COGR

SEPTEMBER 2022 UPDATE

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Announcements

Registration Now Open for October 20-21, 2022, Meeting in Washington D.C.

Registration is now open for COGR's October 20-21, 2022, meeting in Washington D.C. Register online through the COGR Member Portal and book your hotel by September 27 to secure special COGR pricing. A preliminary agenda is available here, and the final agenda will be released a few weeks prior to the meeting.

In an effort to tailor our health and safety protocol to the then-current status of the COVID-19 pandemic, we will continue to assess the situation and will provide a detailed protocol by September 23. Health and safety measures may include but are not limited to implementing vaccination and mask-wearing requirements. Once the protocol is released, we will update our meeting materials page and communicate directly with meeting participants. If you are not able or are unwilling to comply with the Health and Safety Protocol as released, you may cancel your registration by October 14 to receive a full refund. If you have any questions, please contact memberservices@cogr.edu.

COGR Presidential Search Now Open: Applications Due October 14

As announced via the COGR listserv, COGR President Wendy Streitz has announced her plan to retire in March 2023 after almost 20 years of service to COGR and more than 25 years in research administration. You are invited to help us find stellar candidates by nominating individuals or applying for this position. A copy of the position description is available here and may also be found on the Job Bank tab of the COGR Member Portal. Nominations of candidates or applications (a cover letter and curriculum vitae) should be sent to president-search@cogr.edu **no later than October 14, 2022.** We look forward to finding the right person to lead our organization in the coming years.

We greatly appreciate your interest and assistance in this process. Questions may be directed to president-search@cogr.edu.

COGR Membership Portal Launched July 2022

As announced in our June 2022 Update, COGR has now launched the COGR Member Portal, a new service platform that provides COGR members with access to members-only documents, the ability to manage their own contact information, view a members-only directory, register for meetings and webinars, view and post to COGR's job board, view the video library, and much more. Primary representatives and financial billing contacts may renew their institution's membership through the Portal and retrieve their annual dues invoices for processing under the "My Account" – "Invoices & Receipts" tab on the Dashboard. All employees at member institutions are eligible to sign up for an account, and we encourage you to share this information with anyone at your institution who is interested in accessing COGR materials. If you have any questions, please contact memberservices@cogr.edu.

Digging Into DPI Webinar on September 23: Registration is Open

Join us on September 23 for a webinar on Digging Into DPIs (Digital Persistent Identifiers). The National Presidential Security Memorandum 33 (NPSM-33) requires agencies to develop policies on the use of digital persistent identifiers (DPIs, which are also known as persistent identifiers or "PIDs"). More recently, NSF has required the use of these identifiers in the draft cross-agency disclosure forms issued for comment (87 FR 53505). Presenters from the University of Arizona will discuss what DPIs are, how they work, and their role in SciENcv, data management and sharing, and tracking scholarly activities and funding. Registration is still open. The webinar will be recorded, and attendees will receive a link to the recording shortly after the webinar is over. Contact memberservices@cogr.edu if you have any questions.

NIH Data Management & Sharing Policy: Cross Cutting

NIH Data Management & Sharing: Cost Impact & Administrative Burden Survey (NEW)

The Costing and Financial Compliance (CFC) Committee and the Contracts & Grants Administration (CGA) Committee have announced a survey: *Cost Impact and the Final NIH Policy for Data Management and Sharing*. The effective date for implementation of the NIH policy (see NOT-OD-21-013) is January 25, 2023. To date, forty institutions have indicated that they will complete the survey. ***The survey completion deadline is September 16th.*** We expect to present initial? findings from the survey at the October COGR Meeting. If your institution has not responded, but is interested in completing the survey, please contact cogrsurvey@cogr.edu.

Upcoming COGR/ARL Webinar on Institutional Strategies for Implementing NIH's Data Management & Sharing Policy (NEW)

This webinar is tentatively scheduled for Friday, September 30th. The full title for the webinar is *Gearing Up for January 2023: Institutional Strategies for Implementing the NIH Data Management & Sharing (DMS) Policy*. The NIH Data Management and Sharing Policy (NOT-OD-21-013) goes into effect on January 25, 2023. As a new, broader policy, institutions may need to build or enhance existing services and infrastructure to meet compliance and implementation responsibilities. This requires cross-campus coordination between the VPR's office, the library, IT, and others. COGR and the Association of Research Libraries (ARL) are pleased to host an institutional panel that will include representatives from the library and the sponsored programs offices at two institutions who will provide a cross-functional perspective on how each institution is collaboratively developing solutions to implement the new policy. ***Registration will open soon and be announced on the COGR website and via the listserv.***

COGR Readiness Guide on NIH Data Management and Sharing (UPDATE)

In August, COGR released Chapter 3, Part 1 of its NIH DMS Readiness Guide, titled *Implementation Roles & Responsibilities: Considerations for Institutions*. This release introduces the Roles & Responsibilities Chapter, covering considerations for recipient institutions related to institutional culture, resources &

infrastructure, and organizational structure, all of which impact how an institution sets up its roles and implementation plan. Part 2, expected to be released soon, will include a Roles & Responsibilities Matrix to identify key stakeholders and process owners during the various stages and activities in the lifecycle of public data access. In addition, the DMS working group updated version 2.0 (released August 5, 2022) of the NIH Data Management and Sharing Policy Matrix to include NIH Notice NOT-OD-22-189. COGR would like to thank the workgroup members who volunteer their efforts to work on this important initiative. For more information on the NIH Data Management and Sharing policy, including COGR and external resources, please visit our resource page here.

