

An Association of Research Institutions

AUGUST 2021 UPDATE

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Announcements

COGR's October 19-22, 2021, Virtual Meeting: Registration Open

Registration is now open for our upcoming virtual COGR Meeting. COGR members can <u>register online</u> or through paper registration and pay via check. If using the latter to register, please be sure to notify <u>Toni Russo</u> and include a copy of the check and registration form. If your institution will be registering five or more individuals, there is a special pricing code available. Preliminary agenda topics are available on the COGR <u>website here</u>, and a final agenda will be released a few weeks prior to the meeting. Attendees will have the opportunity to ask questions during most of the sessions but are also encouraged to submit their questions or topics of interest in advance here.

Back by popular demand, COGR will again be adding discussion hours to the agenda, in which attendees can engage directly with COGR staff, Committee members, and each other on a variety of meeting related topics. Attendees must register separately for these sessions and registration links will be sent to registered attendees the week before the meeting.

Research Security & Intellectual Property Management (RSIP)

DOE DEC Discussion (UPDATE)

The <u>June Update</u> discussed the Determination of Exceptional Circumstances (DEC) recently issued by DOE to strengthen the domestic manufacturing requirement for DOE-funded inventions. In addition to strengthened penalty provisions for non-compliance, the "U.S. Competitiveness Provision" set forth in the DEC for all DOE awards broadens the standard Bayh-Dole U.S. manufacturing preference for exclusive licenses (35 USC 204). It makes it a binding requirement and applies it to non-exclusive licenses as well as to product sales in foreign countries. As noted in the <u>Update</u>, the Competitiveness Provision also contains some ambiguous language regarding DOE approval of any transfer of rights to subject inventions including license agreements.

On July 23, COGR joined other associations in a call with DOE IP Counsels Brain Lally and Rochelle Blaustein to discuss the new requirement. The DOE representatives explained the purpose and intent of the DEC. It responds to several scenarios DOE has seen that involve emerging energy technologies:

- 1. DOE-funded technology developed and commercialized directly by a small battery company that subsequently was acquired by an "unfriendly" foreign entity;
- 2. U.S. university that issued multiple non-exclusive licenses for DOE-funded technologies; and
- 3. DOE company awardee that decided to focus on foreign sales only and set up manufacturing in China.

In none of these cases did DOE have any binding legal commitment that would have enabled it to enforce a U.S. manufacturing requirement. The DOE representatives also noted the USG concern about disruptive technologies



(e.g. quantum, energy storage) and the February 24 <u>Executive Order</u> on securing critical supply chains. They also mentioned increasing Congressional concerns over the outsourcing of new energy technologies.

The DEC builds on a series of program-specific DECs that DOE has issued over the past eight years. DOE intends to apply the provision prospectively beginning in FY'22 and to a few late FY'21 awards where prior notice has been provided (the long-term national lab contracts will be modified over time). Programs will have flexibilities (e.g., DOE Office of Science may not include the provision in many cases). Also, applicants can request waivers or modifications of the provision upfront (e.g., through submission of US manufacturing plans).

In response to questions about the ambiguous language, DOE indicated that DOE will review mergers only in unusual cases and does not intend to review licenses. Mr. Lally indicated and confirmed in subsequent correspondence that as DOE develops implementation guidance, they will consider FAQs and other explanatory documents to address the various questions and concerns raised and provide the clarity requested by the stakeholder community. In response to a specific question, he indicated that should submission of legal documents (e.g., license agreements) be required, DOE will protect them from FOIA. He also noted that there was discussion of the U.S. manufacturing issue with other agencies as part of the NIST ROI Initiative but nothing further came of it. However, while the interagency discussions in the context of the ROI may not have led further, we understand the Administration now may be considering broadening the domestic manufacturing preference in Bayh-Dole more broadly.

On August 25, COGR joined the Bayh-Dole coalition and AUTM in a <u>follow-up letter</u> to Mr. Lally. The letter encouraged DOE's plan to provide FAQs and further implementation guidance. We are concerned about the potential to adversely affect commercialization of government-funded inventions, especially if this spreads beyond DOE.

Other DOE Developments

New Financial Assistance Guidance (NEW)

During a recent hearing before the Senate Energy and Natural Resources Committee, Dr. Steven Binkley, Acting Director and Principal Deputy Director at DOE Office of Science, was asked by Sen. Barrasso (R-WY), "what's the dept doing to make sure research funding and research results don't go to groups tied to our adversaries...we're concerned about leakage from universities." In his response, Dr. Binkley talked about the security changes they have made in the national labs and also noted the agency is "about to go through rulemaking and put out for notice and comment proposed changes to how we do financial assistance to universities." We previously had heard that new DOE guidance might be forthcoming. We will keep the membership informed.

DOE Order 142.3B (UPDATE)

Concerns continue to be expressed both to COGR and other associations about the foreign national screening requirements under DOE Order 142.3B. Retroactive application of the order has led to researchers, including both PIs and students, being suspended from ongoing projects. In many of these cases no timely approval of their



continued participation has been forthcoming from DOE, resulting in both personal and institutional hardships. The issue mostly involves EERA and NETL at DOE. Earlier this year we met with the Director of NETL to discuss the concerns and have also talked with DOE counsel.

