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### **President's Message**

#### **Summer Transitions**

#### Dear Colleagues,

This summer marks several transitions for COGR as the academic year ends and the association's fiscal year changes. We started with our <u>June Membership Meeting</u>. Thank you to all who attended. I hope it proved a valuable and engaging opportunity to be with colleagues, hear from key federal officials, and discuss important issues, challenges, and opportunities. We'll use the results from evaluation responses we received to inform our planning for the October 24-25, 2024 meeting.

The Board of Directors recently took several noteworthy actions to advance the mission and work of the association, including:

- approving the Emerging Research Institutions (ERI) Pilot Program that will launch in August (see item in this month's COGR Update);
- approving updates to the association's bylaws to reflect how the association currently operates and to be consistent with good governance and accountability practices;
- appointing, effective August 1, Toni Russo of the COGR staff as the association's Secretary, an officer position required under the updated bylaws;
- reviewing the association's finances and approving its FY25 operating budget;
- appointing Stephanie Endy of Brown University as the next chair of the Contracts and Grants Administration (CGA) Committee effective August 1, and
- electing Stephanie Gray of the University of Florida, Vivian Holmes of MIT, and Craig Reynolds of the Van Andel Institute to the COGR Board of Directors effective August 1.

We welcome Stephanie, Vivian, and Craig to the Board and appreciate their volunteering to serve. As their service ends this month, we thank Board members Jeff Friedland of the University of Delaware, who has served as chair of the CGA Committee, and Jeff Silber of Cornell University who previously served as chair of the Costing and Financial Compliance (CFC) Committee and has chaired the Board since 2022, for their contributions and leadership.

On September 3, we will welcome Cynthia Hope as COGR's next Director for Costing and Financial Compliance. She brings deep experience and expertise from her previous positions at Georgia Tech and the University of Alabama and her past service as a COGR Board member and committee chair. Let me note that in August, current CFC Director David Kennedy will transition to the role of Senior Fellow in which he will focus on specific projects.

Lastly, I wish to note two important policy transitions on the horizon and COGR's advocacy to make the updated policies work effectively for research institutions and the federal government. First, last month we sent OMB suggested technical corrections to the final Federal Financial Assistance Guidance. For over a year, the CFC and CGA Committees and members of COGR's working group on the UG update worked diligently to analyze the changes and make recommendations that balance the government's need for accountability and research institutions' need for clear and sensible policy that minimizes compliance burden. Our latest recommendations again strike this balance and demonstrate that COGR members take seriously their responsibility to be good stewards of taxpayers' investments in federal research.

Second, OSTP last week issued the long-awaited Guidelines for Research Security Programs at Covered Institutions, per NSPM-33. For years, COGR's RSIP, REC, and CGA Committees have thoroughly analyzed and developed balanced recommendations related to NSPM-33, agency proposals, and the draft guidelines. In many respects, the final Guidelines are an improvement over the original proposals. As we recommended, they include a call for cross-agency consistency and consideration of administrative burden in developing implementation plans. However, they also afford agencies the ability to adopt different requirements, and they contain several requirements that are yet to be developed (e.g., cybersecurity standards, international travel security training). We will continue to advocate that varying policies be the exception, and not the norm, and urge agencies to seek stakeholder input before finalizing new requirements.

Matt Owens, President



#### Announcements

#### Save the Date: October 24-25, 2024, COGR Meeting in Washington D.C.

COGR's next meeting will be in-person on October 24-25, 2024 at the <u>Washington Marriott in Georgetown</u>. Registration will open in August via the COGR Listserv.

If you do not already have access to the COGR Portal and are interested in registering for the upcoming meeting, please request access here. Contact memberservices@cogr.edu with any questions, and we hope to see you there!

#### Coming August 2024: Emerging Research Institutions Pilot Program



As announced throughout this past year, COGR is launching an Emerging Research Institutions (ERI) Pilot Program on August 1, 2024. This program provides an opportunity for institutions that do not yet meet COGR's membership threshold<sup>1</sup> to formally engage with COGR and participate in COGR activities. The ERI Pilot Program aims to provide a pathway for COGR's direct engagement with ERIs. We hope the program will strengthen the totality of the U.S. research ecosystem by providing resources, information, and opportunities for networking across the wide spectrum of research institutions, many of which collaborate with each other through subawards and other projects.

Additionally, engagement with ERIs will help support and strengthen COGR's advocacy efforts with federal agencies especially on the cost and administrative burden of complying with research regulations and policies.

**Please note:** Smaller public institutions that have staff on COGR's listservs or have participated in COGR events over the years based on their flagship campus's membership are invited to apply for the ERI Pilot Program if they wish to continue to participate in COGR activities.

#### Key Program Information:

- Eligibility: Institutions of higher education reporting less than \$15 million in annual federal research expenditures on the NSF HERD survey are <u>eligible to apply</u>. <u>As there is limited capacity</u>, applications will be considered using a variety of factors to ensure diversity among participating ERI Pilot Institutions.
- **Pilot Duration:** The initial duration of the Pilot Program will be two years and will coincide with COGR's fiscal year. Year 1 will be August 1, 2024 July 31, 2025. Year 2 will be August 1, 2025 July 31, 2026. The Pilot Program will be evaluated in the spring of 2025 for potential extension, transition, or completion.

<sup>&</sup>lt;sup>1</sup> At least \$15M in annual federal research expenditures as reported in the most recently published NSF HERD survey or equivalent.

- **Annual Fee:** *The annual participation fee for the initial phase of the pilot will be* \$3,500 *per year, per institution.*
- What's included? ERI Pilot Institutions may have up to five representatives. Each will have access to the COGR Portal. One representative per institution is permitted to register for in-person Membership Meetings. All representatives may register for virtual Membership Meetings and webinars. In-person meeting registration is currently \$550 per person and virtual meeting registration is approximately \$300 per person, or \$250 per person if registering five or more. ERI Pilot institutions are also highly encouraged to participate in COGR surveys, working groups, and other opportunities to engage that may arise.
- What is not included? Participation in the ERI Pilot Program does not constitute membership in COGR. Representatives from ERI Pilot Institutions are ineligible to serve on the COGR Board of Directors or on one of COGR's four standing committees. However, representatives from ERI Pilot Institutions are eligible to serve on working groups. To facilitate this, at least one representative from each ERI Pilot Institutions will be asked to complete a volunteer form to identify areas and issues of interest.

**Though ERI Pilot Program participation does not constitute COGR membership**, once an ERI Pilot Institution becomes eligible for membership (reporting \$15 million or more in annual federal research expenditures on the NSF HERD), the institution will be invited to apply for membership for the following fiscal year.

Please note: <u>There is a limited number of openings</u> in the first year of the Pilot Program (August 1, 2024 - July 31, 2025). Institutions not selected in the first year are encouraged to apply in year two of the program.

COGR will host a webinar on the Pilot Program for interested and participating institutions in the coming months, and details will be sent to the COGR listserv and on COGR's website. Contact <u>ERIservices@cogr.edu</u> with any questions related to the ERI Pilot Program.

#### **Upcoming Comment Due Dates**

As part of this Update, we have included a consolidated table of upcoming comment due dates by agency, relevant links, and quick notes on COGR actions regarding each (<u>Appendix A</u>).

#### **Reminders**

COGR Membership Renewal – Renew by August 1 in the COGR Portal



If you are your organization's Primary Representative (PR) or billing contact, it's now time to renew your institution's COGR membership and retrieve your annual dues invoice. As a reminder, COGR membership covers the entire institution and provides all staff with COGR <u>Benefits of Membership</u>, including access to the COGR Portal.

*To renew your institution's membership*, log onto the <u>COGR Portal</u>, and from the Dashboard, click on the link in the gray renewal badge. You will be asked to update your contact information and then choose check or EFT/ACH payment. Once that is complete, you will be able to download your institution's annual dues invoice.

#### July 2024 COGR Update

PR's and billing contacts can view and manage their institution's invoice at any time on the COGR Portal Dashboard under "My Account – Invoices & Receipts."

Please ensure your payment records have been updated to reflect COGR's new physical and mailing address:

#### COGR 601 13th Street NW 12th Floor Washington DC 20005

An updated W-9 is available on COGR's <u>website here</u>. If you have questions, need institutional forms updated, and/or would like to set up EFT/ACH payments, please reach out to <u>memberservices@cogr.edu</u> now and allow for additional processing time.

#### COGR Volunteer Survey

Interested in becoming more involved with COGR? Complete the <u>COGR Volunteer Survey</u> and let us know your areas of interest/expertise, the capacity in which you would like to serve, and other relevant information. COGR uses this survey to help identify individuals to serve on COGR's <u>four standing committees</u>, workgroups we convene from time to time on various topics, and more.