Science & Security: Cross Cutting

CHIPS & Science Act (NEW)

Overview & Appropriations. On August 9, 2022, President Biden signed into law the CHIPS (Creating Helpful Incentives to Produce Semiconductors) and Science Act (P.L. 117-167) (hereafter, the "Act"). On August 11, 2022, COGR staff presented a webinar providing a detailed summary of the Act's provisions, and COGR members can access a recording of this webinar and the slides on the COGR website. Additionally, a brief overview of some major provisions of this nearly 400-page Act is included here.

Division A of the Act appropriates $54.2 billion in funds to:

(a) Implement the "CHIPS for America" provisions of the FY 2021 National Defense Authorization Act (NDAA) that authorized Department of Defense (DOD), Department of Commerce (DOC), and Department of State (DOS) activities to promote the domestic manufacture of semiconductors; and
(b) Implement the USA Telecom Act provisions of the FY 2021 NDAA to promote the development of open-architecture telecommunications models to counter the use of telecommunications systems that employ components manufactured by Huawei.

Notably, funding in both these areas comes with restrictions designed to prevent expenditures that would result in the expansion of semiconductor manufacturing in China or other "countries of concern." Both the U.S. House and Senate have published websites summarizing the Act's provisions and providing additional explanatory materials.

Division B of the Act authorizes, but does not appropriate, $169.9 billion for investment in public research and development activities conducted by and through the National Science Foundation (NSF), DOC, National Institute of Standards & Technology (NIST), and the Department of Energy (DOE). This authorization of funds represents an $82.5 billion increase in 5-year authorizations over baseline for the covered agencies, with NSF receiving most of those funds ($81 billion). Division B includes several provisions to address research security and inappropriate foreign influence, as well as

provisions for building up and diversifying the U.S. science, technology, engineering, and math (STEM) workforce.

Key research security provisions in the Act include:

- **DOE**: Development of tools/processes for managing and mitigating security risk and prohibiting DOE "covered support" to "entities of concern" and individuals under their control.
- **NIST:** Development of effective practices, tools, and other resources to assist research institutions in identifying and addressing research-related cybersecurity risks.
- **NSF**: Establishment of a Research Security and Policy Office and developing research security resources for research institutions. Other notable NSF requirements include the prohibition of funding to institutes of higher education with Confucius Institutes; expanding responsible conduct of research requirements (see discussion below); requiring the reporting to NSF of a summary of foreign gifts and contracts greater than $50,000 annually; and contracting with an independent organization to establish a research security and integrity information sharing and analysis organization ("RSI-ISAO").
- **OSTP:** Entering into a contract for the development of on-line research security training and developing guidelines for agencies to follow in developing policies that prohibit federal employee and contractor participation in foreign talent recruitment programs (FTRP) and awardee "covered individuals" participation in malign FTRPs (MFTRPs).

Key provisions concerning build-up and diversification of STEM workforce include:

- **DOE**: Increase collaboration with educators and scientists.
- **NIST:** Increase educational outreach and support for underrepresented communities.
- **NSF**: Appoint a Chief Diversity Officer, develop programs to improve STEM education, and broaden STEM participation.
- **All Agencies**: Reduce barriers to recruiting and retaining underrepresented groups in STEM activities and take action to combat sexual harassment in STEM workplaces.

In many cases, the agencies charged with responsibilities under the CHIPS and Science Act have already taken steps toward their accomplishment, and it is expected that agencies will leverage these prior actions to achieve compliance with several of the Act's mandates. Dr, Rebecca Keiser, NSF Chief of Research Security Strategy and Policy and Dr. Christina Eller, OSTP's Assist. Director of Evidence & Policy will be present at COGR's October membership meeting to discuss OSTP and NSF activities concerning both the CHIPS and Science Act and the NSPM-33 Implementation Guidance.

CHIPS and Science Act Includes First-Ever Funding Authorization for University Tech Transfer

Section 10391(a) of the CHIPS and Science Act authorizes funding for institutions of higher education and affiliated nonprofit organizations to build capacity for technology commercialization. Consortiums including such entities as well as economic development organizations and industry are also eligible. Funding may be provided for staffing, patenting and licensing costs, entrepreneurial education and other activities. 3-year awards of $1M/year are authorized. A separate provision (10391(f)) authorizes funding for Collaborative Innovation Resource Centers to promote regional technology transfer and technology development. Eligibility is similar to 10391(a). NSF is directed to establish commercialization metrics and reporting schedules. A total of $3.1B over the next five fiscal years is authorized for activities under Section 10391[1].

This is the first time an agency has been authorized to directly fund university technology transfer. Institutions' obligations under the Bayh-Dole Act always have been an unfunded mandate. The funding is to be implemented through NSF's new Directorate for Technology, Innovation and Partnerships (TIPS) authorized by the CHIPS and Science Act (Section 10381). It is to be administered according to the purposes set out for TIPS in the Act, with a focus on translational research. These purposes include "advancing novel approaches and reducing barriers to technology transfer, including through intellectual property frameworks between academia and industry, nonprofit entities, venture capital communities, and approaches to technology transfer for applications with public benefit that may not rely on traditional commercialization tools; and … establishing partnerships that connect researchers and research products to businesses, accelerators, and incubators that enable research uptake, prototype development and scaling, entrepreneurial education, and the formation and growth of new companies" (Section 10383). TIPS is directed to establish partnerships and collaborations with HBCUs, other MSIs, EPSCOR institutions, nonprofit and for-profit entities, federal and state agencies, and international entities.

