COGR

Advancing Effective Research Policy

NOVEMBER 2024 UPDATE

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President's Message

Advancing Effective Research Policy

Dear Colleagues,

"Advancing Effective Research Policy" is COGR's new tagline. It crystallizes the association's refreshed mission statement adopted by the Board of Directors this fall. "Advancing" especially captures the nature and spirit of our work. Research and innovation by their very nature are forward moving endeavors. Consequently, our work to positively affect research policy sustains this forward momentum. We believe our new logo helps convey this as we strive, as our mission states: "to empower an unparalleled U.S. academic research ecosystem by advancing sound federal policies and regulations that are vital to U.S. science and innovation leadership and our nation's health, security, and prosperity."

In addition to the refreshed mission statement and accompanying purpose and impact statements, the Board of Directors also took other noteworthy actions this fall, including:

- appointing Jeffrey Silber of Cornell University as the association's Treasurer, effective January 1, 2025;
- appointing Lisa Mosley of Yale University as the next chair of the Contracts and Grants Administration Committee, effective December 1, 2024,
- appointing Jeremy Forsberg of the University of Texas Arlington as the next chair of the Costing and Financial Compliance (CFC) Committee effective January 1, 2025,
- approving new member institutions, and
- discussing COGR's post-election advocacy strategy.

On the latter, with the elections now complete and a new administration and majorities in Congress on the horizon, we are developing an advocacy strategy for the year ahead. Like most recent elections, the 2024 election reinforced the volatility of our nation's politics, policy priorities, and governance. Regardless of political party, a new administration and changed and narrow majorities in Congress make for challenging policy and governing environments. There will be shifts and changes in policy priorities and the people leading the federal government. And there will be both policy opportunities and threats affecting research institutions. Accordingly, while our strategies and tactics may change to meet the moment, our focus on advancing effective research policy will not.

I wish to highlight a few important actions COGR has taken recently. First, COGR and ARIO launched a Survey of Research Integrity Officers on the Final ORI Research Misconduct Rule. Your institution's participation will greatly aid the usefulness of the results that will be aimed at aiding institutional implementation of the final rule. Second, COGR submitted comments on the HHS's Interim Final Rule on Adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements. As HHS and other agencies implement the updated Uniform Guidance, COGR will continue to advocate for the ability of research institutions to take advantage of the improvements as soon as possible. And third, we submitted comments to the Bureau of Industry and Security about an interim final rule on the implementation of controls on advanced technologies. We took the opportunity to commend BIS for its efforts to harmonize export regulations with international partners and to affirm our support for BIS preserving the fundamental research exclusion.

Thank you to all who participated in COGR's October membership meeting. It was the highest registration we've had post pandemic. During the meeting, we welcomed representatives from five new member institutions and the 12 institutions participating in our Emerging Research Institutions (ERI) Pilot Program that launched in August. Also, we announced a change in venue for COGR meetings beginning in 2027 to accommodate the growing membership. Since the membership meeting, we also welcomed The Salk Institute and the University of Nebraska Medical Center as new members and the University of North Florida as a participant in the ERI Pilot Program.

As this year nears its end and we look to the year ahead, I thank you for your engagement with COGR. The COGR team – Cindy, Dave, Kevin, Kris, Krystal, Mary, Toni, and I – wish you a wonderful holiday season.

Matt Owens, President

Announcements

New COGR Member Institutions: Welcome!

Now 225 strong, we are thrilled to announce that COGR has welcomed seven new institutions to the COGR membership since August 1, 2024, helping to further grow, strengthen, and diversify the association's membership. A list of COGR member institutions can be found on our website here.

October Membership Meeting Session Recordings Now Available for Attendees

Thursday sessions at the October meeting were recorded, and those recordings are now available in the COGR Portal for registered attendees (log in required). Session recordings are moved to the COGR Video Library after 90 days and viewable by anyone logged in, so be sure to review all of the rich content in the Video Library from past meetings and webinars as well!

Save the Date – COGR Virtual Meeting February 25-28, 2024

COGR's next membership meeting will be held virtually via Zoom on February 25-28, 2025. Registration will open in December via the COGR listserv and Portal.

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!

COGR's New Membership Meeting Hotel for 2027 & 2028

As announced during COGR's October meeting, beginning June 2027, our in-person meetings will take place at the Crystal Gateway Marriott in Arlington, Virginia. The Gateway is conveniently located one metro stop from Reagan National Airport (DCA) and directly connected to the Crystal City Metro. This venue provides COGR's growing membership with significantly more meeting space, lower nightly hotel costs for attendees, and is conveniently located for travelers and speakers.

In the meantime, COGR's next in-person meeting is June 5-6, 2025, and will take place at our regular location, the Washington Marriott in Georgetown. We will make continued announcements on the upcoming change in venue and provide all relevant information well ahead of our move in 2027. In the meantime, if you have any questions, please contact memberservices@cogr.edu.