#### Follow COGR on LinkedIn



We invite you to follow <u>COGR on LinkedIn</u> and stay up to date on COGR's advocacy efforts, upcoming events, and more. We look forward to engaging with you on LinkedIn.

#### COGR Portal: Sign up for Access Today!

Did you know that all staff at COGR member institutions are eligible and encouraged to <u>sign up</u> for access to the COGR Portal as part of the institution's <u>COGR Member Benefits</u>? The Portal is where you can sign up for our listserv, browse our <u>video library</u>, view the <u>COGR Member Directory</u>, check out <u>COGR's Job Board</u>, and view other members-only materials.

### 2 CFR 200 "Uniform Guidance" Cross-Cutting Issues

#### **<u>COGR Proposes Technical Corrections and Comments for the OMB Guidance (NEW)</u></u>**

At OMB's invitation, COGR provided OMB with recommendations on nine items to address ahead of the October 1, 2024 implementation of the <u>OMB Guidance for Federal Financial Assistance</u> (OMB Guidance).

The <u>letter</u>, dated June 28, 2024, includes recommendations on implementation, technical corrections, and policy concerns. The following nine items were addressed:

- 1. **Implement the Changes to the Equipment and Subaward Thresholds:** COGR proposes that OMB issue guidance to ensure that all institutions are provided a pathway to implement the new thresholds as soon as October 1, 2024.
- 2. Do Not Implement Fixed Amount Awards and Subawards Changes: Partner with the Community to Implement Changes at a Future Date: The language on fixed amount awards and subawards should revert to the 2020 language and include the \$500,000 threshold, which will allow all stakeholders to work towards language that achieves the proper balance between appropriate oversight, achieving performance outcomes, and minimizing administrative burden.
- 3. Reaffirm the Partnership: Streamlining Regulation and Strengthening U.S. Competitiveness in Global Research and Development: The longstanding "Consistency" and "Fair Share" principles should be maintained as part of the OMB Guidance.
- 4. Voluntary Uncommitted Cost Sharing (VUCS): Aligning the Preamble with 200.306(k): Improve VUCS guidance by extending flexibilities to all research entities, not IHEs only. Improve the definition of VUCS as suggested by COGR and eliminate the reference to the almost 20-year-old, outdated memorandum OMB M-01-06.
- 5. Sole Source Procurement is Appropriate for Specialized Scientific Items: 200.320(c): Incorporate FAQ #88, which permits specialized scientific items to be acquired under a sole source procurement action.
- 6. Implementation of Indirect (F&A) Cost Rates in a Timely Manner: 200.414(c)(2): Memorialize OMB's role to address delays and related issues with implementing federally negotiated indirect cost rates.
- 7. Retract the New Text Applicable to Unused Leave: 200.431(b)(3)(i): COGR urges OMB to delete the new text proposed by OMB, which is problematic and will inappropriately disallow an accounting methodology applicable to unused leave that is acceptable under GAAP and that is used regularly by many institutions.
- 8. Retract the New Requirement for Agency Approval of a Subaward Condition: 200.332(d): COGR urges OMB to delete the new text requiring a pass-through entity to notify the federal agency if the pass-through entity implements a specific subaward condition, which creates new burden without any corresponding benefit to oversight of federal funds.
- 9. Eliminate the Expectation for the Prime Recipient to Negotiate Indirect Cost Rates with a Subrecipient: 200.414(f): COGR urges OMB to delete the new text that sets an expectation for the prime recipient to accept an indirect cost rate proposal from a subrecipient and subsequently, negotiate a unique indirect cost rate with the subrecipient as it creates a significant administrative burden which is in direct opposition to the spirit of the new OMB Guidance.

We will be in regular contact with OMB about technical corrections and implementation will keep the membership posted on new developments.

#### The New "OMB Guidance" is Available (REMINDER)

The <u>OMB Guidance for Federal Financial Assistance</u> (Title 2, Code of Federal Regulations; i.e., 2 CFR) was posted to the Federal Register on April 22 and is effective on October 1, 2024. The OMB Guidance covers the following:

- Part 1 About Title 2 CFR
- Part 25 Unique Entity Identifier and System for Award Management
- Part 170 Reporting Subaward and Executive Compensation
- Part 175 Award Term for Trafficking in Persons
- Part 180 Guidelines to Agencies on Debarment and Suspension
- Part 183 Never Contract with the Enemy
- Part 184 Buy America
- Part 200 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

COGR's work and advocacy has addressed the entirety of Title 2, though our primary focus has been on Part 200. While OMB is no longer considering changes, officials indicated they are open to observations and comments related to technical corrections, significant concerns, implementation processes, and other clarifications. We believe this includes addressing the status of the <u>current FAQs</u>, <u>dated May 3</u>, 2021. Accordingly, COGR provided comments and proposed technical corrections (see previous section).

Also of note is the availability of a <u>redline version</u> of the OMB Guidance. This version shows changes between the current version (published in 2020) and the new version published on April 22. COGR's <u>Uniform (OMB)</u> <u>Guidance Resource Page</u> is a resource we will continue to update with new and helpful material. If you have any questions or comments, please contact Krystal Toups at <u>ktoups@cogr.edu</u> and David Kennedy at <u>dkennedy@cogr.edu</u>.

#### The OMB Guidance: Continuous COGR Analyses and "Looks" (ONGOING)

COGR is conducting deep-dive analyses and corresponding education and advocacy efforts to support the membership in the lead up to the October 1, 2024 effective date of the OMB Guidance. Our plan is as follows:

- *First Look: COGR Preliminary Assessment of Selected Items (April 24)*. Covers major changes, including items for which COGR advocated, but were not accepted by OMB. This is meant only to be a "first look" and does not address all changes or the changes in detail.
- <u>Second Look: Webinar on the Final OMB Guidance for Federal Financial Assistance (May 15</u>). Leaders from the Contracts & Grants Administration (CGA) and Costing and Financial Compliance (CFC) committees discussed some of the most significant changes, with a focus on implementation and how they will impact institutions. The slides and video of the webinar are available to all members via the <u>COGR</u> <u>Portal Video Library</u> (log in required).
- *Third Look: Thursday, June 6 COGR Meeting Final OMB Guidance for Federal Financial Assistance, What's Next?* OMB leaders Deidre Harrison, Deputy Controller, and Steve Mackey, Policy Analyst, provided additional insights and responded to questions from the membership. The session included a robust Q&A segment where many of the issues addressed in the June 28 COGR letter were discussed.

- *Fourth Look: COGR Proposes Technical Corrections and Comments for the OMB Guidance*. In a letter dated June 28, 2024 (see previous section), COGR addressed nine items for OMB to consider before the October 1, 2024 implementation date.
- *Fifth Look: Implementation Guide.* We expect this will be available later this summer in advance of the October 1, 2024 implementation date. This COGR publication will address all changes and provide points to consider as institutions prepare to implement the OMB Guidance.

The next important step is the formal adoption of all Parts of the OMB Guidance by federal agencies. We understand that agency plans – including proposed agency deviations – were due to OMB by May 15. Agency plans should be made available to the public in coordination with the October 1, 2024 implementation date.

We will keep the membership updated on all COGR activities and advocacy.

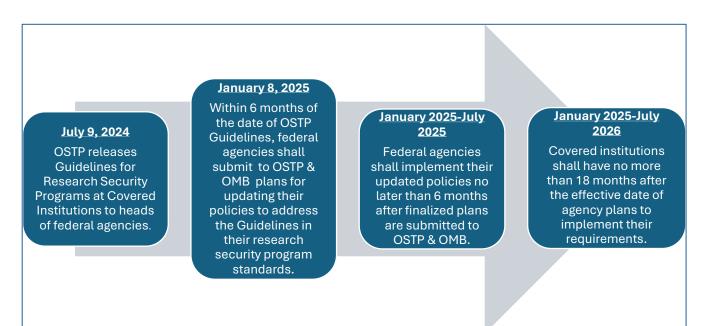
### Science & Security: Cross-Cutting Issues

#### **Overview of OSTP Guidelines for Research Security Programs at Covered Institutions (NEW)**

This overview is also available as a PDF download on COGR's website here.

OSTP published its long-awaited <u>research security program guidelines</u> on July 9, 2024. The Guidelines confirm the four mandatory program elements necessary for a compliant research security program: (1) Cybersecurity; (2) Foreign Travel Security; (3) Research Security Training; and (4) Export Control Training. They also provide an implementation timetable for federal agencies and institutions:

#### **Implementation Timetable:**



The Guidelines represent an improvement from the <u>prior draft standards</u> in certain respects and provide greater flexibility for institutions in developing institutional research security programs. Notably, the Guidelines incorporate a number of existing statutory and policy definitions, which promote consistency. The Guidelines also include a clear definition for "Covered Institution" that cites concrete reference points institutions can use to determine if they meet the financial threshold for establishing a research security program. Importantly, the Guidelines state that they provide "standardized requirements," and they encourage agencies to consider administrative burden and impacts on less-resourced institutions in developing implementation plans.