No funding for these activities is provided by the CHIPS and Science Act. Funding will depend on future appropriations. As with many other authorizations under the Act, it is unclear whether and to what extent the tech transfer provisions may be implemented by NSF in the absence of appropriations to fund them. It also is unclear what metrics NSF might establish for commercialization and how they might compare with other metrics such as the annual AUTM Licensing Survey.

Updated Science and Security Website and Comparison Chart (NEW)

Website: To assist members in keeping pace with the rapidly changing research security landscape, COGR's has launched a new Science and Security webpage. The webpage provides a one-stop location for COGR and external resources on research security conveniently grouped under the following categories: laws, policies, and agency guidance; COGR publications; COGR comment

[1] *For an excellent summary of the provisions, see the AUTM website at https://www.youtube.com/watch?v=CDGWXe3AGnE*

letters; updates to the membership; COGR webinars; and additional resources. COGR will update the site as new laws, guidance and analysis develops, so we encourage you to check back frequently for updates.

Comparison Chart: One important new resource available on the Science and Security website is an updated version of the COGR chart comparing the requirements of various research security laws, policies, and guidance[2]. The new chart now encompasses the CHIPS & Science Act, including effective or due dates that are listed for various provisions of the Act. To make information easier to access, the chart has been divided into three tabs:

- Comparison of federal-wide legislation/policies (e.g., NSPM-33, FY2021 NDAA, CHIPS & Science Act)
- Comparison of federal agency disclosure requirements
- Comparison of federal agency conflict of interest policies

Additional information and tabs will be added as federal units and agencies continue to issue guidance in this area.

NSTC Research Security Subcommittee NSPM-33 Implementation Guidance (NEW)

On August 31, 2022, NSF released for comment on behalf of the National Science and Technology Council (NSTC) Research Security Subcommittee, proposed common disclosure forms for the Biographical Sketch and Current and Pending (Other) support. The forms include proposed instructions for common disclosure forms for senior personnel applying for federal research and development (R&D) funding from federal research funding agencies. Data elements for the forms are summarized in an excel spreadsheet. Also, provided with the forms is an updated table for the NSPM-33 Implementation Guidance Pre- and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending Support (which supersedes Table 2a).

Some notable key takeaways include:

- It is intended that the common forms will replace forms/formats currently used by agencies.
- Elements of the proposed instructions closely align to NSF and NIH requirements.
- The common forms include certification language for senior personnel to attest that the information is current, accurate, and complete for both the biographical sketch and current and pending (other) support. The language states that misrepresentations and/or omissions may be subject to prosecution and liability pursuant to, but not limited to, 18 U.S.C. §§ 287, 1001,

[2] *COGR also released a comparison document "Department of Energy Interim Financial Conflict of Interest Policy and Public Health Service Regulations for Promoting Objectivity in Research" on September 7 to assist institutions in comparing the two provisions, available here.*

1031 and 31 U.S.C. §§ 3729-3733 and 3802.

- The NSPM-33 Implementation Guidance Pre- and Post-award Disclosure table supersedes the original table 2a largely merging the latest NIH and NSF disclosure tables which mostly align. It is noted that this table may be modified by federal agencies where activities are specific the mission of the agency.
- The notice states that variations of the common disclosure forms among research agencies will be limited to cases: (a) where required by statue or regulation; (b) where more stringent protections are necessary for the protection of R&D that is classified, export-controlled or otherwise legally protected; or (c) for other compelling reasons consistent with individual agency authorities and as coordinated through NSTC. The notice additionally states variations may exist to meet programmatic requirements (if necessary) agencies may develop with agency or program specific data elements and instructions. Modifications and/or supplementation of the forms will require clearance by OMB/OIRA. Notably missing from the common disclosure forms is NIH (i.e., Personal Statement) and NSF specific elements (i.e., Synergistic Activities) which is not part of the common disclosure forms instructions or format.

The NSF will serve as the steward for collecting and resolving public comments as specified in the Federal Register Notice. Comments are due by October 31, 2022, and are requested on: (a) if the proposed collection of information is necessary for proper performance of the functions of the agency including if the information has practical utility; (b) the accuracy of the Agency's estimate of the [administrative] burden to institutions in collecting the information (estimate is one hour for the biosketch and one hour for the current and pending (other) support); (c) ways to enhance the quality, utility, and clarity of the information for respondents (including the use of automated collecting techniques or other forms of information technology); (d) ways to minimize the burden of the collection of information for respondents.

COGR is reviewing the common forms and associated documents for analysis and comment. COGR will host a webinar, tentatively scheduled for September 23. ***Information and registration for the webinar will be posted on COGR's website and announced via the listserv once available.***

For questions contact Krystal Toups (ktoups@cogr.edu).

Upcoming COGR Report: Research Security and the Cost of Compliance (NEW)

In September, COGR will release the report, *Research Security and the Cost of Compliance, Phase I: Results from the Initial Phase of COGR's Survey on the Costs of Complying with Research Security Disclosure Requirements.* Immediately upon its availability, we will notify the COGR membership.

The report is six months in the making and is based on results of the COGR "Research Security Costing Model Survey" study, completed by twenty-six COGR member institutions. The findings from the survey include data-driven evidence showing that the cost burden associated with the new NSPM-33 disclosure requirements is significant and severe—and this is true for all institutions engaged in federally funded

research activity. The average cost per institution easily exceeds hundreds of millions of dollars. In addition, the harsh reality of the new cost burden raises these important questions:

- We support the federal efforts to promote research security, but costs are substantial, and the question of "how to pay?" must be contemplated with our federal partners.