On July 12, COGR joined AAU and APLU in a letter to DOE on this issue. We requested a meeting with DOE management to discuss the seriously adverse consequences of the Order. We met with DOE Acting Under Secretary for Science and Energy Kathleen Hogan on August 26. We reiterated the concerns expressed in the letter and discussed some examples. Under Secretary Hogan assured us that DOE understands our concerns and is actively considering the issues. She stated that DOE needs a more transparent and consistent approach to better balance legitimate concerns about research security while ensuring the ability of our institutions to continue to carry out fundamental research critical to DOE priorities and our national security. We also suggested that it would be very helpful to have a designated point of contact in the Department and clear appeals process for these issues. Based on our discussion, we are hopeful that a clarification of DOE's policy will be forthcoming soon.

COGR Research Security White Paper (NEW)

On August 18, COGR released a white paper on Practical Considerations in Developing An Institutional Response to the Federal Focus on Inappropriate Foreign Influence on Research.

The paper discusses actions that the U.S. Congress and funding agencies action have taken to address the perceived threat that the open U.S. academic environment poses to research security. It includes a possible broad-based model for implementing the JCORE <u>Recommended Practices for Strengthening the Security and Integrity of America's Science and Technology Research Enterprise"</u> in a risk-based fashion to different risk-based categories of research, as well as a reference to the COGR Global Engagement Framework.

The paper also includes an extensive discussion of managing conflicts of interest and conflicts of commitment. (COGR also is updating its "Principles for Evaluating Conflict of Commitment Concern as noted in the REC update section of this Update below.) Reporting outcomes from federal research, managing international visitors, cybersecurity, and export control compliance are among other topics covered. The paper discusses security decisions regarding intellectual property (IP), distinguishing formally protected IP from unpublished research findings, data and materials. Considerations regarding startups also are included. The paper also discusses foreign gift and contract reporting (Section 117).

The paper concludes with a discussion of institutional governance and the administrative structure that institutions may use to operationalize their research security processes. The cost implications also are discussed.

Institutions have engaged in a continued assessment of the security and integrity of their research enterprise, and have taken significant steps toward mitigation while maintaining fidelity to the critical academic values of openness and dissemination. Our federal partners are increasingly acknowledging the progress institutions have made. The paper recognizes that only through a balanced risk/benefit analysis can academic institutions develop appropriate research security measures while still achieving their primary goal of widespread education and knowledge dissemination.



NASEM Security Roundtable Holds Third Meeting (UPDATE)

The COGR <u>February 2021 Meeting Report</u> discussed establishment of the National Academies of Science, Engineering, and Medicine (NASEM) National Science, Technology, and Security Roundtable. The Roundtable was called for in the FY'20 NDAA. It is jointly funded by DOD and NIH. The <u>February Report</u> summarized the discussions at the initial meeting.

The Roundtable held their third meeting on July 7—8. The open meeting sessions included a presentation on international collaboration and engagement by AAU-APLU Presidential Working Group co-chairs President Kent Fuchs of the University of Florida and President Farnam Jahanian of Carnegie Mellon University. They discussed the <u>AAU-APLU principles and values</u> document, which outlines principles and values to help foster protection against foreign government interference without damaging these contributions to national and economic security in the U.S. Toby Smith of AAU also provided Roundtable members with an update on legislative actions and the status of current research security provisions in the U.S. Innovation and Competition Act (USICA) as well as the NSF for the Future Act.

Much of the discussion occurred during closed sessions, particularly as to the Roundtable's future direction. The next meeting is scheduled for October 28-29.

Research Security Legislation Advances (UPDATE)

The <u>May Update</u> and <u>June Meeting Report</u> summarized the extensive Congressional legislation that has been introduced on research security, particularly the U.S. Innovation and Competition Act (USICA; S. 1260) and the NSF for the Future Act (H.R. 2225).

Legislative activity has continued over the summer, although the bills have not been finalized. The <u>May Update</u> summarized the USICA research security provisions. A further summary is <u>available here</u>. A summary of the NSF for the Future Act Research Security Provisions of Interest is <u>available here</u>.

COGR has compiled charts that identify provisions in these bills that may potentially require action by and/or place additional administrative burden on institutions of higher education (IHE) and/or research institutions. In the case of USICA, COGR also noted when similar requirements currently appear in current NIH or NSF guidance, NSPM-33, or the Joint Committee on the Research Environment (JCORE) Recommended Practices for Strengthening the Security and Integrity of America's A&T Research Enterprise (JCORE Guidance). This analysis is shown in Tables A & B here.

In addition, the FY'22 NDAA includes additional provisions pertaining to research security. Subcommittee markups were held the week of July 26. The full House Armed Services Committee markup is scheduled for September 1. The Senate Armed Services Committee held their full committee markup a few weeks ago and voted to advance the measure. We will report further when more details are available.



Cybersecurity Developments (UPDATE)

Cybersecurity Maturity Model Certification (CMMC). We've reported in recent COGR Updates and Meeting Reports on DOD's Cybersecurity Maturity Model Certification (CMMC) Program (see COGR May 2021 Update). We understand that the Department of Homeland Security (DHS) has launched a "pathfinder assessment" to examine whether it should implement a new contractor cyber compliance program similar to the CMMC. DHS officials have previously expressed their interest in possibly implementing a similar program to improve the protection of sensitive information stored on contractor networks. It is unclear what exactly the "pathfinder assessment" is looking at, but the notice states that DHS has been watching CMMC very closely and is looking to learn from its implementation.

