COGR
Council On Governmental Relations
*An Association of Research Institutions*

**March 26, 2019**

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# Cross-cutting Areas

## Foreign Influence on U.S. Research

Federal Agency Efforts to Address Foreign Influence on Research and Intellectual Property – Panel Discussion

Members of Congress, the administration, and security and research funding agencies have expressed concern about state-sponsored programs to improperly access or replicate U.S. federally funded research data and information, including proposed research, to gain competitive advantage. Dr. Michael Lauer, Deputy Director for Extramural Research, National Institutes of Health, Rebecca Kaiser, Head of the Office of International Science and Engineering at the National Science Foundation, and Thomas (T.L.) Cubbage III, Deputy Under Secretary for Science, Department of Energy, joined COGR members at the February 28-March 1 COGR meeting to discuss agency efforts to address foreign influence.

Dr. Lauer discussed the December 2018 recommendations from a working group of the Advisory Committee to the Director charged with addressing Foreign Influences on Research Integrity, and steps NIH is taking to address the recommendations. NIH is in the process of developing guidance on disclosure of foreign sources of support and contemplating possible expansion of reportable sources of funding and activities. Guidance may be issued as soon as April. NIH has been contacting institutions to follow-up on potential non-disclosure of foreign research support. Recently, we are hearing from institutions that Science Magazine has made public records requests requesting all communications relating to letters from NIH on the topic of foreign influence between August 20, 2018 (the date Francis Collins addressed the issue in a letter to grantees) and the present.

Dr. Keiser discussed several efforts to address concerns about data misappropriation and diversion of IP. The first is a study that NSF is commissioning by the JASON group, a group of scientists with security clearance that has been advising the federal government on science and security issues for several decades. The group will look at how the research ecosystem has changed and whether there are additional safeguards that should be put in place with respect to sensitive research (e.g., artificial intelligence and quantum computing). A report is expected this summer. NSF is also supporting a National Academies effort to conduct workshops across the country aimed at engaging institutions on how to protect the U.S. research ecosystem while continuing to collaborate with foreign scientists and institutions. A kickoff meeting in May is planned, with a possible convocation at the end. NSF is also looking at clarifying existing reporting requirements for other support.

Deputy Undersecretary Cubbage discussed DOE's Foreign Talent Program Policy which "mandates that DOE federal and contractor personnel fully disclose and, as applicable, terminate affiliations with foreign government-supported talent recruitment programs." The department is concerned about the illicit transfer of knowledge from DOE funded research to foreign governments. DOE federal and contractor personnel will have to disclose participation in a foreign talent program from countries of risk and choose between DOE work/funding or affiliation with a talent program. The policy is expected to be applied to grantees

later this year (a timeframe of approximately 6-12 months has been suggested). The agency is still working through implementation details, including how foreign talent recruitment programs are defined, and plans to engage institutions and higher ed associations.

Health and Human Services Activities Related to Science and Security

*HHS Inspector General Audit Plans*

The HHS OIG released audit work plans in February that include four audits that address foreign influence. The work plans reference a statement from NIH Director Francis Collins "expressing concern about the increasing risks to the security of intellectual property in its biomedical research enterprise" and noted that NIH "is addressing these concerns, in part, by taking steps to improve accurate reporting of all financial interests." The plans also note the agency's concerns about "increasing risks to the integrity of peer review, including the risk of peer reviewers attempting to influence funding decisions inappropriately." The plan notes that Congress, through report language included in 2019 appropriations bills, directed the OIG to "examine NIH's oversight of its grantees' compliance with NIH policies, including NIH efforts to ensure the integrity of its grant application and selection processes and to protect intellectual property derived from NIH-supported research."

Two separate audits involve NIH's implementation of financial conflict of interest (FCOI) regulations and monitoring of extramural researchers FCOI. The first "will determine whether NIH has policies, procedures, and controls in place for ensuring that both foreign and domestic grantees disclose all sources of research support, financial interests, and affiliations." The second FCOI-related audit looks at NIH's oversight and monitoring of FCOI reported by grantee institutions. In a third audit, the OIG will seek to determine the extent to which NIH institutes and centers (ICs) follow their grant application processes related to how scientific review groups (SRGs) "review the results of the SRGs and develop their funding recommendations for the Advisory Council." A fourth work plan describes audits at NIH's ICs to review their "pre-award process for assessing risk of potential recipients of Federal funds and post-award process for overseeing and monitoring of grantees on the basis of risks identified during the pre-award process."

*HHS Inspector General Audit of NIH Controls for Sensitive Data*

The HHS OIG published the audit report *Opportunities Exist for the NIH to Strengthen Controls in Place to Permit and Monitor Access to its Sensitive Data* on February 5, 2019. The report suggests that "NIH has not assessed the risks to national security when permitting data access to foreign PIs" and does not verify that these PIs have completed security training.

The OIG suggests that for foreign PIs with access to genomic data for U.S. citizens, NIH: "work with an organization with national security expertise and knowledge of international risk areas to assess the impact of the potential misuse of genomic data provided to foreign PIs"; develop a security framework, conduct risk assessments, and implement additional security controls; develop mechanisms to ensure that the agency's Genomic Data Sharing Policy keeps current with emerging threats to national security; and

require and verify security training and plans. NIH did not concur with the recommendation to develop a security framework or agree to verify that security training and plans were completed.

The report indicates that the same criteria are used to evaluate data access requests from domestic and foreign PIs, but that the FBI has suggested that foreign PIs could present increased risks. The OIG also "determined that NIH permitted access to genomic data to for-profit entities, including companies from China, such as WuXi Nextcode Genomics and Shenzhen BGI Technology Company (even though the FBI has identified those companies as having ties to the Chinese Government)." It suggests that "NIH officials did not consider risks related to the United States' national security by foreign PIs connected to state-sponsored activities, the presence of United States and international sanctions, or whether the PI is in a foreign country that is on a United States Government watch list." Senator Chuck Grassley has expressed concern about the findings. As we've reported in prior COGR updates, Senator Grassley has exchanged letters with NIH and the HHS OIG regarding the threat of foreign influence on U.S. research.

