COGR

SEPTEMBER 2024 UPDATE

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President's Message

Fall Fruition

Dear Colleagues,

This fall many organizational, program, policy and advocacy endeavors that COGR has been working on have or will come to fruition. On the organizational front, I am pleased to report three significant developments. First, Cindy Hope joined the COGR team earlier this month as the Director of Costing and Financial Compliance. Dave Kennedy transitioned from that role to Senior Fellow, where he is aiding with our efforts on the updated Uniform Guidance and other projects. This made for a seamless transition and has given the association some extra horsepower through January.

Secondly, since July, we welcomed four new members – Morgan State University, City University of New York Central Office, SUNY Upstate Medical University, and University of Tennessee Health Science Center. Each adds strength to the association. COGR's membership now numbers 222 research institutions.

And thirdly, we accepted nine institutions into COGR's Emerging Research Institutions Pilot Program. We continue to accept applications for additional ERI Pilot participants. We look forward to learning from and engaging with these universities.

For program developments, we hosted a webinar earlier this month entitled "*Going AI.*" It was COGR's most attended webinar to date and provided participants with strategies for and examples of how some institutions are applying AI to enhance research administration efficiency.

We hope the strong webinar participation will continue at COGR's next membership meeting on October 24-25 in Washington DC. The agenda features OSTP Director Arati Prabhakar, elections expert David Wasserman, and sessions on COGR's F&A Capstone report, the recent U.S. Supreme Court decision affecting "Chevron Deference," NSF's SECURE Center, the updated Uniform Guidance, and the updated research integrity regulations.

Lastly, we saw the fruits of our policy and advocacy efforts in the updated research integrity regulations, updated Uniform Guidance, and the research security standards. Many of COGR's recommendations for each were adopted or reflected in the final versions. While not all the 'fruit' ripened as we hoped, we will continue to cultivate and plant for the future.

To this end and others, earlier this month COGR's directors and I spent a morning at NSF in which we met with agency leaders. Among the matters we discussed were research security, the updated Uniform Guidance, and the importance of strengthening the partnership between research institutions and the federal government through efficient, effective, and harmonized research policies and regulations. Our time at NSF was invaluable. I was particularly struck by the genuine enthusiasm, strong purpose, and dedicated professionalism with which our NSF colleagues serve the agency and our country.

The COGR team looks forward to seeing many of you at the upcoming membership meeting. For those we will not see, please know you can call on us anytime with questions and suggestions.

Matt Owens
President

Announcements

Registration Still Open: October 24-25, 2024, COGR Meeting in Washington D.C.

COGR's next meeting will be in-person on October 24-25, 2024 at the Washington Marriott in Georgetown. Registration is still open, and the agenda can be found on COGR's Meeting Materials page here.

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

Now Accepting Applications: Emerging Research Institutions Pilot Program

COGR launched an Emerging Research Institutions (ERI) Pilot Program on August 1, 2024. This program provides an opportunity for institutions that do not yet meet COGR's membership threshold[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.

Key Program Information

- **Eligibility:** *Institutions of higher education reporting less than $15 million in annual federal research expenditures on the NSF HERD survey are eligible to apply. As there is limited capacity, applications will be considered using a variety of factors to ensure diversity among participating ERI Pilot Institutions.*
- **Pilot Duration:** *The initial duration of the Pilot Program will be two years and will coincide with COGR's fiscal year. Year 1 will be August 1, 2024 - July 31, 2025. Year 2 will be August 1, 2025 - July 31, 2026. The Pilot Program will be evaluated in the spring of 2025 for potential extension, transition, or completion.*
- **Annual Fee:** *The annual participation fee for the initial phase of the pilot will be $3,500 per year, per institution.*
- **What's included?** *ERI Pilot Institutions may have up to five representatives. Each will have access to the COGR Portal. One representative per institution is permitted to register for in-person Membership Meetings. All representatives may register for virtual Membership Meetings and webinars. In-person meeting registration is currently $550 per person and virtual meeting registration is approximately $300*

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

per person, or $250 per person if registering five or more. ERI Pilot institutions are also highly encouraged to participate in COGR surveys, working groups, and other opportunities to engage that may arise.

Please note: There is a limited number of openings in the first year of the Pilot Program (August 1, 2024 - July 31, 2025). Contact ERIservices@cogr.edu with any questions related to the ERI Pilot Program.

Upcoming Comment Due Dates

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

Reminders

COGR Membership Renewal – Membership Invoices are Now Due

If you are your organization's Primary Representative (PR) or billing contact, it's time to renew your institution's COGR membership. To retrieve your invoice, follow the steps below. If you have already submitted your invoice for payment, please log into the COGR Portal to confirm payment has been received. As a reminder, COGR membership covers the entire institution and provides all staff with COGR Benefits of Membership, including access to the COGR Portal.

To renew your institution's membership or check on your payment status, log onto the COGR Portal, and from the Dashboard, click on the link in the gray renewal badge. You will be asked to update your contact information and then choose check or EFT/ACH payment. Once that is complete, you will be able to download your institution's annual dues invoice. PR's and billing contacts can view and manage their institution's invoice at any time on the COGR Portal Dashboard under "My Account – Invoices & Receipts."

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

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

An updated W-9 is available on COGR's 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.

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.

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

Fifth Look: Readiness Guide for 2024 Uniform Guidance Implementation (NEW)

COGR developed the "Fifth Look" - Implementation and Readiness Guide for the OMB Guidance for Federal Financial Assistance. This resource is designed to help institutions prepare for and implement the 2024 Revisions to the Guidance for Federal Financial Assistance, effective October 1, 2024, as outlined in the OMB Guidance for Federal Financial Assistance; Final Rule – Title 2 of the CFR, published on April 22, 2024.

Sections in the Readiness Guide include:

- General Topics
- Issues to Consider / Take Action
- Issues to Be Aware of / Wait and See
- Appendix I: Facilities and Administrative Cost Rate Implications
- Appendix II: Faculty Talking Points
- Appendix III: COGR Matrix of Federal Agencies' Implementation

The guidance provided is based on COGR's understanding of OMB's implementation. We will review and update this guide as we learn more. If there are significant changes that will impact your institution, which COGR has not covered, or if you have any questions about the information contained herein, please contact memberservices@cogr.edu.

COGR would like to thank the working group members who contributed their expertise to developing this resource for the community.

For more information on 2 CFR 200 "Uniform Guidance," please visit COGR's UG Resource page here.

COGR Proposes Technical Corrections and Comments for the OMB Guidance (ONGOING)

COGR continues to monitor the implementation status of the new and revised Uniform Guidance. We continue to meet with OMB to discuss the issues important to members detailed in COGR's June 28 letter to OMB, as outlined below. We provide the following key takeaways from our meeting with OMB.

First, as anticipated, the Council on Federal Financial Assistance (COFFA) released OMB's Federal Agency Implementation on August 15, 2024. The document provides information to assist Federal agencies with more consistently implementing the revisions, addressing the following topics:

- New Awards and Related Program Documents
- Exiting Awards
- Implementation guidance
- Subawards
- NOFOs and Federal Financial Assistance Applications
- Recipient Implementation of 2 CFR
- Indirect Costs
- *De Minimis* Rates for New and Existing Awards
- Single Audits

As specified in the August 9, 2023 OMB Memorandum M-23-19 establishing the COFFA, it will provide "oversight and management of Federal financial assistance. The COFFA will create a partnership among Federal grant-making agencies, providing a single forum to inform Federal financial assistance policy, oversight, and technology activities. The COFFA will be responsible for providing strategic direction, policy recommendations, and priority-setting for other Government-wide grant-related activities." Potentially, the COFFA could be a forum for COGR to address issues important to the research community – as such, we will stay connected and continue to follow the evolution of the COFFA.

Second, OMB indicated that they would issue technical corrections ahead of the October 1 implementation. OMB is attentive to our concern regarding the new text on unused leave and is expected to address it as a technical correction. (Further discussion is included in the Costing and Financial Compliance (CFC) section below.) Additionally, we raised concern that October 1 is rapidly approaching, and considering the community awaits the technical corrections and guidance from agencies on their adoption of the 2024 revisions, we asked if OMB would consider providing a grace period for enforcement of one year (precedent - Procurement in 2014). At this time, there are no indications that OMB is considering a grace period. OMB did indicate that they are updating existing FAQs and expect to have them posted by October 1.

