COGR

FEBRUARY 2024 UPDATE

TABLE OF CONTENTS

President's Message

New Year, Familiar Challenges, and New Opportunities

Dear Colleagues,

While 2024 is a new year, the challenges before research institutions are familiar and the outcomes, in many cases, uncertain. We are facing questions and troubling developments on federal research investments, march-in rights, and cybersecurity, to name just a few. We also anticipate new policies affecting the Uniform Guidance, use of animals in research, and research misconduct. At the same time, we are also awaiting the long-anticipated final research security program standards from NSTC.

But a new year also provides us with fresh opportunities to communicate the importance of reinvigorating the partnership between research institutions and the federal government by harmonizing and streamlining the bevy of federal regulations and compliance requirements affecting the conduct of research. Chipping away at this is one way to strengthen the research partnership that undergirds our nation's health, security, and economic prosperity.

I hope you will join us for COGR's virtual February Membership Meeting, which includes sessions on both the challenges and opportunities we face this year. The program delves into several of the aforementioned issues and provides an opportunity to hear from experts, peers, and federal officials about the path forward. For those who are new to, as well as those who are familiar with COGR, the *Connect with COGR: Overview & Look Ahead in 2024* session on Feb. 28 will provide not only an overview of the association but an opportunity to learn what is on the horizon for COGR, including the upcoming Emerging Research Institutions Pilot Program.

In addition to this opportunity, please consider these near-term ways to engage with COGR:

- Self-nominate or nominate a colleague to serve on the Board of Directors by March 8;
- Apply or encourage a colleague to apply for the position of Director of Research Security and Intellectual Property by March 4; and
- Respond to COGR's most recent questionnaire on the HHS-OIG survey, by February 23.

Your engagement in these and other ways are important to our continuing efforts to advocate for sound, efficient, and effective federal research regulations that safeguard research and minimize administrative and cost burdens. Thank you for your efforts as we press forward this year.

Matt Owens, President

Announcements

Registration Still Open: COGR's February 2024 Virtual Meeting

The agenda is available online and registration is still open for COGR's February 27-March 1, 2024 Virtual Meeting. Registration is open to all staff at COGR member institutions through the COGR Portal. A special pricing code is available for institutions registering five or more individuals by emailing memberservices@cogr.edu. Please note that promo codes are not retroactive. Please ensure you reach out to Member Services first if registering more than 5 individuals from the institution. Individuals do not have to be registered together in order to use the promo code.

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 in COGR's 2022-2023 Year in Review, COGR is launching an Emerging Research Institutions (ERI) Pilot Program in August 2024. This program will provide an opportunity for institutions that do not yet meet COGR's membership threshold[1] 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. Participation in the ERI Pilot Program will be limited. The ERI Pilot application process, eligibility criteria, and annual participation fee will be announced during the Summer of 2024.

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 will be invited to apply for the ERI Pilot Program in the Summer of 2024*.

If you have any questions about this program, please reach out to Toni Russo, Assistant Director of Member Engagement & Policy at trusso@cogr.edu.

[1] *At least $15M in annual federal research expenditures as reported in the most recently published NSF HERD survey or equivalent.*

October Meeting Session Recordings Now Available in Video Library

Select sessions were recorded during the October 2023 meeting and are now available for anyone logged into the COGR Portal to view. To access the recordings, log into the COGR Member Portal and from the Dashboard, navigate to COGR's Video Library. As a reminder, recorded sessions are made available to registered attendees shortly after the meeting or webinar is over, and then released to the COGR Video Library approximately 90 days later. Slide presentations are posted on COGR's website here.

February 2024 Update on 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 (Appendix A).

Reminders

COGR Has Moved

As announced at the October meeting in Washington D.C., COGR has moved into a new location. As of January 1, COGR's new physical and mailing address is:

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

If you are your institution's Primary Representative and/or Billing Contact, please ensure your institutional records are updated now to reflect our new address. Invoices for FY 25 (August 1, 2024-July 31, 2025) are expected to be ready by May 1, 2024. As a reminder, COGR accepts annual institutional dues payments via check payment or EFT/ACH. An updated W-9 is available on COGR's website here.

If you have questions, need institutional forms updated, and/or would like to set up EFT/ACH payments, please reach out to memberservices@cogr.edu now and allow for additional processing time.

Follow COGR on LinkedIn

We invite you to follow COGR on LinkedIn 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 sign up for access to the COGR Portal as part of the institution's COGR Member Benefits? The Portal is where you can sign up for our listserv, browse our video library, view the COGR Member Directory, check out COGR's Job Board, and view other members-only materials.

2 CFR 200 "Uniform Guidance" Cross-Cutting Issues

Uniform Guidance: What to Expect Next? (NEW)

In the COGR December 2023 Update, we shared our expectations on next steps for the implementation of the Uniform Guidance (2 CFR Chapter 2, Part 200, as well as 2 CFR Chapter 1, Parts 25, 175, 180, 182, and 183). To get further clarification on next steps, COGR invited Deidre Harrison, Deputy Controller to the February 2024 COGR Meeting. She will provide an update on the status of the Uniform Guidance revisions, including OMB's approach to reviewing comments, key consideration factors and metrics used in drafting the revisions, general approach for implementation, and more.

We do not expect Ms. Harrison to be able to speak about specific content of the final version of the Uniform Guidance unless it has been published by the time of the session.

Please reach out to Krystal Toups at ktoups@cogr.edu and David Kennedy at dkennedy@cogr.edu if you have questions or comments related to the roll-out of the Uniform Guidance.

UG: Summary of COGR's Comment Letter to OMB (ONGOING)

As highlighted in the December 2023 Update, COGR submitted a comment letter to OMB in response to proposed revisions to 2 CFR Chapters 1 and 2 on December 4th (also see OMB's "red-line" version to view the proposed revisions). The 51-page COGR letter includes over 100 COGR recommendations and 18 specific, priority requests encouraging OMB to take action on a wide-range of topics applicable (primarily) to 2 CFR Chapter 2, Part 200 (Uniform Guidance) and to 2 CFR Chapter 1, Parts 25, 175, 180, 182, and 183.

The 18 priority requests are the centerpiece of the COGR letter, though the 100+ recommendations are framed in a manner that urges OMB to consider every recommendation. In addition to COGR, many other commenters responded to OMB's proposed revisions (including many COGR members!). There is a "strength-in-numbers" effect and your support of either specific COGR recommendations and/or recommendations important to your institution will impact how OMB responds. In total, over 1,000 comments were received under this docket. Comments can be reviewed on the regulations.gov "Guidance for Grants and Agreements" page.

The COGR letter would not have been possible without the amazing team of volunteers from COGR member institutions who worked tirelessly starting in late October and right up to the December 4 deadline to develop a comprehensive and compelling array of recommendations—and in many cases, detailed analyses in support of the recommendations. The 26 volunteers participated in nine thematic workgroups and diligently combed through every word of the OMB "red-line" version. This is an impressive testament to their work (recognized in Appendix B of the December 2023 Update) and we are grateful for their spot-on and expert contributions.