Department of Defense Activities Related to Science and Security

*Department of Defense Fundamental Research Policy*

The February Update discussed the apparent DOD policy changes with regard to fundamental research in SBIR/STTR contracts. COGR also has been informed by member institutions that this change may go beyond SBIR/STTR and raises doubts about continued DOD adherence to the DFARS 7000 clause fundamental research determination process and policy memoranda on fundamental research.

COGR has informally raised this issue with the DOD Basic Research Office. We were informed that the existing DOD policy remains in place. Subsequent discussion suggests that this may reflect a shift in funding objectives and portfolios with towards funding for applied research (DOD budget categories 6.2 and 6.3) rather than basic (6.1).

*National Defense Authorization Act Pilot Project*

The September Update discussed mandates in the FY2019 NDAA related to science and security. A number of initiatives are underway to address these mandates. In response to NDAA 1286, DOD is conducting a pilot project to explore the feasibility of collecting detailed information (names and unique IDs) on all participants in DOD-funded projects at universities, including non-key personnel. Six institutions have agreed to participate in the pilot which is expected to last two years. They are a mix of public and private institutions, performing both classified and unclassified research.

Little further information is available at this time as to the level of detail that might be provided, how the information will be collected, and what DOD will do with the information. One issue, particularly with the public institutions, is whether they can legally provide detailed personnel information to DOD. Another is whether security agencies can use the data to provide information that could identify potential security risks in a timely way. DOD is discussing possible participation in the pilot with DOE. COGR will continue to follow and report on the pilot as information becomes available.

Department of Education Activities Related to Science and Security

*Department of Education Reporting Requirements for Foreign Gifts*

In a letter dated January 18, 2019, six presidential higher ed. associations led by ACE wrote to Ed. requesting clarification on Section 117 of the Higher Education Act foreign gift reporting requirements. Clarification was requested on four issues: 1) whether the $250k reporting threshold relates to individual gifts or aggregate amounts received from an entity; 2) the Sect. 117 definition of "institution;" 3) whether countries or specific entities should be listed from whom gifts are received; and 4) corrective or amendment mechanisms. The letter stated institutions' concern for compliance and the need for clear guidance.

We understand that COGR member institutions are experiencing challenges with Sect. 117 reporting and are working with other higher ed. associations on follow up to the letter, including these reporting issues. We understand that Ed. plans to respond to the letter, but it is not clear that it will issue the clarifying guidance requested.

Congressional Activities Related to Science and Security

*Protect Our Universities Bill*

On March 12, Rep. Banks (R-IN) introduced the *Protect Our Universities Act* (H.R. 1678). The bill would establish a task force within the Department of Education to address espionage threats at institutions of higher education. The task force would include representatives from other agencies including DOD and DOE as well as security agencies. It would be tasked with creating a list of federally funded "sensitive research projects." Every six months, institutions where the projects are being carried out would be provided with threat and risk information. Proof of citizenship would be required for all students participating in the projects. Participation of students from certain named countries would require approval of the Director of National Intelligence, who also would be required to develop a list of entities posing an espionage risk. Assurances would be required from institutions that any technology developed by an entity included on the list is not utilized in carrying out the sensitive research project. For additional information, see the press release.

The bill follows upon a request to Ed. last year by Rep. Banks and others to establish a working group on foreign threats. The response was not viewed as satisfactory. However, Ed has no jurisdiction over university research, and the bill appears unlikely to advance. It is possible that elements of the bill might be added to other legislation. One concern is the myriad federal activities currently aimed at identifying "critical or sensitive technologies." COGR will work with other higher ed. associations in their efforts to advocate for more a more coordinated approach among the agencies and entities involved.

*Hearings on Chinese Influence and Competition*

The Senate Commerce Committee held a hearing on March 7 on *China: Challenges for U.S. Commerce*. The Senate Foreign Relations Committee held a hearing on March 13 on *A New Approach for an Era of U.S.—China Competition*. Neither hearing was particularly university-centric. A hearing also was held by the Senate Homeland Security Subcommittee on Investigations on February 28 on *China's Impact on the U.S. Education System*. Much of this hearing focused on Confucius Institutes and a related Government Accountability Office (GAO) report (GAO 19-278).

*Export Controls: GAO Undertakes New Study of University Compliance*

The GAO has initiated a new study of U.S. universities' compliance with export control regulations. The review is primarily directed toward agency policy and guidance, and mechanisms to monitor and enforce guidance. However, it also includes review of select universities' policies and security practices.

COGR and AAU representatives met with GAO staff involved in the study. Discussion centered on roles and responsibilities for export control compliance at universities and challenges that universities face. We stressed the heightened visibility of export controls at universities and the relatively recent establishment of full-time export control compliance officers at many universities. GAO staff planning to attend the AUECO annual meeting March 18-20 and arranged one-on-one discussions with a number of universities, which we encouraged. We also mentioned that COGR has developed materials and guidance on export controls for its members over the past nearly 20 years and provided a number of handouts.

One possible area of concern is that our discussion with GAO often spilled over into discussion of larger science and security issues. We repeatedly encouraged the GAO staff to maintain a focus on export controls consistent with their charge. We understand GAO plans to make site visits to ten universities to discuss challenges and the roles and responsibilities of export control compliance officers. The visits will include faculty focus groups, which may prove challenging to manage. As with most GAO studies there is no firm time line for the report. Staff indicated that they hope to complete the review within a year.

**Non-Profit Funder - Research Institution Partnership**

At the October 2017 COGR meeting a panel of non-profit funder and research institution representatives discussed an ongoing and growing partnership aimed at facilitating academic research funded by nonprofit organizations. The partnership is currently supported by COGR and the Health Research Alliance, an organization of non-profit research funders that support biomedical research. As the Nonprofit Funder – Research Institution (NFRI) partnership plans its third major meeting, COGR held a session at its February 28-March 1 meeting with university representatives who are leading efforts to address intellectual property and technology transfer, research project support costs (aka F&A) and streamlining administrative processes, for discussion of current initiatives and to further engage the COGR membership.