However, despite the Guidelines' call for cross-agency consistency and agency consideration of administrative burden in developing implementation plans, they also afford significant latitude to agencies in their interpretation and implementation. Specifically, the Guidelines set forth a clear path that agencies can follow to adopt *different* requirements. Further, they contain no specific means by which administrative burden (particularly burden on lesser resourced institutions) must be measured or limited.

Finally, the Guidelines contain several provisions that cannot be fully assessed because they require significant further development by the federal government. For example, the Guidelines' cybersecurity standards reference a National Institute of Standards and Technology (NIST) resource that has not yet been published. Additionally, the institutional certification system is undefined, and the federal government resource that institutions may use in providing mandated foreign travel security training is not yet developed.

**Background**: The Guidelines were issued to fulfill the mandates of <u>National Security Presidential Memorandum</u> <u>33 (NSPM-33)</u> and relevant provisions of the <u>CHIPS and Science Act of 2022</u>. The Guidelines present a "standardized requirement" for "uniform implementation" across federal agencies.

The Guidelines state that the overarching purpose of federal research security efforts "is to make sure that institutions of higher education (IHE) and other research institutions recognize the altered global landscape and fulfill their responsibilities as the first line of defense against improper or illicit activity." They also note that actions that researchers were encouraged to take a decade ago, including "collaborations with the PRC" are now recognized as presenting risks.

<u>**Guidelines as a Baseline</u>**: The Guidelines state that federal research agencies are permitted "to develop additional requirements for the research security programs" in addition to the four required program elements. Such additional requirements must be reviewed and approved by OMB and OIRA. Federal research funding agencies are instructed to limit additional requirements to the following circumstances:</u>

- When required by statute, regulation, or executive order or action.
- When more stringent protections are necessary to protect classified information, export-controlled technologies, or other legally protected matters.
- When there are "other compelling agency-specific reasons consistent with legal authorities and mission of an individual agency and in coordination with OSTP."

When imposing additional requirements, the Guidelines instruct agencies to determine if concerns can be addressed at the award level. Further, agencies must also consider whether the additional requirements under consideration:

- Address a clear and describable risk "related to an observed or known improper or illegal" transfer of U.S. government-supported research and development (R&D) to a foreign country of concern.
- Are relevant to all fields of R&D conducted at the Covered Institution, including R&D areas that present minimal or no risk of U.S.-government supported R&D transfer to a foreign country of concern.
- Impose a substantial burden on the Covered Institution, particularly if it is a less resourced institution.
- Require the provision of supplemental funds to the Covered Institution to permit the institution to satisfy the additional requirement(s).

<u>Applicability of the Guidelines</u>: Unlike the draft version, the Guidelines provide specific references for institutions to use in determining whether they meet the \$50 million financial threshold for the establishment of a security program. Specifically, the Guidelines provide the following definition of "Covered Institution":

For purposes of this guidance, a participant in the U.S. R&D enterprise is a "covered institution" if and only if (A) it is an institution of higher education, a federally funded research and development center (FFRDC), or a nonprofit research institution; and (B) it receives in excess of \$50 million per year, in fiscal year 2022 constant dollars, under (1) the three-year average of federal R&D obligations provided to participants in the U.S. F&D enterprise as reported in the most recent version of the Survey of Federal Science and Engineering Support to Universities, Colleges, and Nonprofit Institutions;<sup>2</sup> or (2) the three-year average of federal R&D obligations to FFRDCs as provided in the most recent versions of the Survey of Federal Funds for Research and Development.<sup>3</sup>

Additionally, federal research funding agencies are "encouraged to adopt research security requirements similar to those in this memorandum for non-covered institutions that meet the funding threshold" set forth in part (B) of the foregoing definition.

**Definitions**: Aside from the definitions of "Covered Institution" and "Non-covered Institution," the Guidelines do not contain new definitions for defined terms used in the document. Rather, the Guidelines refer to existing definitions for these terms that are set forth in statutes, regulations, or NSPM-33. The main definitional reference cited is the CHIPS & Science Act of 2022.

**Required Elements of a Research Security Program and Certification that Covered Institution has a Security Program**: Each Covered Institution's research security program must include the following four elements: (a) Cybersecurity; (b) Foreign Travel Security; (c) Research Security Training; and (d) Export Control Training, as appropriate.

<sup>&</sup>lt;sup>2</sup> <u>https://ncses.nsf.gov/surveys/federal-support-survey/2022</u>

<sup>&</sup>lt;sup>3</sup> https://ncses.nsf.gov/surveys/federal-funds-research-development/2022-2023

Institutions must certify that they have a research security program that includes these elements. The Guidelines do not describe the mechanism per which institutions will provide this certification to federal agencies. Rather, they state that within 90 days of the Guidelines' issuance, the NSTC Subcommittee on Research Security "will provide agencies with additional details on a system for U.S. government collection of certifications from covered institutions."

<u>Specifications for Cybersecurity</u>: IHEs are required to certify that the institution will implement a cybersecurity program that is consistent NIST's publication of the final version of <u>NIST IR 8481</u>: <u>Cybersecurity for Research</u> <u>Findings and Possible Paths Forward</u> (Aug. 31, 2023). IHEs will have one year after the publication of the NIST document to implement a cybersecurity program that meets the document's requirements. Non-IHEs are required to certify that they will implement a cybersecurity program that is consistent with another "relevant cybersecurity resource maintained by NIST or another federal research agency" that is not specifically named in the Guidelines.

Notably, the referenced NIST document does not identify a specific cybersecurity framework or set of practices that institutions are required to follow. Rather, it constitutes a summary of the study used to create NIST IR 8481, a description of broad categories risks and challenges that research institutions face in the cybersecurity landscape, recommendations for future work, and next steps, along with an appendix of NIST resources for managing cybersecurity risks. The "next steps" include determining "whether additional cybersecurity resources can be tailored for" for general audiences and specific fields of study, as well as coordination "with other federal agencies on cybersecurity for research contexts" and promotion of "consistent application of NIST guidance." Accordingly, it remains to be seen what will emerge as the ultimate cybersecurity resource.

<u>Specifications for Travel Security</u>: The Guidelines require Covered Institutions to provide periodic training on foreign travel security and implement a foreign travel reporting program as follows:

• *Foreign Travel Security Training*: Each Covered Institution must certify that it will provide "Covered Individuals" (as defined in the CHIPS and Science Act of 2022) who are "engaged in international travel, including sponsored international travel, for organization business, teaching, conference attendance, or research purposes" with periodic training on foreign travel security. This training must initially be provided within one year after a federal research agency makes a "foreign travel security training resource" available, and thereafter, at least once every six years.

The Guidance goes on to note that training modules provided by federal research agencies constitute such a "resource," and that NSF, NIH, Department of Energy, Department of Defense, Department of State are coordinating through the NSTC Subcommittee on Research Security to contract for the production of a foreign travel security training module. The Guidelines do not provide a timeline for the module's development.

• *Foreign Travel Reporting Program*: In addition to foreign travel training requirements, Covered Institutions must implement a "travel reporting program" that includes an "organizational record of international travel" "for covered individuals participating in R&D awards when a federal research agency

has determined that security risks warrant travel reporting in accordance with the terms of an R&D award."<sup>4</sup>

As drafted, the reporting program requirement applies to persons who (a) meet the definition of "Covered Individual"; <u>and</u> (b) are participating in an R&D award that the federal research agency has determined presents security risks that warrant travel reporting and includes this requirement in the award terms. This approach differs from the broader language of the NSPM-33 Implementation Guidance.<sup>5</sup>

In terms of the types of travel that are covered under the reporting requirements, the provision makes no explicit reference to including a Covered Individual's personal travel within its scope. However, in providing examples of covered travel, the provision is unclear as to whether the listed examples are exclusive or non-exclusive. Further, the provision does not address travel that is undertaken for one purpose and then incidentally includes one of the other specified activities (e.g., personal travel to a country undertaken for vacation purposes and delivery of an impromptu lecture while visiting).

<u>Specifications for Research Security Training</u>: Each Covered Institution must certify that it has "implemented a research security training program for all covered individuals to address the unique needs, challenges, and risk profiles of covered individuals" and that each Covered Individual completes this training. This requirement may be met in one of two ways:

- Certification that Covered Individuals are required to complete, and have completed, the training modules that NSF has <u>published</u> (or successor training developed by the federal government).
- Certification that Covered Individuals are required to complete, and have completed, a research security training program that (a) includes explicit examples of behaviors that have resulted in "known improper or illegal transfer of U.S. government-supported R&D in the context of the research environment, as described to the covered institution by federal research agencies"; and (b) communicates to Covered Individuals "the importance of U.S. researcher participation in global discoveries, including attracting foreign talent to U.S. research institutions, as a core principle of maintaining international leadership and national security."