COGR's Uniform Guidance Resource Page (ONGOING)

COGR's Uniform Guidance Resource Page will continue to be updated as OMB moves towards final revisions

to 2 CFR Chapters 1 and 2. This page includes past COGR comment letters and other related resources. COGR's first engagement with this topic was in 2011 when, under the auspices of an NIH RFI, we provided comments to the "A-21 Task Force" to address OMB Circular A-21.

Science & Security: Cross-Cutting Issues

OSTP Issues Updated Guidance to Support a Secure and Fair Research Ecosystem (NEW)

On February 14, OSTP released its Updated Guidance to Support a Secure and Fair Research Ecosystem. The press release announced the issuance of two memorandums offering guidance to federal agencies on the common disclosure forms and foreign talent recruitment programs.

In the memorandum "Policy Regarding Use of Common Disclosure Forms for the "Biographical, OSTP outlines the purpose and conditions for the use of the NSTC-developed common disclosure forms by federal research funding agencies. The memorandum's statements are similar in nature to those contained in the NSPM-33 Implementation Guidance, but the memorandum provides additional detail regarding agency implementation of the common forms.

The policy memo opens by stating that federal research funding agencies are required to use the harmonized common disclosure forms for funding application packages for grants and cooperative agreements. It specifies the forms will "replace other forms and formats that agencies currently use to disclose biographical sketch, and current and pending (other) support information." It also states that federal funding agencies may elect to use the forms for contracts as appropriate. However, the memo goes on to state that there may be cases where agencies choose not to use the Common Forms "for reasons specified by statute, regulation, specific agency authorities, or other compelling reasons" or for "a need to collect additional information or to apply more stringent protections to protect R&D that is classified, export-controlled, or otherwise legally protected." Notably, any such deviations require OMB/OIRA review and clearance. Federal research funding agencies with more than $100,000,000 in annual extramural research expenditures must submit an implementation plan to OSTP within 90 days of the policy. The plan must document the anticipated implementation date, plans for any deviations, and information regarding the electronic implementation of the Common Forms.

In the memorandum Guidelines for Federal Research Agencies Regarding Foreign Talent, OSTP provides guidance to federal research agencies regarding participation by agency personnel in foreign talent recruitment programs (FTRPs) and participation by covered individuals on federal research funding proposals in malign foreign talent recruitment programs (MFTRP). This guidance is issued to satisfy specific requirements of the CHIPS and Science Act of 2022, as noted below:

Guidelines regarding Federal Personnel Participation in FTRPs:

- The Guidelines prohibit all personnel of federal research agencies from participating in FTRPs per Section 10631. This includes federal employees, contract employees, independent contractors, individuals serving under the Intergovernmental Personnel Act of 1970, Visiting Scientist, Engineering, and Educator (VSEE) appointments, and special government employees other than peer reviewers. Generally excluded from this prohibition are outside visitors or guests temporarily engaged in research at federal or national
(contractor-operated) laboratory or user facilities and individuals engaged in strategic technical exchange programs from foreign government agencies/organizations (unless they fall under one

of the categories above). Federal research agencies may establish further policies for contractor owned and operated or government owned and contractor operated institutions as warranted.

- The Guidelines establish a definition for a "Foreign Talent Recruitment Program" as required by Section 10631. Note that this differs from the "foreign government sponsored talent recruitment program" definition set forth in the NSPM-33 Implementation Guidance.

- The Guidelines' definition of FTRP excludes a list of international collaborative activities in which federal research agency personnel may engage so long as the activity is not funded, organized, or managed by an entity developed under paragraphs (8) and (9) of Section 1286(c) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 4001 note; Public Law 115-232). These exclusions are consistent with permitting federal research agency personnel to engage in "open and reciprocal exchange of scientific information aimed at advancing international scientific understanding."

- Guidelines regarding Covered Individuals Participation in MFTPs:

  - The Guidelines prohibit Covered Individuals from participating in a federally funded research project if they currently participate in an MFTRP per Section 10631 of CHIPS and Science. Covered Individuals must disclose participation in a MFTRP (Section 10631) and certify they are not involved in a MFTRP (Section 10632). To the extent practicable, recipient institutions are required to prohibit Covered Individuals working on projects supported by federal research and development awards from participating in a MFTRP (Section 10632). Agencies may request supporting documentation from applicants and take funding-related actions if warranted (Section 10633).

  - The Guidelines define "Covered Individuals" consistent with the CHIPS and Science definition and specify that agencies may also define other individuals as Covered Individuals as appropriate and consistent with their mission.

  - The definition of a MFTRP is consistent with Section 10638(4) of CHIPS and Science, and the Guidelines state that agencies' policies on MFTRPs shall not prohibit the international collaboration activities specified in the statute.

- Additional Guideline Provisions:

  - The Guidelines address past Participation in a FTRP or MFTRP by stating that while Sections 10631 and 10632 apply to current and/or ongoing participation in one of these programs, agencies may take mitigation and management actions to address concerns of past participation.

  - The Guidelines emphasize that federal agencies must ensure that their policies and activities in this area are carried out in a non-discriminatory manner.

Research Security Program Standards (UPDATE)

NSTC's timeline for issuing final research security program standards continues to remain unclear. In updates

presented at the January Federal Demonstration Project (FDP) meeting, NSF officials indicated only that the comments provided on the draft standards issued in March 2023 remain under review, and no information was provided as to when the next iteration of the standards will be issued. COGR continues to monitor this issue closely and will keep the membership apprised of any developments.

Chart Documenting Current Status of Agency Implementation of NSPM-33 and 2022 CHIPS and Science Act Research Security Provisions (NEW)

COGR has updated the Quick Reference Table of Current and Upcoming Federal Research Security Requirements and COGR Matrix of Laws, Regulations, and Policies Regarding Science and Security to reflect recent agency actions in the research security arena. Major changes addressed in chart updates include NSF's January publication of the 2024 Proposal & Award Policies and Procedures Guide ("PAPPG-24-1") and research security training modules, as well as DARPA's adoption of DOD's Countering Unwanted Foreign Influence in Department-Funded Research at Institutions of Higher Education program and associated DOD Component Decision Matrix to Inform Fundamental Research Proposal Mitigation Decisions. Chart updates also include agency progress in developing risk assessment and mitigation matrices.

One item of particular note in the chart updates is the new table entitled "NSTC/NSF Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending (Other) Support," which NSF published on its Policy Office webpage. This table differs in some respects from the prior disclosures table, particularly with respect to the issue of consulting. Institutions should note that NIH's foreign interference webpage still contains the previous version of the disclosures table as does its webpage on Other Support, i.e., NIH Pre-Award and Post-Award Disclosures Relating to the Biographical Sketch and Other Support).