Streamlining Administrative Requirements Working Group

***Overview of working group*** (co-chair Vivian Holmes, Boston University: The overarching goals of the group include identifying sources of administrative burden for funders, institutions and investigators, and effective practices and guidelines to streamline requirements. Vivian also discussed progress to date, including areas of agreement and potential deliverables and ongoing activities being carried out by three subgroups.

***Application process subgroup*** (co-chair Marti Dunne, NYU): This group's efforts include expanding the Federal Demonstration Partnership Clearinghouse to include information of interest to nonprofit funders to minimize individual requests for this information; working with Altum, the developer of Proposal Central, to streamline proposal submissions; and identifying areas where funders might allow for just-in-time submission. Future efforts are likely to include coordinating eligibility criteria and applications and guidelines.

***Financial reporting and invoicing subgroup*** (co-chair Charles Greer, UC Riverside): The goals of this group include developing templates for budgets, invoicing and financial reporting; developing recommendations for financial reporting timelines; and evaluating current financial reporting practices and procedures to identify opportunities for streamlining. As part of this effort, the group will be conducting a survey of funders and institutions.

***Contracting subgroup*** (co-chair Missy Peloso, UPenn): This group's initiatives include developing sample contract language that is generally acceptable to both funders and institutions, and creating a white paper explaining the rationale for funder and institution positions on contracting issues. The group has developed a catalog of contract language in current nonprofit funder agreements received by subgroup member institutions and drafted mutually agreeable contract language in a number of areas.

F&A Cost / Research Project Support Costs Update

Cindy Hope (Alabama), Jim Luther (Duke), and David Kennedy (COGR) presented the update on the F&A Cost / Research Project Support Costs (RPSC) working group of the NFRI. The F&A Cost / RPSC working group, to-date, has identified two workstreams: 1) Education, and 2) Allowable Costs.

***The Education workstream*** has focused on education going both ways, where nonprofit funders can better understand and appreciate the research institution perspective and vice versa. A September 2018 F&A Webinar led by Jim Luther and David Kennedy has been used in the nonprofit funder community to provide an "F&A 101" orientation to how research institutions view F&A costs. Similarly, nonprofit funders are developing a series of FAQs designed to help our community better understand their perspective on F&A costs.

***The Allowable Costs workstream*** has focused on developing cost categories (e.g., administrative salaries, data processing and IT, equipment, IRB, etc.) as a means for nonprofit funders to more intentionally identify those types of costs that they are willing to reimburse as direct costs of the projects they fund.

The type of project (e.g., faculty start-up, fellowship, an NIH R01-like/traditional research project, etc.) may inform which costs the nonprofit funder is willing to reimburse. Further, identifying some types of costs (such as data processing or IRB costs) as RPSCs, may incline a nonprofit funder to be more willing to reimburse those costs as a direct cost of the project.

Reimbursement of F&A costs remains an important topic to address. Historically, and today, F&A and infrastructure support have been understood by nonprofit funders to primarily be the role of the federal government. Whereas the federal government and private industry, are normally expected to reimburse the full F&A rate, nonprofit funders limit grantee F&A cost reimbursement according to their organization's internal policies. Many of these organizations recognize F&A costs as essential to research. However, these policies may be set by the organization's Board with the premise that donors expect their contributions to fund only the direct costs of research. Expanding the definition of direct costs to recognize RPSCs may result in an opportunity to provide more equity. However, this would not dismiss the discussion that when a project functions more like an NIH R01 award, application of the full F&A cost rate should be appropriate.

Continuing education, possible development of budget templates, a closer look at funder models, and using pilots to test new reimbursement ideas all are under discussion by the F&A Cost / RPSC working group.

Intellectual Property Working Group

The Intellectual Property (IP) working group has established four subgroups:

***Royalty Sharing*** (Fred Reinhart, UMass, and John Ritter, Princeton): This subgroup is focused on establishing principles and guidelines to facilitate more effective and productive negotiations over the sharing of revenue from successful licensing of inventions. It is seeking consensus on standards, ranges, benchmarks, and possible approaches. A number of factors need to be considered, including: the amount of funding provided by the non-profit funder, the funder's efforts to facilitate commercialization, payment of patent costs, performer's background intellectual property, etc. The subgroup currently is considering various options including possible triggers for and caps on royalty sharing.

***Definition of IP*** (Alex Albinak, JHU, and Kevin Wozniak, Georgia Tech): The subgroup has developed definitions both for background and project intellectual property as well as some guiding principles related thereto. Moving forward, the group will continue to refine the guiding principles, in particular, those related to the certification of contract performers' background intellectual property and the treatment of non-contract performer intellectual property, and work to harmonize these principles with the other IP subgroups. The background IP issue has been contentious, particularly with certain funders (e.g. the Gates Foundation).

***Control of Licensing*** (Sally O'Neil, Stanford, and Jeremy Nelson, U Michigan): The subgroup is discussing control vs. communication for both pre-and post-licensing rights. Pre-license factors include

licensing strategy, choice of licensee, negotiation process, and approval/review rights. Post-license issues center around the licensee's progress and include such considerations as march-in rights.

***Patient Access*** (Felice Lu, UCOP): The subgroup is working on ways to increase the probability that licensees will serve underrepresented disease populations.

Meeting presentations can be found here. Participation is needed and welcome in any of the three working groups and nine subgroups. Contact a group lead or Lisa Nichols at COGR for more information on NFRI and participation in a working group.

Two day-long NFRI meetings are planned in 2019, the first on May 22 and the second on September 24. The meetings will be held in Washington, DC. An agenda and link to registration for the May 22 meeting will be made available soon.