Lastly, we continue to discuss the issues raised in COGR's technical corrections letter dated June 28, 2024. COGR's letter addresses the following nine items:

1. **Implement the Changes to the Equipment and Subaward Thresholds:** COGR proposes that OMB issue guidance to ensure that all institutions are provided a pathway to implement the new thresholds as

soon as October 1, 2024. Additional discussion is included in the Costing and Financial Compliance (CFC) section below.

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

We expect to be in regular contact with OMB in the months ahead, and we will keep the membership posted on all developments.

The New "OMB Guidance" is Available (REMINDER)

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

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

While COGR's work and advocacy has addressed the entirety of Title 2, our primary focus has been on Part 200. As OMB previously announced, public comments will not be considered. However, OMB indicated it would be open to observations and comments related to technical corrections, significant concerns, implementation processes, and other clarifications (which COGR believes includes addressing the status of the current FAQs, dated May 3, 2021). Accordingly, COGR provided comments and proposed technical corrections (see previous section).

Also of note is the availability of a redline version of the OMB Guidance. This version tracks changes between the current version (published in 2020) and the new version made available on April 22. In addition, COGR's Uniform (OMB) Guidance Resource Page will continue to be updated with new and helpful material. If you have any questions or comments, please contact Krystal Toups at ktoups@cogr.edu and Cindy Hope at chope@COGR.edu.

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

COGR has conducted deep-dive analyses and corresponding education and advocacy to support the membership as in advance of the October 1, 2024, implementation of the OMB Guidance. This included:

- *First Look: COGR Preliminary Assessment of Selected Items (April 24)*. Covers major changes, including items for which COGR advocated, but were not accepted by OMB. This was meant only to be a "first look" and not to address all changes, nor to address changes in detail.

- *Second Look: Webinar on the Final OMB Guidance for Federal Financial Assistance (May 15)*. Leaders from the Contracts & Grants Administration (CGA) and Costing and Financial Compliance (CFC) committees addressed some of the most significant changes, with a focus on implementation and how they will impact institutions. The slides and video of the webinar are available to all members via the COGR Portal Video Library (log in required).

- *Third Look: Thursday, June 6 COGR Meeting – Final OMB Guidance for Federal Financial Assistance, What's Next?* OMB leaders Deidre Harrison, Deputy Controller, and Steve Mackey, Policy Analyst, provided additional insights and responded to questions from the membership. The session included a robust Q&A segment where many of the issues addressed in the June 28 COGR letter were discussed.

- *Fourth Look: COGR Proposes Technical Corrections and Comments for the OMB Guidance*. In a letter dated June 28, 2024 (see previous section), COGR addressed nine items for OMB to consider before the October 1, 2024, implementation date.

- *Fifth Look: Implementation Guide*. The Readiness Guide is a resource to help institutions prepare for and implement OMB's October 1, 2024, revision. The design of this COGR publication is to address major changes and provide points to consider as institutions prepare to implement the OMB Guidance. See the section above for additional information.

Other important events include formal adoption of all Parts of the OMB Guidance by federal agencies. NSF has formally issued guidance implementing 2 CFR in the Grant General Conditions (GC-1) (see Contracts & Grants Administration (CGA) section below). Additionally, NASA has also issued its implementation through a Federal Register Notice and Grant Notice 24-01. Furthermore, HHS will publish on 10/02/2024 its plan to adopt the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (see unpublished interim rule).

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

Science & Security: Cross-Cutting Issues

NIH Risk Assessment/Risk Mitigation Matrix (NEW)

On August 15, 2024, NIH's Dr. Michael Lauer posted a blog post that issued a decision matrix that detailed the factors that NIH considers in assessing researcher disclosures for potential inappropriate foreign influence. The NIH decision matrix similar to the DOD Decision Matrix. The NIH matrix examines participation in Malign Foreign Talent Recruitment Programs (MFTRP) disclosure of participation in Foreign Talent Recruitment Programs (FTRP), disclosure of funding from a country of concern (COC) or COC-connected entity, and disclosure of affiliations with institutions/entities in COCs and categorizes these factors as mitigation measures being required, recommended, suggested, or unnecessary. The matrix employs a 5-year look-back period, and COGR has inquired as to how the 5-year look-back period applies to behavior that was not prohibited 5 years ago (e.g., categorization of any MFTRP participation within the last 5 years as "mitigation measures recommended" regardless of whether the participation was disclosed, even though the prohibition on such participation was first enacted with the passage of the CHIPS and Science Act on August 9, 2022).

DARPA Fundamental Research Risk-Based Security Review Policy and Process Workshop (NEW)

On August 26, 2024, DARPA hosted a stakeholder workshop to review DARPA's fundamental research risk assessment and risk mitigation process. COGR staff attended this workshop along with representatives from academic institutions that receive DARPA funding, including several COGR member institutions. DARPA posted the slides presented at the workshop at this link.

Key points from the workshop include the following:

- MFTRP Prohibition: DARPA confirmed that it will not require institutions to have a "public-facing policy" that prohibits covered individuals from participating in an MFRTP. However, DARPA prohibits funding to MFTRP participants, and institutions must have some type of mechanism to implement this prohibition (e.g., policy, procedure, process, etc.). DARPA advised that the Department of Defense (DOD) is still planning on modifying the DOD Component Decision Matrix to Inform Fundamental Research Proposal Mitigation Decisions to reflect this position.

- Risk Assessment Criteria & Statistics: DARPA advised that the key question it asks in its risk assessment is whether there is any compensation (monetary or otherwise) directly provided by an entity of government in a COC to target a covered individual to take certain actions (e.g., filing of patents, recruitment of scientists, etc.) in exchange for the compensation. DARPA completes a line-by-line verification of the information set forth on a covered individual's Form 424 with information that is publicly available using public and commercial validation tools (e.g., Google Scholar). considers the following factors when performing a risk assessment of a funding proposal:
    - MFTRP participation; active participation is prohibited.
    - Patents resulting from federally funded research that are first filed outside of the U.S.
    - Activities with or funding from persons/entities on entity lists specified in DOD's Policy for Risk-Based Security Reviews of Fundamental Research

  DARPA advised that between January 1 and August 1, 2024, 2% of the risk assessments that it performed resulted in required risk mitigation plans vs. 11% for the period October to December 2023.

- Risk Mitigation Plans: Potential components of risk mitigation plans that DARPA may require include:

    - Periodic security communications (e.g., security briefings) between the institution and the covered individual.
    - Requiring a covered individual to update their disclosures more frequently (e.g., quarterly).
    - Requiring a covered individual to more frequently review and attest to the accuracy of their disclosures.
    - Requiring institutions to update their conflict of interest (COI) and/or conflict of commitment (COC) policies and/or to require covered individuals to provide additional COI/COC reports.
    - Requiring an institution to provide documentation that a covered individual has disassociated from specific relationships (e.g., notarized attestation of disassociation signed by the covered individual and back-up documentation such as a letter of resignation).
    - Requiring a plan for "information sequestration" to permit a covered individual to be walled-off from other portions of a research project. DARPA advised that such measures are only used in unique circumstances involving high risk-high value covered individuals.
    - Implementing proactive security measures at the institutions such as additional training and/or travel monitoring.

- Prime Awardees and Sub-Awardees: DARPA will initially notify the prime awardee of security concerns that it has regarding a sub-awardees, but the prime awardee may authorize DARPA to negotiate risk mitigation requirements directly with the sub-awardee. In all events, the prime awardee remains ultimately responsible for the sub-awardee's compliance with any required risk mitigation measures. Further, the prime awardee may require that the sub-awardee undertake additional risk mitigation measures. DARPA also noted that it does not want prime awardees to replace sub-awardees for the sole reason that the sub-awardee is required to enter into a risk mitigation plan.

- Co-Authorship: DARPA is concerned with collaborations that result in co-authorship when (a) a covered individual receives funding from a person/entity within a COC; or (b) DARPA notes that the covered individual has a pattern of disassociation from a co-author in order to receive funding, and then reassociates with that individual after funding is received.

- Metrics and Institutional Suggestions: DARPA asked institutions to consider metrics that demonstrate whether research security restrictions are having positive and/or negative impacts on the conduct of fundamental research. Several institutions suggested that DARPA consider working with OSTP and other federal research funding agencies to establish (a) a secure email/cloud storage workspace where CUI can be easily handled; and (b) a central foreign travel reporting system. Institutions also emphasized the need for DARPA to clearly identify all research security requirements in the proposal solicitation so that there are no surprises.