As COGR previously reported, the DOD implementation is not going smoothly. Small business contractors in particular have raised cost concerns. Also, the Academic Advisory Council to the Accreditation Body discussed in the May Update has yet to be formally established, for unclear reasons. The Accreditation Body also has experienced frequent turnover of personnel.

<u>Legislative Activity</u>. Sens. Warner, Rubio and Collins have introduced the <u>Cyber Incident Notification Act of 2021</u>, which would require federal agencies, critical infrastructure operators, and federal contractors to report data breaches and security incidents to CISA. It would require "covered entities" to report potential cyber intrusions. A similar requirement is included in the DFARS 7012 clause for contractor information systems that include covered defense information. When the 7012 clause was first issued, COGR expressed concerns about the cyber incident reporting requirements for COGR member institutions (see October 2015 <u>COGR Update</u> and <u>Meeting Report</u>. Large research institutions typically experience hundreds of cyber incidents daily. The proposed bill includes a 24-hour reporting deadline which is not realistic. The bill includes other troubling requirements involving preservation of data and waiver of public notice for implementing rules.

Research Ethics & Compliance (REC)

OSTP Community Forum on NSPM-33 (NEW)

On August 11, 2021, the Office of Science and Technology Policy (OSTP) invited COGR and other associations representing academic research institutions¹ to join representatives from federal agencies² at a two-hour virtual meeting to discuss the National Security Presidential Memorandum 33 on United States Government-Supported

¹ In addition to COGR, represented associations included: American Association for the Advancement of Science (AAAS), American Association of Medical Colleges (AAMC), American Council on Education (ACE), American Council of Learned Societies (ACLS), Association of American Universities (AAU), Association of Public & Land Grant Universities (APLU), National Academy of Medicine, and National Academy of Science, Engineering & Medicine.

² The following federal agencies were represented: Dept. of Agriculture (USDA), Dept. of Defense (DOD), Dept. Education (DOEd.), Dept. of Energy (DOE), Dept. of Justice (DOJ), Dept. of State (DOS), Food & Drug Admin. (FDA), National Institute of Standards & Technology (NIST), National Institutes of Health (NIH), National Security Council (NSC), National Science Foundation (NSF), and Patent & Trademark Office (PTO).



Research and Development National Security Policy (NSPM-33). The meeting was a community listening session to kick-off OSTP's development of a cross-agency implementation plan for NSPM-33 over the next 90 days.

The meeting began with an opening statement from OSTP Director Eric Lander in which he emphasized that the openness of science is fundamental to its progress, but there are actors who take unfair advantage of this openness. He further emphasized that OSTP's goal in implementing NSPM-33 is to ensure that researchers have a clear, simple, uniform method of making disclosures about support they receive for their research and their appointments and affiliations. Dr. Lander cautioned that agencies must provide strong reasons to support variances from uniform standards and must ensure that efforts to protect U.S. research do not degrade into prejudice or xenophobia. Dr. Panchanathan, Director of NSF, also made brief opening remarks, followed by a two-minute statement from each association's president.

Meeting attendees then participated in a roundtable discussion, moderated by Dr. Rebecca Keiser, NSF Chief of Research Security Strategy and Policy. The discussion focused on the following three broad topics for which read-ahead questions were provided in advance: (a) disclosure policies; (b) oversight and enforcement; and (c) research security programs. Listed below are some of the major themes that emerged during the meeting:

- Consistency: Both associations and agencies agreed on the need for consistency in agency requirements. Associations note that some agencies have already taken steps to implement NSPM-33 with key differences in their approaches, and they asked OSTP to carefully consider the standard to which it will harmonize and not default to the most burdensome standard.
- **Certification**: The group discussed the individual and institutional certification of disclosure information. Associations pointed out the inherent difficulty in requiring institutions to certify to information regarding a researcher's external activities because these activities are outside the home institution's control.
- Setting a Baseline: Attendees discussed the need for OSTP to take stock of what agencies and institutions are currently doing and to take time to evaluate what is/is not working before developing new requirements.
- Enforcement: In developing approaches to enforcement, attendees discussed the need for processes that avoid profiling based on nationality and that prevent "false positives" with attending reputational damage. Associations urged OSTP to recognize within its implement plan those provisions of Section 223 of the FY 2021 National Defense Authorization Act (NDAA) that limit institutional liability if the institution has appropriately communicated to researchers their responsibilities regarding disclosure and certification. Meeting attendees also discussed the need to consider time frames for enforcement measures, i.e., is NSPM-33 designed to correct all mistakes of the past or to set disclosure policy moving forward?



- Research Security Programs: Associations advocated the use of a risk-based approach to security program requirements with appropriate gradation based on the type and amount of research. NSPM-33 specifies elements that should be considered in research security programs, and OSTP advised these could be approached in a very generalized or prescriptive manner. Attendees discussed the pros and cons of each approach.
- Continued Stakeholder Input: Associations informed OSTP of the importance of continued meaningful stakeholder engagement, including review of requirements, forms, and templates before they are released and the use of pilot programs.