# Committee Reports

### COSTING POLICIES

Committee: Cindy Hope - University of Alabama (Chair) , Joseph Gindhart - Washington University-St. Louis, Lynn McGinley - University of Maryland-Baltimore, Jeffrey Silber - Cornell University, Cathy Snyder - Vanderbilt University, Michael Daniels - Northwestern University, Michael Legrand - University of California-Davis, Sarah Axelrod - Harvard University, Nate Martinez-Wayman - Duke University, Marcia Smith - University of California – Los Angeles, Michael Moody - Massachusetts Institute of Technology, Vivian Holmes - Boston University

**The COGR F&A White Paper Release Schedule**

The COGR F&A White Paper will be made available in April. We will make an announcement on the COGR Listserv when it is available. Our plan is to:

- Make it available to the membership on www.cogr.edu
- Publish bound, hard copies and send complimentary edition(s) to each COGR institution.
- If more copies are desired, we will take orders and ask that you pay for the copies ordered, at cost.

The paper is titled ***Excellence in Research: The Funding Model, F&A Reimbursement, and Why the System Works***. It is a memorial to a wide variety of F&A issues, with the hope that it will be a longstanding educational 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 (see next section below).

The paper was completed through the active and dedicated efforts of COGR leadership and staff, the COGR Board, the COGR Costing Policies Committee, volunteers from the COGR Research, Compliance and Administration (RCA) Committee, and at-large volunteers from throughout the research community. A special "THANK YOU!" goes out to all of those who were involved in this project. We have tried to

recognize all of you in the first two pages of the paper, and if we made an oversight, please accept our apologies and we will make sure you are included.

**President's Budget Request for FY2020 and F&A**

Two years ago, the President's Budget Request (PBR) for FY2018 included drastic cuts to NIH, mostly in the form of imposing a 10 percent capped F&A rate. While the PBR for FY2019 was silent, the recently released PBR for FY2020 has revisited this topic.

The FY 2020 White House Budget is presented by OMB and contains the full overview and detail of the proposed budget. An HHS appendix includes the "small print" for NIH starting on page 19 (435). The most user-friendly read can be found on page 43 of the Major Savings & Reforms document. Below are excerpts from that document {***emphasis added in bold***}:

> The Budget proposes to reduce funding for the National Institutes of Health (NIH) to better target funding to support the highest priority and most critical biomedical research {2019 Enacted - $38.0 million; 2020 Request - $33.5 million; ***2020 Change - ($4.5) million***}
>
> In addition, NIH would take other steps to increase the impact of its resources. For example, the Budget proposes to decrease the cost of research by capping the percentage of investigator salary that can be paid with grant funds, ***and by reducing the limit for salaries paid with grant funds from $189,600 to $154,300*** …
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> … For the past two years, NIH has been prohibited by law from reducing grantee administrative costs and shifting these resources to support direct research on high impact areas, such as cancer, Alzheimer's disease, and heart disease. The Congress imposed this prohibition, which limits NIH's ability to maximize its support of direct biomedical research. ***The Budget proposes to eliminate the current prohibition,*** which would give NIH the flexibility to support more direct research while encouraging research institutions to improve the efficiency of operations.

As you know, COGR has participated in the F&A Association Workgroup (FAAWG) since 2017, when the PBR first proposed the drastic cuts to F&A. This group, which includes AAU, APLU, AAMC, AIRI, ACE, NACUBO, and COGR, remains active and we will address the PBR strategically and accordingly. While we are confident the efforts of the FAAWG from two years ago provide the foundation for blocking implementation of these measures, we will stay focused on all developments and will keep the membership updated.

**Blockchain Technology**

The COGR Costing Committee met with federal representatives from the National Science Foundation (NSF) on Wednesday, February 27th, to learn more about initiatives around blockchain technology. The NSF roundtable included NSF financial and technical leadership and gave a holistic perspective on how the federal government (with an NSF focus) was thinking about blockchain technology.

Below are some very preliminary COGR observations and next steps based on that meeting:

- Blockchain is the underlying technology and should not be considered a "product" or "deliverable" – in fact, some have called it the "next internet." Just as 25 years ago (1994) we could not have predicted exactly what the internet would be, the same may be the case on how we look at what blockchain will mean 25 years from now.

- From a strictly technical perspective, blockchain is a new way to move data across many users by eliminating the "middleman" platform, with one of the "promises" being an innovative and enhanced way to do data security.

- The actual application of this new technology is "too early to tell." However, one potential is a single federal payment method, rather than having ASAP, PMS, ACMS, etc. Another potential (though less clear) is in reinventing the grant lifecycle, which could result in a brand-new way of doing grants management.

- From the NSF perspective, "next steps" at the federal level are: 1) "socialize with the CFO community," 2) development of "proof of concept" trials and pilots, and 3) determine if there is sufficient "buy-in" across federal leaders. Implementation of blockchain technology is consistent with the President's Management Agenda (PMA), with leadership at the federal level coming from Treasury, OMB, HHS, NSF, and others. Who steps up to truly champion this is to be determined. With that said, lots of federal folks are interested and there will be some form of advancement to next steps.

- From the research community standpoint, COGR and the FDP are natural leaders and should be on the forefront. Also, MITRE has been significantly engaged with the federal government; effectively serving as a consultant / project manager to federal agencies. COGR has not directly worked with MITRE, yet, but we plan to introduce ourselves soon and see how best to engage that partnership.

Again, we emphasize the preliminary-nature of COGR observations. Still, we encourage thoughts from the membership. As COGR becomes more engaged, we want to leverage the insights of the membership

and invite you to participate if you have special interest or expertise on this topic. If you are interested or have questions, reach out to David Kennedy at dkennedy@cogr.edu.

**Cloud Computing and F&A**

We have revisited this topic from 2015 in the past several COGR Updates and at the Friday, March 1 COGR Meeting. Specifically, we addressed it in the context 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 base, prohibiting the application of F&A to these costs prompts the concern.

Based on anecdotal feedback from the membership, it appears that there are not enough dollars associated with cloud computing expenditures on federal awards to pursue this issue in the near-term. For the record, one response shared on March 1 was an approach to charge F&A when cloud computing services are purchased from an external vendor, but to waive F&A when utilized from in-house sources. COGR will consider this a back-burner issue for now, but please contact COGR staff if concerns arise.