COGR Meeting with NSF Representatives (NEW)

On September 6, 2024, COGR staff met at NSF headquarters with the following NSF officials to introduce new COGR colleagues and discuss several research-security related issues: Rebecca Keiser, Chief of Research Security Strategy and Policy; Sarah Stalker-Lehoux, Deputy Chief of Research Security; Jean Feldman, Head, Policy Office. Key points from the discussion included the following items:

- Certification Mechanism for Research Security Programs: NSF advised that it is unlikely that SAM.gov will be able to serve as the mechanism that institutions use to certify that they have a required research security program in place. An alternative certification mechanism being considered is having one federal research agency serve as a steward for collection of the certification on behalf of all federal research funding agencies. This solution would require that participating agencies enter into an inter-agency agreement. NSF advised that it is possible that each federal funding research agency will collect its own certification from each covered institution that it funds.

- Definitions of Foreign Talent Recruitment Programs (FTRP): COGR noted that that the OSTP definition of FTRP that appears in the February 14, 2024, memorandum on Guidelines for Federal Research Agencies Regarding Foreign Talent Recruitment Programs is much broader than the definition of FTRP that appears in the Appendix to the Common Disclosure Forms. COGR inquired as to whether NSF would be revising the Common Disclosure Forms to incorporate the OSTP definition of FTRP. NSF advised that at this time it intended to retain the Common Disclosure Forms definition because it had been reviewed and accepted by all the federal agencies comprising the OSTP research security working group.

NSF also noted that unlike participation in MFTRPs, participation in FTRPs is not prohibited; however, covered individuals must be sure to disclose their participation in FTRPs. NSF stated that it plans on publishing some examples of MFTRPs and would consider providing examples of FTRPs as well.

- NIST Cybersecurity Standards: NSF agreed with COGR's analysis that the draft NIST cybersecurity resource referenced in OSTP's Guidelines for Research Security Programs at Covered Institutions – NIST IR 8481: Cybersecurity for Research Findings and Possible Paths Forward – does not provide clear baseline standards to which institutions will be expected to certify. NSF officials plan to meet with NIST officials to discuss the cybersecurity resource that NIST is charged with publishing under the CHIPS and Science Act

- Foreign Financial Disclosure Report (FFDR): NSF reported that there was good institutional compliance with the requirement to submit the initial FFDR report. NSF recognized that the July 31 deadline may present concerns for some institutions because of conflicting year-end obligations. COGR and other stakeholder associations were asked to submit alternate deadline dates for consideration. After polling its committees, COGR reported to NSF that most institutions believe that a September 30 would be easier to implement. NSF is now in the process of considering which collected data points will be made public in the required report mandated by the CHIPS and Science Act.

- Communication of Concerns Regarding the OSTP Guidelines for Research Security Programs at Covered Institution ("Guidelines"): NSF encouraged COGR to continuing gathering member institutions' questions and concerns regarding implementation of the Guidelines (e.g., foreign travel security requirements, cybersecurity standards, etc.) and provide these to OSTP. COGR Directors are working with their committees to collect questions and concerns and prepare a follow-up letter to OSTP.

COGR also met with representatives from the NSF Office of Inspector General (NSF OIG) and discussed the NSF OIG's upcoming report regarding its review of 100 institutions' implementation of the NSF requirement that awardees have a plan in place to prevent sexual harassment and bullying for off-site research. The NSF OIG anticipates that it will publish the report by the end of 2024.

COGR Meeting with Institute for Defense Analysis Science and Technology Policy Institute (STPI) on the Biden Administration Executive Order on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by COCs (NEW)

This Biden Administration Executive Order called for (a) the Department of Justice (DOJ) to develop an Advanced Notice of Proposed Rulemaking (ANPRM) on bulk sharing of U.S. persons' data with COCs; and (b) OSTP to perform a risk assessment to help inform DOJ on the impact of the rule and whether the rule should be expanded to include other "omic" data. COGR submitted comments on the DOJ ANPRM and then met with DOJ representatives to further discuss its response. [*See*, July 2024 Update]

OSTP retained STPI to assist in performing the required risk assessment, and STPI met with COGR as part of its efforts to reach out to stakeholders to obtain information in this regard. During the meeting COGR emphasized the following themes:

- Necessity for genomic data sharing to advance science (e.g., personalized medicine/targeted treatments), promote scientific integrity and efficiency, and prevent scientific misconduct.
- Federal funding agency and journal requirements to share genomic and other data as a condition of funding and/or publication.
- Current security requirements for the protection of human genomic data including applicable laws and funding agency requirements and institutional oversight mechanisms.
- The need for the U.S. government to identify those entities that provide genomic data related services (e.g., sequencing, data storage) that present security threats.
- Inabilty/unwillingness of researchers to engage in complicated processes to obtain licenses to transfer data and need for easy-to-use mechanism to permit scientific sharing of genomic data in connection with privately funded research.

STPI advised that it is interested in gaining additional information on ANPRM's negative impacts on industry and research (e.g., inability to participate in multi-site clinical trials that involve China), particularly with respect to requiring a license for sharing of biospecimens. In follow-up to this meeting, STPI advised that it was developing additional questions for researchers to help gauge such impacts, and it will provide these questions to COGR for sharing with member institutions. STPI plans to make a report to DOJ on its findings at the end of September.

COGR Meeting with GAO Representatives Regarding Genomic Data Security

The General Accountability Office (GAO) was tasked by Congress to examine how Health and Human Services (HHS) research funding agencies and funding recipients are addressing potential national security threats that arise from sharing genomic/genetic data with foreign entities that post security concerns. GAO is evaluating the extent to which institutions use HHS funds for human genomic sequencing service/genetic services provided by entities (or subsidiaries) organized under the laws of a COC. In performing the review, GAO has been instructed to consider: (a) the extent to which COC could obtains U.S. citizens' human genomic information that an agency could reasonably determine will be used in manner inconsistent with U.S. security interests; (b) whether U.S. domestic entities could be used to provide such services; and (c) whether there are data use agreements, or other security measures, in place to address security concerns.

As part of its fact-finding efforts, GAO interviewed COGR and nine research universities (including at least three COGR member institutions). COGR met with GAO on August 6, 2024, and emphasized the following themes during the discussion:

- Federal agency and journal requirements to share data and policy reasons behind those requirements (replication and advance of science, scientific integrity). [NOTE: GAO plans to speak with journal representatives.]

- Multi-layered requirements (federal law, federal funding agency requirements, state laws, international laws, etc.).

- Multi-layered oversight and controls (IRBs, privacy boards, IT group assessment of requirements, export controls, specific mechanisms at institutions that may exist to evaluate data asks, data use agreements, monitoring/auditing).

- Necessity for scientific sharing of information and need to look for appropriately balanced solutions that consider scientific advancement, public health needs, individual privacy rights, and national security.

Meeting with SECURE Center Director and Co-Director (NEW)

On July 31, 2024, COGR RSIP Director Kevin Wozniak met with the following representatives for NSF's award for the establishment and operation of the Safeguarding the Entire Community of the U.S. Research Ecosystem (SECURE) Center: Dr. Mark Haselkorn, Professor, University of Washington and SECURE Principal Investigator and Director and Lynette Arias, SECURE Co-Director, University of Washington. Dr. Haselkorn and Ms. Arias discussed initial goals and objectives for SECURE and agreed to present on the Center at COGR's October membership meeting, along with Dr. Kevin Gamache, the Principal Investigator for the SECURE Analytics project.

Meeting on Assessing Research Security Efforts in Higher Education (NEW)

On September 16, 2024, COGR representatives participated on a panel of experts during a two-day meeting hosted by the National Academies of Sciences, Engineering, and Medicine on "Assessing Research Security Efforts in Higher Education". According to NASEM, the event "will inform a workshop that will explore potential avenues, challenges and opportunities to assess the effectiveness and progress of current and potential U.S. federal government research efforts in higher education."

Foreign Financial Disclosure Report Meeting (FFDR) with NSF (ONGOING)

As previously reported, COGR continues to follow developments related to the inaugural NSF Foreign Financial Disclosure Report (FFDR). As recently shared, NSF provided updated guidance on reporting Multiyear Gifts and Contracts in response to feedback and questions from the community. COGR has since received additional clarification from NSF provided below. Additionally, NSF provided responses to questions raised during the June 2024 COGR Meeting session " NSF & Foreign Gift Reporting Requirements" provided below. NSF plans to incorporate these general thematic areas into the FFDR FAQs.