At the conclusion of the discussion, OSTP advised that it would continue to engage with agencies and the research community as it develops the implementation plan. OSTP published a <u>read-out</u> of the meeting on its website. OSTP also has requested written comments regarding the implementation of NSPM-33, and COGR is working with AAU, AAMC, ACE and APLU on a joint comment letter.

NIH Strategic Plan Components Regarding Inappropriate Foreign Influence (NEW)

On July 30, NIH announced its issuance of the NIH-Wide Strategic Plan for Fiscal Years (FYs) 2021-2021. Of particular note to research institutions is the Plan's third objective: "Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, & Social Responsibility in the Context of Science." This objective discusses NIH's plans to reduce risks to the research enterprise, including those presented by researchers who have failed to disclose support received from foreign organizations. The Plan also describes NIH's work to improve research transparency, rigor, and reproducibility though efforts to promote research integrity, share data broadly, and promoting a diverse and harassment-free workforce.

NIH FAOs on the Reporting of Biosketch Information and Other Support (UPDATE)

Since the June membership meeting, COGR has engaged in conversations with Michelle Bulls, Director of NIH's Office of Policy for Extramural Research Administration (OPERA) regarding questions that COGR member institutions raised concerning NIH's Biosketch and Other Support FAQs. NIH considered inquiries received from the awardee community and made changes to these FAQs to clarify disclosure requirements. Among the more notable changes was NIH's addition of a preamble to the Other Support FAQs that provides a framework within which to read the FAQs, listing important factors and questions institutions should consider when they evaluate the "likelihood of a compliance risk related to improper influence (foreign or domestic)." Importantly, institutions should consider whether any of the relationships that they are reviewing may impact "research integrity, financial conflict of interest, and/or [scientific, budgetary, or commitment] overlap."



The FAQS also clarify that faculty consulting activities must be reported as Other Support only when the consulting activity involves research and "fall[s] outside of an individual's appointment" with their home institution. The FAQS make clear that when consulting activities constitute Other Support, they should be reported as estimates of the amount paid, as opposed to an estimate of time and effort, and further, that they "will not count towards the 12 calendar months of effort."

Additional important "clarifications" in these FAQs include the following items:

- NIH will not require the disclosure of completed support (including completed in-kind support) as Other Support, only current and pending support. (FAQs I.B.3 & I.C.5).
- Institutions need only go back three years in reporting as Other Support materials that were received from external collaborators. (FAQ I.C.7). NIH has provided separate guidance on when data and resources should be acknowledged in grants. [See, FAQs Communicating and Acknowledging Federal Funding.]
- Information may not be redacted from contracts, agreement or other supporting documents that are submitted to NIH. (FAQ I.D.8). [Note that this FAQ differs from some prior NIH verbal statements on this topic.]
- If a researcher has a foreign appointment, affiliation, and/or employment with a foreign institution, they must provide supporting documentation of that relationship, even if they do not have a formal agreement in place. (FAQ I.D.9).

Animal Research

Per the directive of the 21st Century Cures Act, NIH, FDA, and USDA have been reviewing regulations and guidance governing the care and use of laboratory animals for the purpose of determining if revisions can be made to reduce administrative burden while continuing to provide adequate protection for the animals' health, safety and welfare. In line with this mandate, NIH has issued several Requests for Information (RFI) to collect comments on clarifications and administrative flexibilities that NIH has published as means for reducing administrative burden in this arena. REC has provided comments on these RFIs and will continue to do so, including, most recently, those RFIs listed here:

NIH RFI on Clarifying the Reporting Requirements for Departures from the Guide for the Care and Use of Laboratory Animals (NOT-OD-21-161) (NEW)

<u>This RFI</u> seeks comments on "clarifications" from NIH as to when the IACUC is required to report to the institutional official or OLAW deviations from "must," "should," and "may" statements in the Guide. REC will convene a workgroup to develop comments on this RFI. Additionally, the National Association for Biomedical Research (NABR) has reached out about the possibility of having COGR and the other primary



organizations that were involved in drafting the report on <u>"Reforming Animal Research Regulations"</u> develop joint comments.

Response to NIH RFI Concerning Zebrafish (UPDATE)

NIH, through its Office of Laboratory Animal Welfare issued a RFI (NOT-OD-21-118) that stated OLAW would apply the Public Health Service Policy on the Humane Care and Use of Laboratory Animals ("PHS Policy") to zebrafish larvae immediately upon hatching and requested comments on the use of certain flexibilities available under the PHS Policy to lessen the administrative burden of this approach. COGR submitted a response that disagreed with OLAW's stated basis for applying the PHS Policy to larvae at hatching and urged OLAW to reconsider this decision. Failing this reconsideration, COGR fully supported the noted flexibilities.

NIH Guidance on Flexibilities for Conducting Semiannual Inspections of Animal Facilities (NOT-OD-21-164) (UPDATE)

<u>This guidance</u> was issued after NIH collected comments on it via a RFI (NOT-OD-20-145) to which COGR submitted <u>a response</u>. The final guidance addresses some of the comments that COGR raised in its response letter, including:

- Deletion of a provision calling for review of animal facility standard operating procedures, which do not require review of the PHS Policy;
- Clarification that for institutions subject to the Animal Welfare Act (AWA), AAALAC International site visits may be used to meet requirements for an IACUC semiannual inspection when the inspection complies with 9 CFR § 2.31, including having at least two IACUC members participate in the inspection.
- Clarification that IACUCs have the discretion to determine to when conflicts of interest exist regarding semiannual inspections and to determine what methods should be used to minimize bias.
- Deletion of the reference to "field studies" in the provision regarding the use of videos, photos, and other remote methods to conduct inspections, as semiannual inspection of these studies is not covered by the AWA, nor is it *per se* required under the PHS Policy.

