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## **President's Message**

## COGR Is Not Only Vital, But Critical

#### Dear Colleagues,

In the last COGR Update, I had been on the job for less than a week. I noted the vital role COGR plays in the partnership between research institutions and the federal government. Now, two months later, I can say with some experience that COGR's role is not only vital, but critical. The work of the association's leadership, committees, staff, and volunteers to address complicated regulatory issues is needed more than ever. Additional regulatory strains on the partnership continue to emerge. And COGR provides expertise and leadership to help strengthen the partnership that contributes to our nation's health, security, and prosperity.

Let me briefly spotlight a few key COGR actions since the March Update:

- Compliance Costs for NIH's DMS Policy. I encourage you to review the recently released COGR survey results. For mid-size to large institutions, the annual projected cost impact is expected to exceed \$1 million per institution. This and other findings demonstrate the "cost of inaction" with respect to the negative consequences to our nation's research ecosystem if the growth of new regulations is not addressed. COGR will continue to make the case for efficient and effective regulation in which the federal government covers its "fair share" of research and compliance costs.
- *NSPM-33 Research Security Program Standard Requirements*. To aid your efforts in submitting comments (due June 5) to <u>OSTP's RFI</u>, we worked spearheaded an effort with AAU, APLU, ACE, AAMC, EDUCAUSE, and AUECO to develop this <u>key messages document</u>. I encourage your institution to submit comments. This is an important opportunity to shape this new requirement, and the volume of institutional responses will be important to this end. COGR plans to post its letter the week of May 29.
- *COGR Is Now on LinkedIn.* I invite you to follow <u>COGR on LinkedIn</u>. In addition to providing a new engagement platform for COGR members, we will amplify our advocacy with key federal agencies and use the platform to help elevate COGR's effectiveness in affecting federal research policy and practices. Thank you to the hundreds of you who are now following COGR and engaging with our posts.

Also, please know the COGR team is <u>closely monitoring</u> the U.S. debt limit situation. We are mindful of the <u>potential consequences for federally-sponsored research</u> should policymakers fail to reach an agreement. We will engage with the research agencies and provide information to you as warranted. If you have any questions or would like to share how your institution is planning for this potential problem, please contact Krystal Toups at <u>ktoups@cogr.edu</u>.

I look forward to seeing many of you at COGR's <u>June 8-9 Meeting</u> in Washington D.C. Registration is <u>still</u> <u>open</u>, and I hope you will join us.

Matt Owens, President

#### Announcements

## COGR's June 8-9, 2023, Meeting in Washington D.C.

COGR is looking forward to hosting its next member meeting on June 8-9 in Washington D.C. at the <u>Washington Marriott in Georgetown</u>. The agenda is available on our <u>meeting materials page</u>, and <u>registration is still open</u>. In addition, ahead of the meeting, please take a moment to download <u>Poll</u> <u>Everywhere</u> on your laptop or mobile. We'll use PE for live audience participation during the sessions. If you have any questions or need assistance, please contact <u>memberservices@cogr.edu</u>.

## COGR Member 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 Member 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> (that includes recordings of past COGR webinars and meetings), view the <u>COGR Member Directory</u>, check out <u>COGR's Job Board</u>, where member institutions can submit relevant job postings at their institutions, and view COGR members-only materials. In addition, the Portal is where Primary Representatives and financial billing contacts can manage their institutional dues invoices each year<sup>1</sup>. Encourage your team and other research – connected offices to sign up and stay up to date with COGR.

## Save the Date: COGR's 75th Anniversary in Washington D.C. October 26, 2023

Later this year, COGR will celebrate its 75<sup>th</sup> anniversary during the October 26-27, 2023, meeting in Washington, D.C. Originally a standing committee in what is now the National Association of College and University Business Officers (<u>NACUBO</u>), COGR began operating as an independent organization in 1994 and today has a membership of over 200 of the most research-intensive institutions in the U.S. More details to come as we get closer, but for now, save the date!

## New Resource: May 2023 Update Appendix 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 in regard to each (<u>Appendix A</u>). We hope this list is a helpful brief supplement to the detail and analysis provided within this Update on each of these topical areas.

<sup>&</sup>lt;sup>1</sup> COGR institutional annual dues invoices are available to generate now in the COGR Member Portal and due on August 1, 2023. To generate, you must be a Primary Representative or financial billing contact. Click on the 'renewal badge' on the Dashboard, update your contact information, and generate the invoice. Contact <u>memberservices@cogr.edu</u> with any questions.

## NIH Data Management and Sharing Policy: Cross Cutting

#### NIH Data Management and Sharing: Six Months In – Presentation June 8 (NEW)

At the June COGR Meeting, COGR will host a panel with FDP and NIH representatives to discuss updates on Phase I of the <u>NIH Data Management and Sharing (DMS) Pilot</u>. Phase I of the pilot project is to test two DMS Plan templates developed by FDP in collaboration with NIH (ICs, OPERA, and OSP). The panel will discuss progress to date and plans for Phase 2 of the pilot addressing costing policies. Also, as part of this session, COGR will present the results of the COGR Survey: *DMS and the Cost of Compliance* (see below). For more information on NIH's Data Management and Sharing Policy, including <u>COGR's Readiness Guide</u>, visit our NIH DMS resource page here.

#### COGR Report: Cost Impact and Concerns - NIH Data Management & Sharing Policy (NEW)

On May 11, COGR published its survey report: <u>Data Management and Sharing (DMS) and the Cost of</u> <u>Compliance</u>. Thirty-four institutions completed the survey, and we are thankful for your participation! Your thoughtfulness, patience, and effort resulted in high-quality data and enabled us to draw strong conclusions based on the survey results.

Key findings in the report include:

For mid-size to large research institutions, the annual projected cost impact is expected to exceed \$500,000 at the central administrative level, while also exceeding \$500,000 at the academic level—a total impact that exceeds \$1 million per institution. Cost impact is measured both by new expenditures and reallocation of effort away from an individual's current responsibilities. In the case of Researchers and Investigators, this results in a shift away from conducting science in the lab toward tasks that might be considered more administrative in nature. For smaller and emerging research institutions, the cost impact also is expected to be significant, and for these institutions, the disproportionate negative impact may discourage their participation in the federal research ecosystem.

The results of the cost impact survey associated with the new NIH DMS policy represent the second "cost of compliance" study that COGR has completed over the past six months. In November 2022, COGR published <u>Research Security and the Cost of Compliance, Phase I Report</u>, which focused on the cost impact associated with the new NSPM-33 disclosure requirements. When considered in conjunction with one another, these two new compliance requirements put a spotlight on the unceasing progression of new compliance requirements being piled upon research institutions.

As we reference in the *Data Management and Sharing and Cost of Compliance* report, COGR has maintained a running list of new regulations mandated upon research institutions since 1991.<sup>2</sup> The list

<sup>&</sup>lt;sup>2</sup> See, COGR <u>List of Regulatory Changes Since 1991</u>

has grown significantly, continues to grow, and there is no end in sight. Further, each item on the COGR list represents not just one new compliance requirement, but often translates into dozens—and sometimes hundreds—of new compliance actions that must be initiated by an institution. In the case of DMS, COGR supports the principles around transparency, open access, and data sharing. However, it is worth noting that the new NIH DMS policy represents still another regulation added to the list without a viable mechanism for the NIH to pay for its "fair share" of the cost of compliance. While the new policy includes provisions to allow institutions to "direct charge" DMS costs to an award, the high price tag on these costs suggest that, at best, only a small fraction of these costs will be covered by NIH.

