COGR

MARCH 2024 UPDATE

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President's Message

Spring is Here

Dear Colleagues,

The COGR staff is grateful for the robust participation in the February Virtual Membership Meeting. Over four days, 550 individuals participated in 11 sessions in which we heard from 24 expert speakers. A big thank you to all who participated, our speakers, and members of COGR's committees and the Board of Directors who developed many of the sessions. We also appreciated the helpful feedback many of you provided in the meeting evaluation survey. This will help us make the most of our virtual meetings going forward. Please mark your calendars: The next COGR Membership Meeting is June 6-7, 2024, in Washington DC. We will take the opportunity to recognize our colleagues Bob Hardy and Dave Kennedy who are retiring from COGR this summer.

Spring is here and the leaves and flowers are not the only things emerging. Several new requests for information and proposed regulations have or will emerge in the weeks ahead. For example, this month's COGR Update notes our efforts to respond to an RFI from CMS on research data request and access policy changes, a request for comments from USPTO on technology transfer, and an NPRM from HHS on the possession, use, and transfer of select agents and toxins. Additionally, we are anticipating final versions of the Uniform Grant Guidance, research integrity regulations, and the long overdue research security standards this spring. Each will have significant consequences for how institutions administer research, and some will add to institutional compliance costs and burdens. We will work with the membership to identify these to help inform our future advocacy.

In the weeks ahead, I hope you will consider these ways to engage with COGR:

- Respond to COGR's current survey on Research Institutions' Experiences with DoD Policy for Risk-Based Security Reviews of Fundamental Research by April 5th;
- Take our Volunteer Survey to share your expertise areas and interest in engaging with COGR;
- Watch for a job announcement seeking COGR's next Director for Costing and Financial Compliance and help us identify great candidates.

Lastly, this month I marked my one-year anniversary serving as COGR President. I am grateful every day to be a part of this unique and vital membership organization that helps make research go at institutions across our country. I have particularly appreciated the opportunity to meet and learn from so many of you during COGR meetings, campus visits, and individual and group meetings.

COGR's great strength is its people: our small but mighty expert staff team and the many institutional member representatives who participate, volunteer, and share their expertise and talents. After a year on the job, I am even more excited than when I started about the mission and work of COGR. Our collective efforts are more important than ever to shaping sound, efficient, and effective federal regulations that safeguard research and minimize administrative and cost burdens. I look forward to our continued work together.

Matt Owens, President

Announcements

Save the Date: June 6-7, 2024, COGR Meeting in Washington D.C.

COGR's next meeting will be in-person on June 6-7, 2024 at the Washington Marriott in Georgetown. Registration will open in April in the COGR Portal and will be announced via the COGR Listserv. A preliminary agenda will soon follow.

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 you'll save the date!

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.

February Meeting Session Recordings Are Available for Registered Attendees in the COGR Portal

Select sessions were recorded during the February 27-March 1, 2024, Virtual Membership Meeting are available for registered attendees to view. To access the recordings, click here or log into the COGR Portal and navigate to Workspaces – COGR Meeting Session Recordings – 2024 Virtual Meeting – Session Recordings. The session recordings workspace is also bookmarked for all registered attendees. If you have any trouble accessing the recordings, please email memberservices@cogr.edu.

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

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. Recordings for the February virtual meeting are expected to be available in the Video Library in late May. Slide presentations are posted on COGR's website here.

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 Volunteer Survey

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

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 June 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? (UPDATE)

In the past two COGR Updates, we have shared 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 from the Office of Federal Financial Management, OMB, to our February 2024 virtual membership meeting. While Ms. Harrison was not able to speak to specifics, the following is COGR's summary of her remarks.

- **OMB is reviewing all comments.** According to Ms. Harrison, COGR's comments, while quite voluminous, have been well received by OMB.
- **OMB's timing to publish the final version of the Uniform Guidance is "soon."** More specifically, Ms. Harrison indicated sometime in March is the target. Since then, another source shared with COGR that the target now is sometime in April.
- **Implementation date should be October 1, 2024.** While this did not come from Ms. Harrison, a recent NIH Notice on the implementation of the NIH Grants Policy stated: "*The updates to 2 CFR 200 are anticipated to have an implementation date from the Office of Management and Budget of October 1, 2024*." This aligns with OMB's target to release the Uniform Guidance sometime in April.
- **Public comments on the final version will not be considered.** However, if there are gross errors, egregious oversights, or any "surprises," COGR and the community should be prepared to write to OMB. Ms. Harrison agreed with this sentiment, though also suggested she did not anticipate any surprises.
- **Beyond the anticipated implementation date of October 1, 2024,** there will be additional implementation issues (e.g., change of equipment threshold to $10,000, F&A recovery on subawards, processes around selected prior approval items, etc.) that could be nuanced and not fully aligned with an October 1st implementation date. COGR will pay special attention to these issues, and comment accordingly.

As we approach an April release date of the Uniform Guidance, stay tuned for the official announcement. If you have any questions or comments, please contact Krystal Toups at ktoups@cogr.edu and David Kennedy at dkennedy@cogr.edu.

OMB Establishes Council on Federal Financial Assistance (NEW)

OMB's Deidre Harrison reminded us of the recently established Council on Federal Financial Assistance (COFFA)—as specified in OMB Memorandum M-23-19, dated August 9, 2023—and the mission of the COFFA:

> *[To provide] oversight and management of Federal financial assistance. The COFFA will create a partnership among Federal grant-making agencies, providing a single forum to inform Federal financial assistance policy, oversight, and technology activities. The COFFA will be responsible for providing*

strategic direction, policy recommendations, and priority-setting for other Government-wide grant-related activities.

In addition, the Memorandum is clear in stating: "*The Biden-Harris Administration is committed to ensuring that Federal agencies have the tools they need to deliver Federal financial assistance programs in an efficient, effective, and equitable manner, **while also reducing administrative burdens** on Federal financial assistance applicants and recipients*" **[*emphasis added*]**. Ms. Harrison encouraged engagement with COFFA. COGR views the COFFA as a great opportunity for engagement on issues important to the research community. We will stay closely connected to all COFFA developments.

Uniform Guidance: Summary of COGR's Comment Letter to OMB (REMINDER)

As highlighted in the December 2023 Update, COGR submitted its 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 included 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. 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.

COGR's letter was developed by a team of 26 volunteers who worked tirelessly for months to develop comprehensive and compelling recommendations that were supported by detailed analyses. The volunteers (recognized in Appendix B of the December 2023 Update) participated in nine thematic workgroups and diligently combed through every word of the OMB "red-line" version.