Research Security Provisions in NSF PAPPG 24-1 (NEW)

In addition to adopting the NSTC Common Disclosure forms for biosketches and current and pending support (see discussion in COGR Dec. 2023 Update), NSF's recently published PAPPG 24-1 includes the following two new significant research-security related provisions:

> Certification Regarding Non-Participation in Malign Foreign Talent Recruitment Programs (MFTRPs): Section 10632 of the CHIPS and Science Act of 2022 requires each federal research funding agency to establish policies requiring covered individuals included in proposals for research and development awards to certify that they are not parties to MFTRPs, as defined in Section 10638(4) of the Act. Further, each institution submitting a research funding proposal must certify that each covered individual on the proposal that it employs has been made aware of the participation prohibition and certification requirements.
>
> In accordance with these provisions, NSF included a statement that senior/key personnel on a funding proposal must certify they are not a party to a MFTRP. The certification text is contained in the Biographical Sketch and the Current and Pending (Other) Support Documents. Further, PAPPG 24-1 also requires that the Authorized Organizational Representative (AOR) certify that all senior/key personnel "have been made aware of and have complied with their responsibility" to certify that they are not a party to a MFTRP.

Postaward Disclosure of Foreign Financial Support: Per the requirements of Section 10339B of the CHIPS and Science Act of 2022, NSF included in PAPPG 24-1 provisions for the reporting of foreign financial support of ≥$50,000 (including gifts and contracts) "received directly or indirectly" from a "foreign source" (as defined per Section 117 of the Higher Education Act of 1965) associated with a "foreign country of concern." The trigger financial threshold is based on annual, aggregate amounts received from a source.

NSF has been working on the development of a portal for the reporting of the data, which COGR and other higher education associations were provided an opportunity to review (see COGR December 2023 update). In January, NSF reached out to COGR to solicit member institutions to volunteer to beta-test the portal. Several COGR members volunteered and were selected to participate in the beta-testing process. NSF has advised that it was not able to accommodate bulk data uploads into the portal. Rather, institutions will be required to make individual data entries.

Although the CHIPS Act called for institutions to provide a "summary document" of such foreign sources of support, the NSF portal requires the reporting of more detailed information. Reporting requirements encompass financial support received by institutional foundations and related entities that is provided by foreign sources (or their agents or intermediaries) associated with a country of concern. Information that institutions must provide for individual sources of support include the individual's country of citizenship, or if unknown, principal residence. For business entities that provided support, institutions must report the source's country of incorporation/establishment. Tuition payments for specific students (e.g., payment of tuition by a parent) need not be reported, but grants, scholarships, or other financial aid "conditioned on a specific criterion" such as a student's country of origin, or major course of study, must be disclosed when the financial threshold is met.

Institutions will be required to make their first report in the portal no later than July 31, 2024, for data from the period July 1, 2023, through June 30, 2024. Thereafter reports are due annually on July 31 for the preceding July 1 to June 30 period. Institutions must submit negative reports.

Although institutions are not required to submit supporting documents for the financial support to NSF, they must maintain copies of these materials for four years after "the end date of the award," and provide NSF with copies of such documentation on request.

HHS OIG Survey on Reporting of Monetary Donations that Support Research (NEW)

In January 2024, HHS OIG issued the *NIH Recipient Institutions' Reporting of Monetary Donations that Support Research Survey* (OEI-03-22-00570) to all U.S-based institutions that received NIH funding in 2022. The survey presents several scenarios and seeks responses from institutions as to whether they would treat financial support described in the scenario as an unrestricted gift or as "Other Support" that requires reporting to NIH. The survey is anonymous and voluntary, and data will be reported in the aggregate.

A group of COGR staff and committee members met with HHS OIG on January 30, 2024, to discuss questions about the survey that COGR provided in advance. Notes from that meeting are available in the COGR Portal (log-in required).

Two particularly significant items emerged from this meeting:

Extension of Survey Response Deadline from February 8 to February 23, 2024: HHS OIG advised that the survey was sent to contacts on an email list provided by NIH. However, the contacts on this list were not role-based, and as a result, many institutions could not determine to whom at their institution the survey was delivered and/or whether they had received a copy at all. Along these same lines, HHS OIG reported that it had received a large number of email bounce-backs from addresses on the NIH list that appeared to no longer be valid. If an institution is unsure as to whether it received the survey, it should email OIG2024Survey@oig.hhs.gov to determine if, and to whom, the survey was sent.

In view of the difficulties in determining whether and to whom an institution's survey was delivered, COGR wrote to HHS OIG requesting an extension of the survey response deadline. **HHS OIG responded by extending the due date until February 23, 2024.**

Limited Answer Responses: COGR also raised concerns to HHS OIG about the fact that the responses presented for each of the survey scenarios did not always permit institutions to accurately answer the questions presented. In general, scenario responses were limited to identifying the financial support in question as a "gift" or "other support," or answering that the institution did not know. During the meeting with HHS OIG, COGR committee members advised that some of the scenarios described situations that would not be permitted under institutional policies and other scenarios lacked sufficient information to answer the question. HHS OIG advised in such cases institutions should choose the "don't know" response and provide additional detail about their answer in the free text box (A.13). In its follow-up letter to HHS OIG, COGR recommended that because "don't know" was not accurate answer in all cases, HHS OIG should revise the survey to include an "other" answer. HHS OIG stated that it was not possible to revise the survey because completed copies had already been received, and it reiterated its advice that institutions select the "don't know" response and provide additional information in the free text box, making sure to indicated the question number to which the additional information applies.

COGR Questionnaire on HHS OIG Survey for Member Response- Please Complete by 2/23 (NEW)

As discussed above, institutions' use of the "don't know" response in answering the HHS OIG survey may not always accurately describe their circumstances. Accordingly, COGR designed a brief questionnaire to collect information on how often institutions were required to utilize the "don't know" response in answering the HHS OIG survey, and their reasons for doing so. Institutions are asked to complete this survey by February 27, as this information will be presented at COGR's Virtual Membership Meeting on March 1 during the Committee reports session. All information presented will be anonymous and reported in aggregate. This will assist COGR in responding to any recommendations stemming from the HHS OIG survey.

NSF Publishes Research Security Training Modules (NEW)

NSF has published the long-awaited research security training modules. These modules were developed as a means of satisfying the research security training requirements identified in the Guidance for Implementing NSPM-33 and Section 10634 of the CHIPS and Science Act of 2022. Content for the modules were jointly developed by research funding agencies, intelligence agencies, and entities to which NSF made awards for the development of the modules. There are four interactive modules that cover the following topics:

- Introduction to Research Security
- The Importance of Disclosure
- Manage and Mitigate Risk
- The Importance of International Collaboration

A certificate of completion can be downloaded by users who complete the module, but institutions will need to determine if/how they can incorporate the modules into their individual learning management systems used for tracking the completion of required training. The modules are free of cost to users.

Institutions are not required to utilize the training modules and/or they may use them in conjunction with other training materials. Notably, the PAPPG 24-1 does not contain a certification that research security training has been completed, but this certification is expected to be included in the 2025 PAPPG.