The final guidance also includes specific USDA concurrence with the guidance, and some of the provisions were modified to reflect USDA requirements (e.g., provision noting that only live-feed video may be used to conduct inspection of areas housing species regulated under the AWA).



Response to USDA's Notice of Proposed Rulemaking (NPRM) Regarding Contingency Planning [86 FR 33567] (NEW)

The USDA issued a NPRM to amend the AWA regulations (9 CFR Part 2) to require research institutions, dealers, exhibitors, and transporters of animals regulated under the AWA to have contingency plans for handling and care of animals in the event of possible emergences or disasters. COGR fully supported the intent and purpose of the NPRM, noting that the vast majority, if not all, research institutions already have such contingency plans in place. COGR went on to suggest certain changes to improve the proposed regulations including recognition that institutions must have flexibility in plan implementation to meet the individual circumstances of the emergency, as well as flexibility in determining the content and mode of training regarding the contingency plan. COGR also requested that the timeframe for initial and subsequent required training be extended from 60 to 90 days and urged USDA to explicitly accept contingency plans developed to meet the Guide for the Care and Use of Laboratory Animals ("Guide") as being compliant with the proposed rule. COGR also encouraged USDA to reevaluate its estimates of the time it will take institutions to comply with the proposed rule because they were unreasonably low.

Response to OSTP's Request for Information (RFI) to Improve Federal Scientific Integrity Policies [86 FR 34064] (NEW)

OSTP issued a RFI seeking input on the effectiveness of federal scientific integrity policies and the ways in which they could be improved. COGR joined with American Association for the Advancement of Science (AAAS), AAMC, AAU and APLU in submitting a response letter. The letter emphasized the associations' support for White House efforts to restore public trust in science and noted the importance of communicating to the public processes that the federal government employs to ensure "oversight, review, and ethical standards which guard against political interference in the way science is funded or conducted." The letter also emphasized that "building trust requires the engagement of communities whose trust you hope to gain" through broad and meaningful consultation with, and involvement of, those communities in policy review and improvement.

NIH RFI on Developing Consent Language for Future Use of Data and Biospecimens (NOT-OD-21-131) (NEW)

The REC working group established to develop comments in response to this RFI held its first meeting. Comments are being developed and will be submitted by the September 29th deadline.

<u>Update to Principles for Evaluating Conflict of Commitment Concerns in Academic Research ("COC Framework") (NEW)</u>

Since COGR published the <u>initial version</u> of this paper in February 2021, there have been continuing federal agency and legislative efforts aimed at addressing inappropriate foreign influence on federally funded research, NIH and NSF efforts in this space have begun to solidify with the issuance of guidance designed to ensure that researchers are fully disclosing external activities and sources of research support. The REC working group that drafted the paper is currently updating it to reflect recent agency guidance in this area.



The revised paper also will include more specific recommendations for institutions to consider as they review their COC and related policies and processes.

Diversity Toolbox "Fill the Box" Challenge (UPDATE)

At the June meeting, COGR announced the "Fill the Box Challenge" for the Diversity Toolbox webpage. COGR thanks those institutions who have provided tools and encourages others to send in their tools. The tools will be included as a part of COGR's website improvement project. Institutions may email their "tools" (e.g., PDF documents, forms, or links to websites) to REC Director Kris West at kwest@cogr.edu.

COGR/ARIO Project (UPDATE)

The Association of Research Integrity Officers (<u>ARIO</u>) has agreed to work with COGR on producing a webinar and possible paper regarding the nexus between inappropriate foreign influence and the issues of co-authorship, listing of institutional affiliations, and funding. Project progress has been somewhat delayed because of summer vacation schedules, but the group will hold a meeting on August 31 and discuss scheduling of the webinar.

Costing & Financial Compliance (CFC)

Higher Education Emergency Relief Fund (HEERF) & COGR Response to Education (NEW)

First, COGR encourages you to continue accessing the <u>Department of Education HEERF website</u>—there are helpful resources and FAQs around the ongoing topics of allowable charges, treatment of lost revenue and F&A, reporting requirements, audit, and other related topics. Also, the <u>COGR HEERF FAQs (Version 2, last updated April 30)</u> provide helpful content. Note, we submitted specific questions to the Department of Education in July and are awaiting a response. After we receive feedback, our intent is to update the COGR HEERF FAQs.

Second, the <u>COGR Response</u> to the recent Department of Education Federal Register Notice—<u>Docket ID</u> <u>No. ED-2021-SCC-0093. Comments Submitted in Response to Agency Information Collection Activities;</u> <u>Higher Education Emergency Relief Fund (HEERF) I, II, III Data Collection Form</u>—is available on the COGR website. The COGR Response focuses on concerns related to the new reporting requirements and how these may create new administrative burden. Specifically, we encouraged the Department of Education to do the following:

- 1) Accept the COGR requests [described earlier in the letter] and delete both of the following from the data collection request: (1)a) Lost Revenue Documentation and (1)b) Student Demographic Data. And further, reconsider <u>all</u> "after-the-fact" data collection requirements.
- 2) Ensure there is a mechanism for institutions to comment on the usability of the Department-



provided web portal. This will help to make sure that the information technology platform is user-friendly and does not create additional administrative burden.