The Guidelines specify that "a covered institution's certification requirement is met" when it provides a written or electronic attestation to a federal research funding agency that it "meets the relevant research security program requirements." As previously noted, details on the institutional certification system are forthcoming. Additionally, each Covered Individual must certify that they have completed research security training. The Guidelines do not address the mechanism for this individual certification, but as with other research security-related certifications, it may be included in proposal application forms.

<sup>&</sup>lt;sup>4</sup> In implementing this requirement, institutions must also consider any separate agency requirements for reporting sponsored or reimbursed travel (e.g., NIH conflict of interest regulations at 42 C.F.R. §50.603, definition of "significant financial interest").

<sup>&</sup>lt;sup>5</sup> <u>NSPM-33 Implementation Guidance (Jan. 2022)</u> at p. 18 ("Foreign travel security. Agencies should require that research organizations maintain international travel policies for faculty and staff traveling for organization business, teaching, conference attendance, research purposes, or any offers of sponsored travel that would put a person at risk. Such policies should include an organizational record of covered international travel by faculty and staff and, as appropriate, a disclosure and authorization requirement in advance of international travel, security briefings, assistance with electronic device security (smartphones, laptops, etc.), and pre-registration requirements.").

<u>Specifications for Export Control Training</u>: Covered Institutions must certify that Covered Individuals "who perform R&D involving export-controlled technologies"<sup>6</sup> complete training on U.S. export control and compliance requirements. This requirement may be met in one of two ways:

- Certification that such Covered Individuals have completed "relevant trainings" administered by the Department of Commerce's Bureau of Industry and Security (BIS).<sup>7</sup>
- Certification that such Covered Individuals are required to complete training on complying with (a) U.S. export control and compliance requirements; and (b) requirements and processes for reviewing foreign sponsors, collaborators, and partnerships.

Notably, the Guidelines do not cite specific BIS training modules that must be included as a part of required export control training. It is unclear whether agencies are expected to provide additional specificity in their implementation plans, or whether institutions will have complete latitude in this regard.

Additional Principles that Federal Research Funding Agency are Instructed to Follow in Implementing the Guidelines: The Guidelines call for research funding agencies to follow the broad principles set forth below in implementing the Guidelines; however, the Guidelines do not provide much in the way of specific instructions or examples for their implementation:

- Prohibit discrimination, stigmatization, or targeting, on the basis of race, color, ethnicity, religion, sex (including gender, pregnancy, and sexual orientation), national origin, age (i.e., 40 or older), disability, or genetic information. Federal research agencies must require Covered Institutions to certify that they have implemented safeguards to protect the rights of researchers, students, and research support staff, and the Guidelines note that many institutions must already comply with similar requirements under cited civil rights statutes.
- Provide flexibility for institutions to structure their research security programs to best serve their needs and to leverage existing programs and resources.
- Reduce administrative burden on Covered Institutions and Covered Individuals, with particular attention paid to administrative burden on less resourced institutions. In this respect, federal research funding agencies are expected to provide institutions with technical assistance and other resources to aid in compliance.
- Minimize impact to smaller institutions to facilitate their participation in federal R&D programs.

<sup>&</sup>lt;sup>6</sup> The Department of Commerce Export Administration Regulations (EAR) considers technology that arises during, or that results from, fundamental research as being exempt from export control regulations. [15 C.F.R. §734.8]. The Department of State and Department of Energy maintain similar positions in their respective export control regulations. [22 C.F.R. §120.34 & 10 C.F.R. §810.2]. This exclusion is commonly referred to as the "fundamental research exemption" (FRE). However, R&D results not considered fundamental research, as well as controlled research inputs (e.g., highly controlled equipment, third-party proprietary data, technical data subject to International Traffic in Arms Regulations) would be subject to export control regulations and considered "export-controlled technologies." Universities typically manage risks associated with R&D involving export-controlled technologies via technology control plans that frequently include mandatory export controls training for individuals subject to the plans.

<sup>&</sup>lt;sup>7</sup> Note that the Guidelines also reference publicly available resources from the Department of State, Directorate of Defense Trade Controls, and states that these resources may assist an institution "in developing its own individually tailored and robust compliance programs."

COGR will continue to evaluate these Guidelines and consult with COGR members on areas of the Guidelines that require further elaboration or clarification.

#### <u>Follow-Up with Department of Defense (DOD), Army Research Laboratory (ARL), and Defense</u> <u>Advanced Research Projects Agency (DARPA) Representatives on Risk Assessment and Mitigation</u> <u>Processes (NEW)</u>

In March – April 2024, COGR conducted a survey on COGR members' experiences with DOD, DARPA, and ARL, risk assessment and mitigation efforts and published a <u>report</u> on the survey's results. A copy of the report was provided to DOD, DARPA, and ARL representatives. In follow-up, members of COGR's Research Ethics and Compliance (REC), Research Security and Intellectual Property (RSIP), and Contracts and Grants Administration (CGA) committees met with the following agency representatives on June 5, 2024:

- Dr. Bindu Nair, Director, Basic Research, DOD
- Dr. Barton Halpern, Director, Army Research Office, ARL
- Mr. Jesse Watkins, Program Security Officer, DARPA

Drs. Nair and Halpern and Mr. Watkins were provided with a summary of the survey's results, as well as advance questions that were collected from committee members. All the representatives emphasized that their goal in the risk assessment and mitigation process is to get to "yes" if possible. Additional key points from the discussion are set forth below:

- Consistent Use of the <u>DOD Policy for Risk-Based Security Reviews of Fundamental Research</u> and <u>DOD Component Decision Matrix to Inform Fundamental Research Proposal Mitigation Decision</u> (collectively "DOD Policy and Matrix"): DOD does not have a timeline for when DOD components must implement the DOD Policy and Matrix. DOD expects that each component will develop policies and guidance that align with the overarching DOD risk mitigation program requirements and provide these policies and guidance to DOD for review. DOD recognizes that each component has its own level of risk tolerance, and thus, there may be faculty members that receive funding from one DOD unit and not from another because a unit is willing to accept more risk. The representatives noted that DARPA has the highest risk tolerance, while ARL is the least risk tolerant.
- **Risk Mitigation Plan Elements and Templates**: ARL takes a "four-pronged approach" to mitigating risks for Sr./Key Personnel that includes: (1) reporting of all international travel; (2) notification of future collaborations with persons/entities in foreign countries of concern; (3) training on risk assessment; and (4) updates on any changes on at least an annual basis. DARPA has an internal document that provides seven mitigation tools, which are tailored to add address the specific facts of each case.

Both DOD and ARL emphasized that every proposal should be viewed individually and risk mitigation plans are highly fact and proposal specific, so templates may not be possible. However, DOD expects that over time mitigation plan requests will become more standardized and a template document or best practices may eventually be developed.

• **Timeline for Review of Risk Mitigation Plans**: DOD has not mandated any required turn-around times, but DOD, ARL, and DARPA representatives emphasized that they are working to review risk mitigation plans as quickly as possible. ARL typically provides responses to plans in four to six weeks, and DARPA has a two to four week turn-around time.

DOD noted that if an award is part of a program in which multiple awards are being made, DOD will not announce awards individually. Accordingly, if negotiations on a risk mitigation plan are continuing with one awardee, no awards will be announced (including an announcement that risk mitigation plans have been accepted) until all awards are finalized. ARL also noted that if funding is awarded on a proposal, then a risk mitigation plan is considered accepted, even if the institution receives no specific formal response on its proposed plan.

- **Risk Assessment and Mitigation Concerning Co-Authors:** COGR Committee members raised multiple questions regarding how DOD, DARPA, and ARL assess risks posed by co-authors who have connections with foreign countries of concern. DARPA advised that it considers the following factors in evaluating these risks: whether and from whom the co-author received funding; the proposing faculty member's and co-author's position within their institution; whether the foreign institution is a country of concern; respective contributions to publications; and author order. ARL stated that it considers the proposing faculty member's past, present, and proposed relationships; contributions to the paper; and relationship patterns. ARL representatives advised that generally one instance of co-authorship will not result in a funding denial, nor is it problematic if a student works on a project in the U.S. and then appears as a co-author on a paper with the proposer after the student returns to their home country. Rather, ARL looks for active and on-going author relationships and evaluates the risks they pose.
- **Providing Information to Institutions about Risks that Must be Mitigated:** In addition to reviewing the "Section 1286 lists, DOD units also may consider entities on lists that are not publicly available. Further, ARL considers both public and classified information in evaluating risks, and thus may not always be able to provide detailed information to institutions when it requests risk mitigation. DARPA, on the other hand, uses only public information when it reviews proposals involving fundamental research. DARPA's findings and the sources that it consulted in making its decisions are included in the memorandum that DARPA provides to the institution when it requests mitigation.