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

NSF Updates on Research Security (NEW)

During COGR's February virtual membership meeting, NSF's Dr. Rebecca Keiser presented updates on the agency's research security initiatives. Major points from the presentation are set forth below. Meeting attendees may access a recording of the presentation, slides, and a summary of information provided during the questions and answer session via the COGR Portal. After the meeting, COGR sent Dr. Keiser additional questions that were not addressed during the session. The responses she provided to these questions are included in the summary below, and they are also available in the COGR Portal.

- **Reporting of Foreign Financial Support from Countries of Concern**: Dr. Keiser discussed NSF's implementation of the CHIPS & Science Act requirements for institutes of higher education that receive NSF funding to disclose financial support "the value of which is $50,000 or more, including gifts and contracts, received directly or indirectly from a foreign source . . . associated with a foreign country of concern." This $50,000 threshold is calculated on a per source basis (e.g., multiple gifts from one entity that have an annual value of $50,000 or more). Countries of concern presently include Russia, China (including Hong Kong and Macau), North Korea, and Iran. Taiwan is not considered to be a part of China for reporting purposes.

  The first report is due July 31, 2024, and NSF will open the reporting portal and release FAQs on reporting in May 2024. Dr. Keiser acknowledged that NSF is aware of difficulties that the July 31st date poses for institutions whose fiscal years close at the end of June and advised that NSF is considering alternate reporting dates for 2025.

- **Definition of "Gift":** Dr. Keiser addressed questions regarding NSF's definition of "gift," including questions regarding recent Department of Justice settlements in which transactions that provided funding to certain researchers for specific research were not considered to be "gifts" excluded from current and pending support reporting requirements. Dr. Keiser stated that NSF will include information about the definition of a "gift" in the FAQs that it releases in May. COGR will carefully review these FAQs and follow-up as necessary regarding institutional concerns that arise from differences between the NSF's definition of "gift" and the definition used by the Internal Revenue Service, which institutional advancement offices employ.

- **Research Security Training**: The research security training modules are available for institutions to use; however, the CHIPS & Science Act training mandate will not go into effect until 2025. NSF will require annual research security training and plans to develop additional training modules and updates as circumstances change. Institutions' provision of the NSF modules will satisfy the requirement that the training be a part of the Responsible and Ethical Conduct of Research training. Dr. Keiser emphasized that institutions are not required to use the NSF modules, and that alternative training, including research security modules developed by CITI, can satisfy the training requirement.

  COGR inquired as to whether NSF could make the scripts for the training modules available to the regulated community. NSF responded that it does not have scripts for the modules and noted that the modules are not narrated PowerPoint presentations, but rather have information embedded in videos and other interactive components. Accordingly, any "voice-over" scripts would not provide the full content of the modules.

- **Research Security and Integrity Information Sharing and Analysis Organization (SECURE) and Research on Research Security (RORS):** NSF is currently reviewing proposals and anticipates that SECURE will become operational at the end of 2024. SECURE will provide information and resources to members, but it will not provide explicit advice or direction. Rather, institutions may use the resources that SECURE provides in determining how to address specific situations. Information obtained via RORS

will be provided to SECURE, and RORS will look at both the positive and negative aspects of research security initiatives.

- **Malign Foreign Talent Recruitment Programs (MFTRP):** Dr. Keiser advised that the definition of MFTRP in PAPPG 24-1 will be revised to align with the text of Section 10632(d) of the CHIPS & Science Act. Specifically, the revision will make clear that listed collaborative activities (e.g., making scholarly presentations, publishing written materials regarding non-controlled scientific material, etc.) will not be excluded from the definition of MFTRP if they are "funded, organized, or managed by an academic institution or a foreign talent recruitment program" on the lists developed under the McCain National Defense Authorization Act (NDAA).

  Dr. Keiser addressed the required institutional and individual certifications concerning non-participation in MFTRPs. Institutions will only be required to provide certification at the time that proposals initially submitted. The text of this certification will closely align with the requirements of Section 10632 of the CHIPS and Science Act and will require the institution to certify that senior/key personnel have been made aware of and complied with their responsibility to certify that they are not a party to a MFTRP. NSF advised that it will not be possible to collect this certification via SAM.gov, as was originally anticipated.

  Senior/key personnel will be required to provide their certification that they do not participate in a MFTRP at the time of proposal and annually thereafter. NSF is anticipating that these individual certifications will be collected through use of the Account Management functionality in Research.gov, but the system has not yet been finalized, so this may change.

  Dr. Keiser also addressed NSF's expectations in terms of the due diligence that an institution must perform to ensure that a covered individual is not participating in a MFTRP. She emphasized that institutions should focus on ensuring that various reporting systems (e.g., COI, current and pending support, gifts and contracts) can "talk to each other" to identify circumstances that may indicate an MFTRP, even in cases where the institution requires researchers to certify to the institution that they are not participating in an MFTRP. NSF advised that it could not presently comment on due diligence expectations for international travel because it is awaiting OSTP's revised security program standards on this topic.

- **NSF Risk Rubric:** NSF has developed a risk assessment rubric, which is currently being "road-tested" by the JASON group. The JASONs released a report on March 21, 2024 (see section below), and NSF plans to publicly "socialize" the rubric before it is implemented. The rubric will be piloted on quantum proposals beginning May 2024, before NSF rolls it out more broadly. The rubric will encompass items such as researcher affiliations with entities on the NDAA lists and countries of concern, funding sources, and areas of research that may be more sensitive. Application of the rubric may call for the provision of mitigation plan, and confirmation from an institution that the plan has been implemented.

Research Security Program Standards (UPDATE)

At COGR's February virtual membership meeting, Dr. Keiser stated that the Office of Science and Technology Policy (OSTP) is working on a second draft of the research security program requirements that takes into

consideration the public comments that were received. The revised draft is expected to be more streamlined, but the exact timetable for release is unknown. The standards were discussed at a full hearing of the House Committee on Science, Space and Technology Committee on February 15, 2024, at which Dr. Keiser testified, along with Dr. Arati Prabhaker (OSTP Director), Dr. Geri Richmond (Department of Energy Undersecretary for Science and Innovation) and Dr. Michael Lauer (NIH Deputy Director for Extramural Research). Dr. Prabhaker was repeatedly asked when the standards would be available. She replied that OSTP is diligently working on the standards to address concerns regarding administrative burden (particularly for smaller institutions) and to ensure that research security efforts are focused on improving researcher awareness of the altered security landscape, as opposed to a "checklist" on which research administrators sign off.