COGR's Emerging Research Institutions Pilot Program: Still Accepting Applications and Welcome to New Institutions

COGR launched an Emerging Research Institutions (ERI) Pilot Program on August 1, 2024, and is still accepting applications for a limited number of openings. The ERI Pilot initiative aims to create an opportunity for a diverse range of smaller research institutions to formally engage with COGR and its member institutions, and to learn how the association could better represent in its work and advocacy the interests of all U.S. research institutions. We are excited to have already welcomed the following thirteen institutions into COGR's ERI Pilot Program to date, including our most recently accepted institution, the University of North Florida:

These institutions represent 10 publics, 3 privates, 8 R-2s, 2 HSIs, and collectively report over $75M in annual federal research expenditures as of the last NSF HERD survey. We are excited to have them as part of this important Pilot and engaging with them over the two-year Pilot period. More information on COGR's

ERI Pilot can be found on our website here. Please contact ERIservices@cogr.edu with questions.

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 & retrieve your invoice following 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 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."

Representatives from institutions that have not yet paid their dues will be unable to register for COGR's February virtual meeting unless prior arrangements have been made by emailing memberservices@cogr.edu. If you are your institution's Primary Representative or billing contact, please ensure your institution's membership invoice shows 'paid' and contact memberservices@cogr.edu if you have any questions or concerns.

Please ensure your payment records have been updated to reflect COGR's new 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!

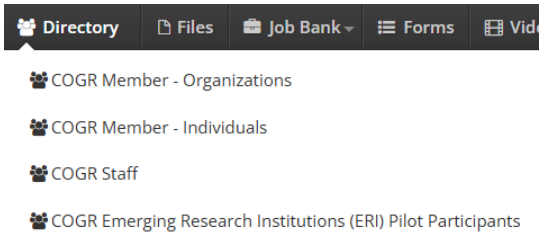
Did you know that all staff at COGR member institutions are eligible and encouraged to sign up for access to the COGR Portal as part of the institution's COGR Member Benefits? The Portal is where you can sign up for our listserv, browse our video library, view the COGR Member Directory, check out COGR's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

COGR Job Bank – New Opportunities Posted

New job opportunities have been added to the COGR Job Bank. Did you know COGR hosts a Job Bank in the COGR Portal? COGR members and ERI Pilot Institutions can submit a relevant job posting via the Portal from the Portal Dashboard and navigating to "Job Bank – Post and Manage Jobs". Under "Job Bank" you can also browse jobs posted by others. This service is complimentary.

COGR Directory Available in the COGR Portal

The COGR Portal also hosts directories to help you find individuals at other institutions that are engaged with COGR. To find the directories, log in to the COGR Portal and from the Dashboard, click on the dropdown "Directory". From there you'll see four directories to choose from:



- *COGR Member Organizations – this is a list of COGR member institutions and their Primary Representatives*
- *COGR Member Individuals – this is a list of all individuals from COGR Member Institutions signed up for access to the Portal*
- *COGR Staff*
- *COGR ERI Pilot Participants – individuals signed up for access to the Portal from ERI Pilot Institutions.*

Be sure to update your account profile so your information is displayed properly. To do this, from the Dashboard click "My Account – My Profile." To update the information that is displayed in your directory listing, click "My Account – My Directory Listing." If you have any questions, please contact memberservices@cogr.edu.

2 CFR 200 "Uniform Guidance" Cross-Cutting Issues

Health and Human Services (HHS) Interim Rule to Adopt the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (NEW)

On October 2, 2024, HHS issued an interim final rule to align its financial assistance regulations with OMB's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Part 200). The rule specifies that HHS will fully adopt 2 CFR part 200, reduce the total number of HHS-

specific changes, and codify those changes in 2 CFR part 300. However, the rule will be implemented in two phases. Phase one, effective October 1, 2024, adopts eight provisions, two already adopted (micro-purchase and SAT threshold and closeout 200.344) and six that increase flexibilities and thresholds for recipients (increased thresholds for subaward MTDC, equipment, supplies, fixed amount subaward and audit thresholds, and the 15% *de minimis* rate). Phase two, effective October 1, 2025, will finalize the adoption of the remaining provisions.

The deadline for public comments on implementation was November 1, 2024. COGR submitted comments recommending that HHS Office of Grants work with its awarding agencies and cost allocation services to facilitate timely implementation of the increased thresholds for equipment and subawards.

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

As previously announced in September 2024, COGR's "Fifth Look" – Implementation and Readiness Guide for the OMB Guidance for Federal Financial Assistance is a comprehensive resource designed to help institutions prepare for and implement the 2024 Revisions to the OMB Guidance for Federal Financial Assistance; Final Rule – Title 2 of the CFR, effective October 1, 2024. The guide addresses major changes, providing detailed insights and preparation strategies. Updates are ongoing, and members are encouraged to check back frequently for revisions.

The Fifth Look is preceded by four others, all of which can be found here.

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

Science & Security: Cross-Cutting Issues

Department of Justice (DOJ) NPRM on Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern (NEW)

In March 2024, the DOJ issued an Advanced Notice of Proposed Rulemaking (ANPRM) on the bulk sharing of U.S. persons' sensitive personal data with certain persons/entities affiliated with the following countries of concern (COCs): China, Cuba, Iran, North Korea, Russia, and Venezuela. COGR submitted comments on the DOJ ANPRM. The DOJ reviewed comments received in response to the ANPRM and then issued the above-mentioned NPRM. COGR plans to submit comments on the NPRM. Comments are due on November 29, 2024.