**Malign Foreign Talent Recruitment Program (MFTRP) Policy:** The DOD risk matrix states that by August 9, 2024 institutions must have a policy prohibiting participation in MFTRPs. DOD advised that it will follow-up with information about whether this must be a stand-alone policy, or if it can be included in other policies or be in a less formal format.

#### Department of Energy (DOE) Development of Risk Assessment and Mitigation Processes (NEW)

COGR and other higher education associations met with DOE representatives on July 1, and DOE advised that it was contemplating the adoption of a risk assessment and mitigation process similar in nature to the process currently employed by DOD. DOE plans to provide additional details on this process in the near future.

#### <u>Department of Justice (DOJ) Advanced Notice of Proposed Rulemaking (ANPRM) Regarding Access to</u> <u>American's Bulk Sensitive Personal Data and Government-Related Data by Countries of Concern</u> (<u>UPDATE</u>)

On June 28, COGR met with DOJ representatives to discuss <u>comments</u> that COGR submitted on the DOJ's recent ANPRM regarding "Access to American's Bulk Sensitive Personal Data and Government-Related Data by <u>Countries of Concern</u>." During the conversation, DOJ representatives advised that a lengthy NPRM would soon be issued, and that DOJ was aware of the need to include provisions in the proposed rule that addressed the sharing of sensitive information in connection with public health emergencies.

#### NSF Risk Assessment and Mitigation Process (REMINDER)

COGR representatives attended a meeting at which NSF presented its proposed process for risk assessment of research proposals and the associated development of risk mitigations plans. The process, which will be known as Trusted Research Using Safeguards and Transparency (TRUST). Sarah Stalker-Lehoux, Deputy Chief of Research Security Strategy and Policy, provided an overview of TRUST at the June COGR meeting. The slides are available here: <u>NSF & Foreign Gift Reporting Requirements</u>.

#### Associations Foreign Financial Disclosure Report Meeting (FFDR) with NSF (REMINDER)

COGR and other higher education associations (AAU, APLU, ACE, and others) were invited to meet with NSF officials from the Office of the Chief of Research Security Strategy and Policy to receive an overview and demonstration of the Foreign Financial Disclosure Report (FFDR) site. The FFDR is a new module in <u>Research.gov</u> (in Manage Financials) to address reporting requirements specified by Section 10339B of the CHIPS and Science Act of 2022, which requires institutions of higher education (IHEs) to report gifts and contracts ≥\$50,000 (received from a source associated with a country of concern (i.e., People's Republic of China, Islamic Republic of Iran, Democratic Republic of Korea, and Russian Federation). The FFDR requirement applies to IHEs that receive a new award or funding amendment on or after May 20, 2024.

Below is a summary of the major highlights from the meeting.

- **Deadline Extended**: In response to community concerns, NSF is providing a one-time grace period for the initial report, extending the deadline to September 3, 2024, at 5:00 p.m. (the submitting organization's local time). The Year 1 report will open on July 1, 2023, for the reporting period July 1, 2023 through June 30, 2024.
- **FFDR Clarifications on Legal Name/Address of Foreign Source**: In response to feedback from the community, NSF removed the street address as a requirement for reporting the foreign source and added an option to provide either DBA or legal name of the foreign source.
- New FFDR Preparer Role Added to Research.gov: A new role has been added to research.gov in response to the community's feedback requesting the ability for non-AORs (such as those who typically complete Dept of Ed Section 117) to complete FFDR. All active AORs will automatically be assigned the new FFDR preparer role and can create a report, edit an existing report, or submit a report created by another FFDR preparer. Research.gov Organizational Administrators can add/remove the FFDR preparer role in their organization's Account Management.

- **FFDR Takeaways**: On July 1, 2024, all individuals designated as an FFDR preparer, will receive a system-generated email notifying them that the IHE must submit an FFDR. Every IHE must submit a report, including a negative report (nothing to report), on Research.gov. A submitted report can be edited up to the deadline. Once a report is submitted to NSF, it cannot be deleted or withdrawn. Requests must be submitted to the Office of the Chief of Research Security Strategy and Policy Office to amend the submitted report.
- **FFDR Demo & Resources:** A <u>demo site</u> is available on <u>Research.gov</u> (in Manage Financials) until June 28, 2024 (after June 28th, the demo site will be replaced by the actual site). NSF also expects to have a webinar to demo the new site in July and plans to host virtual office hours. NSF has developed a <u>Resource Page</u>, with <u>FAQs</u>.

As this is the initial year for the report and each entry will need to be entered (there is not an upload file option), we encourage institutions to review the demo site and start collecting information for the report early.

Sarah Stalker-Lehoux, Deputy Chief of Research Security Strategy and Policy, provided an overview of FFDR at the June COGR meeting. The slides are available here: <u>NSF & Foreign Gift Reporting Requirements</u>.

#### NSF Dear Colleague on CUI: Discussion of NSF Dear Colleague Letter on CUI (NEW)

On June 18, NSF issued a <u>Dear Colleague</u> Letter on NSF's Controlled Unclassified Information (CUI) Program. The letter discussed the application of CUI requirements to principal investigators who submit proposals and merit review panelists. The letter generated a number of questions that COGR and others posed to NSF regarding its application. On June 24, NSF issued a <u>statement</u> that it was withdrawing the Dear Colleague Letter and advised that "there needs to be more clarity when we communicate about NSF's CUI policies and how they conform with overall U.S. Government CUI policies as well as any impacts to the community." NSF advised that it would be developing a set of FAQs on CUI, and that presently, "there are no additional requirements on the research community regarding CUI."

The Research Security & Intellectual Property (RSIP) Committee is discussing possible action by COGR ahead of the FAQs release by NSF.

### **Research Security & Intellectual Property (RSIP)**

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

#### NIH Issues a RFI on Promoting Equity in Access Planning (NEW)

On May 24, NIH issued a Request for Information (<u>RFI; 89 FR 45003</u>) regarding the implementation of a intramural research program policy to facilitate broad access, in particular in underserved communities, to products incorporating NIH licensed technologies. The new policy would apply to commercial patent licenses for drugs, biologics, vaccines or devices developed for the diagnosis, prevention, or treatment of human diseases.

The benefits of access planning were discussed at the <u>Workshop on Transforming Discoveries into Products:</u> <u>Maximizing NIH's Levers to Catalyze Technology Transfer</u> in which panelist largely were NIH technology transfer professional, patient advocates and academics.

The proposed policy is limited to patents issued to NIH as the sole owner, though the RFI states that jointly owned patents will be considered in the future. It is reasonably foreseeable that the policy could be expanded to include NIH extramural funded research in the long term. The policy clearly prioritizes access and affordability with suggestions that an access plan may include measures such as price increases of drugs capped at the rate of inflation, pledges that prices will be homogeneous across markets and inclusion of cost accounting measures to provide more transparency. Access plans will likely increase the compliance obligations of licensees, provided another mechanism for third parties to petition for the termination or amendment of licensing terms, and overall add uncertain into the commercialization process and hinder NIH's ability to license patents vital to creation of new products, processes, and technologies that start-up companies and others rely on to commercialize products and services that benefit our nation's health, security and economy

COGR will be responding to the RFI. Comments are due July 22.

#### <u>Congressional Request: Department of Energy Actions Needed to Assess U.S. Manufacturing Policy and</u> <u>Protect Technology from Foreign Acquisition (NEW)</u>

On June 24, GAO publicly released a <u>study</u> on the impact of DOE's 2021 policy change expanding the U.S. manufacturing requirement in the licensing of technologies resulting from DOE funded research. The study provides six recommendations to increase DOE's oversight on licensing practices and provisions at DOE laboratories and universities. The following summarizes the recommendations:

- implement a strategy or approach to monitor and assess the effectiveness of the U.S. competitiveness provision in accordance with the 2021 policy change;
- create more transparency on the waiver process by providing additional guidance and effectively communicating expectations for the timeline to review waiver requests;
- provide guidance for universities on monitoring compliance with the U.S. manufacturing requirements including the interpretation of "substantially manufactured in the US";
- review university licensing practices to ensure appropriate monitoring and enforcement mechanisms are in place;
- give guidance on license provisions and practices to monitor foreign ownership of a licensee;

We will continue to monitor the implementation of these recommendations and keep the COGR membership informed.