HHS OIG Survey on Reporting of Monetary Donations that Support Research and Related COGR Questionnaire (UPDATE)

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 presented several scenarios and sought 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 provided limited response options for each question, and in a meeting with COGR. HHS OIG suggested that in cases where an institution needed to provide additional information to correctly respond, the institution should utilize the "don't know" response and include comments in the survey's single free text box. The survey closed on February 23, 2024.

COGR asked member institutions to complete a questionnaire regarding the survey, including how many times an institution was required to utilize the "don't know" response and their reasons for doing so. Forty-seven (47) institutions submitted complete responses to the questionnaire, and the results are summarized below:

- 66% of responders submitted or planned to submit the HHS OIG survey.
- 34% stated that they would not submit the survey. One of the main reasons cited by institutions for not submitting was not knowing if the survey was received.
- Scenario 4 ($1,000 donation sent directly to PI and used for research) and Scenario 5 ($2,000 gift from aunt to postdoc used to purchase computer that was used in lab) generated the most "don't know" responses.
- Some of the main reasons that institutions provided "don't know" responses included:
    - Not enough information in the scenario to assess the situation.
    - Need to supply additional information to answer the question.
    - Scenario was not permitted at the institution.
    - Situation would be unlikely to come to the attention of sponsored programs unit (e.g., would be handled by development as a gift).

A more detailed analysis of the questionnaire responses can be found in the Committee Reports slides for the February virtual membership meeting. Notably, responses to the questionnaire raised concerns regarding the definition of gift being employed by agencies for purposes of current and pending support reports vs. the IRS definition of charitable gifts used by development units. After HHS OIG analyzes responses to its survey, COGR will invite the agency to meet to discuss the results. The responses to COGR's questionnaire will assist in preparations for this discussion, and COGR thanks all institutions who were able to participate.

JASON Report – Safeguarding the Research Enterprise (NEW)

On March 21, 2024, the JASON group published its latest research security report, Safeguarding the Research Enterprise ("SRE Report"). The report follows the JASON's 2019 report *Fundamental Research Security* and was drafted in response to NSF's request for comments on steps NSF could take to "identify sensitive areas of research and describe processes NSF might use to address security in those research areas of concern."

The SRE Report focuses on research security issues in the context of national defense, as opposed to economic/trade issues, and it offers recommendations for how NSF should identify projects that may require additional controls. Notably, the SRE Report rejected NSF's posited approach of developing a list of sensitive research areas, and instead recommended that NSF adopt a "dynamic approach for identifying potentially sensitive research topics as they arise" on a project-by-project basis. In determining which research projects are sensitive, the report advised that NSF should consider the sensitivity of potential applications for the research and the "technology readiness level" (i.e., how far along the technology is in development), and it should then use this information to assess the "direct and predictable national security impact of the applications" of each research proposal.

Key points from the SRE Report include the following:

- International Collaborations: The People's Republic of China (PRC) will continue to attempt to exploit U.S. R&D for its benefit, and the "protection of U.S. research from exploitation will be insufficient to ensure U.S. leadership in critical technologies." In this respect, the U.S. will need to consider how to address shortages in the STEM workforce and increase strategic R&D investment. International collaborations with others that "share the ideals or openness and transparency" are beneficial, but the current efforts of the PRC to direct the results of fundamental research to military efforts and restrict the outward flow of information "may severely limit the benefits of collaborations with research organizations within the PRC."

- Fundamental Research and CUI: Fundamental research is critical to the United States' leadership role in science and technology, but the sensitivity of certain research may require additional controls. The report notes that CUI controls are a "blunt instrument" that may increase research costs and inhibit the development of new technologies. It also advises that "NSF should proceed with caution before adding access or dissemination controls to grants or contracts" because of these negative impacts and should instead "weigh the balance between the positive protective benefits and the unintended negative consequences of such controls."

- Categories of Research and Associated Controls: The SRE Report defines four categories of research: 1) classified, 2) CUI, 3) highly sensitive, and 4) sensitive. The SRE Report recommends potential risk mitigations for "sensitive research" that do not eradicate the fundamental research exclusion (FRE) such as changes to the scope of the grant, PI training, training on identifying individuals of concern, increased reporting, and increased security for physical facilities and cyber systems. However, for "highly sensitive research" the report recommends controls (e.g., publication restrictions, restrictions on participants) that would cause the FRE to no longer apply.

- Process for Identifying Sensitive Research and Applying Controls: The SRE Report recommends that sensitive project identification take place "before peer or panel review" and calls for the PI in conjunction with the NSF program officer (and with guidance from the NSF Division Office) to make an initial determination of whether a proposal involves sensitive research.

  The report contemplates that the PI would make an initial determination of the project's sensitivity at the proposal stage by assessing expected research outcomes/applications and potential national security impact (based on NSF guidelines). If the PI determines that a project is potentially sensitive, then the PI would provide details on the intended use of research results, technology readiness level at the beginning and end of the project, and any features of the technology under research that "create national security impact beyond that of technology already discussed in the open literature.

  NSF would then consider the PI's sensitivity assessment in the proposal and make a final determination on the research's sensitivity level. If the project that is determined to be sensitive or highly sensitive is selected for funding, NSF would determine a mitigation plan with the research institution and the PI.

COGR Survey on Research Institutions' Experiences with the Department of Defense (DoD) Policy for Risk-Based Security Reviews of Fundamental Research (FR) (NEW)

COGR member institutions have raised concerns regarding DoD agencies' requests for the provision of risk mitigation measures in response to DoD research-security related risk assessments of fundamental research proposals. Preparing and gaining agency acceptance of these risk mitigation plans may require substantial time and effort. To gather more information about how these plans are being handled by institutions and DoD agencies, COGR is conducting a brief survey[2]. Individual responses will remain anonymous, and the results of the survey will be reported in aggregate and made available to COGR members and the DoD Basic Science Office. COGR hopes to use the information from the study to highlight the effort associated with these plans and the need for implementation consistency across DoD units. **COGR members are encouraged to respond to the survey, which will remain open until April 5.**

[2] *The survey link and a MS Word version of the survey (for reference only) is available on COGR's website here: https://www.cogr.edu/cogrSurvey*

Associations Research Security Meeting with Department of Energy (NEW)

COGR and other higher education associations (AAU and APLU) were invited to meet with DOE officials from the Office of Research, Technology, and Economic Security (RTES), Office of Science, Office of the Undersecretary for Science and Innovation, and Office of the General Counsel. This is the first quarterly meeting expected with DOE and higher ed. associations to discuss various topics on Research Security. Below is a summary of the major talking points from the meeting.