DARPA Adopts Department of Defense (DOD) Policy for Risk-Based Security Reviews of Fundamental Research (UPDATE)

At COGR's October membership meeting, DOD's Dr. Bindu Nair presented on the agency's "Policy for Risk-Based Security Reviews of Fundamental Research Policy" ("DOD Policy"). (The slides and session recording are available in the COGR Portal, log in required.) The DOD Policy includes a risk assessment matrix, which lists four broad areas of risk factors (foreign talent recruitment programs, funding sources, foreign patent filings, and entity lists) that DOD will consider in evaluating funding proposals.
In late December 2023, DARPA issued a memorandum stating that it was adopting the DOD Policy, and that this policy would specifically supersede the prior DARPA Countering Foreign Influence Program (CFIP) policy, DARPA Risk Rubric, and DARPA CFIP Frequently Asked Questions. DARPA will employ the DOD Policy to conduct "risk-based security reviews of all covered individuals" on fundamental research proposals that a DARPA program manager identifies as "selectable and recommended for funding." The new rubric replaces the prior risk categories (i.e., Low, Moderate, High, Very High) with the following "levels of required mitigation": No Mitigation Needed, Mitigation Measures Suggested, Mitigation Measures Recommended, Mitigation Measures Required, and Prohibited. For individuals identified as "Mitigation Measures Suggested," the research institution will be provided with an opportunity to address the risk/suggested mitigation measures.

With respect to the DARPA CFIP FAQs, DARPA advised COGR that it is revising this document to align with the DOD Policy. DARPA hopes to have the new version published sometime in March 2024.

One item in the DOD Policy of particular note is that after August 9, 2024, the following items are considered as prohibited factors that will prevent the award of DOD funding for a proposal:

> (a) a covered individual's participation in a malign foreign talent recruitment program (as defined in Section 10638(4) of the CHIPS and Science Act of 2002); and
> (b) the proposing institution's lack of an institutional policy that prohibits participation in an MFTRP of a covered employee on a DOD fundamental research proposal.

Although the DOD Policy is eventually expected to be adopted by all DOD components, the DOD has not yet issued a deadline by which components must take such action. Accordingly, some units such as the Army Research Lab (ARL) have not yet retired their component specific risk assessment/mitigation processes. (*See,* ARL Devcom Army Research Risk Assessment Protection Program (AARP) Risk Matrix/Rubric).

NSF Effort to Develop Risk Assessment Processes/Matrices and SECURE Center (NEW)

At the January 2024 FDP meeting, NSF presenters stated that NSF is working on the development of an NSF National Security Evaluation Rubric. This rubric will contain "risk-based indicators to inform the basis" of risk analysis of funding decisions.

NSF also provided an update on the establishment of its SECURE (**S**afeguarding the **E**ntire **C**ommunity in the **U**.S. **R**esearch **E**nterprise) information sharing and risk assessment organization. NSF solicited proposals for the establishment of the SECURE Center in August 2023, reviewed received proposals in January 2024, and plans to make an award in August 2024.

COGR Joins Comment Letter on FAR Cyber Incident Reporting (NEW)

The December 2023 Update discussed FAR Case 2021-017 *Cyber Threat and Incident Reporting and Information Sharing* (88 FR 68055). The proposed rule includes detailed incident reporting requirements as well as requirements for contractors to develop and maintain software bills of materials for any software used in the performance of the contract and other requirements.

COGR joined EDUCAUSE and AAU in comments submitted on February 2. The comments made several principal points:

1) the inclusion of a cyber incident reporting requirement in all federal contracts does not appear justified;
2) if the proposed FAR revisions are intended to apply cyber incident reporting requirements to all federal contracts that might entail the use of any information/communications technology (ICT), then the government should recognize that it will be starting down a slippery slope to a significant "signal versus noise" problem in relation to cyber incident reporting;
3) asking researchers, their students and assistants, and their institutions to develop and maintain software bills of materials for any software used in the performance of the contract will continuously siphon time

and resources away from the research for which the agency has contracted without actually improving federal agency cybersecurity;

4) the mandated reporting deadlines would be unnecessary and detrimental to the research for which the government has contracted;
5) the proposed requirement assumes a clear, shared understanding of what constitutes discovery that a security incident may have occurred but the rule provides no guidance for making that determination; and
6) the Federal Register Notice asks how entities would make distinctions between "imminent jeopardy" and "actual jeopardy" for reporting when the relevant question is what the contracting agency, the Cybersecurity and Infrastructure Security Agency (tasked with implementation), and/or the relevant law enforcement agency view as constituting "imminent jeopardy."

Each of these points is discussed in detail in the letter. The letter concludes by stating the proposed requirements would likely have a direct, adverse impact on federally funded research at higher education institutions, increasing the cost of such research to federal agencies without appreciably improving the cybersecurity posture of those agencies.

From COGR's perspective, the most troubling aspect of the proposed rule is that it can be read to apply to all federal contracts, including fundamental research. It is difficult to conceive of any research project not involving some use of ICT, including use for basic administrative purposes. As the comment letter states, possible cyber incidents in such projects pose little if any cybersecurity risk to the agencies for which the research is being conducted. They generally do not entail direct access to federal computer networks or information systems or the transfer of data or technology in formats that would lend themselves to efforts to compromise federal networks or systems. Given the definition of "security incident" on which the proposed rule relies, a minor problem on a graduate research assistant's device, such as installing an innocuous but unauthorized browser extension, could require filing a federal cyber incident report.

We hope the final rule will clarify that the requirements are intended to apply to contracts with ITC service providers and focused on protecting government networks. While concerns about cybersecurity are valid and understandable, as written the rule appears a disproportionate overreaction to these concerns. It will greatly increase burden without improving security.

Long Pending CMMC Rule Published (NEW)

On December 26, DOD published the long-awaited Cybersecurity Maturity Model Certification (CMMC) rule (88 FR 89058). COGR has been following and reporting on CMMC developments for some time (e.g. see COGR February 2023 Update). An interim DFARS rule was effective in November 2020. An updated CMMC program structure (CMMC 2.0) was announced in November 2021. The new rule contains no real surprises over what was previously announced. The basic DFARS ground rules for protecting CUI (Covered Defense Information) have not changed.

The principal change is to move from compliance self-assessments to a requirement for independent third party

assessments for CMMC Level 2 where required by the contract. Otherwise, self-assessments may continue on an every 3-year basis, but contractor (or subcontractor) senior officials must confirm continued compliance with the CUI security requirements annually. (CMMC Level 3 will require DOD assessments, but relatively few COGR member institutions should be affected). "Conditional" self-assessments of compliance are possible with Plans of Action and Milestones (POA&M) to be accomplished over a six-month period. DOD does not plan to reimburse assessment costs. Assessments can be restricted to specific enclaves. Implementation will be phased in over a three-year period. As implementation evolves, there may be changes in the applicable DFARS provisions (i.e. 252.204-7021).

On a positive note, the rule includes a discussion (FR p. 89068) of the concerns expressed by COGR and other associations about the potential impact on fundamental research (see October 2020 Update). In response, the rule states: "CMMC Program requirements apply only to defense contractors and subcontractors who handle FCI and CUI on an information system associated with a contract effort or any information system that provides security protections for such systems, or information systems not logically or physically isolated from all such systems. Fundamental research that is 'shared broadly within the scientific community' is not, by definition, FCI or CUI."