The report concludes with a broad discussion on the "Cost of Inaction"—in other words, the potential consequences of working with an unsustainable cost reimbursement model, which is inadequate to address the ever-growing costs of compliance.

For smaller and emerging research institutions, the cost burden will potentially become prohibitive to their continued participation in the federal research ecosystem. For mid-size research institutions, they will continue to participate, but may choose to retreat from conducting certain types of federally sponsored research. For large research institutions, most likely, they will continue full participation, but even they may choose to restructure the composition of their research portfolios. As for faculty, investigators, and those aspiring to be researchers, the ever-growing administrative burden required to conduct federally sponsored research has and will continue to lead some to seek other careers that are less complicated. And for the United States, our position as the global leader in science and technology will be challenged. Future generations of Americans will bear the cost—a less-creative, less-robust research enterprise that diminishes American ingenuity, imagination, and innovation.

Without a mechanism for the federal government to share in these costs, the risks to the research ecosystem are real.<sup>3</sup> In addition to COGR's work on cost of compliance surveys, COGR recently completed its 2023 F&A Survey and is in the process of analyzing the results (see the <u>Costing and Financial Compliance</u> section of the COGR Update). The convergence of new and expensive regulations with a recognition that the cost burden is not sustainable for many institutions has created an important moment of reflection on how the nation addresses this challenge. COGR will continue to advance our advocacy around the issues of regulatory burden, the cost of research, and fair and equitable reimbursement for the costs of doing research.

If you have questions on the survey, or any of these related topics, please reach out to David Kennedy at <u>dkennedy@cogr.edu</u> or any other COGR staff member.

<sup>&</sup>lt;sup>3</sup> The primary obstacle is defined in <u>Appendix 3, C.8.a. to Title 2, Part 200</u>: "the administrative costs charged to Federal awards… must be limited to 26% of modified total direct costs."

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

#### OMB Update at the June COGR Meeting: Revisions to the Uniform Guidance (NEW)

Policy officials from the OMB Office of Federal Financial Management (OFFM)—*Deidre Harrison, Deputy Controller, and Steven Mackey, Policy Analyst*—will provide an update on OMB activities, including an update on the status of the revisions to the Uniform Guidance. Ms. Harrison has been a leader on the topic of financial innovation and transformation in federal government operations. Several of her ideas are available in <u>an interview</u> conducted through the Bureau of Fiscal Service, U.S. Department of the Treasury. Mr. Mackey is the designated point person in charge of implementing revisions to the Uniform Guidance.

We expect this session to provide insights on how OMB is approaching Uniform Guidance revisions. Some of the ideas and topics COGR has raised were included in COGR's response (see below) to the OMB Request for Information earlier this year. We encourage those attending the session to raise specific questions regarding their "revisions of interest." If you have advance questions or topics of particular interest, contact David Kennedy at <u>dkennedy@cogr.edu</u>.

#### COGR Response to OMB RFI: Revisions to the Uniform Guidance (ONGOING)

On February 9, OMB released a Request for Information (RFI)<sup>4</sup> to inform revisions to 2 CFR Part 200, the Uniform Guidance, and address considerations applicable to the Universal Identifier and Systems for Award Management (Chapter 1, Part 25) and Reporting Subaward and Executive Compensation Information (Chapter 1, Part 170). OMB expects to publish proposed revisions based on responses to the RFI and seek public comment later this year. The original version of the Uniform Guidance was published in December 2014 and the current version of 2 CFR Part 200 was published in August 2020.

The COGR response <u>was submitted</u> on March 13 and addressed a diverse range of topics and proposed revisions (ordered by 2 CFR section number), including:

- Implement active OMB oversight of agency noncompliance with the Administrative Procedures Act (APA) (200.107).
- Delete all references to conflict of interest (COI) in 2 CFR 200 (as this is an inappropriate source for defining agency policies regarding researcher COI) (200.112).
- Codify important federal policies associated with voluntary uncommitted cost sharing (VUCS) (200.306).
- Provide needed flexibility for using fixed amount subawards (200.333).
- Eliminate the current inappropriate and arbitrary mechanism for award termination (200.340).
- Clarify allowability of costs normally incurred after award closeout (e.g., publication, data

<sup>&</sup>lt;sup>4</sup> Comments from all responders to the OMB RFI are available at <u>https://www.regulations.gov/document/OMB-</u> 2023-0007-0001/comment



management and sharing) by permitting alternative methodologies to charge these costs - (200.403).

- Eliminate the DS-2 requirement and work with FAR representatives to modify their expectations on the DS-2 (as described in 48 CFR Chapter 99 Subchapter B 9903.202-1) (200.419).
- Define the telecommunications enterprise as a "facilities" cost and fix the flawed methodology associated with recovering the 1.3 percent (1.3%) utility cost adjustment (UCA) (Appendix III, B.4.a).
- Address the issue of F&A cost rates and fringe benefit rates not being issued in a timely manner (Appendix III, C.6).
- Address inequities associated with the limitation on reimbursement of administrative costs (Appendix III, C.8).
- Codify selected FAQs, as published <u>May 3, 2021, on the U.S. Chief Financial Officers (CFO)</u> website (e.g., purchase of scientific equipment through sole-source, per FAQ, Q-88).

COGR will continue to engage OMB leading up to the publication of proposed revisions and will keep the membership posted on additional developments.

## COGR's Uniform Guidance Resource Page (ONGOING)

COGR has developed a <u>Uniform Guidance Resource Page</u> to serve as an ongoing resource as the revisions to the Uniform Guidance unfold. This page includes past COGR comment letters and other resources applicable to the Uniform Guidance. In fact, our first engagement with this issue was in 2011, when, under the auspices of an NIH RFI, COGR provided comments to the "A-21 Task Force" to address OMB Circular A-21! Contact Krystal Toups at <u>ktoups@cogr.edu</u> and/or David Kennedy at <u>dkennedy@cogr.edu</u> if you have any questions or comments related to the Uniform Guidance.

## **Science & Security: Cross Cutting**

## NSPM-33 and CHIPS & Science Act Research Security Provisions (UPDATE)

As noted in the <u>March 2023 COGR Update</u>, OSTP issued <u>draft research security program standards</u> for public comment (<u>88 FR 14187</u>). The standards cover overarching program requirements and certification, foreign travel security, research security training, cybersecurity, and export control training. Comments are limited to five pages and are due on June 5. COGR is coordinating with other higher education associations to ensure that all issues associated with the proposed standards are adequately addressed. Each association will include in its response support for other associations' comments.

A joint REC and RSIP working group held several listening sessions to gather input from members and developed a draft response that urges OSTP to:



- Ensure that the standards are risk-based, with requirements tailored to the risk presented by the type and circumstances of the research and associated activities being regulated.
- Ensure that there is a single, consistent set of standards across federal research funding agencies.
- Ensure that the standards contain and consistently use a comprehensive set of clearly defined terms that align with any definitions of the same terms used in NSPM-33 and its Implementation Guidance.

COGR encourages institutions to submit comments. To assist in this effort, we have provided a <u>document</u> <u>with key messages</u> that can be used in developing institutional responses. COGR also joined in a joint <u>association letter</u> to NSF requesting stakeholder listening sessions on the proposed standards. COGR will transmit its comment letter the week of May 29 and make it available on our website.

## <u>Department of Education Publishes Final Proposed Section 117 Reporting Requirements and New</u> <u>Section 117 Website (UPDATE)</u>

<u>Reporting Requirements.</u> The Department of Education (ED) published its final proposed <u>Information</u> <u>Collection Request (ICR)</u> for Section 117 Foreign Gift and Contracts Disclosures on May 1. Included is <u>a response</u> to the comments received on the previous ICR.