1. **It seems that in NSF's attempt to align reporting requirements of gifts to "receive," which coincides with the Department of Education's Section 117 reporting, the revised policy inadvertently misaligned the reporting of contracts. The FAQ of concern initially referenced gifts only, but now it also references contracts. Was that the intent, or will NSF remain aligned with the Dept of Ed in how contracts are reported?**

   [Note: Section 117 requires reporting gifts on the money received and the reporting of contracts on the anticipated total value of a contract in the reporting period the contract is executed (see Sec.

117 FAQ GR-Q2 and Sec. 117 FAQ CR-Q4). It also requires estimates for indeterminant contracts such as licenses or clinical trials (see Sec. 117 FAQ AMNT-Q2). Additionally, "received" alone for contracts may require additional clarification, as many entities in accordance with GAAP, record revenue/receipt when a contract is invoiced vs. when executed]

NSF Response: NSF's new guidance for reporting multiyear gifts and contracts is intended to provide a consistent approach for the reporting of multiyear gifts and contracts. Based on the statutory language of CHIPS and Science Act, NSF is requiring IHEs to report financial support when the support is received. NSF acknowledges that this guidance for reporting multiyear contracts will now deviate from the Dept of Education's guidance for how contracts are reported, as Dept of Education's statute specifies that entering into a contract is a reportable event (and differentiates that from receipt of a gift), but NSF has determined that its statue treats the reporting of contracts differently from the Dept of Education's statue.

2. **Institutions that have already submitted their report are concerned about whether they will need to resubmit. There is also concern about potential over-reporting in subsequent years or inconsistencies in data. Can you confirm that IHEs do not have to amend if the report is already submitted and would not be expected to re-report the item in outlier years? If so, will this be one of the FAQs for future reference?**

   NSF Response: NSF confirms that IHEs that prepared their FFDR disclosures based on the previously issued guidance for multiyear gifts or contracts do not need to amend their FFDR submissions to reflect the new guidance. When NSF reviews the 2024 FFDR disclosures, NSF understands that the IHEs prepared their responses based on NSF guidance that evolved, but for 2025 and future FFDR submissions, NSF would expect that IHEs use the new guidance for multiyear reporting. NSF will create an FAQ on this topic to remind IHEs of the new multiyear reporting requirements.

Additionally, as reported above, NSF continues to seek feedback from the community and, as such, is evaluating the July 31 due date for the FFDR report. The consensus from COGR committees is that most institutions believe that September 30 would be easier to manage. NSF indicated that changes to the FFDR process will be included in the PAPPG 25-1, and the community will have an opportunity to comment (as with other PAPPGs). COGR will continue to follow this matter.

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

As previously reported (see July 2024 COGR Update), COGR and other higher education associations met with DOE representatives on July 1, and DOE advised that it was contemplating the adoption of a risk assessment and mitigation process similar in nature to the process currently employed by DOD. Recently COGR joined a multi-association request to DOE's Research, Technology, and Economic Security (RTES) for full engagement with the research community prior to implementation of risk matrices. The letter encouraged DOE to engage with the community and offer a formal comment period prior to implementing the new research security review processes. COGR will continue to follow this topic and update the community accordingly.

Research Security & Intellectual Property (RSIP)

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

DOD Notice of Proposed Rulemaking to Amend the Solicitation Provision at DFARS 252.209-7011 (NEW)

In compliance with Sections 1044 and 1045 of the National Defense Authorization Act for Fiscal Year 2024 (NDAA for FY 2024), the US Department of Defense (DoD) issued a Notice of Proposed Rulemaking (DFARS CASE 2024-D023) on August 15, 2024. Section 1044 of the NDAA for FY 2024 revises the definition of "Confucius Institute" by adding "any program that receives funding or support from the Chinese International Education Foundation, the Center for Language Exchange Cooperation of the Ministry of Education of the People's Republic of China" to the definition established in Section 1062 of the National Defense Authorization Act of Fiscal Year 2021 (NDAA for FY 2021). A "Confucius Institute" was originally defined in Section 1062 as "a cultural institute funded either directly or indirectly by the Government of the People's Republic of China".

In addition to expanding the definition of a Confucius Institute, DFARS CASE 2024-D023 adds a final date to Section 1062 (b) of the NDAA for FY 2021 for the authority of the DoD Office of the Under Secretary of Defense for Research and Engineering to issue a waiver to an institution of higher education hosting a Confucius Institute to receive DoD funding.

USPTO Issues Request for Comments on Experimental Use Exception (NEW)

The United States Patent and Trademark Office (USPTO) issued a Request for Comment (89 FR 53963) on June 28, 2024 seeking public input on whether legislative action should be taken to enact a statutory experimental use exception for patent infringement. The exception to patent infringement is generally limited to actions performed by the potential infringer that are for scientific inquiry and non-commercial. Based on common law determination, there is little guidance on the precise scope of the experimental use exception with the burden of proof being born on the defendant.

Legislative action could potentially harmonize the United States with many other European and Asian jurisdictions that have statutorily defined experimental use exceptions; thereby, potentially limiting a defendant's uncertainty when invoking the exception. After careful consideration, COGR decided not to submit comments to the UPSTO. Comments were due September 26.

BIS Issues Two Notices of Proposed Rulemaking (NEW)

On July 29, 2024, the Bureau of Industry and Security (BIS) issued the Notice of Proposed Rulemaking "End-Use and End-User Based Export Controls, Including U.S. Persons Activities Controls: Military and Intelligence End Use and End Users" (BIS-2024-0029). COGR endorsed the comments submitted by the Association of University Export Control Officers (AUECO). In the comments, BIS was encouraged to maintain the explicit exclusion for routine academic activities in the definition of "support" as proposed in section 744.6(a)(1)(ii)(A).

It was also requested that BIS consider ways to narrow and clarify the meaning of Military-Support End User or otherwise provide guidance in determining whether an organization is subject 15 CFR 744.22.

Concurrently, BIS issued a second NPRM "Crime Controls and Expansion/Update of U.S. Persons Controls" (BIS-2023-0006). COGR supports BIS efforts to develop additional controls to safeguard against violations of privacy from unjust government surveillance. In endorsing AUECO's comments submitted to BIS, COGR wholeheartedly supports the request for clarity in the definition of both Foreign-Security End Users (FSEUs) as well as in the definition of analytic and data centers.

DDTC Notice of Proposed Rulemaking (NEW)

On July 29, 2024, the United States Department of State issued the NPRM (89 Fed. Reg. 60,980) that seeks public comment on revisions to the definition of "defense services and the scope of related controls in the International Traffic in Arms Regulations". COGR endorsed the comments submitted by the Association of University Export Control Officers (AUECO) and fully supports its requests for clarification and the recommendations outlined in the letter.

Invent Here, Make Here Act (UPDATE)

As originally discussed in the February 2023 COGR update, the "Invent Here, Make Here Act" was passed as part of the FY23 NDAA and was limited to DHS programs. The text of the Act, co-sponsored by Sens. Baldwin (D-WI) and Portman (R-OH), mostly duplicated existing requirements in the Bayh-Dole Act. An expanded version of the Act has been introduced to include all federal agencies and may be part of this year's NDAA process. We will keep the membership posted on new developments.

Costing and Financial Compliance (CFC)

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

Changes to OMB Guidance Impacting F&A Cost Rates and Accrued Leave Payouts: COGR Continues to Advocate for Practical Solutions (ONGOING)

The COGR membership remains concerned about how and when changes to equipment capitalization and subaward thresholds impacting the facilities and administrative (F&A) cost rate can be implemented. As described in COGR's Fifth Look: Implementation and Readiness Guide for the OMB Guidance for Federal Financial Assistance, threshold changes that impact F&A cost reimbursement and compliance with federal award requirements are complicated by timing issues and system constraints. Institutions face challenges with multiple dates to consider (new or amended F&A cost rate date, new sponsored project proposal date, new award date, new subaward date, etc.) and many will struggle to navigate these dates while complying with financial accounting requirements to align equipment thresholds across all entities within a system and/or state. COGR is concerned as it has heard that the cognizant agencies for cost, DHHS Cost Allocation Services (CAS) and DOD Office of Naval Research (ONR) Indirect Cost Branch, do not intend to provide flexibility to reopen executed predetermined rates. The opportunity to finalize provisional rates or extend rates using the new thresholds may vary by cognizant agency, or even by branch. COGR will continue to discuss with OMB, CAS, and other

stakeholders the impracticality of implementing compliantly given the various dates to be considered and local system constraints, unless institutions are provided with some flexibility and protection.