- Further, should the "how to pay?" question be considered within the context that research security is a national security issue? If so, federal government participation in the cost burden is even more necessary.

- Return on Investment (ROI)—some agencies seem to be focused on enforcement numbers. Is *security* the "return," or is it *transparency*? Are case numbers the most meaningful "return" metric?

- Will cost implications create barriers to entry for some, particularly smaller, mid-sized, and emerging research institutions?

Institutions have made significant investments in response to federal concerns regarding research security, including the additional agency and NSPM-33 requirements designed to promote full disclosure of information that may bear on conflicts of commitment and/or interest. The issues raised in the COGR paper are serious issues and issues that require a collaborative and healthy partnership between research institutions and the federal agencies. Data-driven evidence should facilitate discussion and solutions, and the paper includes recommendations to OSTP and other federal agencies on how to address the new cost and administrative burden for research institutions.

We will keep the membership updated on all developments, and if you have questions or concerns, please contact Kris West at kwest@cogr.edu or David Kennedy at dkennedy@cogr.edu.

HHS OIG Report "Opportunities Exist to Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support" (UPDATE)

In June 2020, HHS OIG published "Opportunities Exist to Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support," analyzing the results of the survey that it sent to NIH-funded research institutions in October 2020. The survey sought information about institutions' requirements for investigators to report sources of "other support" and "significant financial interests" (SFIs) per the PHS regulations for promoting objectivity in research at 42 C.F.R Part 50, Subpart F ("FCOI Regulations"). It was administered to 773 grantees and had a response rate of 80%, but only one-third of responders were comparable in funding size to COGR members.

COGR staff met with the HHS OIG representatives who conducted the survey to gain further clarification regarding survey data and analysis. COGR advised HHS OIG that many institutions struggled in answering the survey because its wording did not align with regulatory requirements. Further, the data used in the survey was collected at a time when NIH guidance regarding the disclosure of Biosketch and other support

information was still very much evolving, and many of the "clarified" Other Support requirements, were in fact new.

The HHS OIG representatives reviewed the data with COGR and stated that NIH has six months to provide a "final management decision" about the recommendations. In this process, NIH will provide HHS OIG with documentation about how it will address the recommendations, and this documentation may be detailed or more general in nature. HHS OIG reported that at present, it has no plans to conduct additional surveys in this area. However, COGR advised that if this should change, the timing of any such survey should consider the fact that institutions will need time to implement the new disclosure forms and guidance that are expected to be issued by federal funding agencies.

COGR Presentation to National Academies on "Openness, International Engagement, and the Future of the Federally-Funded U.S. Science and Technology Research Enterprise." (NEW)

COGR has been invited to be part of a panel presentation at the National Academies of Sciences, Engineering, and Medicine (NASEM) workshop on "Openness, International Engagement, and the Future of the Federally-Funded U.S. Science and Technology Research Enterprise." COGR staff will be part of a panel discussion focused on the risks and benefits of measures being implemented to address research security threats, as part of the workshop's larger focus on how the benefits of U.S. scientific openness can be maintained, while appropriately considering and mitigating research security risks. The session was initially scheduled to take place in August but has been postponed until later this fall.

Follow Up Activities Continue on ED Section 117 Reporting (UPDATE)

The June Update also discussed the June 23 Department of Education webinar on Section 117 reporting. On July 21, we shared the updated webinar slides with COGR members.

The participating higher ed. association representatives including COGR were not fully satisfied with the information presented by ED at the webinar. Much of it did little more than reiterate points from ED's most recent Information Collection Request on Section 117 (see COGR May 2020 Update).

On August 16, the American Council on Education (ACE) sent a follow up letter to ED asking for a second meeting to address questions which in our view were not fully resolved in the webinar session. The reporting portal and ED's enforcement authority under Section 117 were identified as other topics for discussion. We also mentioned the need to discuss the implications of NSF's new separate ($50k) reporting obligation under the CHIPS and Science Act.

We will continue to keep the COGR membership informed of developments.

DOD Issues Draft CMMC Assessment Process (CAP) Guide (NEW)

On July 26, the DOD CMMC Accreditation Body (AB) issued a "Pre-Decisional Draft CMMC Assessment Process (CAP) Guide for public comment. The draft breaks the assessment for the CMMC program down into four phases: preparation, conducting the assessment, reporting results, and closing out the assessment.

The draft has been heavily criticized by defense contractor groups as premature since the revised DFARS CMMC regulations are not expected to be issued until next March (see COGR May 2022 Update). It was also criticized as an overly complex and burdensome departure from existing cybersecurity compliance requirements. Concerns were expressed that the CMMC program has become "more complex, more burdensome, and more expensive than initially outlined by DOD." DOD also was urged to work with the AB, accredited CMMC certification providers, and other stakeholders to develop CAP documentation that is consistent with the revised CMMC 2.0 rules when they become effective.

COGR agrees that it might be prudent to wait for release of the revised DFARS requirements before further implementation of CMMC assessment requirements. While DOD has encouraged early CMMC assessments prior to the rulemaking for contractors that handle CUI, there seems little justification for the added burdens and expense of following the draft document when the requirements and contract clauses may change.