**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. OMB is sharing with us, on a piece-meal basis, the 2019 CS (which will be a "full version" update). To date, we have reviewed and commented on Part 5, Research & Development Cluster. The most notable change seems to be that the 12 compliance requirements will be rotated on an annual basis. In other words, only 6 of the 12 will be flagged for testing in the 2019 CS. We are awaiting a draft version of Part 3, Compliance Requirements, which could address specific topics of substance such as Procurement (see below) and the Payment/Reimbursement/Documentation issue first raised in regard to the 2017 CS (see COGR Comment Letter, dated October 20, 2017). We will keep the membership posted on all developments.

**Procurement Thresholds (MPT, SAT) and Single Audit**

We are continuing to track possible concerns related to how single audit firms may be viewing the implementation of the Micro Purchase Threshold (MPT) and the Simplified Acquisition Threshold (SAT), under the Procurement Standards (2 CFR 200.317-326) of the Uniform Guidance. A preliminary auditor position in selected cases has been that because a FAR rule has yet to be implemented regarding both the MPT and the SAT, the thresholds referenced in the current version of the Uniform Guidance ($3,000 for the MPT, see 200.67, and $150,000 for the SAT, see 200.88) should be considered the applicable thresholds.

COGR disagrees with this interpretation, and further, single audit representatives seem to have a nuanced view based on conflicting information they have received from OMB. As this issue has been raised by some in the single audit community, COGR is paying attention.

The fact that the higher MPT and SAT thresholds were addressed in the National Defense Authorization Act of 2017 (MPT of $10,000) and the National Defense Authorization Act of 2018 (MPT of $10,000 and SAT of $250,000) has suggested to some that both the MPT and SAT need to be implemented via the FAR before they are "official." However, even though the FAR typically is used to implement provisions from the NDAA, because the MPT and SAT provisions of the NDAA apply to grants, implementation in the FAR may not be the decisive requirement. In effect, this has created a tension between the authority of grants guidance (i.e., Uniform Guidance and OMB memos) versus contracts guidance (i.e., FAR).

COGR understands the tension, but we are strong in our positions: 1) "the law is the law" and the NDAA of 2017 and the NDAA of 2018 are the law, and 2) institutions have definitive cover under OMB Memo M-18-18 (also see NIH Notice NOT-OD-18-219). Per OMB M-18-18:

> "In order to allow maximum flexibility for grant recipients in light of the changes to the NOAA for FY2018, OMB is granting an exception allowing recipients to use the higher threshold of $10,000 for micro-purchases and $250,000 for simplified acquisitions in advance of revisions to the FAR at 48 C.F.R."

Below are four scenarios that could be applicable to your institution. COGR has discussed these with audit leaders, and you should be absolutely "safe" on the first 3. Scenario 4, where your threshold increase is based on the OMB Memo alone, could have minor risk according to audit leaders. But again, COGR's position is that the OMB Memo is loud and clear, and in COGR's opinion, it is reasonable to rely on OMB Memo M-18-18.

1. If you have approval from HHS or ONR to be above an MPT of $10,000, you are fine.
2. If you were at an MPT of $5,000 or $10,000 (for example) prior to implementation of the Uniform Guidance, and have remained at that same level, you are fine.
3. If you increased (for example) the MPT from $5,000 to $10,000 based on the NDAA of 2017, you are fine. In this scenario, you should have "NDAA 2017" clearly documented in your internal records as the rationale for increasing.
4. If you increased the MPT to $10,000 or the SAT to $250,000 based on OMB Memo M-18-18, you should note that even though the Memo header is addressed to Federal Agencies, the Memo also is talking directly to recipients and the instructions are clear. Per COGR, precedent and decades of practice has said we can rely on crystal clear federal guidance, and in this situation, the guidance is crystal clear!

As to working with your auditors if your thresholds are questioned, COGR recommends you go through your scenario and be clear on your basis for supporting your current policy. If your auditors are not in agreement, then ask your auditors to consult their senior partner and to reference the COGR analysis as shown above. If there are questions or concerns, contact David Kennedy at dkennedy@cogr.edu.

## RESEARCH & REGULATORY REFORM

Committee: Lois Brako - University of Michigan (Chair), Kerry Peluso - Florida State University, Suzanne Rivera - Case Western Reserve University, Ara Tahmassian - Harvard University, Lynette Arias - University of Washington, Naomi Schrag - Columbia University, Marti Dunne - New York University, Martha Jones - Washington University – St. Louis, Mary Mitchell - Partners, J.R. Haywood - Michigan State University, Rodolfo Torres - University of Kansas, Debra Thurley - Pennsylvania State University, Michelle Christy - Massachusetts Institute of Technology

### Human Subjects Research

HHS Office for Human Research Protections FAQs and Announcements

The Health and Human Services (HHS) Office for Human Research Protections (OHRP) added eight new Frequently Asked Questions to its list of "Companion Q&As about the Revised Common Rule" on March 15, 2019. The FAQs define "initiated" (initially approved or waived by an IRB or determined to be exempt) in relation to applicability of the pre-2018 or revised rule and indicate that even studies approved prior to the general compliance date with conditions that are verified after that date are subject to the pre-2018 requirements. The FAQs note: that institutions do not need to revise their FWA because of the revised rule; that IRBs must continue to monitor non-exempt studies for which continuing review is no longer required; that the 1998 Expedited Review List is still in effect for research subject to the revised Common Rule until a new list is finalized; and where clinical trial consent forms should be posted as previously indicated. The FAQs are labeled "new" and can be found here.

OHRP announced on March 19 that the March 27-28, 2019 meeting of the Secretary's Advisory Committee for Human Research Protections has been postponed as a quorum was unlikely to be met. The next regularly scheduled meeting is July 30-31, 2019.

### Animal Research Regulatory Reform

Federal Agency Report on Reducing Administrative Burden in Animal Research

COGR previously reported that the NIH Office of Laboratory Animal Welfare (OLAW), U.S. Department of Agriculture (USDA), and Food and Drug Administration (FDA) issued a draft report, *Reducing Administrative Burden for Researchers: Animal Care and Use in Research*, for comment on December 7, 2018. The report follows a review by federal agencies to ensure that regulations and policies associated with research involving laboratory animals are not inconsistent, overlapping, or unnecessarily duplicative

and to improve the coordination of agency regulations and policies as directed by section 2034(d) of the 21st Century Cures Act. As part of their review, agency representatives conducted a series of listening sessions and published a request for information in March 2018. Dr. Pat Brown, Director, NIH OLAW, Bernadette Juarez, Deputy Administrator, USDA Animal Care Program, and Dr. Brianna Skinner, Senior Regulatory Veterinarian, FDA, joined COGR members at the February 28-March 1 meeting to discuss the report and next steps in reform efforts.