The Proposed Rule and preamble are over 100 pages long. It is very complex and contains numerous examples. In brief, the Proposed Rule imposes an export control-like regulatory scheme on the transfer of bulk sensitive personal data of U.S. persons and government-related data to a COC or COC-affiliated person or entity. Covered sensitive personal data includes personal identifiers, health data, genomic data, financial data, and biospecimens that are linked or linkable to individuals. Each category of data has an applicable bulk threshold. Government-related data consists of precise geolocation data for certain U.S. government

facilities and current/former senior government personnel. **There are no exemptions for deidentified, anonymized, or pseudonymized data, and there are no consent-based exemptions (i.e., exemptions based on an individual's consent to share their data with other specified parties).**

The Proposed Rule prohibits certain types of data transactions using covered data unless a specific exemption applies or the DOJ issues either a general license or specific license that covers the transaction. Other types of data transactions are restricted and can be undertaken only if the U.S. person complies with detailed due diligence, compliance, and security requirements. There are also recordkeeping and reporting requirements for transactions covered by the Proposed Rule, including a requirement to report to DOJ any offer from another person to engage in a prohibited transaction that involves data brokerage of covered data.

An overview of the Proposed Rule's major points follows, along with a discussion of potential areas where research institutions will be impacted. On November 18, DOJ held a teleconference with stakeholders to provide an Overview of the Proposed Rule and answer questions. COGR representatives attended this call and information received in response to questions raised during the discussion is included below.

What does the Proposed Rule do?

If adopted in its current state, the Proposed Rule will prohibit or restrict U.S. persons (i.e., U.S. citizens or lawful permanent residents, any person located in the U.S., and any entity organized solely under the laws of the U.S. or a U.S. jurisdiction, including foreign branches of a U.S. company) from entering into Covered Data Transactions that meet all of the following criteria:

(a) The transaction is with COCs or Covered Persons.

- Covered Persons are foreign persons that primarily reside in COCs and foreign entities ≥ 50% owned by a COC or Covered Person, organized under the laws of a COC, having their principal place of business in a COC, or serving as employees or contractors of a COC or a Covered Person. DOJ will also publish a list of persons/entities that it has designated as Covered Persons, regardless of their location.
- A foreign person who is a citizen of a COC but primarily resides in a third country that is not a COC will not be considered a Covered Person unless the foreign person is an employee or contractor of a COC or Covered Person or is designated by DOJ as a Covered Person.
- If a parent company is organized under the laws of a COC and has a *branch* in the U.S., both the parent company and the branch are Covered Persons. However, if a parent company organized under the laws of a COC has a *subsidiary* organized under U.S. law, the parent company is a Covered Person, while the subsidiary is a U.S. person, no matter the parent company's percentage ownership of the subsidiary.
- Any U.S. citizen and lawful permanent resident, as well as any person (including the citizen of a COC) that is physically located in the U.S. is considered to be a U.S. person, unless the DOJ specifically designates them as a Covered Person.

(b) The transaction involves bulk Sensitive Personal Data or Government-Related Data (as defined below).

(c) The transaction involves one of the following activities/agreements:

- **Data Brokerage** – The sale of data, licensing of access to data, or similar commercial transactions involving the transfer of data from a provider to a recipient, where the recipient did not collect or process the data directly from the individuals linked or linkable to the collected or processed data.
  - Note: During the November 18 teleconference, DOJ representatives stated that the term "commercial" does not refer to the purpose of the transaction (i.e., a for-profit or business transaction). Rather, the term commercial includes any transaction that involves the exchange of any type of consideration, monetary or non-monetary, and encompasses transactions conducted by for-profit and non-profit entities, whether funded or unfunded.
- **Vendor Agreement** – An agreement or arrangement (other than an employment agreement) in which any person provides goods or services to another person, including cloud-computing services, in exchange for payment or other consideration.
- **Employment Agreement** – An agreement or arrangement in which an individual (who is not an independent contractor) performs work or job functions directly for a person in exchange for payment or other consideration. Employment agreements include employment on boards or committees, "executive-level arrangements or services," and "employment services at an operational level."
- **Investment Agreement** – An agreement or arrangement in which any person, in exchange for payment or other consideration, obtains direct or indirect ownership interests in or rights in relation to: (1) real estate in the U.S.; or (2) a U.S. legal entity. There is an exclusion for passive investments as defined in the Proposed Rule.

What types of data are encompassed by the Proposed Rule?

(a) Sensitive Personal Data is data in one the following categories that meets the specified numeric bulk thresholds and that is linked or linkable to an individual(s)

- Human genomic data or biospecimens from which human genomic data can be discerned for ≥100 U.S. persons;
- Covered personal identifiers (e.g., entire or truncated government ID numbers, addresses, etc.) for ≥100,000 U.S. persons;
- Precise geolocation data (no numeric threshold);
- Biometric identifiers for ≥1,000 persons;
- Personal health data for ≥10,000 U.S. persons; and
- Personal financial data for ≥10,000 U.S. persons.

To determine if the numeric bulk threshold is met, institutions must examine all transactions that involve transfer of data in the same category to a COC or Covered Person (or a related party) over preceding 12 months.

(b) Government-Related Data is precise geolocation data for any area on a DOJ-compiled list of certain government facilities and certain current/former U.S. government officials that DOJ has determined present a heightened risk of exploitation by a COC.