NIH About Foreign Interference Website (UPDATE)

The NIH updated the webpage *Protecting U.S. Biomedical Intellectual Innovation*. The new reorganized webpage "Foreign Interference" aggregates the information into subtopics including:

- *About Foreign Interference* - former link
- *Requirements for Disclosure of Other Support, Foreign Components, and Conflicts of Interest* - former link
- *Format Pages, Instructions, and Samples* - same redirect links to Other Support and Biosketch. New reference to include the FCOI webpage.
- [**New**] *Process for Handling Allegations*
- *Notices, Statements and Reports* - same references
- [**New**] *Data* - with an updated Brief Summary of NIH Foreign Interference Cases (August 8, 2022)
- *FAQs* – same link to FAQS for Other Support and Foreign Components
- *Contacts* – New reference that allegations can be reported to NIH Research Integrity

DFAR Supplement: Employment Transparency Regarding Individuals Who Perform Work in the People's Republic of China (DFARS Case 2022-D010) (NEW)

Two new DFARS clauses have been issued in an interim rule for DOD contracts (or subcontracts) over $5 million involving people working in the People's Republic of China (PRC). These clauses implement

Section 855 of the FY 2022 NDAA. The rule is in effect now, and the clause may be added to new or existing contracts (or subcontracts) over $5 million. See DFARS clauses 252.225-7057 and 7058.

DFARS 252.225.7057 requires that recipients disclose the need for one or more individuals employed under the contract to work in the PRC as part of the project. The post-award clause 252.225.7058 flows down to subrecipients and requires disclosure of the same in FY2023 and FY2024.

Recipients could request a waiver of disclosure if it could negatively impact national security. DOD estimates that a small number of contractors will be affected (~30). Comments are due October 24, 2022. COGR is reviewing the interim rule and assessing whether to comment. Please contact Krystal Toups at ktoups@cogr.edu if you have any questions.

Research Security & Intellectual Property (RSIP)

Selected Committee activities related to Science & Security are reported above under the Cross Cutting Issues section of the COGR Update. Other items being followed by RSIP are covered below.

BIS Announces New Academic Outreach Initiative (NEW)

The June Update discussed the GAO report: *Export Controls: Enforcement Agencies Should Better Leverage Information to Target Efforts Involving U.S. Universities* (GAO-22-105727). As we reported, the report contained a series of recommendations to export enforcement agencies (Commerce, ICE, and the FBI) to "strengthen… (their) ability to prioritize outreach to at-risk universities."

On June 28, BIS announced a new "Academic Outreach Initiative" to help academic institutions protect themselves from unauthorized foreign acquisition of information and technology. Under this initiative, BIS Export Enforcement will strategically prioritize academic research institutions with elevated risk profiles; assign Outreach Agents to those institutions to help prevent unauthorized exports and brief institutions as to security risks; and provide related training.

The GAO report indicated that DHS/ICE had developed a list of approximately 150 U.S. universities ranked according to their risk of sensitive technology transfer. We presume BIS is using this list, or a similar list, to prioritize institutions for the expanded outreach. On July 28, we joined AAU, APLU and ACE in a letter to GAO requesting the list of at-risk universities. We plan also to follow up with BIS on the new Academic Outreach Initiative. We understand at least one COGR member institution has been contacted by BIS pursuant to the initiative. We would appreciate hearing from others of similar contacts. Please contact Robert Hardy at rhardy@cogr.edu.

NIST: Meeting with New NIST Director; New iEdison System Launched

Meeting with NIST Director. On July 21, AAU, APLU, AAMC, COGR and AUTM representatives met with new NIST Director Laurie Locasio and several colleagues. In the discussion we learned that NIST may combine a revised ROI "Green Paper" NPRM on 37 CFR Part 401 (see COGR February 2021 Update) with another unspecified one. While the NPRM march-in and government use license proposals were controversial, most of the proposed NPRM changes involved removal of obsolete material and updating references. NIST also had proposed appropriate changes to Part 404 of the regulations, which deal with the licensing of government owned inventions. At the meeting we expressed hope that most of these changes would be included in the revised NPRM.

In the discussion, the NIST representatives indicated that NIST sees its oversight role for Bayh-Dole as assuring compliance with the law but not as a policy role. This appears to be a narrower view than under the previous NIST Director, Walter Copan. Domestic manufacturing and supply chain issues also were discussed in the context of the recent DOE DEC (COGR March 2022 Update). So far, no other agency has gone as far as DOE. We also mentioned continuing concerns about march-in. Finally, we discussed the rebuilt iEdison system (see below), and our hope that it would provide greater transparency for items such as the status of domestic manufacturing waiver requests.

New iEdison System Launched. On August 9, NIST launched the new iEdison reporting system for federally funded inventions, and a copy of the NIST announcement was sent to the COGR membership. . In addition, responsibility for the system was formally transferred from NIH to NIST.

COGR has followed and reported on the development of the iEdison redesign over the past few years. The hope is it will facilitate the reporting of federally funded inventions and transparency of invention reports. The updated system includes a modernized user interface and new messaging features that are intended to make it easier for organizations to communicate with their funding agencies. While these enhancements should be beneficial, the new system reinforces the need for timely and accurate invention reporting.

COGR Joins Higher Ed. Association Letter to HHS on Bayh-Dole (NEW)

COGR joined AAU, APLU, AAMC, AUTM, and the Bayh-Dole Coalition in a July 27 letter[3] to HHS Secretary Becerra. The letter responded to a June 23 bicameral Congressional letter to Secretary Becerra urging him to use the Bayh-Dole march-in and government use rights to lower prescription drug prices.

[3] *Sent to the COGR listserv via the COGR News Digest on July 27 and posted to COGR's website here: https://www.cogr.edu/sites/default/files/Assn.March-in.HHSLtr.Final%207.27.22.pdf*

Our letter pointed out the adverse effects on the licensing of university patents and commercialization of new technologies that would result from the exercise of these rights for this purpose. It cited the purpose of march-in as seeking to assure commercialization of government-funded inventions. Use of the government Bayh-Dole rights to control pricing would be a misuse of Bayh-Dole, not supported by the language, intent or history of the Act. It concluded that "In addition to being an ineffective mechanism to reduce drug prices, such an action would significantly undermine university innovation and the benefits it delivers to the American people and indeed, as in the case of COVID-19 vaccines, the entire global community."