While this statement appears to confirm our understanding that fundamental research is excluded from the CMMC program, some concerns remain. As stated in our previous comments to DOD, we remain concerned about contracting officer determinations of certification levels and how potential misapplications of certification requirements to fundamental research activities will be resolved. Also, without specific guidance from the DOD to the contrary, prime contractors are very likely to simply extend the security requirements for the overall project to subcontracts, regardless of whether they apply. We believe that additional formal guidance would be helpful in clearly defining how the DOD, our members, and other stakeholders (e.g., companies that often serve as primary contractors) can ensure that fundamental research activities do not face inappropriate CMMC requirements.

We are considering submitting comments to DOD on the lengthy (234 page) CMMC FR notice. The comments would express appreciation for the acknowledgment of fundamental research, but reiterate the concerns expressed above about implementation by DOD contracting officers and prime contractors. We also are discussing with EDUCAUSE identification of possible additional concerns. These include the apparent conflation of "Security Protection Data" with CUI, timeframe for completion of POA&M objectives, availability of qualified assessors for the university environment, alignment with the NIST security requirements, and CUI marking.

Comments are due Feb. 26.

Research Security & Intellectual Property (RSIP)

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

COGR Joins Other Associations in Submitting Comments on Draft March-in Framework (NEW)

The December Update discussed the NIST RFI on the draft guidance Framework for agencies to consider in the

COGR's Session on NIST Framework at Upcoming 2/29 Virtual Meeting

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Moderated by:

Todd Sherer, *Associate Vice President for Research, ED Emory University*

Panelists:

Walter Copan, *Vice President for Research & Technology Transfer, Colorado School of Mines*

Kirsten Leute, *Partner Osage University Partners*

Dennis Liotta, *Professor, Department of Chemistry, Emory University*

use of march-in rights under the Bayh-Dole Act. Among other concerns, the proposed Framework would provide agencies with justification to use pricing as a consideration to exercise march-in rights if inventions (and resulting patents) were developed with taxpayer funding: On February 2, COGR joined five other higher education associations in submitting comments on the RFI. In addition, COGR submitted separate comments expanding on some of the points made in the joint letter. Both letters are posted to COGR's website here.

Major points in the joint letter are:

- No changes in the Bayh-Dole Act are necessary given its success in the past forty years in developing inventions arising from federally-funded research;
- The Framework increases uncertainty and ambiguity around the criteria for Bayh-Dole march-in consideration, which will have a detrimental and destabilizing effect on university and medical school technology transfer efforts and planning;
- Agency considerations on petitions for march-in should be based on the original intention of the Bayh-Dole Act not a reinterpretation to achieve certain market goals.

The letter discusses these points in greater detail, in the context of five questions posed by NIST in the RFI. The letter notes that including 'reasonable pricing,' an undefined and inherently subjective term, in the Framework for agency decision-making undermines the balance of the delicate symbiotic relationship amongst research universities, start-ups licensing their nascent technologies, and venture capital that helps bring technological advancements to society.

The Framework is overly complicated and highly likely to be interpreted differently at each federal agency which will bring even more complexity to technology transfer efforts. The ability to second-guess pricing, which is a complex commercialization decision that is far removed from the licensing component, heightens the risk calculation for future private sector partnering and investment. While aimed at drug pricing, the Framework is overbroad. Such a framework will inherently be unable to properly address all stages of development and types of technology that are subject to the Bayh-Dole Act. The letter concludes by stating the "Framework will not solve the problem as has been intended by the Administration and will cause far too much collateral damage to be justifiable." It urges NIST to rescind the draft Framework.

The COGR letter emphasizes that the addition of price as a factor for agencies to consider in evaluating march-in under the first two statutory criteria of Bayh-Dole unquestionably will have a chilling effect on the ability of federal funding recipients to partner with industry to commercialize federally-funded inventions. This will undermine Administration priorities such as the CHIPS and Science Act programs that are premised on industry co-investments and public-private partnerships. Additionally, the Framework largely will be ineffectual in affecting drug prices since almost all drugs on the market are covered by multiple patents

and other intellectual property, much of which is not subject to Bayh-Dole. However, the Framework will undermine the utilization of Bayh-Dole subject inventions in all technology sectors. To further compound the problem, the RFI uses vague and unclear terms with regard to product pricing ("unreasonable", "extreme", "unjustified," etc.). Finally, the COGR letter notes the potential for gamesmanship, by providing a roadmap for large companies and others to challenge and harass small companies to undercut their product pricing. It concludes by also asking NIST to withdraw the Framework.

Over 50,000 comments were submitted to NIST in response to the RFI. Many of these were short "canned" comments from private individuals supporting the use of price as a way to reduce drug prices. However, statements of opposition were submitted by representatives of almost all sectors of the economy[2]. A large number of research institutions submitted comments opposing the Framework. Other groups such as the National Venture Capital Association, National Association of Manufacturers, U.S. Chamber of Commerce, and disease-focused and patient advocacy groups also opposed the Framework. Many individuals also submitted negative comments including former senior government officials and distinguished legal scholars (including retired judges). There is no clear timeline for NIST to respond to the comments.

COGR will hold a session on the March-in Framework and drug pricing at the virtual meeting on February 29. The session will be moderated by Todd Sherer, Associate Vice President for Research, Executive Director at Emory University and COGR Board member. Panelists include Walter Copan, Vice President for Research and Technology Transfer, Colorado School of Mines and former Director of NIST, and Dennis Liotta, a researcher at Emory who is an award-winning co-inventor of HIV drugs and therapies (e.g. Truveda).

NIST RFI on Domestic Manufacturing Waiver Request Form (NEW)

On December 7 NIST issued an RFI (88 FR 85243; Federal Register: Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Domestic Manufacturing Waiver Request Form) requesting comments on plans to develop a common form for submission of domestic manufacturing waiver requests to funding agencies in the iEdison invention reporting system. Comments were due February 5. The December Update mentioned NIST's plans to issue an RFI for guidance on waivers.

The RFI was confusing because while it discussed plans to develop a form, it did not actually include the form. COGR contacted NIST to ask for clarification. NIST stated that the Paperwork Reduction Act requires a two-step process: a 60-day notice followed by a 30-day notice. The final form is not required for the 60-day notice. NIST still is finalizing the form. It will be made available when the 30-day notice is filed. At that point there will be a 30-day comment period.

Since the actual form was not available, COGR did not comment. We do not object to the concept of a common form for waiver requests. In fact, it could be helpful if actually used by agencies. We look forward to reviewing and commenting on the form once it is available.

[2] *See https://ipwatchdog.com/2024/02/05/public-comments-reveal-widespread-unity-opposition-nists-march-rights-framework/id=172851/*

Contracts & Grants Administration (CGA)

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

NIDDK Data Management and Sharing Template (NEW)

COGR is following feedback from the community involving requests from National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) during Just-in-Time (JIT) for the specific name of the institutional official that will provide oversight of the DMS plan (Element 6). This request appears to go beyond NIH policy, which specifies to describe how the *plan will be monitored and managed, frequency of oversight, and by whom (e.g., titles, roles)*.