[For purposes of this overview, bulk Sensitive Personal Data and Government-Related Data will be collectively referred to a "SP/GR Data."]

What transactions are prohibited by the Proposed Rule?

The Proposed Rule defines two types of Covered Data Transactions that are prohibited unless the U.S. person making the transfer falls under an applicable exemption or operates under a general or specific license granted by the DOJ:

(a) Transactions Involving Human Genomic Data and Human Biospecimen Transactions – There is a complete prohibition on a U.S. person knowingly engaging in Data Brokerage or a Vendor, Employment, or Investment Agreement that involves access to bulk Human Genomic Data or biospecimens by a COC or Covered Person.

(b) Data Brokerage – There is a complete prohibition on a U.S. person knowingly engaging in the sale of, licensing access to, or "similar commercial transactions" that involve access to SP/GR Data by a COC or Covered Person that did not collect or process the data directly from the individuals to whom the data is linked or linkable.

- **Onward Transactions with Non-COC Foreign Persons** – If U.S. persons enter into a Data Brokerage transaction for SP/GR Data with **any** foreign person that is not a COC or Covered Person, they must include contractual provisions that require the foreign person to refrain from using the transferred data in a subsequent Data Brokerage transaction with a COC or Covered Person. In addition, the contract must require the foreign person to report any known or suspected violations of this contract to the U.S. person, who in term must report the incident to the DOJ. Importantly, the preamble to the Proposed Rule sets forth the substantial due diligence expectations for institutions that engage in these in transactions:

  Third, consistent with the overall approach to compliance and enforcement under the proposed rule, the Department ***expects U.S. persons engaged in these kinds of data brokerage transactions to take reasonable steps to evaluate whether their foreign counterparties are complying with the contractual provision as part of implementing risk-based compliance programs under the proposed rule****. Absent indications of evasion, conspiracy, or knowingly*

directing prohibited transactions, U.S. persons that conduct adequate due diligence as part of a risk-based compliance program would not have engaged in a prohibited transaction if the foreign counterparty later violates the required contractual provision or if the U.S. person fails to detect such violations. ***Depending on the circumstances, a U.S. person's failure to conduct adequate due diligence may subject the U.S. person to enforcement actions if that failure would constitute an evasion of the regulations, such as repeatedly knowing of violations by a foreign person and continuing to engage in data-brokerage transactions with that foreign person***. [89 F.R. at 86130. Emphasis added.

What transactions are restricted by the Proposed Rule?

Restricted Transactions Include: Covered Data Transactions between a U.S. person and a COC or Covered Persons that involves at least one of the following types of agreements: (a) Vendor Agreement; (b) Employment Agreement; and (c) Investment Agreement.

Due Diligence Requirements for Restricted Transactions: To undertake a restricted transaction, an U.S. institution must implement a data compliance program and comply with the Cybersecurity and Infrastructure Agency (CISA) Security Requirements for Restricted Transactions that are specified in a separate proposed rule. The data compliance program must include a written policy, risk-based procedures for verifying and logging the details and data flows in restricted transactions, and procedures used to verify the identity of any vendors involved. Due diligence also requires an annual third-party audit of the institution's compliance with and effectiveness of its security measures, conducted in accordance with the specifications of the Proposed Rule.

Does the Proposed Rule provide for any exemptions?

The Proposed Rule exempts several different types of data transactions. These exemption categories are briefly summarized below, but institutions must carefully review the details of an exemption to determine if it can be applied to particular circumstances:

- **Personal Communications** – Postal, telephonic, or other personal communications that do not transfer anything of value.
- **Information/Information Materials** – Expressive materials that convey thoughts and ideas; however, underlying data, marketing and business consulting materials, and materials not fully in existence at the time of the transaction are excluded from this exemption.
- **Data Transactions Incident to International Travel** – Arrangement of travel, payment of living expense abroad, etc.
- **Official Business of the U.S. Government** – Activities of U.S. government employees, grantees, or contractors, including transactions conducted pursuant to a federal grant or contract.
    - Note: During the November 18 teleconference, DOJ representatives stated that although federally funded research activities would fall under this exemption, in the case of projects that are funded by both private and federal sources, the exemption apply to sharing of

covered categories of data with COCs/Covered Persons, only to the extent that the data sharing is part of the federally funded activities. DOJ representatives also noted that funding agencies may impose restrictions on data-sharing, and the purpose of this exemption is to prevent dual regulation by DOJ and other federal agencies.

- **Financial Services** – Data transactions that are ordinarily incident to and part of the provision of financial and banking services.
- **Corporate Group Transactions** – Certain types of data transactions between a U.S. subsidiary or affiliate located in or subject to the ownership, direction, jurisdiction, or control of a COC and ordinarily incident to and part of administrative or ancillary business operations such as human resources or payroll.
- **Transactions Required/Authorized by Federal Law or International Agreements**
- **Investment Agreements subject to a CFIUS Action**.
- **Telecommunications Services –** Non-data brokerage transactions that are ordinarily incident to and part of providing international telecommunication programs.
- **Drug, Biological Product, and Medical Device Authorizations –** Data transactions using deidentified data associated with regulatory approval in COCs of medical products.
- **Other Clinical Investigations and Post-marketing Surveillance Data** – Data transactions using deidentified data that are ordinarily incident to, and part of clinical investigations regulated by FDA or that support FDA research and marketing applications.
- **Publicly Available Data** – Data that is lawfully publicly available from federal, state, or local government records or through widely distributed media such as sources that are generally available to the public through unrestricted or open-access repositories.
- **Public or Non-Public Data that does not Relate to an Individual** (including trades secrets and proprietary information).