Allowable reimbursement for payouts of accrued time-off at the end of employment, either as a direct, cash-based charge or through inclusion of a factor in the fringe benefit rates, is also addressed in the Fifth Look. §200.431Compensation – Fringe Benefits was revised to state that entities using the cash basis of accounting must allocate those payouts as a general administrative expense and some CAS officials indicated that inclusion in the fringe benefits rate was not an accrual basis of accounting. OMB issued a technical correction (to be published in the Federal Register October 1, 2024), stating that it, "inadvertently removed the option to include these payments in a fringe benefit rate under any circumstances." The revised language is:

> § 200.431 Compensation – fringe benefits.
>
> * * * * *
>
> (b) ***
>
> (3) ***
>
> (i) When a recipient or subrecipient uses the cash basis of accounting, the cost of leave is recognized in the period that the leave is taken and paid for. Payments for unused leave when an employee retires or terminates employment are allowable in the year of payment and should be allocated as a general administrative expense to all activities or included in the fringe benefit rate.
>
> * * * * *

Further, OMB's explanation for the correction calls out the replacement of "must" with "should" and that "Paragraph (b)(3)(i), as revised, continues to describe the two options that will generally be used for these types of payments under subpart E." COGR interprets this to mean there might be other allowable options, such as a direct charge at the time of payment but with a lookback to ensure the amount of such a payout allocated to federal awards is reasonable in comparison to the individual's salary allocation when the time off was earned.

COGR will continue to advocate for solutions that are equitable for all institutions and that do not create new administrative burden, including protection such as that found in the FAQs applicable to the original issuance of Uniform Guidance. "Effective Dates and Federal Awards Made Previously - Non-Federal entities wishing to implement entity-wide system changes to comply with the Uniform Guidance after the effective date of December 26, 2014, will not be penalized for doing so." COGR staff is scheduled to meet again with OMB and will engage other federal officials, as necessary.

CAS Requirement to Adjust F&A Cost Pools (NEW)

COGR has learned of a new development that indicates CAS again is expected to remove from F&A cost pools the portion of salary costs exceeding the Executive Level II salary cap (often referred to as the NIH cap but also applicable to other HHS agencies).

Last October, COGR members reported learning of this requirement during negotiation of their F&A cost rates with CAS. This new requirement was based on a finding in an HHS Office of Inspector General (OIG) report,

Cost Allocation Services Needs to Update its Indirect Cost Rate Setting Guidance (see p. 23, Indirect Cost Rate Proposals Included Potentially Unallowable Compensations Costs). COGR elevated its concerns to the HHS Office of Grants and understands that office communicated with the Program Support Center (PSC), to which CAS reports. In the February 2024 COGR Update, we reported that CAS informed members it would not require an adjustment to the F&A cost pools until receiving notice from the HHS Office of Grants. As reported in subsequent updates, there has been no communication from federal officials on the status of the issue.

In recent weeks, however, CAS has unofficially commented that it has been informed that the HHS Office of General Counsel has opined that the salary cap was always applicable to all salaries (direct and indirect) charged to awards subject to the cap. In reengaging with the HHS Office of Grants and the PSC, COGR learned that PSC and CAS were awaiting an official communication from HHS Office of Grants, as PSC and CAS do not set policy. Subsequently, HHS made available its October 2024 Grants Policy Statement, in which the section on the Salary Rate Limitation (SRL) includes, *"The HHS SRL applies to: • The majority of HHS awards. • Both direct and indirect costs under applicable HHS awards. Effective October 1, 2024, when HHS is the cognizant agency for indirect costs or when HHS is acting as the shared-service provider for another cognizant agency for indirect costs, the HHS component that reviews and negotiates indirect cost rate proposals and cost allocation plans will issue NICRAs that incorporate the HHS SRL, to comply with the HHS Appropriations Act requirement."*

In COGR discussion with OMB, OMB confirmed that this is a legal issue, not a policy decision. COGR will continue to follow this issue alongside AIRI (Association of Independent Research Institutes), which represents non-profit research institutions that would be disproportionately impacted by implementation of this requirement. We also understand, however, that this will likely create unreasonable administrative burden for the COGR membership (e.g. salary cap changes in effect after the date of the negotiated F&A cost reimbursement rate).

Please contact Cindy Hope, chope@cogr.edu, if you receive instructions to adjust F&A cost pools for the salary cap or any other related information.

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

During the October Membership Meeting, leaders of the Costing and Financial Compliance (CFC) Committee will present observations and findings from the F&A Capstone Report – an upcoming COGR report including analysis of F&A cost rate trends and other observations related to F&A cost rates and reimbursement. One hundred twenty COGR institutions completed the F&A survey in 2023, and the F&A Capstone is the final product of this initiative. The presentation will be based on the "final draft" version of the F&A Capstone, and the final version is expected to be available to the COGR membership before the end of the calendar year.

The three reports currently available from the 2023 F&A Survey Report page (login required) are:

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

The Summary of Responses report contains charts and graphs documenting the results of the 120 institutional survey responses and addresses topics such as methodologies used in F&A proposals, negotiation experiences, institutional resources committed to the F&A process, and other areas of interest. These reports are meant to be used for institutional purposes only and should not be shared beyond the institution.

Threats to F&A Cost Reimbursement (ONGOING)

In previous updates, May 2024 Update (p. 19), and July 2024 Update (p. 22), we reported on legislative attempts to eliminate or further cap F&A costs reimbursement. For example, the *No Subsidies for Wealthy Universities Act*, is a bill targeting universities with endowments over $2 billion but also capping reimbursements for all other universities. While it appears unlikely to advance, and COGR is unaware of any other imminent legislative threat, we continue to work with our colleague associations to dispel myths and combat misinformation. Our efforts are aimed at informing policymakers and others of the required process research institutions must follow to receive reimbursement of F&A costs and the activities and costs necessary to support research (or even for research itself).

In addition to considering how best to revitalize previous COGR publications, Finances of Research Universities (June 2014) and Excellence in Research: The Funding Model, F&A Reimbursement, and Why the System Works (April 2019), we are working with AAU, APLU, AAMC, and AIRI to update existing F&A educational materials and develop more effective communications. COGR recommends reviewing your institution's websites and other communications that include information about F&A costs and ensuring they are up-to-date and accurately refer to F&A cost payments as reimbursements, not a source of revenue.

COGR will continue to keep the membership posted on new developments.

Federal Offices of Inspectors General (OIG) Audit Plans and Reports (REMINDER)

COGR members are encouraged to follow the audit activity of relevant Offices of Inspectors General (OIGs) including the HHS OIG Workplan, as well as completed reports posted under All Reports and Publications (select by HHS Agency). Of note is the August 2024 item added to the workplan, Audit of NIH Other Transactions Award Recipients' Costs.

The NSF OIG also makes available its Annual Audit Workplans and the NSF OIG Reports & Publications page lists recently completed reports. Further, the NSF Management Responses to External Audits is a helpful resource for reviewing NSF OIG audit resolutions. For example, NSF OIG findings that institutions applied new, lower Negotiated Indirect Cost Rate Agreement (NICRA) established rates to awards subject to higher rates included in the NICRA in effect as of the date of the awards were not sustained in audit resolution. The Resolution and Advanced Monitoring Branch, instead, classified the reimbursement difference as voluntary uncommitted cost sharing.

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.

2024 OMB Compliance Supplement is Available (REMINDER)

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

NSF 2022 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). This information is frequently used by COGR in its advocacy for equitable cost reimbursement regulation, policy, and practice. Release of fiscal year 2023 survey result is expected in November.

Please contact Cindy Hope at chope@cogr.edu to discuss any of the issues above, or other Costing and Financial Compliance topics.

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.

NSF Revision of NSF Award Terms and Conditions (NEW)

On August 28, 2024, NSF announced the release of updated Award Terms and Conditions to implement the 2024 revisions to 2 CFR (Uniform Guidance) in the Federal Register. Additionally, NSF announced that the federal-wide Research Terms and Conditions (RTC) and NSF Agency Specific Requirements are archived effective October 1, 2024. The updated Grant General Conditions (GC-1) will apply to all NSF grants and cooperative agreements with budget periods beginning on or after October 1, 2024. As indicated by NSF, the updated suite of award terms and conditions includes:

- Grant General Conditions (GC-1)
- Cooperative Agreement Financial & Administrative Terms and Conditions (CA-FATC)
- 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
- Cooperative Agreement Modifications and Supplemental Financial and Administrative Terms and Conditions for Mid-Scale Research Infrastructure Projects
- Special Terms and Conditions for Administration of NSF Conference or Travel Grants (FL 26).