Panelists discussed a number of the steps agencies are proposing to reduce administrative burden, including guidance on flexibilities related to IACUC inspection, enhancing resources to facilitate use of DMR, outlining what is exempt from IACUC review, eliminating the USDA requirement for annual review, streamlining data submission, eliminating the requirement to renew USDA registration each year, indicating that policy documents are clarifications of law and regulation and not legally binding, coordinating requirements with DoD and VA, and a number of other areas. The presentation can be found here.

COGR Survey Report on Institutional Administrative Requirements for Animal Research

In the February 2019 COGR update we included a link to findings from a survey of COGR members on actions that institutions can take to reduce administrative burden associated with animal research and institutional animal care and use committees. We found that institutions are more likely to take action to reduce administrative burden when federal agencies provide clear directives and address uncertainty, and when agency regulations are harmonized. COGR has provided NIH, USDA, and FDA with the summary results of the survey to assist in their efforts to reduce administrative burden. In partnership with the Federation of American Societies for Experimental Biology, NIH OLAW, and the USDA, we have also conducted a webinar highlighting areas of the report where institutions may not be taking action to reduce administrative burden and where a review of agency requirements and flexibilities could facilitate a change in practice. This included areas such as protocol review, animal numbers, literature searches, and pain and distress classifications.

The first webinar, *Streamlining Institutional Requirements for Animal Research*, which was geared towards research and IACUC administrators, was held on March 18. The archived webinar can be found here. The second, *Understanding Federal Versus Institutional Requirements for Animal Research*, is more specific to investigators and took place on March 25. An archived version will be made available using the same link in the next few days.

**Meeting with NIH Staff on Research Regulatory Reform Updates and Implementation**

The RRR, RCA, CIP and Costing committees met with Michelle Bulls, Director, Office of Policy for Extramural Research Administration, NIH, on February 27, 2019 to discuss research regulatory reform and other areas. On the topic of regulatory reform, Michelle described a number of reform efforts underway via the Research Business Models subcommittee and HHS and OMB initiatives. Michelle mentioned a draft proposal that is currently under consideration to capture expenditure data at the time of

draw down and eliminate quarterly reports. Also mentioned were efforts to develop a standard "page one" Notice of Award and single sign-on platform for access to services across the department (e.g. eRA, Grants Solutions, Grants.gov, and PMS). Michelle also noted that effective January 1, 2020, SAM will become the central repository for common government-wide certifications and representations required of NIH applicants and recipients. The RBM is also considering clarifications to the requirements of 2 CFR § 200.331, "Requirements for pass-through entities," to clearly articulate the Federal government's expectations of the Pass-Through Entity relating to subrecipient monitoring that would address risk assessment and audit resolution responsibilities.

HHS has not yet taken steps to lead a review of regulations and policies related to the disclosure of financial conflicts of interest or make revisions to harmonize existing policies and reduce administrative burden as direct in Section 2034(a) of the 21st Century Cures Act. The May 25, 2018 Research Business Models subcommittee report to Congress indicated that the RBM may engage in a review and consider ways to harmonize requirements across agencies. The RBM Subcommittee is currently drafting a second report to Congress in response to the American Innovation and Competitiveness Act requirements.

**Research Transparency and Reproducibility**

The Research and Regulatory Reform committee met with Shai Silberberg, Director of Research Quality, and Devon Crawford, Health Program Specialist, National Institute of Neurological Disorders and Stroke (NINDS) on February 27, 2019, to discuss research quality and reproducibility and the possibility of developing communities of rigor champions at institutions and beyond. COGR will continue to work with federal partners in identifying opportunities for institutions to facilitate research transparency and reproducibility.

**NSF Info Brief on FY2017 Science and Engineering Obligations to Academic Institutions**

NSF released an Info Brief on federal science and engineering obligations to Institutions of Higher Education (IHEs) on March 19, 2019. The brief notes that federal agencies obligated $32.4 billion to IHEs for science and engineering in FY17, up 2% from FY16. Funding specific to R&D increased 4% to $29.8 billion. Support for historically black colleges dropped 17% (S&E) and 9% (R&D) respectively. The report indicates that "twenty higher education institutions receiving the largest amounts of federal S&E support accounted for 37% of all S&E support obligations by the federal government" and that "Six federal agencies accounted for 97% of all S&E support to higher education institutions in FY17: the Department of Health and Human Services (HHS), which includes the National Institutes of Health (59%), NSF (17%), the Department of Defense (DOD) (13%), the National Aeronautics and Space Administration (NASA) (3%), Department of Energy (DOE) (3%), and the Department of Agriculture (USDA) (3%)."

## CONTRACTS AND INTELLECTUAL PROPERTY

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

### COGR Joins in Comments on Patent Subject Matter Eligibility

COGR joined other associations in comments on patent subject matter eligibility (Section 101 of the Patent Act; 35 USC 101). As noted in previous COGR Updates, recent judicial decisions have resulted in confusion and uncertainty over what subject matter is patent eligible. (The recent Federal Circuit decision in the Athena Diagnostics case, invalidating medical diagnostic patent claims on "law of nature" grounds, has heightened the concerns).

On March 8 we sent comments jointly with AAU and APLU to USPTO on the PTO *2019 Revised Patent Subject Matter Eligibility Guidance* [Docket No. PTO-P-2018-0053]. Our comments expressed the view that the new guidance is a significant step forward insofar as it seeks to narrow overly broad judicial interpretations of Section 101 that have had a detrimental effect on university innovations. AUTM submitted separate comments. We expressed agreement with AUTM that adherence to and implementation of other statutory requirements, such as §§ 102, 103, and 112 will have a beneficial effect on university inventions. We also supported the new guidance on "Examining computer-implemented functional claim limitations for compliance with 35 USC 112."