Note that in the case of biospecimens (including plasma and blood products), there is **no exemption** for their export to COCs for direct medical use. DOJ is seeking comments on whether such an exemption is necessary, and COGR's comments will address this issue.

Reporting and Recordkeeping Requirements:

U.S. Persons that engage in restricted transactions will be required to keep prescribed records regarding all covered transactions, including written policies that describe the institution's compliance program and implementation of applicable security requirements. These policies must be certified by an institutional officer, executive, or employee responsible for compliance. In addition, an annual report is required for certain cloud-computing arrangements. Importantly, all U.S. persons that have received and formally rejected an offer (including automated rejections) to engage in a prohibited transaction with a data broker must file a report on the rejected transaction with DOJ within 14 days of the rejection.

How will the Proposed Rule impact research programs and collaborations?

(a) Research Exemptions: As noted, the Proposed Rule provides an exemption for official U.S. government business that covers federally funded research conducted by grantees and contractors. It also provides exemptions for (a) the transfer of deidentified bulk Sensitive Personal Data to regulatory authorities in COCs as part of activities necessary for the initial and continuing authorization of drugs, devices, and biologics in COCs; and (b) the transfer of deidentified bulk Sensitive Personal Data that are part of clinical investigations regulated by the U.S. FDA or deidentified clinical care data necessary to monitor regulated product performance and safety, support FDA post-marketing approval, or maintain FDA product authorization.

(b) No Exemption for Non-federally Funded Research: The Proposed Rule **does not** provide any exemption for non-federally funded research that involves the transfer of SP/GR Data to COCs or Covered Persons. For example, if as part of a public health research project funded by a private foundation, a U.S. researcher transfers a set of linkable personal health data for more than 10,000 U.S. persons to a collaborating researcher-subawardee living in a COC for analysis, the transaction would be subject to the Proposed Rule. Support services for non-federally funded research projects also may be covered. For example, it would be a prohibited transaction if as part of a privately-funded basic science research project, a U.S. research institution contracted with a genomic sequencing lab in the U.S. that is a branch of a parent company organized under the laws of China to process more than 100 biospecimens.

(c) Informal Collaborations: It is unclear whether informal, unfunded, unpaid, non-commercial scientific collaborations that involve the transfer of bulk Sensitive Personal Data from a U.S. researcher to a researcher in a COC are research collaborations will be covered by the Proposed Rule. For example, a U.S. researcher's exchanges of more than 100 U.S. persons' biospecimens over the course of 12 months with a researcher primarily resident in a COC as part of informal, unpaid, unsponsored activities to determine if a particular line of research is feasible. Given the DOJ's broad definition of "commercial" to include transactions involving any type of consideration, the exchange of specimens or data may be considered sufficient to trigger application of the Proposed Rule. COGR's comments on the Proposed Rule will seek clarity on this issue.

(d) Publicly Available Information: It is unclear whether data in NIH repositories (e.g., NIH genomic data repositories) will be considered publicly available information if they are "controlled-access" (i.e., will "controlled-access" requirements be deemed the same s "restricted access").

Note: This issue was discussed during the November 18 DOJ teleconference. Initially, DOJ representatives state that NIH would be responsible for controlling access to its data repositories. However, when attendees subsequently asked if NIH would have sole oversight regarding sharing of data from its repositories with scientists in COCs, DOJ seemed to suggest that transactions would need to be analyzed under the Proposed Rule and any applicable exemptions. COGR will ask for clarification on this item in its comments.

(e) Post-Docs Accessing Bulk Sensitive Personal Information while Working in U.S. Labs: Foreign persons are considered to by "U.S. Persons" while they are physically present in the U.S. unless they DOJ specifically designates them as Covered Persons. As U.S. Persons, they will be subject to all restrictions applicable to U.S. Persons. Because a post-doc may be considered as being subject to an "Employment Agreement" under the Proposed Rule, institutions will need to vet them against the DOJ list of Covered Persons if they may have access to any SP/GR Data.

(f) Licensing of SP/GR Data to Companies: Institutions will need to vet entities to which they intend to license any SP/GR Data to determine whether the licensing will be considered a Covered Data Transaction. In this regard, COGR comments will seek clarification as to whether a data use agreement is considered "licensing of data."

(g) Start-Up Companies: Start-up companies must vet any foreign investors to determine if they are Covered Persons and whether the investment arrangement constitutes a Covered Data Transaction.

How will the Proposed Rule impact research institutions' business operations?