#### **<u>CISA Cyber Incident Reporting Requirements for Critical Infrastructure (UPDATE)</u></u>**

On April 4, the Cybersecurity and Infrastructure Security Agency (CISA) issued a Notice of Proposed Rulemaking (<u>NPRM; 89 FR 23644</u>) for the Critical Infrastructure Act of 2022 (CIRCIA) cyber incident reporting requirements for covered entities. The requirements include Title IV-funded institutions of higher education in

their scope as covered entities ("education facility;" 226.2(b)(9)(ii); p. 23768 in print version). Concerns included content and timing of incident reports, data preservation and enforcement.

While COGR did not submit comments, we generally support the <u>comments submitted</u> by EDUCAUSE on July 1. Comments were due July 3.

### **Contracts & Grants Administration (CGA)**

Select Committee activities related to Uniform Guidance and Science & Security are reported above under the Cross Cutting Issues section of the COGR Update. Other items followed by CGA are covered below.

#### NASA Biosketch and Current and Pending Support Disclosure Policy (NEW)

On June 28, the National Aeronautics and Space Administration's (NASA) Grants Policy and Compliance (GPC) in the Office of Procurement <u>published</u> a request seeking comment on the Agency's forthcoming policy on disclosures made in grant applications and annual certifications. NASA plans to implement the <u>NSTC common</u> forms for the Biographical Sketch and Current and Pending (Other) Support starting on October 1, 2024, for NASA grants and cooperative agreements. NASA states in the notice they plan to implement the common forms "with minor deviations" and it is unclear from the notice what those will be. NASA will have a table entitled "NASA Pre-award and Post-award Disclosure Requirements," which will provide reference information regarding pre-award and post-award disclosures. NASA is proposing a unique definition for Senior/key persons as *all Principal Investigators (PIs), all co-Principal Investigators (CoPIs), and co-Investigators (Co-Is) proposing to spend 10 percent or more of their time in any given year on a NASA-funded grant or cooperative agreement.* 

To comply with CHIPS and Science Act of 2022, which requires certifications that senior/key personnel are not a party to a malign foreign talent recruitment program, NASA will collect certification but will require award recipients to maintain original forms with digital signatures and make them accessible to NASA in accordance as digital signatures are not retained in their system (NSPIRE).

COGR is preparing comments in response to the request. Comments are due by July 30, 2024. Please contact Krystal Toups at <u>ktoups@cogr.edu</u> for questions or to provide input.

#### NIH Public Draft Public Access Policy (NEW)

COGR previously <u>reported</u> and <u>commented</u> on NIH's plan for public access. On June 19, 2024, NIH published a request for information (RFI) in the Federal Register, the NIH Draft Public Access Policy. The policy will apply to any manuscript accepted for publication in a journal, on or after October 1, 2025. The NIH is soliciting comments from the public on the draft policy and two supplemental draft guidance documents regarding government use license and rights and costs for publications. CGA is reviewing the RFI for comment and welcomes any feedback you may have by reaching out to Krystal Toups at <u>ktoups@cogr.edu</u>.

#### Grant & Contract Administration: Other Issues (NEW & ONGOING)

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

#### SAM.gov (ONGOING)

As reported in <u>September 2023</u>, <u>February 2024</u>, and <u>March 2024</u>, COGR is actively engaged with GSA on the challenges members report with SAM.gov renewals/registration. COGR hosted Ms. Ivana Henry, Management and Program Analyst, U.S. General Services Administration, who presented an <u>Overview of System for Award Management (SAM) Registration Process – Challenges & Tips.</u> COGR continues to engage federal officials, including OMB, on the concerns of the community and will keep the COGR membership updated on all developments. We encourage COGR members to contact Krystal Toups at <u>ktoups@cogr.edu</u> if they are experiencing challenges or have comments or concerns to report related to SAM.gov registration.

#### NIH Data Management and Sharing (DMS) (ONGOING)

NIH published <u>NOT-OD-24-123</u> on May 9 announcing changes planned to the Research Performance Report (RPPR) instructions to address DMS. NIH plans to implement new questions for the RPPRs submitted on or after October 1, 2024. Additionally, NIH has published a <u>notice</u> in the Federal Register for formal comment. CGA is following this topic and will update the community accordingly.

#### Research Environment (ONGOING)

CGA has been closely following developments related to the NSF OIG Review of award recipient compliance with NSF's harassment policies. As part of the FY 2024 Annual Audit Work Plan, NSF will assess whether the policies and procedures at a sample of 100 NSF-funded institutions comply with NSF's harassment terms and conditions. The report is expected to be issued by August 2024. CGA has gathered preliminary information on common themes and observations of the review. CGA has sent a list of clarifying questions to NSF OIG concerning, expectations of the findings of the report for NSF and the community, the anonymity of the 100 institutions selected for the review, availability, and expectations of the document *NSF's Promising Practices Harassment Guidance* cited in the review as a criteria but not accessible to the community, and a criteria of the review to mirror NSF language exactly in institutional policies and subaward agreements. NSF OIG has stated in response to our questions that they will schedule a meeting with the 100 institutions included in the review to discuss the likely content of the report, how the reporting process will impact them, and provide an opportunity for Q&A likely addressing our questions. CGA will continue to follow this topic. Feel free to contact Krystal Toups at ktoups@cogr.edu for any questions.

### **Costing and Financial Compliance (CFC)**

Select CFC activities related to the Uniform Guidance are reported above under the Cross-Cutting Issues section of the COGR Update. Other issues followed by CFC are covered below.

#### F&A / Indirect Cost Caps Back in the News (NEW)

In the May 2024 Update (p. 19) we reported on the *No Subsidies for Wealthy Universities Act* – a bill that would eliminate facilities and administrative (F&A) costs reimbursement (*aka*: indirect costs) on grants for universities with endowments over \$5 billion, cap reimbursements to 8% for universities with endowments between \$2-\$5 billion, and cap reimbursements at 15% for all other universities. The bill also would require reporting on federal funds used towards administrative and DEI staffing. All indications at this time are that this concerning bill will not advance.

However, in a new development, the House Labor, Health and Human Services, Education, and Related Agencies Subcommittee released its FY 2025 bill that included the following provision:

SEC. 237. None of the funds made available by this Act to the National Institutes of Health may be used for facilities and administration costs (as defined in section 200.414 of title 2, Code of Federal Regulations) that exceed 30 percent of an award to an applicable educational institution that is an organization subject to taxation under section 4968 of the Internal Revenue Code of 1986.

This, too, is concerning. Our colleague associations are working with key Congressional offices to help ensure that this provision will not advance. COGR is reviewing F&A educational materials in light of these recent proposals. As we shared previously, the reemergence of proposals to cap F&A reimbursement costs provides an opportunity to dust off two important, and still relevant, COGR publications: <u>Finances of Research Universities</u> (June 2014) and <u>Excellence in Research: The Funding Model, F&A Reimbursement, and Why the System Works</u> (April 2019).

We will keep the membership posted on new developments.

#### 2024 OMB Compliance Supplement is Available (NEW)

OMB has published the <u>2024 Compliance Supplement</u>, dated May 2024. Auditor guidelines for auditing research programs can be found in <u>Part 5</u>, <u>Clusters of Programs</u> (see Research & Development programs, pp. 5-2-1 thru 5-2-5). We welcome COGR members to contact us on audit issues that arise, including issues applicable to the Compliance Supplement. When appropriate, we will reach out to our contacts at OMB and the audit firms and engage, accordingly.

#### F&A Cost Rate Survey and Capstone Report (REMINDER)

The publication date for the 2024 F&A Capstone Report – an upcoming COGR report and analysis on F&A cost rate trends and other observations around F&A cost rates and reimbursement – has been moved to later in 2024.

However, a third report will be added to the <u>2023 F&A Survey Report page</u> (login required). The three reports that will be available are:

- F&A Cost Rates (and other demographics) by Institution
- Off-Campus / MTDC Definitions by Institution
- Summary of Responses to Selected Survey Questions

The Summary of Responses report contains charts and graphs documenting the results of the 120 institutional survey responses and addresses topics such as methodologies used in F&A proposals, negotiation experiences, institutional resources committed to the F&A process, and other areas of interest. These reports are meant to be used for institutional purposes only and should not be shared beyond the institution. In addition, both a June 2023 presentation and an October 2023 presentation at past COGR meetings featured analyses that may be of interest to the COGR membership.