- **Update on DOE S&T Risk Matrix**: DOE now has made available an unclassified version of the S&T matrix that is widely accessible and shared broadly with the national lab community. The unclassified version contains the yellow and green portions and omits red portions controlled by classified information. The document is expected to be broadly available and COGR will keep the membership apprised of its release.

- **Update on DOE Financial Assistance and Due Diligence**: The RTES Office established a Policy Working Group that is across departments intended to establish more consistency in policy across departments and raise awareness with the various DOE programs. DOE is also looking into developing a matrix or rubric similar to what other agencies have developed for transparency of determinations made around foreign talent recruitment participation. Additionally, DOE are looking at the additional following areas Digital Persistent Identifiers (DPIs), improving consistency of how things are defined in funding opportunity announcements (ex. entity of concern, foreign entity of concern) and associated regulations, and improvements to the foreign national review process.

- **Update on DOE COI Notice of Proposed Rule Making**: DOE stated this has been on hold as they work through various processes, but hopefully it will be posted soon, and will be posted for public comment. Expect it to align closely with what was put out for public comment a couple of years ago.

- **Preliminary Comments on DOE Implementation of E.O. on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern**: DOE is awaiting DOJ to issue regulations that will inform any future actions by DOE in response to the E.O.

- **Update on DOE Adoption of the Common Forms**: DOE is working on developing a plan by the 90-day deadline in response to the OSTP Policy Memo regarding the implementation of the NSTC Common Forms. DOE stated they are currently considering several different ways in which they will be using the Common Forms but probably will not use the Common Forms in their exact language. They do not expect to greatly deviate from the forms but have DOE-specific concerns they are discussing internally as they believe they have statutory obligations that are not quite met by the forms and working with DOJ to evaluate. If they do vary from the forms, they will go through the appropriate approval process and there will be a public comment period.

The associations asked if DOE has plans to develop a resource for the community that consolidates

information related to research security for public consumption and awareness. DOE said this has been raised and is a consideration. Also, regarding the risk reviews, the associations cautioned an approach of defining risk reviews on broadly based categories of technology as research is either fundamental or not, and determinations based on the actual research award. Additionally, the associations inquired if DOE had seen an increase in manufacture waivers in response to the DOE US competitiveness clause for domestic manufacturing implemented a couple of years ago. DOE said they have not seen a significant uptick in waiver requests or enforcement.

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 Multi-Association Comments on CMMC (NEW)

The February Update discussed the Cybersecurity Maturity Model Certification (CMMC) rule published by DOD last December. On February 26, COGR joined ACE, AAU, APLU and EDUCAUSE in submitting comments.

The letter expressed appreciation for the clarifications from the version released two years earlier, particularly regarding fundamental research. While the new rule recognizes that fundamental research does not fall within the scope of the CMMC program, the associations expressed the need for additional clarifications to avoid the inappropriate application of CMMC to fundamental research.

In addition to the critical issue of the treatment of fundamental research, the letter made the following points:

- The importance of integrating prior DoD guidance on CUI designation and marking into the program regulations to improve the ability of DoD contract officers to work effectively with researchers and institutions in ensuring that CMMC Program requirements are only applied as appropriate;
- The need to revise the proposed rule to eliminate the inappropriate extension of CUI security requirements to Security Protection Data (SPD), or in the absence of that, to incorporate an actual definition/scope of SPD as well as the costs and downstream effects of extending program requirements to it in the DoD's regulatory analysis and program implementation;
- A call for the DoD to return to allowing Plans of Action and Milestones (POA&Ms) to cover a much broader array of assessment requirements, as well as to extend the timeframe for fulfilling a POA&M to 360 days;
- A recommendation that the DoD extend the overall phase-in period for adding certification requirements to solicitations or allow organizations to fulfill CMMC Level 2 requirements via self-assessment through Phase 4 of the phase-in process due to expected long-term challenges with assessor and assessment professional availability;
- The disconnect that will emerge between the proposed rule and the Defense Federal Acquisition Regulation Supplement (DFARS) regarding the version of NIST SP 800-171 that institutions must follow once the latest version of 800-171 is released, which will almost certainly occur before the proposed rule is finalized; and

- A proposal that the CMMC Program regulations require the lead assessors of CMMC assessment teams to have knowledge and experience in the industry of the organization that is being assessed.

Detailed discussion of these points is included in the letter. We appreciate EDUCAUSE's lead in developing the comments on this complex and sensitive topic.

ARPA-H IP Provisions Raise Concerns (NEW)

ARPA-H NITRO[3] program agreements include intellectual property (IP) and other provisions that have raised concerns. While the NITRO FAQs (NITRO Frequently Asked Questions | ARPA-H), indicate that IP rights are to be negotiated, a number of institutions have received specific troubling IP provisions in NITRO awards from ARPA-H. The awards were made under ARPA-H's Other Transaction (OT) authority.

NITRO specifically focuses on three technical areas (TAs): injectable bone regeneratives, injectable cartilage regeneratives, and replacement joints built from human cells. For the first two TAs, performers will create therapeutics to fully regenerate damaged joints. The NITRO Program seeks to fund the research and development outlined by TAs 1-3 with the result being affordable healthcare outcomes for OA patients. To be successful, the Program must meet scientific/technical, *and* equity and affordability metrics initially established in the solicitation. Awards are at the $20M level.

Of greatest concern from an IP standpoint was a provision that the government can effectively march in and transfer the license should the Performer or its licensee "commercialize a therapeutic solution at >25% of the current cost of care for the selected Therapeutic Area (TA) (including any/all intellectual property)." The provision further stated: "If the Performer, assignee or exclusive licensee refuses a reasonable request from the Government, ARPA-H has the right to grant such a license itself if ARPA-H makes a reasonable determination such action is necessary because the Performer, Commercialization Partner, assignee, or exclusive licensees fails to comply with the ≤25% affordability metric (i.e., the resulting therapeutic solution must be ≤25% of the current cost of care for the selected TA including any/all subject inventions included in the solution). The Government's rights considered in this section will extend to IP developed by the Performer under all Federal Government-funded awards (i.e., awards where Bayh-Dole applied)."

We understand there have been extended discussions about these and other agreement terms between institution representatives and ARPA-H. Most of the agreement issues have been resolved. Fortunately, the purported extension of the IP provisions to other federal awards generally has been dropped. There is now a specific background IP table to which the provisions apply only if the background IP is necessary for the specific product. ARPA-H will not remove the pricing language unless it turns out in fact that the IP can't be commercialized if subject to these terms, at which point it will reconsider.