- 3) Recognize there is an administrative burden and cost impact component to HEERF. Naming this provides another level of transparency and will be a helpful point of reference in future engagements between the Department and colleges and universities.
- 4) Finally, fostering collaboration between the Department and colleges and universities in determining how data is presented to the public could prove beneficial to both the Department and colleges and universities. Stakeholders expect data to be presented in a user-friendly format that conveys an accurate depiction of how institutions implemented HEERF. By seeking input from colleges and universities on how best to present information, stakeholders will be able to accurately assess the data and determine that HEERF was implemented using the highest standards of compliance and stewardship of federal funds.

Also, COGR is regularly collaborating with other Higher Ed Associations (e.g., American Council on Education, Association of Public and Land-grant Universities) on all HEERF-related topics. We expect questions and issues around HEERF implementation, compliance, and audit will be hot topics of discussion for at least the next year, and COGR will continue to provide resources to the COGR membership and serve as a liaison (when needed) to the Department of Education. Contact David Kennedy at dkennedy@cogr.edu with questions, concerns, and/or other issues you would like to address.

2021 Compliance Supplement (NEW)

The 1,787 page 2021 Compliance Supplement was posted on August 13, 2021, on the OMB, Office of Federal Financial Management (OFFM) website. Comments on the 2021 Compliance Supplement were due on to OMB by August 30, 2021 (late comments will be considered to the extent practicable). Comments will be addressed in the development of the 2022 Compliance Supplement—however, COGR's view is that if significant, we will advocate for comments to be addressed sooner.

On August 30, COGR submitted a <u>comment letter</u> and it is available on the COGR website. As a result of the many new programs created under each of the three major federal relief bills passed during the COVID-19 pandemic (e.g., HEERF), the new audit guidance has not always been clear and in some cases, auditor interpretation has not been clear, either. Any and all comments to OMB will be helpful to our community. If you submitted a comment, you can send a copy to David Kennedy at <u>dkennedy@cogr.edu</u>.

As a sidenote, COGR reminds the membership of the standing of the <u>UG FAQs (May 3, 2021)</u> within the 2021 Compliance Supplement. As stated on page 3-2 of the Compliance Supplement (page 28 of 1,787 per the PDF): In addition to the guidance in 2 CFR 200 ... OMB provides answers to Frequently Asked Questions (FAQs) that are found on the CFO.gov website. These FAQs are meant to provide additional context, background, and



clarification of the policies described in 2 CFR Part 200 and should be considered in the single audit work plan and reviews. The FAQs are informal in nature and in the case of any perceived discrepancy between the FAQs and the guidance itself, the guidance at 2 CFR 200 governs.

Finally, note, we expect there will be a 2021 Compliance Supplement Addendum to be released by OMB in the fall. COGR will follow all developments and keep the membership posted.

NSF OIG Audit Finding: Concerns on Application of the F&A Cost Rate (UPDATE)

As we have previously reported, on May 14, COGR wrote a <u>letter</u> to the National Science Foundation (NSF) to address recent NSF Office of Inspector General (OIG) audit findings concerning the application of the F&A cost rate to a new award. Specifically, the NSF OIG cited the following as an audit finding: 1) an F&A cost rate was proposed at 52 percent, 2) at the time of award a new F&A cost rate of 54 percent had been negotiated, and 3) institutional policy allowed the proposed 52 percent F&A cost rate to be used on the award.

The NSF OIG position is that 2 CFR 200 (Uniform Guidance) requires the F&A cost rate of 54 percent to be used for the life of the award, rather than the proposed (and lower) 52 percent. (NOTE: A similar situation could exist in a PI transfer situation when the PI transfers their award(s) to a new institution with a higher negotiated F&A cost rate. Institutional policy may allow the original, lower F&A cost rate to be honored.) COGR's position in both examples is that if institutional policy allows the lower 52 percent F&A cost rate to be used, proposed direct costs for the PI can be maintained and there is no harm to NSF. Note, NSF has indicated to COGR that they have discussed the issue with the NSF OIG and that OMB is preparing a communication to address the concerns shared in COGR's May 14, 2021 letter. We will keep the membership posted on developments.

NSF OIG: NSF Award Recipient COVID-19 Audits and Capstone Report (NEW)

We have been reporting on this NSF Office of Inspector General (OIG) initiative—NSF Award Recipient COVID-19 Audits—since early 2021. The ten audits are now completed and can be found on NSF OIG Audit Reports (see External Report links). Also, the NSF OIG released: Capstone Report (OIG-21-6-003): Observations on the OMB COVID-19 Flexibilities (prepared by Cotton & Company LLP, August 3, 2021). Below we note Page 1 of the report (page 6 per the PDF), which summarizes "WHAT WE LEARNED":

NSF award recipients used the COVID-19 flexibilities to continue performing essential research and services during the COVID-19 pandemic, as summarized in Appendix II, and were generally prudent in their stewardship of federal resources {COGR emphasis added}. Specifically, we noted that the flexibilities were appropriately used by award recipients to:

• Continue employing and paying salaries to individuals unable to perform work due to COVID-19-related shutdowns.