At the January 2024 FDP meeting, NIH's Michelle Bulls briefly addressed this topic, specifying that she did not think that the agency could mandate a particular individual be named. She also cautioned about placing the responsibility solely with the PI due to concerns about monitoring for compliance.

COGR has contacted NIH for additional clarification and will inform the community of any new information.

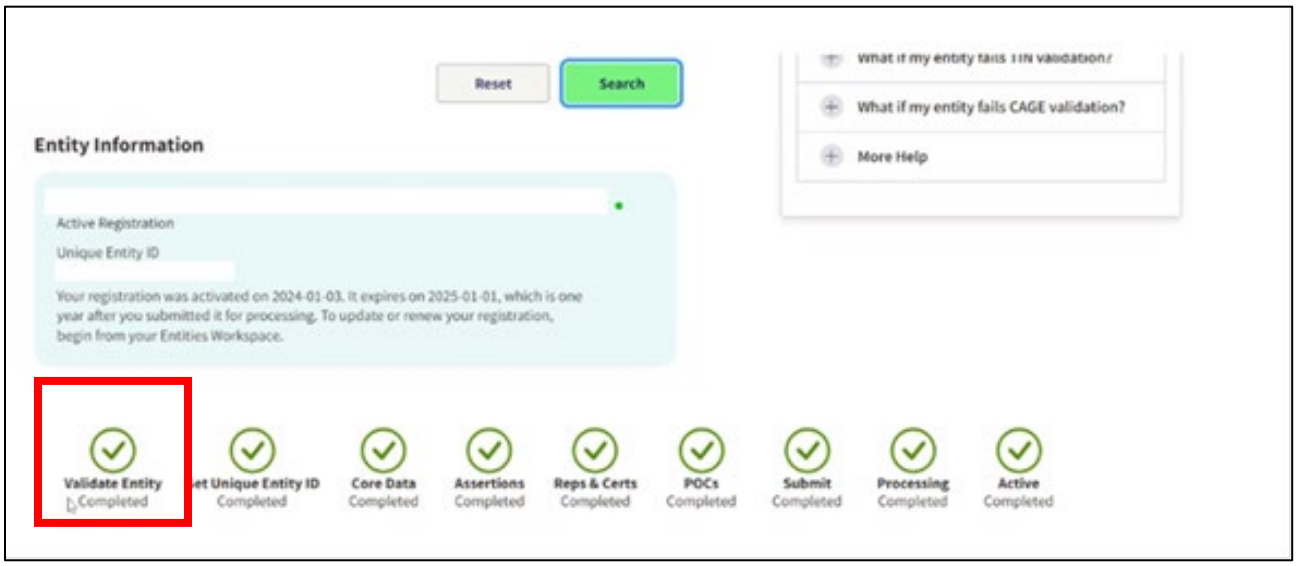
SAM Registrations (UPDATE)

In September 2023, we reported that several members contacted COGR with challenges regarding SAM renewals/registration. Reports include challenges with the lack of timely and effective communication from the General Services Administration's Federal Service Desk (FSD), issues with verification documents to validate entity information, and ineffective remedies for entities with multiple UEIs, which require extensive time and effort to resolve and risk a lapse in their status.

Over the past several months, COGR has met with GSA to bring the issues to their attention and escalate individual institutional cases facing challenges with their SAM renewal. This engagement has provided insight into the common challenges our members face, and as such, we offer the following information.

Entity Validation Process – Many institutions report that documents provided previously for renewals that were 'accepted' are no longer satisfactory for clearing the entity validation process. GSA shared that when the system transitioned from Duns & Bradstreet to SAM in 2022, entities deemed low-risk (such as COGR member institutions) automatically went through a bypass process of the Entity Validation Service (EVS). So, although documents were provided, these documents did not receive a manual review for consistency with EVS Documentation Requirements to move forward with renewal. Now, as entities are up for renewal, the EVS team verifies that institutions are validated. If the institution has not been validated, the EVS will proceed with a review per the EVS Documentation Requirements. Institutions can check if they previously cleared validation on the home page of the entity's profile at SAM.gov.

Entities with a green check mark for 'Validate Entity' are validated (example provided below as indicated by the red square). If the check mark is not green, the entity must be validated for EVS Documentation Requirements.



Once an entity satisfies the EVS documentation requirements and receives validation (green check mark), the entity will automatically proceed through the EVS process for renewals unless the entity changes its legal name or address. Entities that receive a renewal but have not satisfied the EVS documentation requirements will manually be reviewed by the EVS team for future renewals until the entity is validated.

Validation Documents/EVS Documentation Requirements – A significant challenge institutions report is satisfying the EVS Documentation Requirements. The documents on the lists are restrictive and do not align with the operational construct for many of our institutions (for example, producing a utility bill). Additionally, communication with the EVS team remains challenging, and institutions report no clear path to escalate issues or request an exception/bypass. COGR has raised these issues with GSA, emphasizing a need for EVS to accept documents unique to institutional operations for validation. However, the EVS vendor/helpdesk lacks the authority to approve exceptions, often resulting in what several institutions report as many weeks of misguided communication from the EVS vendor, with no clear path for escalating the issue to the relevant GSA authority. Institutions unable to satisfy the EVS documentation requirements are often renewed through a bypass, resulting in perpetuating the problem for future renewals until the EVS documentation requirements are met. GSA has expressed interest in understanding what documents institutions can provide that are approved by an Authoritative Source to expand the list or give an alternate option.

Multiple Unique Entity ID (UEI) – Institutions with multiple UEIs report significant challenges renewing their SAM registration. They report requests from the EVS team to consolidate into one UEI. The uniqueness of an entity is classified as a distinct combination of legal business name and physical address; if those two are the same, it's considered a multiple UEI. Again, this requirement does not account for the unique construct of institutions. Many of which have multiple UEIs for reporting purposes, security clearance, large system schools with multiple campuses, etc. GSA is aware of this issue and is working on solutions for entities that require multiple UEIs. We also shared with GSA that institutions have requested resources for consolidating to one UEI, noting that all awards must be transferred to the primary UEI. Institutions unable to consolidate should indicate as such in their correspondence with the EVS helpdesk requesting the issue be escalated, as consolidation is not an option due to active awards.

In summary, for institutions approaching their SAM renewal, it is recommended to verify your validation status (indicated by a green check mark). If the institution is not validated, we recommend starting the process well in advance, ideally at least a month before the expiration date. This becomes especially crucial if your institution has multiple UEIs or encounters challenges in producing documents per the EVS Documentation Requirements. It is important to note that EVS communicates through a help desk ticket system, and these tickets automatically close if there is no communication for five days. Therefore, maintaining open communication is pivotal. Through COGR's engagement, GSA has established a dedicated team to escalate cases for resolution. Cases that warrant escalation include those involving multiple UEIs and entities unable to produce a document per the EVS Documentation Requirements. To escalate a case, specify to the EVS helpdesk that you request the ticket be escalated. You may also contact COGR to assist with escalating the issue.

GSA will present on these topics and more on during COGR's virtual meeting on Thursday, February 29 at 2:00 - 3:15 p.m. Contact Krystal Toups at ktoups@cogr.edu if you have any concerns to report or comments related to SAM registration.