[3] *Novel Innovations for Tissue Regeneration in Osteoarthritis (NITRO), see: https://arpa-h.gov/research-and-funding/programs/nitro*

The problematic IP provisions may be specific to the NITRO program and not to ARPA-H awards generally. While there appears to have been a reasonable resolution, we may consider ways to bring to the attention of ARPA-H leadership that such terms are likely to seriously inhibit commercialization of technologies developed with ARPA-H funding.

Proposed NIST March-In Framework Elicits Large Response (UPDATE)

The February Update discussed the extensive comments submitted in response to the Framework proposed by NIST for agencies consideration of requests for exercise of march-in rights under the Bayh-Dole Act. This also was the subject of a panel discussion at the virtual COGR February virtual membership meeting featuring Walter Copan, Vice President for Research & Technology Transfer at Colorado School of Mines and former Director of NIST, renowned inventor Dennis Liotta and Professor of Chemistry at Emory University, and Osage University Partners Kirsten Leute. The session was moderated by Todd Sherer, Associate Vice President for Research at Emory University[4] and COGR Board Member.

There have been many public and Congressional responses over the past month (including COGR's comment letter and joint association response on February 1). The Bayh-Dole Coalition website contains many of these responses. These include dueling Congressional letters to the President, ranging from the need for the government to take additional steps to impose price controls on drugs to a bipartisan letter setting forth serious adverse consequences threatening innovation.

It is not known whether, when, or how NIST may take further action on the proposed Framework. However, the Administration clearly remains focused on drug price controls as a major initiative. This may not bode well for withdrawal of the Framework as recommended by COGR and other higher education associations as well as many commentators.

USPTO Requests Comments on Encouraging More Innovation (NEW)

On March 15, the United States Patent and Technology Office (USPTO) issued a request for comments on *Unlocking the Full Potential of Intellectual Property By Translating More Innovation to the Marketplace* (89 FR 18907). Comments are due May 14.

The Notice discusses current USPTO initiatives and asks for comments on what USPTO might do to incentivize the commercialization of green, critical and emerging technologies both directly and in collaboration with other agencies. It includes 15 questions for which information is sought. Some of these are specific to green and critical and emerging technologies, or specific USPTO initiatives. Others are more general.

COGR is considering submitting comments. Some of the obvious challenges are issues we have discussed many times before, such as the concerns raised by the proposed NIST March-in Framework discussed in the February

[4] *See video recording link below for registered attendees.*

Update and the panel session on march-in rights at COGR's February virtual membership meeting[5]. It is unclear how helpful raising these issues would be, especially since they are not in USPTO's purview.

The COGR RSIP Committee will discuss possible COGR comments. We also may join with other higher education associations in comments and will keep the membership apprised.

Contracts & Grants Administration (CGA)

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

SAM.gov Registrations (UPDATE)

As reported in September 2023 and February 2024, COGR is actively engaged with GSA on the challenges members report with SAM.gov renewals/registration. COGR hosted Ms. Ivana Henry, Management and Program Analyst, U.S. General Services Administration, who presented an Overview of System for Award Management (SAM) Registration Process – Challenges & Tips. She addressed the following key areas.

- **Entity Validation**: GSA provided a flow chart of the entity validation process from start to finish. SAM.gov uses an entity validation services (EVS) to independently verify the existence, location, and uniqueness of an entity, noting that every entity must validate against EVS provider's database and data sources, even if they have an active registration. A list of comprehensive acceptable and unacceptable documents is available here. If an institution experiences difficulty locating documents from the acceptable list, GSA advises to attach what documentation you have and add a short comment on the documentation page. When an EVS agent replies from FSDSupport@GSA.gov, provide complete details about your situation including if you have active federal awards to maintain.

- **Timeline for Starting Registrations**: Start updates and renewals early. If an institution has not yet validated successfully with EVS or have a business name or address change to make, GSA advises starting 60 days in advance. If your entity was successfully validated by EVS and there are no changes to the business name or address as it appears in your current registration, the GSA recommends starting at least 30 days before expiration. To check if your entity is validated use the Check Entity Status tool.

- **How to Escalate an Issue**: GSA has established a path for escalation and a dedicated team of case managers to work with individual cases. To escalate a case, provide the requested documents to the EVS helpdesk and any justification on why documents may not match or may not be available. Also, explain if there are any open awards and that the registration needs to remain active. The EVS team will then escalate the case to dedicated case managers for support, who will open a brand new separate ticket and will be the dedicated point of contact.

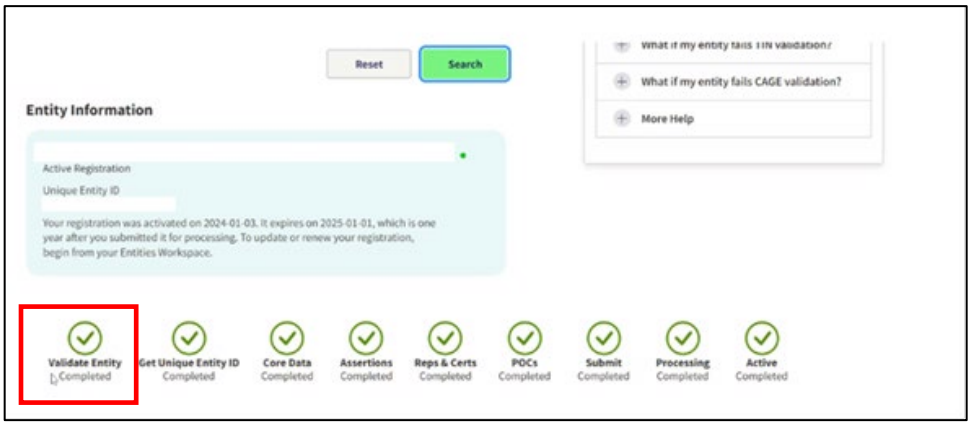
A recording of the session is available for meeting attendees in the COGR Portal for more information.

[5] *Meeting attendees can view the recording here: https://cogr.member365.org/sharingnetwork/workspace/view/41*

As documented over the past several months, COGR has met with GSA to bring reported issues to their attention and escalate individual institutional cases facing challenges with their SAM.gov renewals. Reports include challenges with the lack of timely and effective communication from the 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.

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 SAM.gov by clicking Check Entity Status. 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 60 days 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's 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.

COGR has engaged federal officials, including OMB, on the concerns of the community and will keep the COGR membership updated on all developments. Additionally, to assist with our advocacy efforts, COGR has established a workgroup with members from the community.