- Donate N95 respirator masks, gloves, and other personal protective equipment (PPE) purchased with federal funds to hospitals across the country.
- Purchase air purifying systems, sanitizing materials, no-touch tools, and other PPE to help ensure the health and safety of employees performing federally sponsored research.
- Donate computing cluster processing resources at an NSF major facility to support COVID-19 vaccine-related research activities.
- Allow employees to change or cancel trips booked with federal funding so that they could safely return home and/or avoid unnecessary travel.

Although the audited recipients generally complied with relevant COVID-19 flexibility guidance and developed some effective practices for monitoring their compliance, as summarized in Appendix III, we identified three common themes affecting whether and how recipients used the flexibilities ...

Additional detail and observations are included in the remainder of the report. Gleaning from both the Capstone report and our observations of the COGR membership throughout the pandemic, COGR's interpretation is: 1) our community was stellar during the heights of the COVID-19 pandemic, and 2) our community provided the highest level of stewardship over federal and institutional resources during a time of great crisis. *Our community, clearly, rose (and continues to rise) to the occasion.*

Challenges with the Payment Management System (UPDATE)

COGR continues to follow challenges with the Payment Management System (PMS). The items below are ongoing, with a recent update specific to NIH Notice NOT-OD-21-149 (see below). Currently, we are following:

- NIH Notice NOT-OD-21-102 (April 2, 2021) and NIH Notice NOT-OD-21-128—both were intended to be a reminder/update on the 120-day closeout requirement. However, the Notices were not clear on the new approval process (if greater than 120 days was requested). COGR asked for clarification and NIH Notice NOT-OD-21-149, Updated Process for Requesting Drawdowns Outside of the Liquidation Period (July 8, 2021), was released. COGR's assessment is the new approval process—using the prior approval module in eRA Commons—provides a clear pathway to request exceptions to the 120-day closeout/liquidation period. We will pay attention as the process unfolds. COGR appreciates NIH's attention to this matter. The important take-away is that the community needs to be diligent on complying with the 120-day closeout requirement and to be discerning on requests for extensions. We expect NIH (and HHS) to be more attentive to (and strict on) enforcing the 120-day closeout deadline.
- o <u>NIH Notice NOT-OD-21-060</u> (February 4, 2021) and <u>NIH Notice NOT-OD-21-138</u> (June 4, 2021) provided "leniency" on late Final Federal Financial Reports (FFRs), due to the problem created by new PMS edit checks. The edits checks were loosened allowing institutions to submit the Final FFR as an Interim FFR. The June 4 Notice reiterated the "leniency" described in the February 4 Notice, and



further indicated that institutions should use the "Remarks" section to indicate if the submission is a Final FFR.

- The Final FFR PMS submission issue also is applicable to Training awards (T32s). Due to student timing issues, a T32 award may have an unliquidated obligation, which creates the same submission challenge. COGR's understanding is the solution is similar to that described above: loosened edit checks allow institutions to submit the Final FFR as an Interim FFR.
- Some COGR members have reported delays to carry-over request approvals. This challenge is related to changes in PMS processes and to recent personnel changes in the NIH Office of Financial Management. NIH is aware of the issue and has indicated new staff is being on-boarded and soon will be up to speed. In the interim, contact your Grants Management Official (GMO) if approval is time sensitive.
- o COGR continues to follow the promised elimination of the Federal Cash Transactions Report (FCTR), which will solve the reconciliation issue between the FCTR and the Final FFR. The most recent update we have received is that this will be addressed later in the 2021 calendar year.
- o Finally, the longstanding G-account closeout issue also is a PMS issue. COGR's understanding is that HHS/PMS will continue a methodical approach to closing legacy G-accounts—and importantly, there should be no issues around inappropriate and/or unilateral closeouts, nor issues around debt collection actions. However, if your institution is struggling to resolve issues, please contact COGR.

COGR and the community appreciate the hard work being done by HHS, NIH, and PMS to resolve these challenges. We will keep the membership posted on all developments.

National Endowment for the Humanities (NEH) and F&A Cost Reimbursement (NEW)

Several COGR members shared with COGR a term in their awards restricting F&A cost reimbursement in situations where the school has a provisional F&A cost rate established with their cognizant agency for indirect costs. COGR shared concerns on this restriction with leadership at NEH, and after their review, we were informed NEH will be lifting the restriction on all NEH awards, past and present.

NEH indicated they have several awards whose period of performance has expired, and for those they will honor the "Negotiated Indirect Cost Rate Agreement" (NICRA). For those awards with an active period of performance, NEH will issue a revised Notice of Action lifting the restriction. For those awards with an expired period of performance, NEH will: 1) issue a revised Notice of Action lifting the restriction, and 2) provide recipients 60 days to draw the remaining provisional rate award funds and submit the final or a revised final FFR. NEH acted quickly to address this concern, and COGR appreciates the outcome.