The Proposed Rule also has the potential to impact a wide variety of U.S. business operations that take place both within the U.S. and abroad. Institutions will need to vet vendors, contractors, IT providers, sub-contractors/awardees, investors, and employees to determine if they meet the definition of/or have been designated by DOJ as Covered Persons. If so, institutions will need to carefully analyze any associated data flows to identify SP/GR Data, determine if the transaction is prohibited or restricted, and determine coverage under any exemption or general license. If an institution determines that it wants to engage in a restricted transaction for which a specific license is required, the Proposed Rule discusses the application process and notes that DOJ hopes to initially respond to applications within 45 days of receipt. There are also procedures for obtaining advisory opinions. In all cases, institutions will need to abide by any applicable reporting and recordkeeping requirements.

Finally, institutions should note that they also must be mindful of any data brokerage contract with any foreign persons/entities that involve transfer of or access to the various categories of covered data. Such contracts will be required to include provisions that prevent onward data brokerage transactions with COCs/Covered Persons and that mandate reporting of breaches of these provisions to the institution, which in turn must notify DOJ. As discussed, data brokerage is defined very broadly to encompass transfer or access to covered categories of data for any type of consideration, and as previously noted, institutions that enter into these transactions must "take reasonable steps to evaluate whether their foreign counterparties are complying with the contractual provision as part of implementing risk-based compliance programs under the proposed rule." [89 F.R. 86130].

DOD Cybersecurity Maturity Model Certification Program Final Rule (UPDATE)

The U.S. Department of Defense (DoD) issued the Final Rule (DoD-2023-OS-0063) "Cybersecurity Maturity Model Certification (CMMC) Program" on October 15, 2024. Commonly referred to as CMMC 2.0, this Final

Rule updates the mechanism for DoD contractors and subcontractors to certify security measures to safeguard Federal Contract Information (FCI) and Controlled Unclassified Information (CUI) have been implemented for the specified CMMC level.

COGR, in collaboration with AAU, APLU, and EDUCAUSE, previously expressed concern about fundamental research within the CMMC framework and requested clarity in 2020. In February 2024, COGR joined ACE, AAU, APLU and EDUCAUSE in submitting comments in response to a DoD solicitation for comment. The Final Rule acknowledges that fundamental research generally does not include FCI and CUI, so CMMC does not apply in those cases. However, there is no absolute declaration by DoD in the rule, leaving open the possibility of instances that might necessitate the application of CMMC requirements for what is otherwise considered fundamental research. In response to comments received during the rulemaking process, DoD declined to amend the preamble to exclude the possibility that information may be subsequently designated as CUI during the contract period and further states: "(w)hen the DoD does determine that research meets the definition of CUI, safeguarding requirements of DFARS clause 252.204 – 7012 will apply regardless of whether the contractor's work is fundamental research."

COGR has been actively monitoring and reporting on CMMC developments for several years. For additional information about our efforts, please refer to the October 2020, February 2023, February 2024, and March 2024 COGR Updates.

Security Requirements for Restricted Transactions Under E.O 14417 (NEW)

On February 28, 2024, President Biden issued Executive Order 14117 on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern. The EO instructed the Department of Justice (DOJ) to develop a rule to regulate the transfer of certain classes of sensitive data to designated countries of concern. The March COGR Update summarizes the DOJ Advance Notice of Proposed Rulemaking (ANPRM) and the May COGR Update outlines the key points of our response prepared by COGR's REC Committee.

On October 29, 2024, the DOJ issued the corresponding Notice of Proposed Rulemaking, and the Cybersecurity and Infrastructure Security Agency (CISA) published the Request for Comment (CISA-2024-0029) on "Security Requirements for Restricted Transactions Under Executive Order 14117." The proposed security requirements for restricted transactions would apply to that category of transactions defined in the regulations issued by the DOJ.

After careful consideration, COGR has decided not to submit comments to CISA. Responses are due November 29, 2024.

Department of Energy (DOE) Financial Assistance Letter (FAL), Research Security Training Requirements for all R&D Financial Assistance Awards (NEW)

The DOE issued FAL 2025-02 on October 7, 2024, addressing DOE's implementation of research security training requirements, under Section 10634 of the CHIPS and Science Act. The guidance applies to all DOE and National Nuclear Security Administration (NNSA) notice of funding opportunities, financial assistance

agreements, congressionally directed spending projects, and non-competitive financial assistance agreements that include R&D activities. The training becomes mandatory for all R&D NOFOs and awards starting May 1, 2025, though it remains optional until then.

The FAL requires all "covered individuals," to certify completion of research security training within 12 months immediately preceding the application date. DOE defines a "covered individual" at minimum to include principal investigator (PI); project director (PD); co-principal investigator (Co-PI); co-project director (Co-PD); project manager; and any individual regardless of title that is functionally performing as a PI, PD, Co-PI, Co-PD, or project manager. DOE has an expanded designation that may include technical staff (e.g., postdoctoral fellows/researchers and graduate students) as covered individuals, as designated by DOE. Additionally, any new covered individuals added during a project's performance period must complete the training within 30 days of joining the project.

To fulfill the training requirement, applicants may use the NSF's four one-hour training modules or develop their own programs aligned with Section 10634(b) of the CHIPS and Science Act. Prime applicants must verify and certify that all listed covered individuals have completed the required training as a condition of applying for DOE funding. Certifications for individuals are incorporated into the Current and Pending Support disclosures, while organizations provide certifications through DOE's Financial Assistance Certifications and Assurances (SF-424). Recipients are required to maintain records of compliance for covered individuals and must extend/flow down the requirement to any and all subrecipients.