The Congressional letter requested a meeting with the Secretary. We are not aware that such a meeting took place. The recent passage of the Inflation Reduction Act authorizing Medicare to negotiate pricing for certain

prescription drugs may alleviate some of the pressure to invoke other authorities such as Bayh-Dole to control drug prices.

RSIP Committee Releases Updated *Technology Transfer Myths* (NEW)

On August 2, COGR released a revised version of *Technology Transfer in U.S. Research Technology Universities: Dispelling Common Myths*, first released in March 2000. The revised document updates the discussion of a number of commonly held myths about university technology transfer and seeks to provide a better understanding of the actual purpose and nature of these activities. It combines some of the material that was included in the 2010 *21 Questions About University Technology Transfer* with the *Myths* document.

Issuance of the revised *Myths* completes the revision of the Intellectual Property and Innovation materials on the COGR website undertaken by the RSIP Committee over the past couple of years. We will continue to revise and update these materials as needed.

Research Ethics & Compliance (REC)

Selected Committee activities related to Science & Security are reported above under the Cross Cutting Issues section of the COGR Update. Other items being followed by REC are covered below.

Cannabis & Controlled Substances Research Updates

Meeting Regarding Research on Marijuana (NEW)

At the beginning of August, several members of a COGR Cannabis and Controlled Substances Working Group met with Jeremy Marsh, Constituent Representative and Legislative Aide to Congresswoman Dina Titus (Nevada), to discuss obstacles that researchers face in carrying out researching using marijuana.

Representative Titus sought this information in connection with legislation she is considering developing to make the conduct of such research easier. The Working Group advised that significant hurdles include the inability to legally access for research strains of cannabis that are currently available in states in which marijuana has been legalized, as well as the inability to conduct observational research in campus research settings and the significant state and federal requirements for gaining state/federal approvals to conduct research using marijuana and other Schedule I controlled substances. Mr. Marsh thanked the group for this information, and the group made clear that it is important to conduct research in this area to develop solid scientific evidence regarding marijuana's potential benefit and harm.

Request for Information (RFI) Regarding Cannabis Research (NEW)

A number of NIH institutes and centers have jointly issued "Request for Information (RFI): Investigators' Interests in and Barriers to Research Studies on the Health Effects of Cannabis and its Constituents" (NOT-AT-22-026). The RFI seeks comments "about barriers, scientific interests, and needs associated with therapeutic cannabis or cannabinoid research from investigators conducting or interested in conducting research on cannabis, cannabinoid phytochemical constituents, and related compounds (synthetic compounds, terpenes etc.)."

Volunteers from the COGR Working Group will consider the RFI and develop comments to be submitted by COGR.

Responsible Conduct of Research Changes (NEW)

REC members are considering the impact of updated requirements for responsible conduct of research (RCR) training issued by NIH and required for NSF. In February 2022, NIH issued "FY2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research" (NOT-OD-22-055) which, beginning in FY2022-223, expands RCR content to include safe research environments, responsibility to maintain confidentiality in peer review, tools for analyzing data (e.g., digital images) and recordkeeping practices, and secure and ethical data use. Section 10337 of the CHIPs and Science Act requires NSF to add to RCR training requirements mentor/mentorship, research security threat awareness, and export controls, and to expand the training to "postdoctoral researchers, faculty, and other senior personnel," The Act, however, does not provide a specific effective date for this requirement. Institutions are taking stock of current institutional training programs (e.g., sexual harassment training, data use and management training, etc.) and determining how this content can be leveraged to satisfy curriculum requirements. Institutions are also considering how RCR tracking mechanisms must be modified to record and document satisfaction of the training requirements.

Animal Research

News[4] concerning the relocation of beagles from a commercial breeding facility in Virginia that was accused of Animal Welfare Act violations, have focused public attention on the use of canines in research, and legislation has been introduced that would prohibit NIH funding to be used for the purpose of "conducting biological, medical, or behavioral research involving the testing of dogs." Given the importance of animal models in many research endeavors, and the need to ensure that this research is carried out in full compliance with applicable laws and regulations designed to protect animal health and welfare, REC has invited representatives from the Office of Laboratory Animal Welfare (OLAW) to meet with it to provide an update on OLAW's activities and any new initiatives. OLAW representatives will meet with REC members during the Committee's October meeting.

Human Subjects Research

Comment Letter to Office of Human Research Protections (OHRP) on Guidance Regarding the Use of Single IRBs (NEW)

In July, OHRP released its draft guidance entitled "Use of a Single Institutional Review Board for Cooperative Research," and COGR submitted comments in response. Interestingly, this draft guidance was issued long after the single IRB requirement went into effect. COGR noted that agencies have issued policy and guidance during this time and encouraged OHRP to ensure consistency and harmonization between these existing policies and the OHRP guidance. COGR noted the importance of local context, including local laws, and recommended that OHRP amend the Guidance to call for the single IRB to rely upon the local IRB for accessing and applying state and local laws and regulations. COGR also requested that OHRP consider the development of additional exceptions to the single IRB requirement.