We encourage COGR members to contact Krystal Toups at ktoups@cogr.edu if they are experiencing challenges or have comments or concerns to report related to SAM.gov registration.

Revision of NSF Award Terms and Conditions (NEW)

On March 25, 2024, NSF announced the release of updated Award Terms and Conditions to align with NSF Proposal and Award Policies and Procedures Guide (NSF 24-1). The revised award terms and conditions will apply to new NSF awards and funding amendments to existing NSF awards made on or after May 20, 2024. Below are the updated suite of award terms and conditions and the associated Summary of Changes document:

- NSF Agency Specific Requirements to the Research Terms and Conditions (ASR) [Summary of Changes];
- Grant General Conditions (GC-1) [Summary of Changes];
- Cooperative Agreement Financial & Administrative Terms and Conditions (CA-FATC)[Summary of Changes];
- Cooperative Agreement Modifications and Supplemental Financial and Administrative Terms and Conditions for Major Multi-User Research Facility Projects and Federally Funded Research and Development Centers [Summary of Changes];
- Cooperative Agreement Modifications and Supplemental Financial and Administrative Terms and Conditions for Mid-Scale Research Infrastructure Projects [Summary of Changes];
- International Research Terms and Conditions (IRTC) [Summary of Changes];
- Special Terms and Conditions for Administration of NSF Conference or Travel Grants (FL 26) [Summary of Changes]; and
- Special Terms and Conditions for Administration of NSF Conference or Travel Grants Made to International Organizations (FL 26 for IRTC) [Summary of Changes].

Notable key changes include the following:

- **Project Reporting Requirements**: Applicable articles supplemented to address certification requirements for the PI or co-PI in annual and final annual project reports, including an annual certification that each postdoctoral scholar and graduate student who receives substantial NSF support must have an individual development plan.
- **Format, Content and Timing of Required Reports**: Applicable articles supplemented to address the requirement above (Project Reporting Requirements) as well as an article to incorporate the new institutional annual reporting requirement mandated by Section 10339B, "Foreign Financial Support", of the CHIPS and Science Act of 2022 (42 U.S.C. § 19040). The Foreign Financial Support report must be submitted by July 31 of each calendar year.
- **Safe and Inclusive Working Environments for Off-Campus or Off-Site Research**: Applicable articles supplemented with language to address post-award requirements associated with the plan for safe and inclusive working environments.
- **Publications**: Applicable articles updated to align with the NSF Policy on Brand Standards and the NSF Brand Standards Manual.
- **Notification Requirements Regarding Sexual Harassment, Other Forms of Harassment, or Sexual Assault**: Applicable articles updated to improve clarity of language and NSF's expectations.
- **Malign Foreign Talent Recruitment Program Certification**: A new article that address Section 10632 of the CHIPS and Science Act of 2022 (42 U.S.C. § 19232). Each PI and co-PI identified on a proposal

submitted or due on or after May 20, 2024, that results in an award, must certify annually in Research.gov, for the duration of the award that such individual is not a party to a malign foreign talent recruitment program. These certifications do not apply retroactively to proposals submitted prior to May 20, 2024.

- **Post-award Additions of Postdoctoral Scholars or Graduate Students**: A new article that addresses requirements associated with post-award additions of postdoctoral scholars or graduate students.
- **Individual Development Plans for Postdoctoral Scholars and Graduate Students**: A new article that implements the Section 10313 (42 U.S.C. § 18993) of the CHIPS and Science Act of 2022 requirement that each postdoctoral scholar and graduate student who receives substantial NSF support must have an individual development plan.

OASH Periodic Performance Project Report (PPR) for Grants and Cooperative Agreements (NEW)

On March 12, 2024, The Office of the Assistant Secretary for Health (OASH) released an Information Collection Request (ICR), Document Number: 2024-05162. OASH is seeking OMB approval on a new information collection, the OASH Standard Periodic Performance Project Report (PPR) for Grants and Cooperative Agreements, aimed at standardizing progress reports in a web-based system for individual grants and cooperative agreements managed by OASH. Comments are due on May 13, 2024.

CGA is reviewing the ICR to fully understand any impacts on the community and welcomes any feedback you may, by reaching out to Krystal Toups at ktoups@cogr.edu.

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.

Personal Information and Federal System Log-on Concerns (NEW & ONGOING)

Initially a "sleeper" issue, this topic has grown to a topic of significant concern across the research community. The issue has been further perpetuated by President Biden's February 28, 2024 Executive Order, FACT SHEET: President Biden Issues Executive Order to Protect Americans' Sensitive Personal Data.

COGR first reported on this topic in the COGR September 2023 Update (p. 20) in relation to the Automated Standard Application for Payments (ASAP). The ASAP is maintained by the U.S. Department of Treasury and is used to transfer payments to recipient organizations. Many federal agencies (e.g., DOE, USDA, DOJ, etc.), though not all, use ASAP as their baseline system to process payments. The Invoice Processing Platform (IPP) is a related electronic system, also managed by Treasury, which requires regular access by grantees. COGR members have shared 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.

Most recently, the Payment Management Services (PMS) has caused consternation. PMS, like Treasury, manages a separate payment system used to transfer payments to recipient organizations. PMS is maintained by the Program Support Center (PSC)—a shared services organization of Health and Humans Services (HHS). HHS operating divisions, which includes NIH, use PMS as their baseline system to process payments. In the case of

PMS, two concerns have emerged:

1) PMS now requires the user to have an ID.me account to serve as a secure sign-in protocol. ID.me normally is associated with establishing a personal account (and submitting personal information) associated with accessing one's IRS or Social Security Administration personal accounts. Requiring an employee to utilize an ID.me log-on procedure for a workplace application—such as accessing PMS—blurs the line of home and the workplace and is a potentially intrusive and inappropriate expectation.

2) Further, PMS recently blasted an email notice to all users with the headline: EXERCISE VIGILANCE: Payment Management System. PMS went on to state:
   The Payment Management System Account (PMS) Services Team have seen numerous compromised email accounts in our Grant Recipient communities. Bad actors have social engineered their way through Grant Recipient IT help desks to gain access to recipient's email accounts … it is essential that you report this event to your IT department and the PMS Account Services at PMS_IT_Support@psc.hhs.gov immediately.

While different in substance, both PMS-related issues compound concerns around accessing federal systems. In particular, the PMS requirement for users to use ID.me—rather than the seemingly less intrusive Login.gov as the secure sign-in protocol—has heightened the already significant concern requiring employees to enter personal information to access federal systems.