Costing & Financial Compliance (CFC): Other Issues (ONGOING)

The items below are ongoing issues that the CFC Committee is following:

Facilities and Administrative (F&A) Cost Rates Under COVID-19. In April, COGR released the paper, F&A Cost Rates and Reimbursement Pressures Under COVID-19: Maintaining a Fair and Reliable System, and a corresponding Executive Summary. Both are available on the COGR website. For additional information, please contact David Kennedy at dkennedy@cogr.edu and/or Toni Russo at trusso@cogr.edu.

Tracking NSF and HHS OIG Activity and DOJ Settlements. We encourage the membership to stay connected to federal audit activity and settlements. For recent NSF OIG activity, we recommend reviewing both the Audit Reports (see Internal and External Report links) released by the NSF OIG <a href="maintenance-audits-and-audits-aud

Uniform Guidance (UG) and FAQ Reminder. Electronic versions of <u>2 CFR Part 200 (Uniform Guidance)</u> and the corresponding <u>UG FAQs (May 3, 2021)</u> are available and easily accessed on the World Wide Web.

2019 NSF Higher Education Research & Development (HERD) Survey is Available. The release includes the <u>InfoBrief</u> summary and the complete suite of <u>2019</u> <u>Data Tables</u> (which includes the popular *Table 21 – Higher education R&D expenditures, ranked by all R&D expenditures, by source of funds: FY 2019*).

Please contact David Kennedy at <u>dkennedy@cogr.edu</u> to further discuss any of these issues above, or other items that have not been covered.

Contracts & Grants Administration (CGA)

NIH Modular Grants Cap and Data Management and Sharing Costs (NEW)

COGR continues to discuss possible approaches for covering data management and sharing costs under NIH's Final Policy on Data Management and Sharing (effective January 2023). One strategy that was discussed was to recommend that NIH raise the cap on modular budgets, which raised the question of whether the NIH modular grant application policy/process continues to meet the original intended goals of capturing the majority of applications and reducing investigator, reviewer, programmatic and institutional burden. COGR considered doing



an analysis of modular grants over the last two decades but subsequently learned that NIH is conducting its own analysis and plans to release a blog in the next few months to share the results. COGR looks forward to reviewing the data and will keep the membership apprised. Contact Jackie Bendall at jbendall@cogr.edu for additional information.

Updated NIGMS Guidelines for Funding Investigators with Substantial Other Research Support (NEW)

On July 2, 2021, the National Institute of General Medical Sciences (NIGMS) released notice <u>NOT-GM-21-053</u>, announcing updated guidance regarding <u>NIGMS Funding for Investigators with Substantial Research Support</u>.

Per the Notice, NIGMS will require Other Support to be reported as total costs, as opposed to direct costs, as the criterion for determining proposals selected for Council review under the Institute's policy. This is likely to disadvantage grantees with higher indirect cost rates since it will appear as if those researchers have more research funding than researchers at institutions with lower indirect cost rates. COGR will join the Association of Independent Research Institutes (AIRI) in engaging NIH on this issue. We hope that NIGMS and NIH will recognize the unintended consequence of this effort to enhance Other Support reporting and will permit applicants to report both direct and indirect costs. Contact Jackie Bendall at jbendall@cogr.edu for additional information.

NIH UNITE Initiative (NEW)

The CGA Committee recently hosted Dr. Marie Bernard, Chief Officer for Scientific Workforce Diversity (COSWD) at NIH, to discuss the NIH <u>UNITE initiative</u>, created to identify and address structural racism in the scientific community and to develop efforts to promote diversity and inclusion in the biomedical sciences. In April 2021, COGR <u>responded</u> to NIH's RFI on Suggestions to Advance and Strengthen Racial Equity, Diversity, and Inclusion in Biomedical Research and Advance Health Disparities and Health Equity Research (NOT-OD-21-066). Dr. Bernard indicated that NIH continues to review the more than 1100 responses received to the RFI. The focus is to determine reasons for the low numbers of applicants, primarily focusing at this time on African Americans and Blacks and to develop more pathways for these populations to receive R01 grants.

CGA suggested that Dr. Bernard engage with COGR and other associations and stakeholders for feedback prior to instituting policies and procedures affecting grantees. COGR will monitor the progress of UNITE initiatives over the next several months and hopes to continue to partner with NIH to help ensure success of this important initiative. Please contact Jackie Bendall at jbendall@cogr.edu for additional information.

Cannabis Research (UPDATE)

On July 14, 2021, Senators Chuck Schumer, Cory Booker, and Ron Wyden released draft legislation titled the <u>Cannabis Administration and Opportunity Act</u>. Of particular interest is information on page 5 of the document entitled, "Removal from Controlled Substances Act, Transfer of Federal Agency Function," proposing removal of cannabis from the Controlled Substances Act within 30 days of enactment. A new definition of cannabis would be established within the Federal Food Drug and Cosmetic Act (FFDCA) under title 21 of the



U.S. Code, which establishes requirements for food, dietary supplements, drugs (including biologics), devices, cosmetics, and other substances such as tobacco. This definition would retain the existing exception for hemp.

On August 10th, the U.S. Senate included a provision in the infrastructure bill that would allow U.S. researchers to study marijuana from state-legal dispensaries. COGR has long been an advocate for reducing the barriers for scientists to study cannabis, especially the strains that are currently being used by consumers. COGR will continue to follow the legislation closely. Stay tuned for further updates.



COGR would like to thank COGR Board Chair David Norton (University of Florida) 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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Stephanie Gray	University of Florida
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