Secretary's Advisory Committee on Human Subject Research (SACHRP) Regarding "Engagement in Research" (UPDATE)

In follow-up to SACHRP's discussion at its March 2022 meeting of recommending to OHRP that it modify the definition of "engaged in research," and further discussion of this topic with SACHRP Subcommittee on Harmonization Co-Chair Mark Barnes, COGR submitted a letter to SACHRP supporting its efforts. COGR's letter was included in SACHRP's July meeting materials, and SACHRP provided recommendations concerning "engagement in research" that reflected many of COGR's comments and substantially improved upon those discussed at the March meeting. SACHRP's recommendations include the following items:

[4] *See, e.g.,* https://www.nytimes.com/2022/07/12/us/envigo-beagles-breeder-adoption.html and https://www.washingtonpost.com/national/last-group-of-beagles-taken-from-troubled-breeding-facility/2022/09/02/e63e2702-2ae8-11ed-a90a-fce4015dfc8f_story.html.

- A party is "engaged in research" if it (or its employees, staff, or agents) has/have a key role in designing the research, conducting the research, analyzing, and interpreting the results, or gaining informed consent from human subjects.
- Parties with peripheral roles or whose activities are wholly directed by persons who are "engaged in research" would not need to be included within the scope of the modified definition.
- If obtaining informed consent is the sole basis for considering a person/entity to be engaged in research, then guidance should "accommodate the possibility" that the person/entity need not be considered engaged in research for low risk, noninterventional studies where there is ample opportunity to engage in consent discussions with the primary research team.

Office of Research Integrity (ORI) RFI Regarding Research Misconduct Regulations (NEW)

The Secretary of Health and Human Services (HHS) through the Office of Research Integrity (ORI) has issued a "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct." ORI is considering revising the 2005 regulations on research misconduct (42 CFR Part 93), and is seeking input on which sections should be retained unchanged, removed, or modified. REC has formed a working group that will review the RFI and develop responsive comments.

Additional Research Ethics & Compliance Committee Issues (NEW & ONGOING)

- **COGR Conflict of Interest (COI) Publication (Update)**: REC has organized a working group to review and revise the COGR publication "Recognizing and Managing Personal Financial Conflicts of Interest."
- **Research Environment (Update)**: REC and CGA have organized a working group to address recent federal requirements designed to promote a research environment free of harassment and bullying. The group will be organizing two sessions on this topic at the October membership meeting: (a) a presentation by agency representatives; and (b) a presentation by institutional representatives. In addition, the group will develop corresponding written materials.

Costing and Financial Compliance (CFC)

Selected CFC activities related to Science & Security and NIH Data Management & Sharing are reported above under the Cross Cutting Issues section of the COGR Update.

Cost of Compliance: Science & Security and Data Management & Sharing (NEW)

The Costing Committee is heavily engaged in two cost of compliance surveys: Science & Security and Data Management & Sharing. Both initiatives are described in other sections of this COGR Update. As cost of compliance and its associated cost burden have been highlighted for these two federal compliance requirements, the importance of data-driven evidence to support claims about significant cost and

administrative burden is essential. The two surveys take two different approaches to documenting the cost of compliance. As the need continues to complete these types of surveys, we encourage the COGR membership to share feedback on any challenges for completing the two recent surveys, as well as any other input that could be helpful to how COGR implements such surveys.

F&A Cost Rate Negotiations and Engagement with Cost Allocation Services (NEW)

COGR members, and for that matter, other institutions that negotiate F&A cost rates (and fringe benefit rates) with Cost Allocation Services (CAS), have been concerned about not being able to complete timely negotiations and receive final rate agreements. CAS has a unique placement in the U.S. Department of Health and Human Services (HHS) as an entity under the Program Support Center (PSC). According to the PSC website: "PSC is a shared services organization dedicated to providing support services to help its customers achieve mission-critical results. More than 40 services and products support three crucial business areas ..."

One of the sub-organizations under PSC is Indirect Cost Negotiations, and as what has become common knowledge across the COGR membership, CAS is experiencing significant staff shortages. In fact, these shortages have been exasperated by the fallout from the COVID-19 pandemic. Consequently, this has led to long delays in completing timely negotiations and receiving rate agreements from CAS. COGR and CAS recently have engaged with one another with the goal of finding solutions to reduce these long delays, and further explore other opportunities that could be beneficial to the community. We will keep the membership updated on how we progress.

Costing & Financial Compliance: Other Issues (ONGOING)

The items below are issues that the CFC Committee has recently reported and/or issues that we continue to follow:

> ***2022 Compliance Supplement and Reimbursement Requests.*** The 1,968 page 2022 Compliance Supplement was posted in May. We are awaiting a response from OMB regarding the June 2022 comment letter sent to OMB. The COGR letter addresses the longstanding topic on the timing for requesting reimbursement from federal agencies. At issue is the common practice when institutions request federal reimbursement upon initiation of a payment to a vendor. One version of audit expectation is that the reimbursement request should be made after the vendor processes the payment. This is a problematic expectation and not consistent with standard business practices. Note, this has not been identified as a universal audit concern, but it has been raised by selected auditors. Addressing this in the Compliance Supplement could alleviate this ongoing issue.
>
> ***Proposed NASA Term and Condition Regarding Procurement.*** COGR sent a Comment Letter to NASA in April raising a concern about a proposed NASA term and condition. The last we heard, NASA currently is reviewing all comments and will keep the community posted on developments. While COGR fully supports robust and proactive initiatives to expand procurement opportunities for small minority businesses, women's business enterprises, and labor surplus area firms, the

proposed term would be problematic on several fronts and would be inconsistent with 2 CFR 200.321, *Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms*.