#### Costing & Financial Compliance: Audit and Other Topics (ONGOING & REMINDERS)

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

#### New CAS Requirement to Adjust Indirect Cost Pools

Since engaging this issue last fall, there has been no communication from federal officials on the status (also see March 2024 Update, p. 22). At issue was the Cost Allocation Services (CAS) position that required adjustments to me made to indirect cost pools for salaries exceeding the Executive Level II (NIH, HHS) salary cap. The genesis of this position was based on a finding in an HHS OIG report, <u>Cost Allocation Services Needs to Update</u> its Indirect Cost Rate Setting Guidance (see p. 23, Indirect Cost Rate Proposals Included Potentially Unallowable Compensations Costs). For now, the CAS/OIG position has been reversed and the salaries are <u>not</u> capped. While this may be a "no news is good news scenario," we will pay attention to developments from OMB and HHS as we believe they are reviewing the case. As appropriate, we will continue advocacy work with AIRI (Association of Independent Research Institutes) to bring this issue to a favorable closure.

#### Personal Information and Federal System Log-on Concerns

We provided an update in the <u>March 2024 Update</u> (pp. 21-22), in addition to prior updates going back to the fall of 2023. This issue involves federal reporting systems, safe and secure system log-ons, federal policy, and other federal agency technology applications – all of which, combined, have created operational and administrative challenges at COGR member institutions. Primary examples of the challenge have been demonstrated by new security protocols required for logging into the <u>Automated Standard Application for Payments (ASAP)</u> and the <u>Payment Management Services (PMS)</u> federal payment systems, maintained by the Departments of Treasury and HHS, respectively. The concern is demonstrated by the personal identifying information (PII) required to log-in to these systems (e.g., <u>ID.me</u> to login to PMS). While ASAP and PMS are primary examples, please contact COGR is you are aware of other examples where one's PII is required to be used in the workplace. COGR has raised concerns to OMB, though the solution is not obvious. However, we will continue to research and engage this issue and will keep the COGR membership updated on all developments.



#### Financial Reporting Developments at NASA

We continue to follow developments at NASA (most recently, <u>March 2024 Update</u>, pp. 23-24). Over the course of this period, COGR has developed a strong working relationship with <u>NASA's Grants Policy and Compliance</u> <u>Team (GPC)</u> led by Antanese Crank, Chief, and her team of four other individuals (see GPC webpage for complete point of contact information). The two financial compliance initiatives we have engaged are the *Transition from FCTR to FFR* and implementation of the *Routine Monitoring–Financial Transaction Testing Review program*. Prior COGR reports have detailed the issues, challenges, and advocacy around these two topics, and while we have not achieved ideal resolutions, we have made progress. We will stay in communication with NASA and the GPC team, as needed, but also encourage COGR members to reach out to the GPC team when issues arise.

#### OMB and the Council on Federal Financial Assistance (COFFA)

We continue to follow the evolution of the <u>Council on Federal Financial Assistance (COFFA)</u> – as specified in OMB Memorandum <u>M-23-19</u>, dated August 9, 2023 – and its mission: [To provide] oversight and management of Federal financial assistance. The COFFA will create a partnership among Federal grant-making agencies, providing a single forum to inform Federal financial assistance policy, oversight, and technology activities. The COFFA will be responsible for providing strategic direction, policy recommendations, and priority-setting for other Government-wide grant-related activities. Potentially, the COFFA could be a forum for COGR to address issues important to the research community – as such, we will stay connected to COFFA developments.

#### Federal Office of Inspectors General (OIG) Developments

COGR members are encouraged to follow NIH-related audit activity posted in the <u>HHS OIG Workplan</u>, as well as completed reports posted under <u>All Reports and Publications</u> (select by HHS Agency). For activity from the NSF OIG, the <u>NSF OIG Reports & Publications page</u> lists recently completed reports. Further, the <u>NSF Management</u> <u>Responses to an External Audits</u> is a helpful resource for reviewing NSF OIG audit resolutions. COGR members are welcome to contact us when audit issues arise. When appropriate, we can connect institutions and/or provide feedback on the issues in question.

#### NSF Project Reporting Compliance Program

We first reported on this topic in the <u>COGR September 2023 Update</u> (p. 20). NSF introduced a pilot *Project Reporting Compliance* program for three participating NSF Divisions: Computing and Communication Foundations (CCF); Civil, Mechanical and Manufacturing Innovation (CMMI); and Information and Intelligent Systems (IIS). NSF will temporarily withhold payments for an award if the PI fails to submit annual project reports 90 days prior to the end of the annual budget period of the project. Several implementation concerns have emerged, and when reported to NSF, officials have been open to addressing them. We encourage COGR members to contact NSF and/or COGR when issues arise.



NSF 2022 Higher Education Research & Development (HERD) Survey

The 2022 HERD results were released on November 30, 2023. Included are the <u>InfoBrief</u> and the complete suite of <u>2022 data tables</u> (which contains the popular *Table 22 – Higher education R&D expenditures, ranked by all R&D expenditures, by source of funds: FY 2022*). Also of interest is Table 4 from the <u>InfoBrief</u>, which presents data on recovered and unrecovered indirect costs, in aggregate, for all institutions. For FY2022, the total recovered indirect costs were \$16.1 billion (out of \$22.3 billion incurred) and the total unrecovered indirect costs were \$6.2 billion (up from \$5.9 billion in FY2021).

Please contact David Kennedy at <u>dkennedy@cogr.edu</u> to discuss any of the issues above, or other items that you would like to address.

### **Research Ethics & Compliance (REC)**

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

#### <u>DOE Notice of Proposed Rulemaking (NPRM) on Financial Assistance Regulations-Conflict of Interest</u> and Conflict of Commitment Policy Requirements (NEW)

DOE issued a <u>NPRM</u> seeking comments on its proposed requirements for institutional financial conflict of interest (COI) and conflict of commitment (COC) policies. REC has formed a working group to develop comments by the August 19, 2024 deadline. Some of the key points of the NPRM include the following:

- **Policy Development**: Under the NPRM, DOE funding applicants/recipients are required to establish written and enforced COI and COC policies that address actual, apparent, and potential COIs and COCs, "both foreign and domestic." The NPRM proposes an effective date of 30 days after publication of the final rule.
- **Coverage of COCs**: Unlike NIH and NSF, DOE's NPRM requires policies that cover both COIs and COCs. The NPRM broadly defines COC as:

[A] situation in which an individual accepts or incurs conflicting obligations, whether foreign or domestic, between or among multiple employers or other entities. This may include conflicting commitments of time and effort, including obligations to dedicate time in excess of institutional or DOE policies or commitments. Other types of conflicting obligations, including but not limited to, obligations to improperly share information with, or to withhold information from, an employer or DOE, can also threaten research technology or economic security and integrity. Examples of situations that may give rise to conflicts of commitment include, but are not limited to, current or pending employment; positions, appointments, or affiliations such as titled academic, professional, or institutional appointments, whether remuneration is received and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary positions); and participation in or applications to foreign government-sponsored talent recruitment or similar programs.

- Persons Subject to the COI and COC Policies: The NPRM calls for institutional COI and COC policies to apply to "covered individuals," a term that encompasses more than PIs and PDs and can be expanded through designation by DOE or additional requirements in the Federal Notice of Award (FOA). DOE may designate as a "covered individual" "any individual (including an individual at the masters or baccalaureate level) that contributes in a substantive, meaningful way to the development or execution of a "subject project" that the applicant/awardee institution in the application for funding, approved budget, progress report, "or any other report submitted to DOE." Additionally, DOE can expand the FOA to include "any person who participates in the purpose, design, conduct, or reporting of a projected funded by DOE or proposed for funding by DOE, including, for example, collaborators, consultants, graduate (master's or Ph.D.) students, and postdoctoral associates."
- **Training**: The NPRM states that institution must provide each covered individual with initial training on COI and COC prior to engagement in a funded project and refresher training every two years thereafter, as opposed to every four years under NIH's policy requirements.
- **Disclosures of COIs and COCs**: Under the NPRM, covered individuals must update reports of COI and COC "as soon as any new actual, apparent, or potential COI or COC exist" vs. the 30-day reporting period in place under PHS COI policy requirements.
- **Reporting of COIs and COCs to DOE**: The NPRM states that requirements for reporting COIs and COCs to DOE can vary depending on the terms of the FOA. The standard reporting requirement calls for institutions to report to DOE any COI or COC that can't be eliminated or appropriately managed or reduced PLUS "any actual, apparent, or potential COI or COC reported to the recipient by a subrecipient, involving any foreign governments, their instrumentalities, or any other entities owned, funded, or otherwise controlled by a foreign government, as well as any measure the entity has taken to eliminate, or where appropriate, manage or reduce the COI or COC." Additional requirements that DOE can add to the FOA include: (a) disclosure of all covered individuals' COIs and COCs "including those COIs and COCs determined by the non-federal entity to be appropriately managed or reduced"; and (b) disclosure of supporting documentation to demonstrate how the COI and COC was managed or reduced and sufficient information to enable DOE to assess COI or COC and whether mitigation is appropriate. DOE also may require an institution to routinely, or upon request, submit some or all of a covered individual's disclosures.