On March 14 we joined AAU and APLU in responding to a series of questions from Sen. Tillis's (R-NC) Section 101 Roundtable (Sen. Tillis chairs the Senate Judiciary Subcommittee on Intellectual Property). Again, we expressed the view that Section 101 should perform a broad gatekeeping function that should be subsequently narrowed by application of other parts of the patent law on eligibility. We stated that the confusion and inconsistency resulting from recent judicial decisions have had a destabilizing effect on university technology transfer processes and planning. We expressed the hope that any Congressional work in this area will take steps towards ensuring greater clarity around patent eligibility by strengthening current criteria for patenting through reinforcing terminology made explicit in existing statutes and not by appending unclear court terminology (e.g. "abstract ideas" or "natural phenomena") to the language of the statutes.

Copies of both comment letters are posted on the COGR website. We understand Sen. Tillis plans to have a draft bill on Sect. 101 by June.

## Drug Pricing Legislation Continues to be Introduced

The February Update mentioned several bills that have been introduced in this Congress that address drug pricing concerns. To this point at least 18 bills have been introduced in Congress that relate to these concerns. More recent bills include the CREATES Act, reintroduced by Sen. Leahy (D-VT) on Feb. 6 with over 30 co-sponsors. This bill seeks to promote competition by facilitating the entry of lower cost generic and biosimilar versions of generic drugs. It would allow generic drug competitors to sue when brand name companies refuse to share equivalent samples of branded products and allow the FDA to approve alternative safety protocols. On Feb. 7, Rep. Collins introduced the Prescription Drug Price Transparency Act (H.R. 1035). It contains a number of transparency requirements for prescription drugs. On March 5, Sen. Collins (R-ME) introduced the Biologic Patent Transparency Act (S. 659) with five co-sponsors. It contains patent "thicket" disclosure requirements and allows challenges to late-filed patents earlier in the product development process.

Fortunately, the focus of the more recent bills has moved away from compulsory licensing.

## Tech Transfer Updates

### Innovation to Entrepreneurs Act

The February Update mentioned the bill (H.R. 539), which expands the NSF I-Corps program to participation by any SBIR/STTR grantee from any federal agency. We previously had endorsed the bill, which passed the House last year. On February 25 the bill again passed the House. Sen. Coons (D-DE) has introduced a companion bill in the Senate (S. 118). For more information see this press release.

### ITIF Report

On March 4 the Information Technology & Innovation Foundation (ITIF) released a report: *Preserving Bayh-Dole: The "Inspired" Law that Underpins U.S. Leadership in Life-Science Innovation.* The report discusses the life science innovation cycle and the key role played by the Bayh-Dole Act. It notes the Act has played a catalytic role in stimulating innovation across many sectors, especially in the life sciences. However, it also mentions the calls made to use the march-in provisions to control drug prices. It states that this threatens to undermine the currently successful ecosystem and reduce the pace of U.S. biopharmaceutical innovation. COGR reviewed the ITIF report in draft and made a number of suggestions, most of which are reflected in the final version.

The report was discussed by a panel at the U.S. Capitol on March 7 that included the AUTM Executive Director. The session was well-attended. It included a representative of Knowledge Ecology International (KEI), who challenged the panel on march-in rights (KEI has filed a number of unsuccessful march-in petitions with NIH). For the event summary and webcast see here.

Passing of Senator Birch Bayh

COGR notes with sadness the passing of Sen. Bayh on March 13. In addition to the landmark legislation that bears his name, Sen. Bayh was the main author of both the 25th and 26th amendments to the Constitution. He also wrote the Title IX Education Act amendments. For more on Sen. Bayh and his many accomplishments see here and here.

AUTM noted in a tribute to Sen. Bayh that the Act that bears his name has led to millions of people living better and more productive lives due to its impact. As also demonstrated in the ITIF report, it was this legislation that transformed U.S. innovation. Dr. Francis Collins of NIH also paid tribute to Sen. Bayh, nothing that by authoring the Bayh-Dole Act, he paved the way for medical inventions made by NIH-supported researchers to be commercialized.

Some of us at COGR had the privilege of meeting Sen. Bayh a number of times over the years. He always was warm and friendly in person and very unpretentious, just as stated in the obituaries. He will be missed, but he leaves a tremendous legacy that will endure.

## RESEARCH COMPLIANCE AND ADMINISTRATION

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

### Sexual Harassment in Research

NIH Sends Update on Sexual Harassment Efforts

After a 2018 National Academies report on sexual harassment of women in science found that "federal agencies may be perpetuating the problem of sexual harassment," NIH has taken steps to improve the culture and climate of its employees and expects grantee recipients to do the same. The February NIH update on Sexual Harassment provides information regarding the first meeting of the Working Group of the Advisory Council to the Director (ACD) on Changing the Culture to End Sexual Harassment. During the meeting, experts of the #MeTooSTEM movement shared stories frighteningly similar to those already heard by the NIH Anti-Harassment Committee, sounding alarms for NIH to further improve its internal systems, communication efforts, and disciplinary actions to reinforce the importance of a safe and harassment-free work environment.

The working group developed four themes during the meeting: demonstrating accountability and transparency; clarifying expectations for institutions and investigators to ensure a safe workplace and to notify the agency in certain circumstances; providing clear channels of communication to NIH; and listening to victims and survivors of sexual harassment to incorporate their perspectives into future actions. Interim recommendations from these themes will be submitted to the ACD in June with final recommendations anticipated in December. Stay tuned for additional updates.

NIH Creates Mail Box for Sexual Harassment Allegations

Following the National Science Foundation's efforts to create a mechanism for institutions to report findings/determinations and administrative leave or administrative actions regarding allegations of sexual harassment, other forms of harassment, or sexual assault, NIH has required and continues to require notification when such actions result in senior/key personnel changes that would impact a grant.