A summary of changes is provided in the document, including the following notable changes:

- **Recipient Responsibilities and Federal Requirements**: Clarified that GC-1 applies to all recipients unless otherwise specified and recipients must notify NSF of significant developments impacting awards between reporting dates.
- **Prior Approval Requirements**: Specific information on flow down provisions removed, and prior approval requirements consolidated in one section.
- **Participant Support Costs**: Updated with the revised definition of participant support costs as per 2 CFR § 200.1.
- **Equipment**: Revised in accordance with 2 CFR § 200.313 to clarify specifics on acquisitions and inventory information.
- **Allowable Costs**: Expanded to reference applicable cost principles for IHEs and non-profits.
- **Payments**: Emphasizes timing requirements for payments as per 2 CFR § 200.305.
- **Project Reporting Requirements**: Updates include addressing significant developments between reporting periods and the switch to SAM.gov for integrity and performance tracking.
- **Responsible and Ethical Conduct of Research**: Incorporated into GC-1 and applies for IHEs only.
- **Reporting Subawards and Executive Compensation**: Reflects revised terms from Appendix A to Part 170.
- **System for Award Management (SAM.gov) and Universal Identifier Requirements**: Reflects revised terms from Appendix A to Part 25.
- **Academic Technology Transfer and Commercialization of University Research**: Incorporated into GC-1 and applies for IHEs only.
- **Copyrighted Material**: The term "nontransferable" has been deleted and updated royalty-free license rights for consistency with 2 CFR part 200.
- **Program Income**: Full definition from 2 CFR § 200.1 added for clarity.
- **Intangible Property**: Links to NIST Bayh-Dole Regulations and waiver forms added.
- **Audit and Records**: Updated with access requirements from 2 CFR § 200.337.
- **Termination and Enforcement**: Updated for consistency with revised 2 CFR 200 suspension and termination requirements.
- **Whistleblower Protection**: Incorporates 41 U.S.C. § 4712 requirements for greater transparency.
- **Build America, Buy America**: Aligned with 2 CFR part 184.
- **Foreign Financial Disclosure Report (FFDR) (CHIPS and Science Act of 2022)**: Incorporated into GC-1 and applies for IHEs only.
- **Resolution of Conflicting Conditions**: Specifies that 2 CFR governs if GC-1 is silent on an issue and establishes an order of precedence for resolving inconsistencies between 2 CFR (including part 200) and the NSF Proposal and Award Policies and Procedures Guide (PAPPG).
- **National Policy Requirements for Recipients of NSF Awards**: Revised to list only the national policy requirements applicable to NSF grants and renamed accordingly.
- **Prior Approval Matrix**: Updated for consistency with revised 2 CFR part 200, now only listing requirements relevant to NSF grants and renamed the NSF Prior Approval Matrix.

A recording of NSF's webinar on September 12, 2024, covering the revisions, is available as part of the 2024 Policy Office Webinar Series.

COGR is closely monitoring concerns from the community about the archiving of the federal-wide RTC. COGR intends to raise this issue with federal agencies, underscoring the essential role that federal-wide RTCs play in standardizing terms and conditions across agencies. Additionally, COGR will advocate for the reengagement of the interagency RTC workgroup to update and reinstate the RTCs.

HHS Adopts New Rules for Federal Financial Assistance (2 CFR Part 200) and Publishes Updated Grants Policy Statement (GPS) to Make Grants More Accessible and Transparent (NEW)

On September 27, 2024, HHS announced the release of an updated Grants Policy Statement (GPS) Award Terms and Conditions to implement the 2024 revisions to 2 CFR (Uniform Guidance) in the Federal Register. The GPS is effective for applications under discretionary grant programs, awards, and award modifications that add funding made on or after October 1, 2024, including supplement awards and competing and non-competing continuations. The GPS replaces the HHS Grants Policy Statement dated January 1, 2007, and is a notable update. Institutions with HHS awards are encouraged to review.

NIH RFI on Recommendations on Re-Envisioning U.S. Postdoctoral Research Training and Career Progression Within the Biomedical Research Enterprise (NEW)

On July 29, 2024, the National Institutes of Health (NIH) released a follow-up Request for Information (RF), Document Number: 2024-16649 (89 FR 60907). The NIH is seeking input from the research community to inform the implementation of recommendations from the Advisory Committee on Re-envisioning NIH-Supported Postdoctoral Training. The goal is to gather feedback on how to enhance the postdoctoral experience and better align training with evolving career paths in the biomedical research field. Comments are due on October 23, 2024, and can be submitted electronically here.

COGR is currently reviewing the RFI for potential comments and welcomes input from the community. Those interested in providing feedback can reach out to Krystal Toups at ktoups@cogr.edu.

NASA Biosketch and Current and Pending Support Disclosure Policy (UPDATE)

As previously reported (see COGR July 2024 Update), on June 28, 2024, the National Aeronautics and Space Administration's (NASA) Grants Policy and Compliance (GPC) in the Office of Procurement published a request seeking comment on the Agency's forthcoming policy on disclosures made in grant applications and annual certifications. COGR submitted comments in response to the request, emphasizing the importance of standardizing NASA's Biosketch and Current and Pending Support Disclosure Policy with the National Science and Technology Council (NSTC) common disclosure forms, with no deviations. The document advocates for the adoption of NSTC common forms to ensure uniformity, reduce administrative burden, and facilitate compliance across federal research agencies. COGR's Director and Chair for the Contracts and Grants Committee had an opportunity to meet with NASA policy staff at their request to underscore issues highlighted in COGR's letter and the need for consistent standards across federal research agencies to ensure effective implementation and compliance.

On September 5, 2024, NASA published Grant Notice (GN) 24-01, announcing on October 1, 2024, NASA will release a revised *Grant and Cooperative Agreement Manual (GCAM)*. The revised GCAM will consolidate the

Grant and Cooperative Agreement Manual (GCAM) and the Proposer's Guide. The revised GN 24-01 will implement the updated Biographical Sketch and Current and Pending (Other) Support policy. The updated disclosure requirements will apply to new grant and cooperative agreements awards and funded amendments issued on or after October 1, 2024.

NASA will make the updated forms available on its Grants Policy and Compliance website.

NIH Public Draft Public Access Policy (UPDATE)

COGR previously reported and commented on NIH's plan for public access. On June 19, 2024, NIH published a request for information (RFI) in the Federal Register, the NIH Draft Public Access Policy. The policy will apply to any Manuscript accepted for publication in a journal on or after October 1, 2025. NIH solicited comments from the public on the draft policy and two supplemental draft guidance documents regarding government use licenses and rights and costs for publications. COGR joined a multi-association response on the draft policy posted here.

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

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

SAM.gov (ONGOING). As reported in September 2023, February 2024, and March 2024, and the presentation Overview of System for Award Management (SAM) Registration Process – Challenges & Tips, COGR is actively engaged with GSA on the challenges members report with SAM.gov renewals/registration. COGR continues to engage federal officials, including OMB, on the concerns of the community and will keep the COGR membership updated on all developments. Please contact Krystal Toups at ktoups@cogr.edu if your institution is experiencing challenges or has comments or concerns related to SAM.gov registration.

NIH Data Management and Sharing (DMS) (UPDATE). NIH published NOT-OD-24-123 announcing changes planned to the Research Performance Report (RPPR) instructions to address DMS. NIH will implement then new questions for the RPPRs submitted on or after October 1, 2024. For more information on the updated process, see this recent post from NIH. CGA will continue to follow this topic.

Research Environment (ONGOING). CGA has been closely following developments related to the NSF OIG Review of award recipient compliance with NSF's harassment policies. As part of the FY 2024 Annual Audit Work Plan, NSF will assess whether the policies and procedures at a sample of 100 NSF-funded institutions comply with NSF's harassment terms and conditions. CGA has gathered preliminary information on common themes and observations of the review. CGA has sent a list of clarifying questions to NSF OIG concerning expectations of the findings of the report for NSF and the community, the anonymity of the 100 institutions selected for the review, availability, and expectations of the document *NSF's Promising Practices Harassment Guidance* cited in the review as a criteria but not accessible to the community, and a criteria of the review to mirror NSF language exactly in institutional policies and subaward agreements. In response to our questions, NSF OIG scheduled an exit meeting with the 100 institutions included in the review. Additionally, COGR staff met with OIG (see section above in Science & Security: Cross-Cutting Issues). The NSF OIG anticipates that it will

publish the report by the end of 2024. CGA will continue to follow this topic. Feel free to contact Krystal Toups at ktoups@cogr.edu for any questions.