NIH Salary Cap for FY 2024 (NEW)

NIH published on January 29, 2024 Guidance on Salary Limitation for Grants and Cooperative Agreements for FY 2024 (NOT-OD-24-057). The cap level for Executive Level II salary increased from $212,100 to $221,900, effective January 1, 2024. Recipients may rebudget funds to accommodate the current Executive Level II salary level for active awards, including competing awards issued in FY 2024 that were restricted to Executive Level II, if adequate funds are available and if the salary cap increase is consistent with the institutional base salary. NIH continues to operate under a continuing resolution, NOT-OD-24-059. All legislative mandates that were in effect in FY 2023 remain in effect under this CR, including the Ruth L. Kirschstein National Research Service Award predoctoral and postdoctoral stipend levels and tuition/fees as described in NOT-OD-23-076.

NSF Proposal & Award Policies & Procedures Guide (PAPPG) (NSF 24-1) (NEW)

On January 22, 2024, NSF released the revised version of the PAPPG (NSF 24-1) effective for proposals submitted on or after May 20, 2024. As previously reported, COGR responded to NSF's request for comment on the proposed PAPPG in a letter. A notable comment addressed in the final version of the PAPPG is the request to align the definition of the Malign Foreign Talent Recruitment Program (MFTRP) with CHIPS & Science. NSF provides a Summary of Changes that includes several notable items, including:

- New sections to address Malign Foreign Talent Recruitment Programs (also mentioned above in the Cross Cutting section)
    - Parties to Malign Foreign Talent Recruitment Programs restriction for senior/key person. Note that PAPPG NSF 24-1 originally listed the effective date as March 25, 2024. COGR contacted NSF who made a technical correction and updated the date to May 20, 2024.
    - Organizational certification requirement regarding MFTRP
    - Certification Regarding Non-Participation in Malign Foreign Talent Recruitment Programs for senior/key persons in the Biographical Sketch and the Current and Pending (Other) Support.
- Postaward Disclosure of Foreign Financial Support (see above in the Cross Cutting section)

- Implementation of the common disclosure forms for Current and Pending (Other) Support developed by the National Science and Technology Council's Research Security Subcommittee.
- Mentoring plan and Individual Development Plans expanded to include graduate students.

NSF Seeks Comments on NSF Public Access Plan 2.0: Ensuring Open, Immediate, and Equitable Access to National Science Foundation Funded Research (UPDATE)

As noted in COGR's December 2023 Update, NSF released a Request for Information (RFI) seeking public input on implementing NSF Public Access Plan 2.0 Ensuring Open, Immediate, and Equitable Access to National Science Foundation Funded Research. The plan represents an update to NSF's current public

access requirements in response to recent Office of Science and Technology Policy guidance comments on a proposed revised framework for evaluating and scoring peer review criteria for NIH research project grant applications. COGR joined a multi-association letter in response to the request, applauding the NSF's plan for "several positive contributions" to advancing "public access to research data and publications" but expressing concern by "the lack of clarity for sharing scientific data for juried conference proceedings and the definitions of scientific data and metadata." The letter also raised concern that NSF's consideration of extending public access requirements to software "merits careful consideration." The letter also recommended institutional repositories be identified as appropriate to house scientific data and that NSF encourage the inclusion of adequate funds for public access in research grant funding.

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.

Possible Movement: New CAS Requirement to Adjust Indirect Cost Pools (UPDATE)

Recently, an individual from a COGR member institution shared that they have been informed by Cost Allocation Services (CAS) that adjustments no longer will need to be made to the indirect cost pools. However, until there is an official notice from the HHS Office of Grants (our primary point of contact on this issue) we will remain in "wait-and-see" mode and continue our advocacy work with AIRI (Association of Independent Research Institutes) to bring this issue to closure.

As we wrote late last year, at the direction of the Department of Health and Human Services, Office of Inspector General (HHS OIG), CAS began requiring institutions to remove salary costs from their indirect cost pools for the portion of the salary cost (of an individual) exceeding the Executive Level II (NIH, HHS) salary cap. This new requirement was based on a finding in an OIG report, Cost Allocation Services Needs to Update its Indirect Cost Rate Setting Guidance (see p. 23, *Indirect Cost Rate Proposals Included Potentially Unallowable Compensations Costs*).
Effectively, the HHS OIG finding revised longstanding 30+ year policy as to how the Executive Level II salary cap applies to F&A cost recovery. At issue is the HHS OIG is recommending CAS to direct grantees to apply the salary cap to direct salaries and indirect salaries. The negative impact on COGR members is significant on two

fronts: 1) it adds new administrative burden, and 2) it harms fair F&A cost recovery. In particular, nonprofit research institutions are disproportionately impacted and implementation of this requirement will have a huge impact on their F&A cost rates. Interestingly, in the CAS response to the audit report, CAS did not agree with the HHS OIG finding (see p.26). However, to date, the HHS OIG position has held.

We have been in regular contact with the HHS Office of Grants, and in turn, it has been in communication with the Program Support Center (who oversees CAS). COGR's position has been three-fold: 1) this new requirement, emanating from the HHS OIG, violates the proper protocol for policy setting; 2) it further violates the statutory intent of the salary cap, which was first implemented in 1990; and 3) it violates a ruling by the HHS General Counsel, also from 1990, that the salary cap is not applicable to indirect salaries.

We will update the membership on new developments.

F&A Cost Rate Survey and Capstone Report (UPDATE)

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—will be published later this year (target date, June/July 2024). In addition, COGR has posted two reports (cost rates by institution and definitions) on its 2023 F&A Survey Report page (log in required). Further, we anticipate publishing a third report that shows the cumulative results of many of the survey questions. These reports are meant to be used for institutional purposes only and should not be shared beyond the institution. In addition, both a June presentation and an October presentation at the past two COGR meetings featured analyses that may be of interest to the COGR membership.

Financial Reporting Developments at NASA (ONGOING)

Leaders from COGR's CFC Committee met with leaders from NASA's Grants Policy and Compliance Team (GPC) on October 25, 2023 to discuss financial reporting developments with NASA over the past eight months. Since that meeting, we have stayed engaged with the GPC (and their Director, Antanese Crank), and we will continue to monitor the following two financial compliance initiatives.

- *Transition from FCTR to FFR*. COGR continues to share its concerns with NASA that a transition to a Federal Financial Report (FFR) for each individual NASA award would be excessively burdensome, especially for institutions that have numerous NASA awards. The good news is that rather than requiring a quarterly FFR, only a semi-annual FFR will be required. The first semi-annual FFR will be due by April 30, 2024, covering the 6-month period from October 1, 2023 – March 31, 2024.

- *Routine Monitoring–Financial Transaction Testing Review program*. The program requires institutions to provide a quarterly expenditure list for selected NASA awards. In a May 2, 2023 meeting with the GPC, we raised concerns around the burden and intent of this program. While NASA officials indicated their commitment to maintain the program, they agreed to be more transparent and flexible in their outreach to grantees.