COGR is engaging federal officials, including OMB, and we will keep the COGR membership updated on all developments.

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

We reported in the February 2024 Update (p. 21) that an individual from a COGR member institution shared that they have been informed by Cost Allocation Services (CAS) that adjustments no longer 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 of this writing of this Update, we have no further information. COGR will stay in regular contact with the HHS Office of Grants (who oversees the Program Support Center and CAS). COGR's position will remain 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 (REMINDER)

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 the 2023 F&A Survey Report page (log in required). ***Further, we anticipate publishing a third report that shows the cumulative results for 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 2023 presentation and an October 2023 presentation at past COGR meetings featured analyses that may be of interest to the COGR membership.

Timeliness of F&A Cost Rate Negotiations: F&A Survey Results (ONGOING)

The timeliness of completing F&A cost rate negotiations (as well as fringe benefit rates) has been problematic for institutions over the past several years. Anecdotally, the time between submitting an F&A cost rate proposal and arriving at final negotiation of cost rates could exceed two years. We addressed the "timeliness" concern in the F&A Cost Rate Survey and crafted several survey questions around this topic. For one of the questions included in the survey, the results showed:

- 84 out of 120 survey respondents indicated their F&A cost rates were up-to-date and "all was good."
- For the remaining 36 survey respondents, 22 responses also suggested "all was good."
- However, 14 of the remaining 36 indicated some level of concern around timeliness—for example: *We have submitted a proposal and our rates have expired, we are officially concerned.*

The survey results suggest there may be a systematic problem around timeliness rather than anecdotal only. Still, the systematic problem may be more regionally based rather than national. In the case of institutions that work with the Northeast region of Cost Allocation Services, timeliness seems to be less of a concern. Whereas in other regions, the concern is heightened.

F&A cost rate negotiations are a fluid process and what was true one year ago may not be true today. As such, we are asking COGR members to keep COGR updated on concerns around timeliness. In December of 2022, COGR sent a letter to Mak Karim, the National Director for Cost Allocation Services at the U.S. Department of Health and Human Services, to address the concern. Over the past year, we have continued to lift the concern to OMB within the context of our Uniform Guidance responses. We are also considering a short survey of the membership as an update to COGR's F&A Cost Rate Survey from last year.

Please reach out to COGR if your institution is experiencing a problem around this topic. We will continue to advocate for solutions as long as this issue persists.

Financial Reporting Developments at NASA (ONGOING)

There appears to be a "settling in" after the flurry of engagement with NASA's Grants Policy and Compliance Team (GPC) throughout 2023. Still, COGR will stay engaged with the GPC (and its Director, Antanese Crank) and 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 is 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 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, as needed, 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) when concerns specific to your institution arise.

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 (ONGOING)

OMB expects the 2024 Compliance Support (CS) to be published in mid-May. 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). While we don't expect any significant changes to the 2024 CS, we will closely review key sections when it is available. 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 OMB and the audit firms and engage, accordingly.

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 under All Reports and Publications (select by HHS Agency). 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. Several implementation concerns have emerged, and when reported to NSF, officials have been open to addressing them. We encourage COGR members to contact NSF and/or COGR when issues arise.

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).

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.

COGR Submits Comments on EPA Scientific Integrity Draft Policy (UPDATE)

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. COGR submitted comments on the draft policy that fully supported the policy's goal of promoting "a continuing culture of scientific integrity," but urged EPA to clarify how and when the policy applies to the activities of recipients of EPA research awards versus the activities of EPA employees.

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

On February 28, 2024, President Biden issued an Executive Order on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern instructing the Attorney General, in coordination with the Department of Homeland Security, to develop a rule to regulate the transfer of certain classes of American's sensitive personal information to designated countries of concern. In

response, DOJ issued this ANPRM identifying the following three classes of restricted data transactions that involve the transmittal of six categories of bulk U.S. sensitive personal data to specified countries of concern:

Classes of Restricted Data Transactions	Categories of Bulk U.S. Sensitive Personal Data
Vendor Agreement (including agreements for technology services and cloud-services)	Covered personal identifiers
Employment Agreements	Personal financial data
Investment Agreements	Personal health data
	Precision geolocation data
	Biometric identifiers
	Human genomic data (including biospecimens)

The ANPRM identifies the countries of concern as China, Russia, Iran, North Korea, Cuba, and Venezuela.

The ANPRM states that DOJ is considering exempting data transactions to the extent they are for "the conduct of the official business of the United States government by its employees, grantees, or contractors" and "transactions conducted pursuant to a grant, contract, or other agreement entered into with the United States government." This exemption would permit federal agencies, including the Department of Health and Human Services and NSF, to implement their own grant and contract-based conditions to address "risks that countries of concern can access sensitive personal data," thereby avoiding duplicative requirements from multiple agencies.

At the February membership meeting, Dr. Keiser advised that NSF was not currently contemplating additional restrictions on the transfer of such sensitive data. During conversations with NIH, Dr. Lauer stated that NIH would consider the responses to the DOJ ANPRM in determining how it would proceed.

The foregoing exemption would encompass only federally funded research and contracts, as opposed to privately funded research. Accordingly, non-federally funded clinical trials (e.g., international multi-site drug trials in which the drug will be licensed in the U.S. and China) that may involve the transfer of genomic, or other sensitive data could be covered by the proposed regulation. Importantly, the definition of "bulk" being contemplated for genomic data ranges between 100 and 1,000 individuals.

The REC Committee has established a working group to develop comments on how the ANPRM will impact institutions' research efforts. Institutions should note that the ANPRM may also impact certain operational vendor agreements, as illustrated by the following examples included in the ANPRM:

> *Example 20.* A medical facility in the United States contracts with a company headquartered in a *country of concern* to provide IT-related services. The medical facility has bulk *personal health data* on its U.S. patients. The IT services provided under the contract involve *access* to the medical facility's systems containing bulk *personal health data.*
>
> *Example 21.* A U.S. company, which is owned by an entity headquartered in a *country of concern* and has been designated a *covered person,* establishes a new data center in the United States to offer managed

services. The U.S. company's data center serves as a vendor to various U.S. companies to store *bulk U.S. sensitive personal data* collected by those companies.

Comments are due by April 19, 2024. A DOJ fact sheet on the ANPRM can be found at this link.

