforts by the Chinese government to "supplant us [United States] as the world's superpower" through influence campaigns and the stealing of scientific research. Citing the NIH letter on foreign influence, Chairman Grassley raised concerns about the theft of federally-funded research from universities and asked the FBI if universities and government agencies were aware of these threats. Additionally, there were concerns raised about Confucius Institutes and the perceived threat they pose to academic freedom. Some senators and witnesses suggested updating the Foreign Agents and Registration Act

(FARA), including how it relates to Confucius Institutes, to better track and respond to Chinese espionage. (For more particularly on the FBI statements click here.