Institutions with DOE applications and awards, should prepare for full implementation of these requirements by May 2025.

DOE discussed this and other research security topics during the October COGR meeting; slides are available here.

COGR's Comments and Potential Regulation of Other 'Omic Data:

COGR's REC Committee is developing comments on the Proposed Rule for submission to DOJ. One area for which DOJ has specifically requested comments is the potential expansion of the Proposed Rule to encompass other "omic" data, including epigenomic, glycomic, lipidomic, metabolomic, mictobiomic, phenomic, proteomic, and transcriptomic data. Institutions are encouraged to advise their researchers about the potential regulation of this additional 'omic data and ask them to assess impact on current and future research. Institutions should also consider commenting, as DOJ is likely to consider the number of comments submitted.

Please contact Kris West (kwest@cogr.edu) with any concerns your institution would like to see raised in the COGR comment letter.

Prohibition on Unmanned Aircraft Systems From Covered Foreign Entities (NEW)

On November 12, 2024, the Department of Defense (DoD), the General Services Administration (GSA), and the National Aeronautics and Space Administration (NASA) published Interim Rule "Prohibition on

Unmanned Aircraft Systems from Covered Foreign Entities" (FAR Case 2024-002) prohibiting the procurement, operation, or use of Federal funds on UAS prohibited by the Federal Acquisition Security Council (FASC). FASC-prohibited drones are defined as unmanned aircraft systems manufactured or assembled by a covered foreign entity.

The rule will be implemented in two phases, with the initial phase in effect on November 12, 2024. This initial phase amends FAR part 40 to add new sections 40.200 through 40.202, which are to be included in all solicitations issued, contracts awarded, options exercised, or modifications made to extend the contract period of performance. During this phase, continued use of previously acquired subject drones is permitted, provided such UAS is not a deliverable under the contract.

The second phase of the interim rule goes into effect on December 22, 2025. It is more prohibitive and may have a greater impact on university research activities. In this phase, Federal contractors (and subcontractors) are prohibited from "using Federal funds on" subject drones, including for the procurement and operation of FASC-prohibited UAS.

The COGR RSIP Committee is discussing the extent this rule impacts research activities and whether comments are warranted. We will keep the membership apprised.

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.

USDA Statement on Research Access to Germplasm Developed with Federal Funds (NEW)

The United States Department of Agriculture (USDA) published a statement on October 8, 2024 ("USDA Statement"), affirming the agency's commitment to support efforts that make federally-funded germplasm widely available to the at-large research community to accelerate the development of new plant varieties.

The genesis of the USDA Statement appears to be the March 2023 USDA report "More and Better Choices for Farmers: Promoting Fair Competition and Innovation for Seeds and Other Agricultural Inputs." The report discusses, among other things, how consolidation in the seed industry has reduced competition, making it more difficult for small and medium-sized breeders to compete, stifling innovation, and ultimately increasing costs.

The report's authors made seven recommendations to USDA, including:

- Promote broader adoption of IP strategies that enable third-party research and breeding with commercially licensed technologies when such technologies result from federally funded research.
- Promote standardization of material transfer agreement best practices that provide "research and breeding exemptions."

- Look at the Bayh-Dole Act for ways it can "appropriately support breeding programs and further cultivar development."

COGR is a signatory to "Nine Points to Consider in Licensing University Technology" and fully supports the documents principals including the reservation of rights for the university, other non-profit organizations, and the federal government and broadly sharing research tools, as appropriate as determined by the university on a case-by-case basis. COGR is concerned that any government prescription of the disposition of intellectual property could substantially affect COGR member institutions' ability to transfer technology to the private sector for commercialization.

COGR and APLU have discussed the USDA statement with several of our respective members who, upon reading the statement, have shared our concerns.

The RSIP Committee is coordinating with other higher education associations on opportunities to engage with USDA and a possible written response. We will keep the membership apprised.

Interim Final Review on Controls for Quantum, Semiconductor Equipment and Additive Manufacturing Technologies (NEW)

On September 6, 2024, the Bureau of Industry and Security (BIS) issued the Interim Final Rule "Commerce Control List Additions and Revisions; Implementation of Controls on Advanced Technologies Consistent With Controls Implemented by International Partners" (RIN 0694-AJ60). The rule imposes stricter controls on the export and deemed export of quantum, semiconductor equipment, and additive manufacturing technologies to align U.S. export control regulations in these areas with our nation's international partners.

COGR expressed concern with the possibility of BIS implementing a quantum-specific deemed export licensing policy in the future but expressed appreciation for BIS's efforts to minimize this rule's impact on the deemed export procedure and the potential regulatory burden on our member institutions. Additionally, COGR reaffirmed our support for BIS's preservation of the fundamental research exclusion.

Markup on Three Bills to Strengthen U.S. Patent System (UPDATE)

The Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act (S.2220) would modify the Patent Trial and Appeal Board (PTAB) procedures to address unnecessary and costly patent litigation proceedings currently incurred by patent owners in the United States.

The Patent Eligibility Restoration (PERA) Act (S.2140) would harmonize the United States patent eligibility criteria with other countries and broaden the scope of innovations eligible for patent protection.