COGR joined ACE and many other associations in submitting comments on February 27 on the previous ICR (see <u>March 2023 COGR Update</u>). In summary, ED made very few changes in response to the comments, although it added some clarifications, including:

- On the requirement to disclose intermediaries, ED included additional language referencing "reasonable due diligence" in collecting information from "intermediaries." It noted that "this reporting is also consistent with, but not necessarily identical to, the requirements for institutions to provide information about related parties in their annual audited financial statement submissions required under 34 CFR § 668.23 new language/ (d)."
- On the requirement to disclose anonymous donor names and addresses, ED added a new boxchecking option to identify "if the name or address of the foreign source in this transaction to be a trade secret or commercial or financial information that is privileged or confidential and exempt from public disclosure pursuant to FOIA."

It is unclear what, if any, practical effect these two changes will have. The only other substantive change is an acknowledgment that the 10 hours estimated reporting burden was too low. ED increased the estimated burden estimate to 20 hours. This is still far below what many institutions have estimated.

Comments are due June 5. COGR is working with ACE and others on a response.

<u>Redesigned Website</u>. On May 15, ED published <u>a redesigned</u> "Foreign Gift and Contract Reporting" website. The "Notice of Interpretation" on its enforcement authority that ED previously published has been deleted (see <u>October 2020 COGR Meeting Report</u>). A list of "Open Compliance Reviews" is included, all of which were initiated on or before January 15, 2021. The website also includes a list of

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published guidance, webinars and recordings, and other resources including reports and responses to inquiries.

## **Department of Defense Risk Assessment Matrices (UPDATE)**

COGR has raised concerns about DOD-related entities' use of inconsistent risk assessment matrices for analyzing proposals to determine if they present inappropriate foreign influence concerns. In 2021, the Defense Advanced Research Projects Agency (DARPA) issued a <u>risk assessment matrix</u> for the evaluation of researcher disclosures. COGR and other associations alerted DARPA to institutional concerns regarding the originally issued matrix, and DARPA made changes that addressed stakeholder input.

In 2023, the U.S. Army Combat Capabilities Development Command (DEVCOM), Army Research Laboratory issued its version of a <u>risk assessment matrix</u> for use in evaluating activities of senior/key personnel. This matrix differs from the DARPA matrix. COGR invited DEVCOM personnel to attend the June COGR meeting to discuss this new matrix. DEVCOM personnel are unable to attend the June meeting; however, Dr. Bindu Nair, Director of Basic Research at DOD will present on DOD efforts to promote cross-unit consistency in risk assessment approaches. In addition, COGR committees will meet with Isaac Natter, Associate General Counsel, Acquisition & Logistics, prior to the June meeting to discuss the consistency initiative and other topics.

## NIST Issues Revised Security Requirements (UPDATE)

On May 10, NIST <u>released</u> revised draft security requirements for protecting CUI (NIST SP 800-171 Rev. 3). This is an update to a revised draft issued in July 2022<sup>5</sup>. According to the announcement, the goals of the revision include removing outdated requirements and trying to reflect current best cybersecurity practices, in turn helping to ensure a consistent defense against high-level security threats such as "state-level espionage."

Significant changes include updating the requirements to reflect:

- updates to <u>NIST SP 800-53 Revision 5</u> (security requirements for federal information systems);
- updated tailoring criteria;
- clarifying ambiguity in the requirements;
- increasing flexibility for better risk management; and
- a prototype CUI overlay.

The draft includes a <u>helpful set of FAQs</u>, and a <u>detailed analysis</u> of the changes from the previous version. According to the FAQs, "many organizations are overwhelmed with the number of different security and risk management frameworks in use by the public and private sectors. To better align two widely

<sup>&</sup>lt;sup>5</sup> See: <u>https://csrc.nist.gov/publications/detail/sp/800-171/rev-3/draft</u>



used NIST resources, a strategy has been initiated to transition the security requirements in NIST SP 800-171 to the control language in NIST SP 800-53." Three new security requirement families have been added to Revision 3 to maintain consistency with the NIST SP 800-53B moderate control baseline. The families include the Planning (PL) family, the System and Services Acquisition (SA) family, and the Supply Chain Risk Management (SR) family.

COGR and other higher education associations currently are analyzing the changes. Comments are due July 14. NIST expects to release one more draft version before releasing a final version early next year.

## NIST Issues RFI on Cybersecurity for R&D (NEW)

On April 17, NIST <u>issued an RFI</u> seeking input from institutions of higher education and other interested parties to support implementation of the research cybersecurity effort detailed in <u>Section 10229</u> of the CHIPS and Science Act. The RFI includes a series of questions intended to help NIST identify an initial set of common challenges related to research cybersecurity at institutions of higher education and to develop potential cybersecurity resources (e.g., white papers, quick start guides) that could help to address identified challenges.

The questions involve common challenges, assessing and managing risks, resources including NIST for cybersecurity risk management, further research to address cybersecurity challenges and risks, and the role NIST might play.

Comments are due June 30. A comment template form is included in the notice.

COGR is discussing with EDUCAUSE possible comments. NIST has also approached COGR, as well as APLU and EDUCAUSE, to arrange a meeting to discuss issues related to the RFI.

#### NSF Requests Input on New Research Security Organization (NEW)

On May 4, NSF issued a <u>Dear Colleague Letter (DCL)</u> requesting input from the research community on the development of the Research Security and Integrity Information Sharing Analysis Organization (RSI-ISAO), mandated by Section 10338(b) of the CHIPS and Science Act.

The DCL seeks to solicit feedback, ideas, and proposed recommendations from the research community to ensure the products, services, and tools provided by the RSI-ISAO align with the needs and expectations of the research community. According to the DCL, the RSI-ISAO is meant to empower the research community to address foreign interference issues, support a security-informed decision-making structure, and serve as a conduit that connects research community stakeholders with USG officials and expertise as appropriate. NSF will enter into an agreement with a "qualified independent organization" to establish and operate the RSI-ISAO.

The RSI-ISAO will not provide official recommendations and/or determinations on potential research security and integrity risks on a case-by-case basis. The stated goal is to help the research community make better-informed decisions in response to current and evolving research security and integrity risks in the current and future research environment.

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The letter poses a series of questions organized around six thematic areas:

- current research security and integrity issues;
- informational resources for the research community;
- priorities for the RSI-ISAO;
- integration of RSI-ISAO resources;
- benefits to the institution; and
- liaison roles for the RSI-ISAO.

White papers (2-3 pages) responding to these questions are due to NSF June 30. NSF also hosted two webinars (May 18 and May 24) and is scheduling a series of "listening sessions" with higher education associations, including COGR. These sessions will include discussion of more targeted questions as to how best the RSI-ISAO can serve the research community.

## <u>Commerce Department's Bureau of Industry and Security (BIS), Office of Technology Evaluation</u> (OTE) Assessment of the U.S. Civil Space Industrial Base (CSIB) (UPDATE)

On March 27, COGR hosted a Zoom meeting with BIS representatives and representatives from member institutions that received the CSIB assessment<sup>6</sup>. BIS noted that the purpose of the data collection was to provide insight into the structure of organizations that participate in CSIB, including potential supply chain deficiencies. Prior to the meeting, BIS extended the deadline for universities to respond and noted that institutions that received multiple surveys could contact BIS to request that the surveys be combined<sup>7</sup>. BIS noted during the meeting that institutions should provide data concerning institutional departments and labs with "space" and "space-related" activities. BIS also emphasized that the survey was not limited to federally funded projects and that it also encompasses private space/space-related funding as well. After collecting and analyzing the responses, BIS will provide a report containing aggregated data to Congress.