Treatment of Procurement and Related Rebates. We believe this issue is resolved, but we will continue to monitor as needed. Last fall, Cost Allocation Services (CAS, HHS) raised an issue on the treatment of rebates associated with institutional p-cards and similar lump-sum procurements—CAS maintained these rebates should be identified to individual federal awards. When a rebate can be identified to an award with a high degree of accuracy, the rebate must be applied to the award. However, when a rebate cannot be identified to individual federal awards with a high degree of accuracy, there should not be an expectation to develop a complex methodology to do so. We summarized many of the nuances related to this issue in the February 2022 Update, and while there are still situations where institutions may have questions on how to address this issue with CAS, the COGR summary from the February 2022 Update should be a helpful resource.

Retirement of the FCTR by the U.S. Department of Health and Human Services. On April 1st, the U.S. Department of Health and Human Services (HHS) retired the Federal Cash Transactions Report (FCTR), i.e., OMB Standard Form 272. This was announced in NIH Notice NOT-OD-22-099 and further promoted in an HHS-department wide announcement. This initiative culminates a 5-year+ process of engagement between COGR, NIH, and HHS, and solves the longstanding and problematic reconciliation issue between the FCTR and the Final FFR. It further reduces administrative burden—by cancelling the FCTR, it eliminates the redundant and unnecessary step of completing the FCTR, which became obsolete since HHS/NIH introduced "subaccounts" more than five years ago. COGR appreciates the patient and dedicated work by individuals from NIH and HHS to make this happen.

Federal Office of Inspectors General (IG) and Single Audit Developments. We regularly report on audit developments and we included a detailed update in the June 2022 Meeting Report. We encourage COGR members to follow the HHS OIG Workplan and the NSF OIG Reports & Publications page. Further, the NSF Management Responses to an External Audits is a helpful resource for reviewing NSF OIG audit resolutions. We encourage COGR members to contact COGR when audit issues arise. When appropriate, we can connect institutions and/or provide feedback that may be relevant to the issue at hand.

2020 NSF Higher Education Research & Development (HERD) Survey. The 2020 HERD was released on December 27, 2021, and includes the InfoBrief summary and the complete suite of 2020 data tables (which includes the popular *Table 21 – Higher education R&D expenditures, ranked by all R&D expenditures, by source of funds: FY 2020*). Also of interest is *Table 16 – Higher education R&D expenditures, by highest degree granted, institutional control, and type of cost: FYs 2010-20.* Table 16 includes data on recovered and unrecovered indirect costs, in aggregate, for all institutions. For FY2020, the total recovered indirect costs were almost $14 billion and the total unrecovered

indirect costs were $5.7 billion. Also note, the results from the 2021 HERD Survey should be released before the end of the year.

Please contact David Kennedy at dkennedy@cogr.edu to further discuss any of these issues above, or other items that you would like to address.

Contracts & Grants Administration (CGA)

Selected Committee activities related to Science & Security & NIH Data Management and Sharing are reported above under the Cross Cutting Issues section of the COGR Update. Other items being followed by CGA are covered below.

Grants.gov Extended Downtime for Cloud Migration September 2022

Grants.gov will be unavailable for an extended period between **September 23 through September 29, 2022**, and back online Thursday, September 29, 2022, at 11:59 PM ET. During this period, grants.gov will be migrated to the cloud. See grants.gov notice "What to Expect" for additional details. NIH and AHRQ announced adjustments to due dates for applications that fall on or between September 22 and September 30 date which will move to October 3, 2022. See NOT-OD-22-190. Institutions should be aware that although grants.gov states that the transition "is expected to be completely seamless," the outage is within days of the major October deadline period for NIH, which is not factored into the adjustments announced in NOT-OD-22-190. Additionally, there are still funding opportunities posted on the grants.gov website that lists closing dates for applications that fall within September 23rd - September 29th for ETA, USDA, USAID, HHS, NIH, etc. COGR has reached out to grants.gov for clarification and a designated grants.gov point of contact if issues should arise for members.

Contact Krystal Toups at ktoups@cogr.edu with any questions or to report issues.

OSTP Public Access: Ensuring Free, Immediate, and Equitable Access to Federally Funded Research (NEW)

On August 25, 2022, the White House announced the Office of Science and Technology Policy (OSTP) new policy guidance Ensuring Free, Immediate, and Equitable Access to Federally Funded Research, which includes two important changes for the research community:

- Plans to eliminate any embargo period between the time of publication and release of the information to the public, and
- Strengthening data sharing plans to make data available immediately upon publication, or within a reasonable time frame for other research data.

This is a topic COGR responded to jointly with AAU and APLU in May 2020. COGR is reviewing these documents to better understand potential impact and will be monitoring agency responses.

EO 14042 "Ensuring Adequate COVID Safety Protocols for Federal Contractors: (UPDATE)

The Eleventh Circuit Court of Appeals blocked the Executive Order mandate in seven states, as such on August 31, 2022, the administration issued updates to the Safer Federal Workforce guidance for federal contractors and FAQs, which state "the Government will take no action to enforce the clause implementing requirements of Executive Order 14042, absent further written notice from the agency". Institutions should consider this update when receiving new contracts that include EO 14042. See COGRs EO 14042 Ensuring Adequate COVID Safety Protocols for Federal Contractors & OSHA Emergency Temporary Standard: Guidance and Considerations Resources for additional information.

COGR would like to thank COGR Board Chair Jeffrey Silber (Cornell University) and the COGR Committee members for their time, dedication, and expertise, without which the efforts and activities conveyed in these updates would not be possible.

Contracts & Grants Administration (CGA)

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