NIH expects all members of the NIH community to comply with laws, regulations, and policies protecting the rights and safety of individuals working on NIH-funded projects. Recipients of NIH funding are required also to comply with applicable federal civil rights laws and regulations, as outlined in the NIH Grants Policy Statement (NIH GPS), as a term and condition of award. As stated on its website, NIH also expects awardee organizations to:

- "develop and implement policies and practices that foster a harassment-free environment;
- maintain clear, unambiguous professional codes of conduct;
- ensure staff are fully aware and regularly reminded of applicable laws, regulations, policies, and codes of conduct;
- provide an accessible, effective, and easy process to report sexual harassment, and provide protection from retaliation;
- respond promptly to allegations to ensure the immediate safety for all involved, investigate the allegations, and take appropriate sanctions; and
- inform NIH of administrative actions or other circumstances that change the status of senior/key personnel on an NIH award."

In contrast to NSF's policy of a secured system to report finding/determinations, NIH has created an interim process via an email address. Emails can be sent to GranteeHarassment@od.nih.gov. Although we understand that the ACD working group's recommendation is to provide a more secure portal mechanism, the interim requirement has sparked the need for additional reassurance in areas of confidentiality (see FASEB letter) and whether the information submitted will be subject to the Freedom of Information Act (FOIA). We understand that these questions have been submitted to NIH counsel. Stay tuned for additional updates on this matter.

In anticipation of the June meeting, **COGR staff want to hear from you on how the implementation aspects of the NSF term and condition for reporting sexual harassment, other forms of harassment and sexual assault is working out at your institutions.** Please submit your comments to jbendall@cogr.edu.

Combatting Sexual Harassment in Science Bill, H.R. 36

We mentioned in the February update that Sara Barber, legislative staff of Ranking Member Eddie Bernice Johnson (D-TX) and Chairwoman of the House Science, Space, and Technology Committee would present an overview of Rep. Johnson's bill H.R. 36 entitled "Combatting Sexual Harassment in Science Act of 2019." H.R. 36 was reintroduced in the House by the new Congress on January 3, 2019. COGR staff were pleased to have the opportunity early on to provide feedback to Ms. Barber on the content of the bill and were well prepared to respond with recommendations after providing similar feedback in response to the National Science Foundations (NSF) new term and condition on reporting sexual harassment.

A number of comments shared after the presentation sparked concerns with several portions of the bill, including: the definition of grant personnel (includes not only principal investigators and co-principal investigators, but also other personnel supported by a grant and trainees); the broad definition of sexual harassment, extending beyond that of NSF and those used on campuses through Title VII and Title IX; the requirement to notify funding agencies when grant personnel are on administrative leave or upon imposition of any administrative action. COGR notes that the term "administrative action" is broad and could include actions taken early on while investigations are only being considered and may not occur or ultimately end in a finding. There is also concern about how the information reported by institutions will used, shared, and kept confidential. Ms. Barber appreciated our comments and said she would share them with Rep. Johnson. On February 12, 2019, H.R. 36 was referred to the Subcommittee on Research and Technology on February 12, 2019; no further action has been taken. COGR will provide updates as additional information is forthcoming.

Ms. Barber was also joined at the February COGR meeting by Joanne Carney, Director, Office of Government Relations at the American Association for the Advancement of Science (AAAS), who shared information on the new Societies Consortium on Sexual Harassment in Science, Technology, Engineering, Mathematics, and Medicine (STEMM). Joanne mentioned that the goal of this Consortium is to help societies fulfill their roles as leaders in the STEMM fields they represent through the creation of a variety of research and evidence-based resources and guidance on sexual harassment.

## Communicating Research Misconduct

Dr. Patricia Valdez, Research Integrity Officer at NIH attended Friday morning's session to discuss and answer questions pursuant to the October 17, 2018 Guide Notice (NOT-OD-19-020), "Responsibilities of

Recipient Institutions in Communicating Research Misconduct to the NIH." Prior to the COGR meeting, a joint association letter was submitted that expressed a number of concerns, including the requirement for institutions to report **"suspected "** situations of research misconduct that "**might** impact the conduct of an NIH-supported project or affect the integrity of the NIH supported research." COGR, ARIO and AAMC stressed that assessing "suspicion" absent a definition of suspicion would be particularly difficult and noted how it differs from a determination that the allegation is sufficiently credible and specific to warrant an inquiry or has sufficient substance to warrant an investigation – determinations that institutions already routinely make under the PHS Regulations.
Dr. Valdez commented that they don't need to know early on about an allegation but do want to know early enough (discretion exercised) if the 'suspicion' could impact the performance, conduct or integrity of the NIH funded award. COGR members also had questions around confidentiality of the information reported and how it would be reported. Dr. Valdez described a process similar to the NIH process for reporting concerns of sexual harassment, i.e., the creation of a mailbox that would be monitored only by her with information shared only with those with a need to know.

As of the writing of this report, COGR still awaits a response to the joint letter. We understand from Dr. Valdez that we can expect to see a response from NIH and ORI in the near term. For additional information, please contact jbendall@cogr.edu. Stay tuned for updates.

**Higher Education Research & Development Survey (HERD)**

As reported in February COGR update, the RCA Committee was joined by NSF's Michael Gibbons, Project Officer at the National Center for Science and Engineering Statistics, to discuss the NSF HERD Survey. Mr. Gibbons has recently acquired this position and is welcoming questions and concerns from COGR members about the current reporting requirements. In advance of the Committee meeting, and in order to make the best use of his time, RCA developed a list of questions. Click here to review the questions and NSF responses.

We continue to welcome your concerns and/or recommendations on how to reduce the administrative burden of these reporting requirements. We understand that the HERD survey is detailed and time consuming. Any recommendations for improving the accuracy of the results reported will benefit all institutions and create an even playing field. COGR will continue to engage with NSF on this matter. Please submit your concerns/recommendations to jbendall@cogr.edu.

**Confidentiality Scenarios in Research Misconduct (Ad Hoc Working Group)**

The COGR Confidentiality Scenarios have moved through the Committee review process and will be submitted to the Board for review at the end of March. We anticipate having the scenarios published prior to the June meeting.