## JASON Report on Research Security Research (NEW)

In March, NSF posted the JASON-authored report entitled <u>Research Program on Research Security</u>. The NSF commissioned report addresses elements necessary for an NSF-sponsored research program on research security. The report is framed around the following core issues:

- Distinction between "research security" and "research integrity."
- Whether the definition of research security is discipline dependent.
- Central research and security themes and questions that should be addressed in research.
- Research communities must be engaged to ensure the research is successful.
- Required data and privacy controls for data used in research.

<sup>&</sup>lt;sup>6</sup> COGR invited institutional participation via the COGR listserv in March 2023 via the COGR News Digest.

<sup>&</sup>lt;sup>7</sup> See COGR Listserv message 3/20/23 for details.



Notably, the report recognizes that although the definition of research security does not differ across scientific disciplines, the "consequences of breaches in research security and the measures to be taken to prevent breaches" are discipline-specific, depending upon how wide-spread and "democratized" certain technologies are. The report also cites the need to collect data from stakeholders (e.g., universities, funding agencies, private companies, law enforcement) on the number and nature of security breaches, and it advocates that NSF work with universities and private companies to access such data in a protected manner for use in research. Further, the report encourages NSF to work with other federal research funding agencies to develop a database of research security breaches at government labs and funding recipients that can be accessed by the NSF research security research program.

## NASEM Workshop Report on Openness, International Engagement, and the Federally Funded Science and Technology Research Enterprise (UPDATE)

The <u>November 2022 COGR Update</u> discussed the NASEM workshop held last year and summarized the COGR presentation. It focused on how institutions are implementing NSPM-33's requirements for disclosing biographical and research support and associated costs, based on COGR's Phase I <u>Research</u> <u>Security and Cost of Compliance Report</u>.

The NASEM workshop proceedings will be <u>published shortly</u>. It will include a high-level summary of points made by COGR representatives (Robert Hardy and Kristin West). These include the significant costs of compliance with new federal risk management requirements, the need for clarity and consistency in regulatory requirements, and how federal agencies might help mitigate the compliance costs.

## **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 being followed by RSIP are covered below.

## **<u>COGR Joins Letter Opposing Expansion of TRIPS Covid-19 Waiver (UPDATE)</u></u>**

The June 2022 COGR Update outlined concerns about the World Trade Organization (WTO) decision to adopt a temporary TRIPS<sup>8</sup> waiver on intellectual property rights to COVID-19 vaccines. On May 5 COGR joined AAU, APLU, AAMC and AUTM in a letter to the International Trade Commission expressing our concerns about the possible expansion of the TRIPS waiver to include COVID-19 diagnostics and therapeutics.

The associations expressed the belief that the original decision to waive TRIP rules for COVID vaccines did not result in an outcome that warrants expanding waivers of IP protection for COVID-19 diagnostics and therapeutics. The letter also noted:

• No country has made use of the vaccine waiver.

<sup>&</sup>lt;sup>8</sup> "Trade-Related Aspects of Intellectual Property Rights"



- Healthcare infrastructure and distribution capacity are the principal issues in expanding vaccine access.
- Further expansion of the waiver is likely to yield the same result, while damaging the innovation ecosystem through the resulting uncertainty in IP protection.
- Strong intellectual property protections are vital to the research enterprise and the cycle of innovation.
- Any uncertainty can stymie future research endeavors and investment.

The letter also cautioned that once these precedents are set, similar actions to strip intellectual property protections from other technologies, such as clean energy and agriculture, could follow. The associations concluded the letter by urging WTO to reject any further waivers of TRIPS.

## <u>NIST Requests Comments on Continued Authorization of i-Edison Information Collection</u> (UPDATE)

On May 4 NIST published an ICR on continued i-Edison information collection.

COGR has supported the redesign of the i-Edison reporting system for federally funded inventions and has directly discussed reporting issues with NIST (e.g., see the <u>June</u> and <u>September 2022 COGR</u> <u>Updates</u>). The ICR notes "there has been an increased interest across the government in the impact of federally funded research and resulting inventions as well as compliance with the Bayh-Dole requirements, especially as it relates to domestic manufacturing requirements. As a result, the interagency working group for Bayh-Dole decided that all agencies would begin to request this information, and the questions would be amended and expanded upon so that the agencies could get a clear picture of the commercialization plans for subject inventions, what the licensing landscape looked like, what products were resulting, and where those products were being manufactured." Collection of gender data in iEdison filings also is included in the request.

COGR has long advocated for the expansion of i-Edison to all federal agencies. We plan to work with the other higher ed. associations on comments supporting the proposed expansions. Comments are due July 3.

## **NIST Publishes Revised Bayh-Dole Regulations (NEW)**

On March 24 NIST published a <u>final revision</u> to the Bayh-Dole regulations. This was the culmination of a long and contentious process (see <u>May 2021 COGR Update</u>)

NIST <u>published an NPRM</u> in January 2021 that included a number of findings and recommendations from the previous Administration's ROI "Green Paper" (see <u>September 2020 COGR Update</u>). COGR was involved in comments and meetings on the ROI beginning in 2018<sup>9</sup>. COGR joined AAU, APLU,

<sup>&</sup>lt;sup>9</sup> See July 27, 2018 joint association letter: <u>https://www.cogr.edu/sites/default/files/Higher%20Ed%20Associations%20RFI%20Response-</u> %20Federal%20Technology%20Transfer%20Authorities%20and%20Processes.pdf



ACE and AAMC <u>in comments</u> on the NPRM in April 2021. By far the most contentious issue in the NPRM was a provision that "march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention." The associations' comments supported this clarification (with the deletion of "exclusively"). However, NIST received 81,000 comments, most of the form letter variety opposed to the proposed march-in clarification. In July 2021 <u>Executive Order 14036</u> directed NIST to consider not finalizing "any provisions on march-in rights and product pricing" in the NPRM.

The final rule states: "Given the comments received, NIST's examination of them, and the Executive Order, NIST removed this provision from the final rule... NIST intends to engage with stakeholders and agencies with the goal of developing a comprehensive framework for agencies considering the use of march-in provisions." The <u>March 2023 COGR Update</u> noted "HHS and the Department of Commerce (DOC) have announced efforts to pursue a whole-of-government approach to review its march-in authority as laid out in the Bayh-Dole Act. According to the announcement, "the Interagency Working Group for Bayh-Dole will develop a framework for implementation of the march-in provision that clearly articulates guiding criteria and processes for making determinations where different factors, **including price** (emphasis added) may be a consideration in agencies' assessments." We understand that this group has been actively meeting and may issue recommendations shortly.

The revised regulations include some additional clarifications and updates from the previous NPRM. These appear relatively straightforward and non-controversial. The rule is final, effective April 24, 2023, and not open for further comment.

#### NIST CHIPS Act Program Licensing Restriction (NEW)

On March 23, the NIST CHIPS Program published <u>a proposed rule</u> stating "CHIPS Incentives Program funds may not be provided to a foreign entity of concern, such as an entity that is owned by, controlled by, or subject to the jurisdiction or direction of a country that is engaged in conduct that is detrimental to the national security of the United States." This proposed rule includes a detailed explanation of what is meant by foreign entities of concern, as well as a definition of "owned by, controlled by, or subject to the jurisdiction or direction of."