Research Ethics & Compliance (REC)

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

Office of Research Integrity Final Research Misconduct Rule (NEW)

The Office of Research Integrity (ORI) has published its new Research Misconduct regulations, which make significant updates to the 2005 Research Misconduct Rule. [42 C.F.R. Part 93]. At the end of 2023, COGR worked with the Association of Research Integrity Officers (ARIO) to develop responsive comments, which each association submitted separately. [COGR's comments can be found at this link.]. COGR and ARIO encouraged other associations and institutions to submit comments, and ORI received 269 comment letters in total. ORI considered these comments and revised the NPRM to address the vast majority of concerns raised by associations and institutions. These revisions resulted in a new rule that will continue to provide for robust review of allegations of research misconduct, while making implementation easier for institutions.

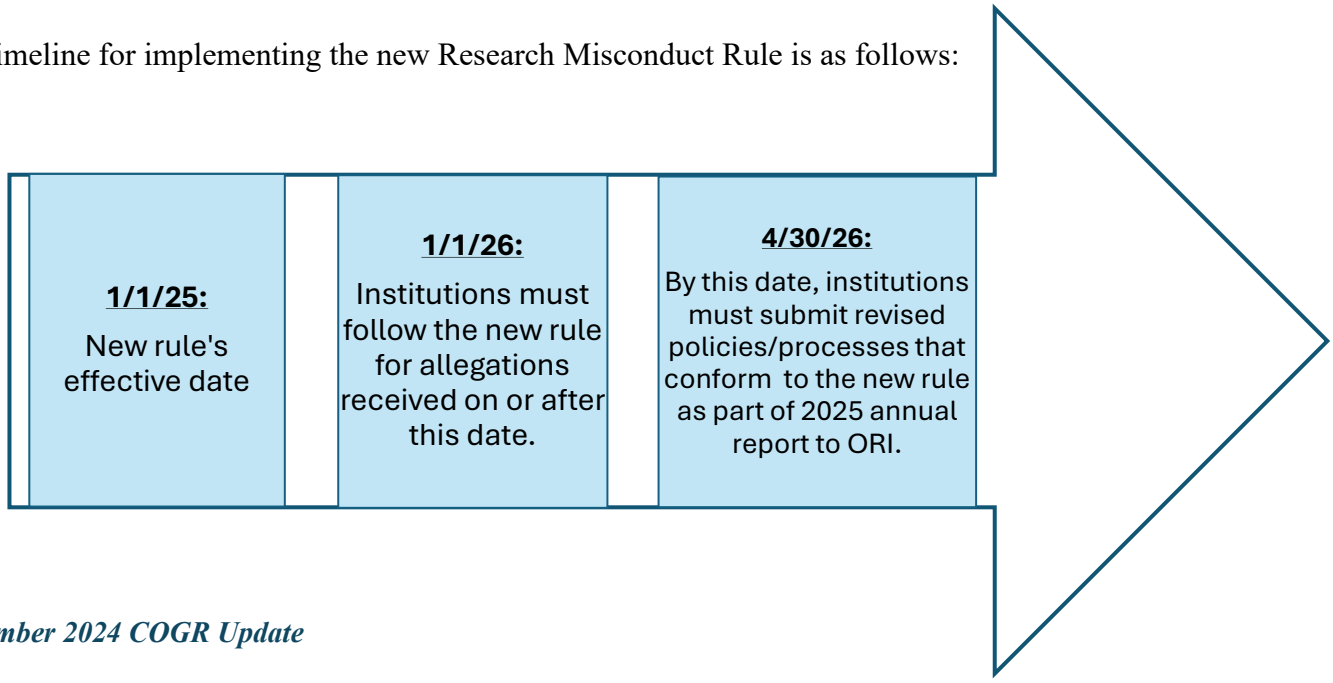
In its comment letter, COGR identified four broad areas of concern, and suggested specific modifications to the NPRM to address them. The resulting revisions to the new rule are summarized below under each category of concern. [We note, that in several cases, ORI implemented revisions that include regulatory language suggested in the COGR response letter.]

- **Broad NPRM Concern**: Inappropriate Limits on Institutional Authority During Pre-Investigative Review Process
- **Outcomes in Final Rule**:
  - "Assessment" definition retained but the new rule contains a clear statement that assessment only involves review of readily accessible information relevant to the allegation(s). [§93.204]
  - Eliminated automatic advancement to inquiry if an assessment is not completed in 30 days. [§93.306].
  - Eliminated requirement for a formal assessment report, BUT the institution must retain documentation of the assessment, which ORI may review even if the institution does not proceed to inquiry. [§93.306].
  - Eliminated prohibition of consideration of honest error and difference of opinion at the inquiry stage. [§93.307(g)].
- **Broad NPRM Concern**: Transition from Peer-Driven to Prosecution Focused Review Process; Lack of Flexibility
- **Outcomes in Final Rule**:
  - Eliminated requirement for unanimous decision at investigation.
  - Eliminated requirement to inform ORI before an institution can determine that the subsequent use exception does not apply; HOWEVER, an institution must document its determination. [§93.104]
  - Eliminated prohibition on split decisions at investigation. [§93.313]

- Eliminated requirement that an institution document its determination that certain sequestered records are not relevant/duplicative and include these documents in index; HOWEVER, the institutional record must still include a "general description" of sequestered records that were not considered or relied on. [§93.220]
- Eliminated requirement for transcribing interviews at assessment & inquiry.
- Extends inquiry period from 60 to 90 days and retains the NPRM's 180-day period for investigations (increased from 120 days in the 2005 Rule). [§§93.308, .311]
- Removed time constraints on the institution's appeal process; affirmed institutional appeals are within institution's purview; advised that the institutional record need not be sent to ORI until any institutional appeal is concluded. [§93.315].

- **Broad NPRM Concern**: Increased Complexity and Confusion and Inadequate Confidentiality Protections
- **Outcomes in Final Rule**:
  - Clarified/simplified many proposed definitions and eliminated several unnecessary definitions.
  - Eliminated requirement that prime awardees are responsible for subrecipients' assurances. [§93.102].
- **Broad NPRM Concern:** Inadequate confidentiality protections for Respondent
- **Outcomes in Final Rule re. Additional Confidentiality and Other Process Protections for Respondent:**
  - Maintained burden of proof requirements and adverse inference from failure to provide research records (with some modifications). [§93.105].
  - Maintained requirement to restore reputation of respondent against whom there are no findings. [§93.304].
  - Clarified confidentiality "period"; made clear journals/editors/publishers may have a "need to know"; made clear institutions can correct the research record; and eliminated subsection regarding need-to-know disclosures to third party institutions prior to a finding of research misconduct. [§93.106].
  - Eliminated provision that would have permitted ORI to publish institutional research misconduct findings & actions.

The timeline for implementing the new Research Misconduct Rule is as follows:



Note that for allegations received in the interim period between the new rule's effective date of January 25, 2025, and the required implementation date of January 1, 2026, an institution and respondent may enter into a written agreement to apply to the new rule to such allegations.

REC will further analyze the new rule and develop additional materials to assist institutions in their implementation of its requirements.

COGR Response to Department of Energy (DOE) NPRM on Financial Assistance Regulations - Conflict of Interest and Conflict of Commitment Policy Requirements (UPDATE)

On August 16, 2024, COGR, AAU, and APLU submitted a joint comment letter to DOE on its NPRM on conflict of interest (COI) and conflict of commitment (COC) policy requirements for institutions. COGR's July 2024 update contains a summary of the NPRM. The comment letter expressed the following two primary concerns with the NPRM:

(a) Development of a Stand-Alone COC Policy: The NPRM calls for institutions to develop a stand-alone COC policy. The comment letter noted that DOE's present current and pending support and biosketch disclosure requirements and its upcoming implementation of the Common Disclosure Forms already address COC issues. Accordingly, requiring institutions to adopt a separate COC policy is duplicative and disregards the harmonized approach to COC requirements advocated by NSPM-33 and the NSTC Research Security Subcommittee, of which DOE is a member. The letter also noted that currently no other federal research funding agency requires institutions to have a separate COC policy, relying instead on the current and pending support/biosketch disclosure requirements.

(b) Abandoning the Interim DOE COI Policy: The Interim DOE COI Policy was expressly patterned after the PHS COI Regulations at 42 CFR Part 50, Subpart F to promote cross-agency harmonization and ease implementation burden. The NPRM abandoned this approach, and instead proposed a rule that differed in several key respects from the PHS COI Regulations. This approach would require institutions to develop and implement substantially different COI policies, processes, and training to achieve compliance and create confusion among researchers.