We will stay in communication with NASA and the GPC team, but also encourage COGR members to reach out

to both Antanese Crank (antanese.n.crank@nasa.gov) and her assistant Corey Walz (corey.a.walz@nasa.gov) with concerns specific to your institution.

2022 NSF Higher Education Research & Development (HERD) Survey (REMINDER)

The 2022 HERD results were released on November 30, 2023. Included are the InfoBrief and the complete suite of 2022 data tables (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 InfoBrief, 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).

Costing & Financial Compliance: Audit and Other Topics

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

Single Audit & the 2024 Compliance Supplement (NEW)

COGR is in communication with OMB about the rollout of the 2024 Compliance Support. Normally, COGR receives a draft version and comments on those parts that impact higher education and research institutions. We were pleased with the OMB engagement and their rollout of the 2023 Compliance Supplement and in particular, changes made to the Cash Management section (see page 3-C-3). We welcome COGR members to contact us on audit issues that arise, including issues applicable to the Compliance Supplement. When appropriate, we can reach out to our contacts at the audit firms and/or engage in other ways that may be helpful to address issues and concerns.

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

COGR members are encouraged to follow NIH-related audit activity posted in the HHS OIG Workplan, as well as completed reports posted by the Office of Audit Services and the Office of Evaluation of Inspections. For activity from the NSF OIG, the NSF OIG Reports & Publications page lists recently completed reports. Further, the NSF Management Responses to an External Audits 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 (ONGOING)

We first reported on this topic in the COGR September 2023 Update (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. Severalimplementation 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.

ASAP, IPP, and ID.me: Personal Information and Log-on Concerns (ONGOING)

We first reported on this topic in the COGR September 2023 Update (p. 20). The Automated Standard Application for Payments (ASAP) is an electronic payment system maintained by the Department of the Treasury that is used by many federal agencies (e.g., DOE, USDA, DOJ, etc.) to securely transfer money to recipient organizations. The Invoice Processing Platform (IPP) is a related electronic system, also managed by Treasury, which requires regular access by grantees. COGR members have shared significant concerns with new ASAP and IPP log-on procedures requiring personal information such as one's social security number, copies of one's driver's license and/or passport, and other sensitive personal information. Intersecting with these log-on procedures are the log-on procedures associated with ID.me, which allows one to access their personal information at the Social Security Administration, the IRS, and other government entities. While the focus has been on ASAP, issues around "Personally Identifiable Information" (PII) and "Protected Personally Identifiable Information" (PPII) transcend ASAP and may be larger issues that need additional attention. COGR is following developments and will advocate, accordingly.

Please contact David Kennedy at dkennedy@cogr.edu 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.

Office of Research Integrity's (ORI) NPRM on Research Misconduct Regulations (UPDATE)

Thanks to all COGR members who submitted responses to ORI's NPRM on Research Misconduct Regulations! ORI stated that it received close to 200 responses and that it is currently in the process of reviewing the comments that were received and that it will respond to "relevant comments in the Final Rule." ORI stated in the NPRM that it expected to issue a final rule in the summer of 2024, with an effective date of January 1, 2025. It is not known what impact, if any, the number of comments received may have on that timeline. COGR's December 12 response can be found here[3].

Kick-Off of REC's Review of COGR's Framework for Review of Individual Global Engagements in Academic Research (UPDATE)

A lot has happened in the research security arena since COGR published this important framework for analyzing international academic research affiliations and activities in January 2020. Under REC's leadership, a working group of members of members from REC, CGA, and RSIP are undertaking a review of the Framework to update

[3] *For additional background, see COGR's December 2023 Update: https://www.cogr.edu/sites/default/files/December%202023%20Update.pdf#page=19*

the questions and scenario analyses contained in the document. The working group plans to present on this update at the June 2024 COGR membership meeting in Washington D.C.

EPA Scientific Integrity Draft Policy for Comment (NEW)

At the end of January 2024, EPA published its draft scientific integrity policy for public comment. [89 FR 4606] EPA published this draft policy in response to the 2021 Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-based Policymaking, which called for agencies to review existing scientific integrity policies and make any changes consistent with the memorandum to ensure policies are evidence-based and not distorted by political considerations.

Other federal agencies have taken similar action with respect to their scientific integrity policies (*see, e.g.,* Draft Consumer Product Safety Commission Scientific Integrity Policy, Request for Comments on Draft HHS Scientific Integrity Policy, Request for Information on Social Security Administration Scientific Integrity Policy). Many agency's scientific integrity policies are limited in scope to the agency's employees, with separate requirements for grant awardees (*see, e.g.,* HHS draft scientific integrity policy, NIH draft scientific integrity policy). The EPA draft policy, however, states that it will also encompass contractors and grantees. Accordingly, REC is reviewing the draft policy to consider whether to comment. Comments are due February 23.

FDA Draft Guidance on the Use of Data Monitoring Committees (DMC) in Clinical Trials (NEW)

The FDA recently issued Draft Guidance on the Use of Data Monitoring Committees (DMC) in Clinical Trials to update its current guidance regarding when a data monitoring committee (also known as a data safety monitoring board [DSMB] or independent data monitoring committee [IDMC]) should be considered for clinical trial monitoring, along with policies and procedures for DMC operation. Institutions, sponsor-investigators, IRBs, and other components of an institution's human research protections program (HRPP) should consider reviewing this draft guidance for insight on the FDA's thoughts as to when a DMC is necessary; entities that should be involved in the review of trial safety data, DMC composition, and DMC standard operating procedures.

FDA Draft Guidance on Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products (NEW)

Institutional sponsor-investigators responsible for developing clinical investigation protocols and associated documentation, along with HRPP components responsible for their review may want to consider this guidance. The FDA draft guidance contains recommendations for collecting demographic data from participants in clinical trials of FDA-regulated products. The guidance provides specific question formats for the collection of data on race and ethnicity that comport with OMB directives in this area.

HHS Final Rule on Confidentiality of Substance Use Disorder Patient Records (NEW)

This final rule is scheduled for publication in the Federal Register on February 16, 2024. It is designed to increase protections for the confidentiality of patient records for persons treated for substance abuse disorders while facilitating better care coordination.

The final rule contains provisions that address research, including:

- the relationship between the rule and other federal provisions protecting research subjects from being compelled to disclose their identifies (e.g., certificates of confidentiality);
- use and disclosure of patient identifying data for research;
- requirements for the conduct of research using patient information covered by the rule; and
- the relationship between the rule and the HIPAA privacy and security rules.

HHS has prepared a fact sheet that summarizes major changes in the new rule.

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Appendix A – Upcoming Comment Due Dates

Agency	Description	Due Date	Notes
EPA	Draft Scientific Integrity Policy	February 23	COGR is reviewing the policy.
DOD	Cybersecurity Maturity Model Certification (CMMC) rule (88 FR 89058)	February 26	COGR is considering drafting comments.
FDA	Draft Guidance on the Use of Data Monitoring Committees (DMC) in Clinical Trials	April 15	COGR is reviewing.
FDA	Draft Guidance on Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products	April 29	COGR is reviewing.

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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