The rule requires CHIPS Incentives Program recipients to enter into an agreement with the Commerce Department restricting engagement by the funding recipient or its affiliates in any significant transaction involving the material expansion of semiconductor manufacturing capacity in foreign countries of concern. Exceptions are allowed for certain transactions involving older (legacy) semiconductor manufacturing in a foreign country of concern. The Technology Clawback section of the CHIPS Act (<u>15</u> U.S.C. 4652(a)(5)(C)) bans funding recipients from engaging in joint research or technology licensing efforts with foreign entities of concern that relate to a technology or product that raises national security concerns. The proposed rule extends this prohibition to the funding recipient's affiliates, to ensure the purpose of the prohibition is not circumvented. Violations of either of these prohibitions may result in recovery of up to the full amount of Federal funding provided.



While some of the terms and definitions in the proposed rule may be problematic, they appear to closely track the statutory requirements. Concerns have been raised about the licensing restriction. Some fear it may effectively block the licensing of any technology by funding recipients developed with a foreign entity of concern. AUTM is analyzing the restrictions. Comments were due May 22. Given the lack of consensus on the potential implications, COGR chose not to comment.

#### Nature Article Attacking Patents and Bayh-Dole Raises Concern (NEW)

A recent editorial in *Nature* claimed that the Bayh-Dole Act restricts knowledge sharing among researchers and the ability to access new medicines (<u>The WHO at 75: what doesn't kill you makes you stronger (nature.com</u>)). It also criticized the TRIPS agreement.

Given that *Nature* is a highly respected journal, the editorial has caused consternation in the university tech transfer community. The Bayh-Dole Coalition responded with a <u>letter to the editor</u>, and other ways to refute these claims are being discussed by the Coalition.

#### **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 being followed by REC are covered below.

#### FDA Guidance Documents (NEW)

The FDA issued the following two guidance documents that recognize the changing nature of clinical trials. Unlike traditional clinical trial models in which data is manually collected and monitored at a single physical site, today's trials frequently involve the collection and review of data from multiple points using various technologies.

- <u>FDA Draft Guidance Decentralized Clinical Trials for Drugs, Biological Products, and Devices</u>: Clinical trials have become more decentralized with data collection being conducted via home health agencies, pharmacies, community clinics and other health system access points. Decentralization accelerated during the COVID-19 pandemic, and in recognition of this trend, FDA issued this draft guidance for sponsors and investigators involved in the conduct of clinical trials that include activities at non-traditional trial sites. The guidance discusses when decentralized trials are appropriate, strategies for conducting remote clinical trial visits, the use of technology to collect data directly from subjects, appropriate delegation of duties, and management of investigational drugs and devices.
- <u>FDA Final Guidance A Risk-Based Approach to Monitoring of Clinical Investigations</u>, <u>Questions and Answers</u>: The FDA finalized its draft guidance on this topic, which was issued in 2019. The Guidance outlines factors that sponsors (including sponsor-investigators) should consider in developing monitoring plans for clinical trials. The guidance includes useful discussion on the use of centralized monitoring as well as an outline of elements that should be included in monitoring plans.



FDA, in conjunction with the Office of Human Research Protections (OHRP) also issued the following draft guidance on the process for submitting certain research involving children as subjects to FDA and/or OHRP for review: FDA Draft Guidance – Research Involving Children as Subjects and Not Otherwise Approvable by an Institutional Review Board: Process for Referrals to Food and Drug Administration and Office for Human Research Protections. This Guidance concerns research with children as subjects that involves greater than minimal risk with no prospect of direct benefit to individual subjects and which is not likely to yield generalizable knowledge about the subjects' disorder/condition but does present a "reasonable opportunity" to further understanding of a serious problem affecting children's health and welfare. FDA and/or OHRP approval must be obtained to conduct this type of research and the draft guidance outlines the process that Institutional Review Boards (IRBs) should follow for agency review/approval. REC considered the guidance document and determined that it helped to clarify current regulations and declined to submit comments.

## <u>Secretary's Advisory Committee on Human Research Protections (SACHRP) Consideration of</u> <u>GAO Report on Institutional Review Boards – Actions Needed to Improve Federal Oversight and</u> <u>Examine Effectiveness (GAO-23-104721) (UPDATE)</u>

In January 2023, the GAO <u>issued a report</u> that considered the shift in the IRB landscape from universitybased IRBs to independent IRBs, particularly with respect to clinical trials involving the FDA-regulated investigational drugs (e.g., in 2012, independent IRBs reviewed 25% of protocols involving FDAregulated drugs v. 48% in 2020). The report contained recommendations for OHRP and FDA to conduct regular risk assessments to determine whether they are conducting an adequate number of IRB inspections and to convene stakeholders to look at approaches for measuring IRB effectiveness in protecting human subjects.

In response to this latter charge, SACHRP, at its <u>March meeting</u>, considered what constitutes "effectiveness" in protecting participants, including means for measuring effectiveness. SACHRP, however, did not come to any final conclusions with respect to the definition of "effectiveness" or metrics. SACHRP will consider the topic again at its July meeting, with the aim of having a report and recommendation by October 2023.

## <u>Release of COGR Publication "Analyzing Personal Financial and Institutional Conflicts of</u> <u>Interest in Academic Research Contexts" (UPDATE)</u>

REC <u>updated its previous publication</u> on financial COIs of researchers to reflect changes in regulations and funding agencies current thinking regarding personal financial COIs of researchers and institutional COIs of universities, academic medical centers and independent research institutions that may impact research activities. Significantly, the report addresses federal research funding agencies' renewed interest in financial COIs in the context of inappropriate foreign influence. The report discusses common situations in which COI issues frequently arise (e.g., consulting, licensing, procurement) and addresses the GAO's view that conflict of commitment is a type of non-financial conflict of interest. Finally, the report contains an appendix with multiple case studies that can be used in training activities.

Note that at the time of publication, both the Department of Energy and NASA published interim or

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proposed COI policies, but final versions had not been issued. COGR will provide an update when these agencies publish their final policies.

## NSF Definition of Significant Financial Interest (SFI) (UPDATE)

The <u>NSPM-33 Implementation Guidance</u> [p. 5] states that "[r]esearch agencies should require that recipient organizations instruct covered individuals on how to disclose information related to potential financial conflicts of interest, including but not limited to: private equity, venture, or other capital financing." In response, NSF amended its definition of "significant financial interests" that must be disclosed per institutional conflict of interest processes to include "venture or other capital financing." [Proposal and Award Policies and Procedures Guide (NSF 23-1) at p. IX-1]. COGR alerted NSF to members' questions regarding the new definition because the COI process focuses on the disclosure of individual researchers' SFIs, while venture and other capital financing is typically directed to companies with separate legal standing (e.g., start-ups), as opposed to individuals. In response, NSF issued the following FAQ:

What are NSF's expectations for disclosure of a significant financial interest in instances where investigators may have an equity stake in a company, but do not know who the investors in the company are?

Investigators must disclose their equity stake. If a venture capital firm does not provide investment information, investigators must obtain a letter from the venture capital firm stating that the firm does not disclose who or what they have invested in, or who the other investors are.

This FAQ does not address the original question of how the COI process, which is directed to individuals, can/should encompass disclosure of funding to separate corporate entities or how the COI reviewing officials should consider this information once it is disclosed. Accordingly, COGR followed-up with NSF officials and expressed concerns that the requirement to obtain a letter from venture capital firms may have a chilling effect on investment. Unfortunately, NSF disagreed with this assessment. The requirement stands for now, pending further OSTP review.

## <u>COGR Response to Request for Information (RFI) on Update to NOT-OD-05-034 Guidance on</u> <u>Prompt Reporting of Noncompliance (NEW)</u>

The Office of Laboratory Animal Welfare (OLAW) issued <u>this RFI</u> as part its continuing response to the mandate of the 21<sup>st</sup> Century Cures Act (<u>Pub. L. 114-255</u>) for USDA, FDA and HHS to work together to consider how to reduce burden on researchers conducting animal research, while still ensuring robust protections for the health, safety and welfare of animal subjects.