#### **DEA Rescheduling of Marijuana (NEW)**

On May 21, the Drug Enforcement Administration (DEA) released <u>an NPRM</u> proposing to reschedule marijuana from schedule I to schedule III of the Controlled Substances Act (CSA). Although marijuana will still be considered a controlled substance, under the rescheduling, investigators conducting research on marijuana will no longer need to comply with the extremely stringent security requirements that apply to schedule I controlled substances. However, the NPRM does not address the continuing inconsistency between federal law and the law in states that have approved marijuana for medical and/or recreational use, including researchers' ability to access strains of marijuana available in those states for use in research.

COGR's controlled substances and cannabis working group reviewed the NPRM and developed potential comments that were included in a draft letter. This letter was shared with American Association of Medical Colleges (AAMC), as AAMC and COGR have previously commented jointly on proposed regulations and RFIs that impact research using marijuana. AAMC joined in <u>COGR's comment letter</u>, and the comments were submitted to DEA on July 12. Comments to the NPRM are due on July 22.

The letter set forth support for the rescheduling of marijuana. It urged DEA to reconsider its exclusion of synthetic THC from the scope of the rulemaking, and instead consider synthetically derived delta-9-THC under the Controlled Substances Act's eight factor analysis that was applied to natural marijuana. Once the rescheduling is complete, AAMC and COGR recommended that DEA quickly update guidance documents regarding the conduct of research using marijuana. Specific clarification was requested on the NPRM's references to the continued application of "existing marijuana-specific requirements" and "additional controls" after the rescheduling occurs. Finally, the letter urged DEA to provide guidance on how the rescheduling will/will not impact researchers' ability to access for research purposes marijuana products that are available in states that permit medical/recreational use of marijuana, and it emphasized the importance to public health of facilitating research on these products.

#### U.S. Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential and Implementation Guidance (DURC PEPP Policy and Implementation Guidance) (NEW)

In May, OSTP published the <u>DURC PEPP Policy</u> and <u>Implementation Guidance</u>, which supersedes the 2012 United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern (Federal DURC Policy), the 2014 United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (Institutional DURC Policy), and the Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO Framework). The Policy and Implementation Guidance establish a unified federal oversight framework for federally funded research on biological agents and toxins that pose risks to public health or national security, and complements existing federal regulations, including USDA and HHS regulations regarding Select Agents and Toxins. The Policy has an effective date of May 6, 2025. By that date federal agencies must issue rules that conform to the Policy, and institutions must abide by the new rules.

The current DURC Review Process is limited to life sciences research that involves 15 named agents and toxins and seven categories of experiments. The new DURC Policy will encompass much broader categories of agents and nine categories of experiments, and NIH anticipates that the number of protocols that require institutional and federal review will increase from hundreds to thousands to 1000s each year. Under the new DURC Policy, DURC research is referred to as "Category 1 research." Category 1 research must be reviewed by the institution's Institutional Review Entity (IRE), which must develop a risk assessment and risk mitigation plan. [NOTE: An institution's institutional biosafety committee (IBC) may serve as the IRE.] The federal funding agency must approve the risk assessment and risk mitigation plan prior to the commencement of the research.

Similarly, the new PEPP Policy covers a broader scope of pathogens than the current policy for the review of Potential Pandemic Pathogen Care and Oversight (P3CO). The P3CO Policy is limited to "potential pandemic pathogens" that are likely highly transmissible and likely capable of wide and uncontrollable spread in human populations and are likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

The new PEPP Policy, however, encompasses <u>any</u> pathogen modified in a way that is <u>reasonably anticipated</u> to result in the development, use, or transfer of a PEPP, including the development of new potential pandemic pathogens (PPP), enhancement of an existing PPP, and any eradicated or extinct PPP that may pose a "significant threat to public health, health system capacity to function, or national security." Under the new PEPP Policy, PEPP research is referred to as Category 2 research and requires two levels of federal review: (a) review of an IRE and PI-developed risk assessment and risk mitigation plan by the federal funding agency at the departmental level; and (b) review of the risk assessment and risk mitigation plan by a multidisciplinary review entity convened at the federal agency level.

Given its research portfolio, NIH is the federal research funding agency that is expected to be most impacted by the new DURC PEPP Policy.

On June 5, REC Committee members met with Dr. Michael Lauer, NIH's Deputy Director for Extramural Research to discuss NIH's plans for implementation of the new policy. Dr. Lauer advised that the OSTP policy was the result of inter-agency efforts, and that Congress and the administration are interested in seeing that the new policy is rapidly implemented. Dr. Lauer recommended that institutions review the Implementation Guidance but noted that the guidance was written generally, and that NIH has certain latitude in how it will address the policy requirements and plans to leverage existing relationships with institutions to facilitate smooth communications. Similarly, institutions can develop internal processes that require PIs to work through sponsored research, institutional biosafety, or other institutional offices.

Dr. Lauer confirmed that the scope of projects to be reviewed will increase dramatically, and the Policy will place significant new responsibilities for risk assessment and mitigation on PIs and institutions. Institutions, in turn, will need to examine their existing review processes and infrastructures to ensure that they can handle this additional workload. In response to questions from COGR committee members, NIH indicated that it does not expect the current threshold amounts for Select Agents and Toxins to apply under the DURC PEPP Policy and confirmed that if research shifts from Category 1 to Category 2, it must be halted until federal review of the research takes place.

NIH is developing its implementation requirements and anticipates issuing a Request for Information in the autumn of 2024 to gather stakeholder input. Dr. Lauer emphasized that the May 6, 2025, implementation date applies to institutions, and is not just the date by which agencies must issue their policies. Currently, NIH is contemplating applying the policy prospectively and handling initial assessment at Just in Time, but these processes have not yet been finalized. NIH expects that its review process will be centralized, as opposed to being carried out by program officers, and it expects that it will leverage NIAID's existing review processes for Category 2 research.

#### **OLAW Webinar on Research Using Agricultural Animal Species (UPDATE)**

In March, OLAW <u>conducted a webinar</u> regarding research using agricultural animal species. The webinar discussed when the Animal Welfare Act (AWA) applies to such research. Institutions raised concerns to REC that the webinar's statements regarding the application of the AWA to some types of research were much broader than previous interpretations. COGR is working with NABR to look into these concerns and obtain clarification as to whether USDA's interpretation of the AWA's scope has changed. In response to these concerns, OLAW issued the following clarification under the text of the <u>webinar transcript</u> for slide 16:



\*\*POST-WEBINAR CLARIFICATION FROM USDA:\*\* As of 5/16/24, USDA is clarifying its position on regulation of horses and other farm animals as presented in this webinar. Although USDA has statutory authority to regulate horses used for research and other farm animals used for biomedical and nonagricultural research, we are not changing our current inspection procedures and regulatory oversight of horses and other farm animals at this time. USDA's regulation of horses and other farm animals remains limited to farm animals being used as models for diseases of humans. Should any changes occur in the future, adequate notice will be provided to the regulated community.

#### Draft Guidance on Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies (NEW)

In June, FDA issued <u>this draft guidance</u> to assist sponsors and sponsor-investigators in meeting requirements for the submission of diversity action plans for certain clinical trials of drugs, devices and biological products in accordance with amendments to the Federal Food, Drug, and Cosmetic Act. These plans are "intended to increase enrollment of participants who are members of historically underrepresented populations in clinical studies to help improve the strength and generalizability of the evidence for the intended use population." The requirement to provide a plan will go into effect for Phase 3 IND study or any other "pivotal study" of a new drug and any clinical trial of an investigational device that is not IDE exempt that is submitted 180 days or longer after publication of the final FDA guidance. The plans must specify goals for clinical study enrollment that are "disaggregated by race, ethnicity, sex, and age group demographic characteristics of the clinically relevant population," along with the sponsor's rationale for these goals and plans for how the goals will be met. COGR has reviewed the draft guidance and does not plan to submit comments. Comments are due September 26, 2024.



### **Appendix A – Upcoming Comment Due Dates**

Agency	Description	Due Date	Notes
NIH	Request for Informationon Draft NIH IntramuralResearch ProgramPolicy: Promoting EquityThrough Access Planning	July 22	COGR will submit comments.
DEA	Schedules of Controlled Substances: Rescheduling of Marijuana	July 22	COGR has submitted <u>comments</u>
NASA	Request for Comments:Biosketch and Currentand Pending SupportDisclosure Policy	July 30	COGR will submit comments
DOE	Financial Assistance Regulations-Conflict of Interest and Conflict of Commitment Policy Requirements	August 19	REC has formed a working group and COGR will submit comments
FDA	Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies	September 26	COGR has reviewed and does not plan to submit comments

#### **JULY 2024 UPDATE**

## COGR

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.

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