The joint comment letter urged DOE to retain its interim COI policy instead of moving ahead with the NPRM and suggested several improvements to provisions in the interim COI policy for consideration. This approach would enable institutions to continue to leverage their current COI policies/processes initially developed in response to PHS requirements in 2012, as well as promote cross-agency consistency in this area which improves compliance and reduces implementation burden.

NIH NOT-OD-24-157 Implementation Update for Data Management and Access Practices Under the Genomic Data Sharing Policy (Jul. 25, 2024) (NEW)

NIH issued this notice to announce changes designed to modernize "security standards provided in the NIH Security Best Practices for Controlled-Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy, and establish "minimum expectations for access to controlled-access data by developers." The requirements in the notice become effective on January 25, 2025.

Under the modifications, users of NIH controlled-access data under the GDS Policy, must attest that their institutional IT systems and any third-party systems that they use for data analysis and storage are compliant with NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations. Non-U.S. users that cannot attest to NIST SP 800-171 may alternatively attest to compliance with ISO/IEC 27001/27002.

NIH controlled-access data repositories that provide access to or long-term storage of human genomic data covered by the GDS Policy must attest that they have implemented the following data security standard:

- NIST SP 800-53 Moderate baseline. [The notice states that "compliance with "FedRAMP Moderate or FISMA Moderate satisfies implementation of NIST SP 800-53 Moderate baseline controls."]

If a third-party IT system or cloud storage provided (CSP) is used, then the institutions must attest that such systems comply with these standards.

In addition to implementing these security standards, the notice also establishes a new Developer Use Statement (DUS) requirement that "Lead Developers" who accesses GDS-covered data must provide. All Lead Developers, individuals they directly supervise, and their institutions must agree to abide by the terms of the DUS. For extramural research, PIs and PDs are considered "Lead Developers." The notice states that "developer work" includes "testing platforms, pipelines, analysis tools, and user interfaces that store, manage, and interact with human genomic data from NIH controlled-access data repositories, as well as providing infrastructure development and repository maintenance, but does not include research (e.g., methods development)."

Lead Developers will be expected to provide executed DUS to the NIH's Developer Data Access Committee no later than "just-in-time." Each DUS must include the following elements:

- Justification for access.
- Intended activities.
- If activities include repository management, attest that the developer will adhere to NIH Security Best Practices for Users of Controlled-Access Data and list the standard being implemented.
- If using third-party software or a CSP, provide the name of the software/CSP, attest to its compliance with NIH Security Best Practices, and list the standard followed.
- Acknowledge that institution, Lead Developer, and individuals directly supervised by the Lead Developer will adhere to the requirements of the DUS and any other NIH requirements.
- If the Lead Developer works with a developer partner that is not funded by NIH, they must provide the partner's (and their institution's) names, and the Lead Developer and developer partner must enter into a contract agreeing to the DUS requirements.

NSF RFI on Research Ethics (NEW)

NSF published a Request for Information on the CHIPS and Science Act Section 10343. Research Ethics. NSF Program Director the Ethical and Responsible Conduct of Research Jason Borenstein joined REC at its September 10, 2024, meeting to discuss the RFI and encourage COGR and institutions to submit comments. The RFI was

developed in response to the CHIPS Act Section 10343's mandate to NSF to incorporate: "'ethical, social, safety, and security considerations' into the agency's merit review process and to develop strategies for mitigating the potential harms of scientific research and amplifying societal benefits from such research."

The RFI poses several broad on general considerations as to how NSF should consider ethical, safety, and security considerations in the proposal and review process (e.g., be included in instructions to proposers and reviewers and considered as part of the criteria for research design), and what NSF should do to address these issues. Dr. Borenstein advised that NSF is seeking input from the STEM community on how to define "security," as well as any other terms for which the federal government does not currently have established definitions. NSF is also seeking stakeholder input on how to identify foreseeable and quantifiable risks to society as research proceeds.

REC has assembled a working group to develop comments. In its comments, REC will encourage NSF to leverage existing systems and principles that consider ethical principles and assess risk. REC will also encourage NSF to identify overlap with existing requirements (e.g., the Broader Impacts Statement), and how existing requirements can be modified to capture additional risk/benefit information. Comments are due November 15, 2024.

Framework for Nucleic Acid Synthesis Screening (UPDATE)

Institutions should take note that the OSTP Framework for Nucleic Acid Synthesis Screening ("Framework"), which "outlines a unified process for screening purchases of synthetic I acids [SNAs] and benchtop nucleic acid synthesis equipment ["SNA Equipment"], will begin to take effect on Oct. 26, 2024. By that date, if federal funds are used to procure SNAs or SNA Equipment, federal funding agencies will require that the "Providers" and "Manufacturers" of these items adhere to the following requirements for screening purchases for sequences of concern (SOCs) and take steps to assure the legitimacy of customers:

- Attest to following the Framework via a statement on public website or provided to federally funded customer and federal funding agency.
- Screen purchase orders for SNAs to identify SOCs in accordance with the Framework's applicable screening requirements (see discussion below).
- Screen customers submitting purchase orders of SNAs with SOCs and purchase orders of SNA Equipment to verify legitimacy and report potentially illegitimate purchase orders.
- Retain records regarding purchase orders for SNAs and SNA Equipment.
- Take steps to ensure cybersecurity and information security.

The Framework will apply to the distribution of SNAs by Providers and Manufacturers, and these parties must also ensure that the Framework is followed by any third-party vendor or intermediary.

The Framework will have a notable impact on academic labs and core facilities because "Providers" are defined to include certain "non-traditional" providers, including:

- **Core Facility/Academic Core Facility**: "An institution-based capability that either facilitates orders to third parties or that has in-house equipment intended to provide services to faculty and research staff at that university or others and not otherwise to customers from the general public (e.g., the ability to create nucleic acid sequences de novo from benchtop synthesizers)."

- **Cloud Lab**: "A highly automated research laboratory possessing a diversity of analytical and synthesis capabilities across the life sciences and that can be remotely operated by specifying experimental protocols via software."

In addition to expanding the definition of "Providers," the regulations also substantially increase the requirements for screening SNAs for SOCs post-October 13, 2026. Prior to that date, the Oct. 2023 HHS Screening Framework Guidance for Providers and Users of SNAs require the screening of "DNA or RNA, single- or double-stranded, 200 nucleotides (nt) or longer." After October 13, 2026, the size of the screening window will be reduced to 50 nucleotides, and the following criteria must be considered in determining SOCs:

- "Scientific evidence establishing that the sequence contributes to pathogenicity or toxicity in humans and animals."
- "Degree to which this sequence is likely to be recognized as a candidate for misuse, based on the extent to which its function is widely known."
- "Ease with which this sequence could be misused, for example through de novo assembly of a pathogen or insertion into a backbone."

These changes are part of a larger framework of changes to biosafety/biosecurity requirements for federally funded research that will impose additional burden on biosafety committees and biosafety officers. As noted in COGR's July 2024 Update, in May 2025, there will be major changes to the requirements for the review of Dual Use Research of Concern (DURC) and the review of Pathogens with Enhanced Pandemic Potential (PEPP) per the requirements of OSTP's May 2024 DURC PEPP Policy and Implementation Guidance. NIH is anticipated to issue an RFI concerning these new requirements on which COGR expects to offer comments.

Recent FDA Guidance Documents Regarding Decentralized Clinical Trials (NEW)

The COVID pandemic demonstrated the need for institutions to consider conducting clinical trials in non-traditional settings outside the facilities of academic medical centers. The FDA recently issued two guidance documents that provide recommendations for the design and conduct of these trials:

FDA Final Guidance on Conducting Clinical Trials with Decentralized Elements: This guidance document contains recommendations for clinical trials that incorporate remote locations, telehealth visits, and digital health technologies to transmit trial data.

FDA Draft Guidance on Integrating Randomized Controlled Trials for Drug and Biological Products into Routine Clinical Practice: This document provides recommendations for clinical trials that involve participants' local health care professionals performing certain clinical activities apart from routine care and providing data from those activities.

Appendix A – Upcoming Comment Due Dates

Agency	Description	Due Date	Notes
NIH	**Request for Information (RFI) on Recommendations on Re-Envisioning U.S. Postdoctoral Research Training and Career Progression Within the Biomedical Research Enterprise**	October 23, 2024	COGR is reviewing RFI for potential comment.
NSF	**Request for Information on the CHIPS and Science Act Section 10343. Research Ethics**	November 15, 2024	COGR is developing comments.

COGR would like to thank COGR Board Chair (Naomi Schrag, Columbia 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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