In its response, <u>COGR noted</u> that OLAW had missed an opportunity in this RFI to revise the examples of reportable situations set forth in the <u>2005 Guidance on Prompt Reporting to OLAW</u> under the <u>PHS</u> <u>Policy on Humane Care and Use of Laboratory Animals</u> ("PHS Policy"), some of which encompass the



reporting of non-serious/non-continuing instances of unintended and/or technical noncompliance that go beyond the PHS Policy requirements to report "serious or continuing noncompliance" and "serious deviation" from the provisions of the <u>Guide for the Care and Use of Laboratory Animals</u>. On the positive side, COGR applauded OLAW's removal of the requirement that Public Health Service (PHS) grant numbers be routinely included in noncompliance reports, and encouraged OLAW to work with the agencies for which it provides oversight – NSF, VA, NASA – to align their requirements with those of PHS and not require the provision of grant numbers. COGR also included suggestions for clarifying the RFI's examples of situations that need not be reported to OLAW as non-compliance.

## <u>Request for Information (RFI) on Clarification of Animal Activities Exempt from PHS Policy</u> <u>Requirements for IACUC Review (NOT-OD-23-119) (NEW)</u>

Issued on April 25, <u>this RFI</u> is also released as part of OLAW's response to the Cures Act mandate to examine ways in which to reduce administrative burden on investigators conducting research using laboratory animals. The RFI summarizes activities exempt from IACUC review, and requests comments on these exemptions. REC will submit a response. Comments are due July 31, 2023.

## **OLAW and USDA Survey on Efforts to Reduce Administrative Burden (NEW)**

OLAW and USDA are conducting a survey to evaluate their various efforts to reduce administrative burden on investigators conducting research using laboratory animals. The voluntary, online survey is directed to individuals who are involved in the oversight of their institution's animal care and use program policies and operations (e.g., IACUC administrators, coordinators).

The survey is designed to collect data on whether institutions are aware of OLAW flexibilities and USDA updates aimed at reducing administrative burden as described in the <u>report Reducing Administrative</u> <u>Burden for Researchers: Animal Care and Use in Research</u> including whether institutions have implemented the flexibilities/updates and their resulting impact. The survey will open on June 1 and close on August 31, 2023. Only one response per institution is permitted. OLAW will administer and distribute the survey directly to contacts at OLAW Assured and USDA Registered institutions and it will also collect and analyze the data.

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

Select CGA Committee activities related to NIH Data Management and Sharing are reported above under the Cross-Cutting Issues section of the COGR Update. Other issues followed by CGA are covered below.

## **National Science Foundation (NSF) Proposal and Award Policies and Procedures Guide (PAPPG)** 24-1 (NEW)

On April 13, NSF <u>announced</u> proposed changes to its Proposal & Award Policy & Procedure Guide (PAPPG) (24-1), expected to become effective in January 2024. The Guide includes several proposed

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changes, and members are encouraged to review the NSF Policy Office <u>marked-up version</u> of the Guide in detail.

The proposed new PAPPG 24-1 includes the following (this is not an exhaustive list):

- Several new definitions, including Foreign Country of Concern, Institution of Higher Education, Malign Foreign Talent Recruitment Program;
- Inclusion of other transactions as an award mechanism for Broad Agency Announcement (BAA);
- Clarifications on the use of Concept Outlines and the ProSPCT tool;
- Several revisions pertaining to Tribal Nations, including a new check box on the coversheet for potential impacts on Tribal Nations and a new requirement to consult to obtain Tribal Nation Permission for proposals that may impact their resources or interest;
- Clarification on procedures to justify proposals that include a subaward or consultant arrangement to a foreign organization or individual;
- New language prohibiting individuals who are a party to a Malign Foreign Talent Recruitment Program from serving as senior personnel on an NSF proposal;
- Clarification that proposals are due by 5 p.m. organization's local time rather than the PIs time;
- New Malign Foreign Talent Recruitment Programs certification requirement for the AOR (proposal certification) and senior personnel (Biosketch & Current and Pending (Other) Support [CPS]). AOR must certify that all senior personnel associated with the proposal are aware of the policy requirement and have complied that they are not a party to a malign foreign talent recruitment program. Senior personnel must certify prior to proposal submission that they are not a party to a malign foreign talent recruitment program;
- New Post award Disclosures / Foreign Gifts and Contracts Disclosures for institutions to report annually (July 31), all "current financial support, the value of which is \$50,000 or more, including gifts and contracts, received directly or indirectly from a foreign source" consistent with Section 10339B of the Chips and Science Act of 2022. Proposed data elements under this requirement are available <u>here;</u>
- Changes to Biographical Sketch(es), including removing the 3-page limit for the biographical sketch to no page limit, a new footnote stating NSF will approve the PI and any co-PIs in any resulting award notice, and updated language for disclosing a foreign talent recruitment program that may contain an appointment;
- Removed Synergistic Activities from the Biographical Sketch and moved to a new Senior Personnel document type;
- Modified CPS language to incorporate the term "Conflicts of Commitment" as defined in NSPM-33 Implementation Guidance;
- Expanded mentoring plan requirements to include graduate students in addition to postdoctoral researchers;
- References to "Data Management Plan" have been updated to "Data Management and



Sharing Plan";

- Language updated for projects requiring advanced computing, data, and analysis capabilities;
- New proposal type added for Research in Undergraduate Institutions (RUI) and Research Opportunity Awards for Predominantly Undergraduate Institutions (ROA-PUI);
- Definition of senior personnel updated for consistency with NSPM-33 Implementation Guidance;
- New category added to Proposal Not Accepted or Returned Without Review due to "credible information of a national security concern." NSF will develop an NSF Risk Rubric comprised of risk-based indicators to inform the basis of this decision-making process (expected to be published on the NSF website);
- New Certification Requirement for Annual and Final Annual Reports attesting the work provided in the report is complete and original work of the signatories or individuals working under their supervision. Also, for awards that support graduate students or postdoctoral scholars, PI certifies for the award the development of an individual development plan that is annually updated;
- Additions to Other Post Award Requirements and Considerations, including E.O. 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," and E.O. 12898, "Environmental Justice": and
- New definition added for Scientific Integrity.

COGR is preparing comments in response to the request. Comments are due by June 12, 2023. Please contact Krystal Toups at <u>ktoups@cogr.edu</u> for questions or to provide input.

## Reminder – NIH Policies for NRSA Stipends, Compensation and Other Income (NEW)

NIH issued this notice (NOT-OD-23-111) as a reminder to the extramural community of the policies surrounding stipends, compensation, and other income for trainees and fellows supported under Ruth L. Kirschstein National Research Service Award (NRSA) grants. The notice specifies: "While stipends are not provided as a condition of employment, this policy is not intended to discourage or otherwise prevent recipient institutions from hiring NRSA trainees and fellows as employees or providing them with benefits consistent with what the institution provides others at similar career stages."

COGR received feedback from several members seeking clarification of this statement and if this is a policy change. COGR obtained clarification from NIH that the notice is not an expansion or change in policy. The intent behind the notice is to clarify existing policies for employment eligibility (per GPS <u>11.2.10.2</u>) and benefits support beyond health insurance (which institutions may supplement from non-PHS funding) for trainees and fellows supported by NRSA grants. While this notice provides clarification, concerns remain about: how to fund additional costs, inequities created by existing policies, and the implications to tax and benefit requirements, as noted in COGRs response to RFI NOT-OD-23-084 listed below.