FDA Draft Guidance for Sponsors, Investigators, and Institutional Review Boards on Key Information and Facilitating Understanding (NEW)

The FDA recently issued Draft Guidance on Key Information and Facilitating Understanding in Informed Consent to better align its informed consent requirements with those under the Common Rule. The Guidance encompasses both HHS-supported and FDA-regulated studies and provides information on developing the key information section of the consent document and addressing both basic and additional elements of information consent in that section. Comments are due on April 30, and the REC Committee is developing a response.

HHS/USDA Notices of Proposed Rulemaking – Select Agent Regulations (NEW)

As part of their biennial review of the current list of select agents and toxin, HHS and USDA have issued proposed rules (89 FR 5823 [HHS] & 89 FR 5795 [USDA]) removing certain select agents from their lists, and making changes to certain definitions, exemptions, and training requirements. The REC Committee is working with a group of biosafety personnel to develop comments in response to the proposed changes. Comments are due on April 1.

CMS Request for Information: Research Data Request and Access Policy Changes (NEW)

CMS recently announced changes to the options by which researchers can request identifiable claims data for their research. Currently, researchers can request physical data extracts that they can use at their institutions, provided certain cybersecurity requirements are met, or they can access the data via CMS' virtual data center. CMS plans to eliminate the option for physical data extracts for new studies in 2024 and transitioning existing studies that use extracts to the virtual data center in 2025.

COGR member institutions have expressed concerns that the elimination of physical data extracts coupled with increased fees for accessing the virtual data center will greatly impede research on CMS claims data, particularly at emerging research institutions. A REC Committee subgroup will develop comments in response to the RFI. Additionally, institutions should encourage their researchers to submit comments, as many of the questions in the RFI are directed to specific impacts on research projects. The RFI is open for comments until May 15.

Biden Administration Executive Order on Advancing Women's Health Research and Innovation (NEW)

On March 18, 2024, the Biden Administration issued an Executive Order on Advancing Women's Health Research and Innovation. The Order outlines initiatives for better integrating research on women's health into federal research programs, and contains several provisions that will impact research funding and research protocols, including:

- Requiring funding applicants to explain how study designs will consider/advance women's health.
- Requiring funding agencies to consider women's health in evaluating research proposals that address

medical conditions that affect women differently or disproportionately.
- Requiring grantees to regularly report on their implementation of and compliance with research and data standards related to women's health, including recruiting milestones.
- Improve recruitment and retention of women in federally funded clinical trials.

COGR will monitor agencies' implementation of this order.

Notice to Rescind NOT-OD-21-080 "Updated Notice of Limited Availability of Research Non-Human Primates (NEW)

NIH issued this notice (NOT-OD-24-080) which ends the priority recommendations for COVID-19 related research using non-human primates or non-human primate facilities.

New OLAW Guide Notices Issued (NEW)

OLAW issued the following two final guidance notices: Guidance on Flexibilities for Conducting Semiannual Inspections of Animal Facilities (NOT-OD-24-075) and Guidance on Flexibilities for Conducting Semiannual Program Review (NOT-OD-25-076). Both of these guidance documents provide an overview of flexibilities available to IACUCs in conducting these functions, and they discuss differences in how the flexibilities may apply to AWA-regulated species.

COGR submitted comments in response to proposed guidance on semiannual inspection facilities, and the final version of this guidance incorporated these comments as follows:

- Text was added to item 3 to clarify that the PHS Policy and Animal Welfare Act Regulations are "silent on determining conflict of interest regarding semiannual facility inspections" and to state that IACUCs have the discretion to determine how to manage inspection circumstances that may post conflicts of interests.
- The guidance added references to applicable Animal Welfare Act requirements in item 8.

Both guidance documents on semiannual inspections and semiannual program reviews of AWA-regulated facilities now state that although the IACUC may use a subcommittee to conduct the inspection/program review, the subcommittee must present the findings from their reviews to a "convened quorum of the IACUC for approval." Further, areas housing AWA-regulated species must be physically inspected, as opposed to using remote methods (e.g., video, photos). The guidance on semiannual inspections also sets forth the process for having IACUC members sign the inspection report that is provided to the Institutional Official and notes that digital and scanned signatures, or email acknowledgments accepting the report, are acceptable.

COGR comments on the draft guidance for semiannual inspections noted the PHS Policy does not require the review of institutional standard operating procedures and urged OLAW to leave the timing of SOP review to IACUCs. Although OLAW deleted the reference to SOP review in the semiannual inspection document, the program review guidance requires SOPs referenced in protocols to be "reviewed by the IACUC at appropriate intervals, or at least once every three years." SOPs that are reverence in training programs must be reviewed at a

frequency considered adequate to ensure that personnel are qualified and trained to carry out their duties." For other animal facility SOPs, the IACUC has the discretion to determine the method and frequency of review.

Revisiting the 2017 Joint Association Report on Reforming Animal Research Regulations: Workshop Recommendations to Reduce Regulatory Burden (UPDATE)

In 2017, COGR worked with NABR, AAMC and FASEB to conduct a workshop on reforming animal research regulations to "promote regulatory efficiency, animal welfare, and sound science." The workshop resulted in a report that was submitted to regulatory agencies. COGR is again working with our partner associations to consider hosting a new workshop to evaluate progress made in this area, particularly in light of USDA and OLAW efforts over the past several years to evaluate policies and procedures to identify potential areas for administrative burden reduction. The associations have agreed to discuss a possible workshop later this spring after gaining additional information from two important upcoming events: a) the National Academies April 2024 workshop on potential topical updates to the Guide for the Care and Use of Laboratory Animals (2011), and b) OLAW's publication of the results from a 2023 survey of researchers regarding the impact of its efforts to reduce administrative burden.

Appendix A – Upcoming Comment Due Dates

Agency	Description	Due Date	Notes
USDA	Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List	April 1	COGR will submit comments.
HHS	Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins	April 1	COGR will submit comments.
FDA	Draft Guidance on the Use of Data Monitoring Committees (DMC) in Clinical Trials	April 15	COGR is reviewing.
DOJ	National Security Division; Provisions Regarding Access to Americans' Bulk Sensitive Personal Data and Government-Related Data by Countries of Concern	April 19	COGR is developing comments.
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.
FDA	Draft Guidance on Key Information and Facilitating Understanding in Informed Consent	April 30	COGR is developing a response.
OASH	OASH Standard Periodic Performance Project Report (PPR) for Grants and Cooperative Agreements	May 13	COGR is reviewing for impact.
USPTO	Unlocking the Full Potential of Intellectual Property By Translating More Innovation to the Marketplace	May 14	COGR is considering submitting comments.
CMS	Request for Information: Research Data Request and Access Policy Changes	May 15	COGR will develop comments.

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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