#### NIH Updated Policy Guidance for Subaward/Consortium Written Agreements (NEW)

On May 19, NIH released <u>NOT-OD-23-123</u>, announcing updates<sup>10</sup> to NIH Grants Policy Statement (GPS) <u>Section 15.2</u>, expanding the requirements for foreign subrecipients. The updated policy will require foreign subrecipients to provide copies of all lab notebooks, all data, and all documentation that supports the research outcomes described in the progress report to the prime recipient at least every three months. The requirement will be incorporated in the FY24 publication of the GPS, effective October 1, 2023. Any subrecipient unwilling to accept the requirement cannot be issued a subcontract. To ensure compliance, NIH may request copies of agreements, which must be documented in a written formal agreement signed and agreed to by both parties.

CGA has concerns about this expansive new requirement which will create a significant burden impact on the subaward process and may dissuade foreign collaborators. COGR will engage with NIH on these concerns and will provide additional information as we learn more.

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

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

# COGR Responds to RFI "Re-envisioning U.S. Postdoctoral Research Training and Career Progression within the Biomedical Research Enterprise" (NOT-OD-23-084). COGR

submitted a <u>response</u> on April 14 to this request for information. COGR recommended increasing modular budget caps, which are steadily squeezed in absorbing costs for new requirements (i.e., DMS) and costs to support personnel and trainees critical to projects. Additional recommendations included: increasing NRSA stipend levels, creating an equitable benefits structure for NRSA trainees, and evaluating long-standing NRSA policies. COGR will continue to follow this topic and provide updates on any developments.

## COGR Responds to RFI "NIH Plan to Enhance Public Access to the Results of NIH-

*Supported Research"* (<u>NOT-OD-23-09</u>). COGR's <u>response</u> highlighted the following issues related to public access:

- costing concerns shifting towards an Article Processing Charges (APC) publication model,
- continuing cost burden and squeeze to modular budget caps to absorb all costs in a limit that is over 20 years old,
- covering costs beyond the award period (post-grant funding), and
- reducing burdens associated with scholarly publication deposits.

<sup>&</sup>lt;sup>10</sup> In response to HHS Office of Inspector General and Government Accountability Office audits.



To monitor evolving costs, COGR recommended that NIH perform an assessment to identify equitable funding models. To increase the findability and transparency of research, COGR recommended community dialogue to discuss policies related to PIDs and metadata and that policies should maximize efforts for harmonization across agencies. CGA continues to monitor issues related to Public Access and will keep the membership informed.

If you have questions, comments, or concerns on the above topics, please contact Krystal Toups at <u>ktoups@cogr.edu</u>.

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

Select CFC activities related to NIH Data Management & Sharing and 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 Cost Rate Survey: Update at the June COGR Meeting (NEW)

The F&A Cost Rate Survey closed at the beginning of May and the CFC is in the process of analyzing the results. CFC will provide preliminary results at a Thursday morning session at the June COGR Meeting. The results will provide a resource for the membership to benchmark key metrics and assist COGR in advocacy efforts around F&A issues. *Note, all survey results will be kept in the COGR Member Portal (log in required)*<sup>11</sup>, and any results that are made public will de-identify institutions and be aggregated. The final report will be published later this year.

#### **2023** Compliance Supplement is Available (NEW)

The <u>2023 Compliance Supplement</u> (see the *Resources and Other Information* section of the OMB, Office of Federal Financial Management web page) is now available. As noted in previous updates, Mitzi Mayer from OMB (replacing the retired Gil Tran) is the new point person for the Compliance Supplement. COGR has worked diligently with Ms. Mayer to address our longstanding concern with an audit position related to the appropriate timing for requesting cash reimbursements from federal agencies. COGR most recently wrote to this topic in a June 30, 2022 Comment Letter to OMB.

The 2023 Compliance Supplement has addressed this issue and changes have been made to the <u>Cash</u> <u>Management section (see page 3-C-3)</u>—specifically Audit Objective 4—to be consistent with what COGR has requested.

"OLD" 2022: For grants and cooperative agreements to non-federal entities that are paid on a reimbursement basis, supporting documentation shows that the costs for which reimbursement was requested were paid prior to the date of the reimbursement request.

<sup>&</sup>lt;sup>11</sup> COGR's 2017 F&A Survey reports are available in the <u>COGR Member Portal</u> (log in required).



"REVISED" 2023: For grants and cooperative agreements to non-federal entities that are funded on a reimbursement basis, determine that expenditures, as defined by 2 CFR 200.1, were incurred prior to the date of the reimbursement request.

This is a positive development, and we are thankful to Ms. Mayer and OMB for addressing this issue. COGR will continue to monitor developments around the Compliance Supplement and the single audit, and we encourage members to contact COGR when there are concerns.

#### NASA-NSSC: Routine Monitoring-Financial Transaction Testing Review Program (NEW)

COGR has raised concerns to NASA's <u>National Shared Services Center (NSSC)</u> about its Routine Monitoring–Financial Transaction Testing Review program. The program requires institutions to provide a quarterly expenditure list for selected NASA awards. In an email to NASA-NSCC (shared with the membership via the COGR Listserv on April 27), COGR raised concerns about:

- how the intent of the program has been communicated,
- the level of detail that is expected,
- duplication with single audit objectives,
- creation of administrative burden, and
- the 14-day deadline.

In a May 2 meeting between NASA–NSCC leaders and members from the CFC Committee, these concerns were discussed. On May 18, NASA-NSCC provided the responses to six statements/questions raised by COGR via email. Those statements/questions and responses are included as <u>Appendix B</u> of this Update. COGR will continue to follow developments around the NASA–NSCC Routine Monitoring–Financial Transaction Testing Review Program. Please contact David Kennedy at <u>dkennedy@cogr.edu</u> with questions and if your institution is experiencing problems with the program.

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

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

*Timeliness of F&A Cost Rate Negotiations and COGR Advocacy.* In December, <u>COGR sent a</u> <u>letter to Mak Karim</u>, the National Director for Cost Allocation Services at the Department of Health and Human Services. The letter raised concerns that some institutions have not been able to negotiate F&A cost rates (and fringe benefit rates) in a timely manner with Cost Allocation Services (CAS). In addition to CAS, COGR has raised this issue with OMB and with the HHS Grants Policy Office. Please contact David Kennedy at dkennedy@cogr.edu if this is a concern for your institution.

*Federal Audit Clearinghouse to be moved to GSA in October 2023.* A Federal Register Notice, dated December 22, 2022, announced the movement of the Federal Audit Clearinghouse (FAC) from the U.S. Census Bureau, to GSA, effective in October 2023. COGR submitted a letter to



<u>GSA</u> on February 21. A <u>FAC Transition website</u> has been established that can be checked for updates on the transition. No recent updates have been published.

**ARPA-H and Indirect Costs.** The FY23 Omnibus Appropriations Bill, passed in December, included the authorization of <u>ARPA-H</u>. COGR followed congressional negotiations last year on the problematic proposal applicable to indirect costs. The final provision reads as follows: "*awards grants and cooperative agreements, which shall include requirements to publicly report indirect facilities and administrative costs, broken out by fixed capital costs, administrative overhead, and labor costs.*" While this is not ideal and raises questions, COGR will engage with NIH and ARPA-H as appropriate to ensure that this new statutory requirement does not create unintended and unnecessary administrative burden.

**HHS-OIG** Audit of the NIH Grant Closeout Process. This <u>new audit initiative</u> was announced by the HHS Office of the Inspector General (HHS-OIG) in November and is aimed at the NIH's management of the grant closeout process. In that announcement, the HHS-OIG indicated: "We will determine whether NIH closed its grants in accordance with Federal requirements and departmental guidance. We will also determine which actions NIH took to address noncompliance with closeout requirements." Key federal requirements include compliance with both the 2016 GONE Act and 2 CFR 200.344(b) Closeout. While the HHS-OIG audit is focused on NIH management practices, findings from the audit could have repercussions for the grantee community.

*Federal Office of Inspectors General (IG) and Single Audit Developments*. COGR members are encouraged to follow the <u>HHS OIG Workplan</u> (see above, HHS-OIG Audit of the NIH Grant Closeout Process) and the <u>NSF OIG Reports & Publications page</u>. Further, the <u>NSF Management Responses to an External Audits</u> is a helpful resource for reviewing NSF OIG audit resolutions. COGR members are welcome to contact COGR when audit issues arise. When appropriate, COGR can connect institutions and/or provide feedback on the issues in question.

2021 NSF Higher Education Research & Development (HERD) Survey. The 2021 HERD was released on December 15, 2022, and includes the InfoBrief summary and the complete suite of 2021 data tables (which includes the popular Table 22 – Higher education R&D expenditures, ranked by all R&D expenditures, by source of funds: FY 2021). Also of interest is Table 17 – Higher education R&D expenditures, by type of cost, highest degree granted, and institutional control: FYs 2010-21. Table 17 includes data on recovered and unrecovered indirect costs, in aggregate, for all institutions. For FY2021, the total recovered indirect costs were \$14.7 billion (rounded) and the total unrecovered indirect costs were \$5.9 billion (rounded).

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



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

Agency	Description	Due Date	Notes
Office of Science & Technology Policy (OSTP)	<u>NSPM-33 Research</u> <u>Security Program</u> <u>Standard Requirements</u>	June 5	COGR has posted <u>key messages</u> <u>document</u> and plans to post comment letter w/o May 29.
Department of Education (ED)	Information Collection Request on Final Proposed Section 117 Reporting Requirements	June 5	COGR working on joint association comments with ACE, others.
National Science Foundation (NSF)	<u>PAPPG 24-1</u>	June 12	COGR is preparing comments.
National Institutes of Standards & Technology (NIST)	RFI on Cybersecurity for R&D	June 30	COGR in discussion with Educause on possible comments.
NSF	Dear College Letter on RSI-ISAO	June 30	2-3 page white paper on six thematic areas. COGR participating in listening session.
NIST	Continued Authorization of i-Edison Information Collections	July 3	COGR working with other higher ed. associations on joint comments.
NIST	Revised Security Requirements for Protecting CUI (NIST SP 800-171 Rev. 3)	July 15	COGR currently analyzing changes.
National Institutes of Health – Office of Laboratory Animal Welfare (NIH- OLAW)	RFI on Clarification of Animal ActivitiesExempt from PHSRequirements for IACUCReview (NOT-OD-23-119)	July 31	COGR will submit a response.

## COGR

## Appendix B– NASA–NSSC: Routine Monitoring–Financial Transaction Testing Review Program (NASA-NSCC Email response – May 18, 2023)

In an email correspondence on May 18, NASA-NSCC provided the following responses (in blue) to six statements/questions raised by COGR. Those statements/questions and responses are shown below.

- 1) **<u>COGR Statement/Question</u>** The NSCC program will request only several awards per quarter (some of our members received over 10 requests last quarter). Data for an award will be requested one time only.
  - <u>NASA Response</u> The Financial Transaction Testing Review is designed to be a random sampling of awards based on the end date of the period of performance. Some recipients, particularly those with many awards with NASA, may receive multiple requests for Transaction Testing documentation for a particular quarter but that is the exception rather than the rule. The NASA Shared Services Center (NSSC) will continue to review the awards selected to ensure any particular entity will not be overwhelmed with several requests at once.
- <u>COGR Statement/Question</u> Confirm the intent of the program is <u>not</u> a duplication of any single audit / 2 CFR 200 activities, rather this is strictly a review of allowable charges to an award.
  - <u>NASA Response</u> You are correct this is not a duplication of the annual single audit requirements for recipients who expend \$750,000 or more in federal grant dollars. Transaction testing applies regardless of the amount of expenditure levels of Federal awards.
  - Transaction testing is designed to be proactive, thus enabling NASA to provide assistance where necessary, whereas Single Audits are reactive.
  - Transaction Testing does examine allowability in the expenditure list but also examines other aspects of the charges to the federal award. In general, the purpose of transaction testing is to systematically test all payment/expenditure transactions from a selected quarter; identify potential unallowable, unallocable, or unreasonable costs, evaluate compliance with certain national policy directives, and assess the likelihood that recipient errors would result in a material effect on Federal awards.
  - The methodology we used to create the transaction testing Review was based on our collective experience with the procedures of other Federal award issuing agencies balanced with a desire to ensure our processes were minimally intrusive to both NASA staff performing the review and the recipients. Our philosophy when creating the Transaction Testing Review was based on the desire for NASA to be able to, at a minimum, answer the following questions at the outset of the review:
    - Was the cost incurred during the period of performance?
    - Does the cost represent an expressly unallowable cost as cited in 2 CFR 200, 2 CFR 1800, NASA policies, Federal law or the award terms and conditions?
    - $\circ$  Is the cost reasonable and allocable to the award under review?



- Please see <u>grant\_and\_cooperative\_agreement\_manual\_\_oct.\_2022\_0.pdf (nasa.gov)</u> for a full explanation of the methodology for Transaction Testing. Transaction Testing begins on page 130.
- 3) **<u>COGR Statement/Question</u>** NASA will work with grantees to encourage timely response to NASA's data request, and do so with "reminder" notices, <u>not</u> "delinquent" notices.
  - <u>NASA Response</u> Effective next cycle/quarter NSSC will issue the first notice as a "reminder notice".
  - Additionally, effective next cycle/quarter, NSSC will remove the PI from all notices. All notices will be sent to the Authorized Organizational Representative (AOR) only.

## 4) **<u>COGR Statement/Question</u>** - Extensions can be requested if the 14-day timeline cannot be met.

- <u>NASA Response</u> Correct. These will be reviewed and decided on a case-by-case basis. Requests for extension to the deadline should be submitted to the grant officer (GO) responsible for the award and contain sufficient information to justify the extension.
- NASA did an analysis of the requests for extension regarding the 14-day requested deadline to provide an accounting record pull for transaction testing. We noted that 66 out of 75 (88%) requests for transaction testing data were met within the initial 14-day deadline.
- 5) **<u>COGR Statement/Question</u>** NASA will provide a response after the review has been completed. For example: "We have reviewed your submission, identified no exceptions, and this inquiry is closed."
  - <u>NASA Response</u> This is currently part of the transaction testing policy. Please see the link provided in response to question 2. Page 134 G3.4.9 Final Transaction Review Report Issuance outlines the requirements for issuance of a summary once the report has been completed.
- 6) <u>COGR Statement/Question</u> Encourage harmonization with other agencies and OMB. COGR would like to stay connected to how the NASA program unfolds, in particular, in the context of similar monitoring programs from other agencies. Doing so will provide a good firewall against excessive administrative burden.
  - <u>NASA Response</u> Where possible and permissible, NASA will continue to look for ways to align our practices to the best practices from across the Federal awarding agency family and evaluate our current posture in an effort to create policy and process harmony. We are plugged into the OMB to ensure that the latest directives from the administration are available to relevant NASA staff and all NASA award recipients.
  - NASA has been considered late to the process of Federal awarding agencies requesting transaction testing data. As such, implementation of this policy was identified in multiple NASA audits as necessary in order to address a longstanding (six year) finding and recommendation.

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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