The Inventor Diversity for Economic Advancement (IDEA) Act (S.4713) directs the United States Patent and Trademark Office (USPTO) to collect demographic data on inventors who have filed for statutory protection on a voluntary basis and to make that data publicly available.

All three bipartisan bills are widely viewed as positive for the academic technology transfer community and the U.S. innovation ecosystem. The bills were scheduled for markup on November 14, 2024. The IDEA Act was approved. The Judiciary Committee delayed consideration for both the PREVAIL Act and the PERA Act.

AAU, ACE, APLU and AUTM sent a joint letter to Senate Judiciary Committee in support of the bills. COGR shares the favorable views expressed by its partner organizations on the three bills. Each will have positive impacts in strengthening the U.S. patent system and encouraging broad participation in the innovation ecosystem. We will continue to monitor the progress of the legislation and provide the membership updates 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: 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 facilities and administrative (F&A) cost rates 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.

The cognizant agencies for cost, HHS Cost Allocation Services (CAS) and DOD Office of Naval Research (ONR) Indirect Cost Branch, have stated that they do not intend to reopen executed predetermined rate agreements and only CAS has expressed openness to finalizing provisional rates or extending rates using the new thresholds. Further, once new F&A cost rates are in effect, institutions will continue to need systems and processes to manage older awards subject to previous rate agreements and the previous 2 CFR, with its $5,000 equipment threshold for application of the management requirements found in § 200.313.

During the October COGR membership meeting, members of the CFC and CGA committees met with OMB Policy Analyst Steven Mackey and shared specific examples of situations with no practical solution. Resolution is not yet in sight, but Mr. Mackey acknowledged the difficulties institutions face and left with our suggestions for mitigating the problems. COGR will continue to discuss with OMB, CAS, and other stakeholders, as implementing compliantly is impractical given the various dates to be considered and local system constraints. COGR maintains that institutions must be provided with flexibility and protection during the transition period. As part that effort, in its Response to Health and Human Services Adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2

CFR Part 300), COGR recommended HHS Office of Grants work with HHS awarding agencies and CAS to provide a flexible path for institutions to implement the new thresholds.

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

As reported in the September COGR Update, HHS issued a new Grants Policy Statement effective October 1, 2024 that includes application of the Salary Rate Limit (SRL, often referred to as the NIH Salary Cap) imposed by the HHS Appropriations Act to all salaries (i.e. direct salaries and salaries included in F&A cost pools):

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.

Beginning with HHS awards, including continuation and supplemental awards, made on or after October 1, 2024, HHS recipients that do not have an approved indirect cost rate that complies with the HHS SRL requirement must take and document the following actions:

- *Identify any HHS award where HHS funds are used to pay any salary that exceeds the SRL using the HHS award. This includes both direct and indirect costs, both in whole and any portion of a salary that at a full-time equivalent exceeds the SRL.*
- *Have written policies and procedures that ensure the recipient does not draw down HHS award funds, whether as direct or indirect costs, to pay for salaries above the HHS SRL.*

NIH published a Grants Policy Notice on this topic November 14, 2024, superseding the information in its current Grants Policy Statement and aligning with the above HHS language.

COGR confirmed in discussions with OMB and HHS that this is a legal issue, not a policy decision. HHS Office of Grants, therefore, does not perceive any flexibility to delay implementation, but also clarified that it is not interested in restricting salary reimbursement any further than is legally necessary and plans to revise the policy if the wording in the appropriation changes. While most COGR members are subject to and above the cap of 26% on administrative cost reimbursement and will unlikely experience a significant financial impact, COGR shared concerns about administrative burden and unintentional non-compliance. The HHS Office of Grants expressed understanding and offered to take what steps it can to mitigate the issues, particularly during the transition period prior to negotiating F&A cost reimbursement rate agreements adjusted for the SRL.

COGR will continue to engage in this discussion alongside AIRI (Association of Independent Research

Institutes) and will notify the membership of any significant updates. AIRI represents non-profit research institutions, which will be disproportionately impacted financially by implementation of this requirement.

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

During the October Membership Meeting, leaders of the Costing and Financial Compliance (CFC) Committee presented observations and findings from the F&A Survey Capstone Report (Capstone) – 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 Capstone is the final product of this initiative. The presentation was based on the final draft and the Capstone 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 cost proposals, negotiation experiences, institutional resources committed to the F&A cost process, and other areas of interest. These reports are meant to be used for COGR member purposes only and should not be shared beyond the institution.

Threats to F&A Cost Reimbursement (ONGOING)

In previous updates, May 2024 Update and July 2024 Update, 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 these efforts seemed to stall as the election approached, we anticipate legislative threats to equitable reimbursement to return, potentially even more aggressively. COGR will 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.

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 have worked with AAU, APLU, AAMC, and AIRI to update existing F&A cost educational materials and we are continuing to develop more effective communications. COGR recommends reviewing your institution's websites and other communications that include information about F&A costs to ensure 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.

Accrued Leave Payouts (REMINDER)

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 addressed in the Fifth Look. §200.431, Compensation – 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 subsequently issued a technical correction, 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 the word "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, and OMB verbally confirmed, 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.

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.

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

Release of fiscal year 2023 HERD survey results is expected this month. COGR frequently uses information from the annual HERD results in its advocacy for equitable cost reimbursement regulation, policy, and practice.

As a reminder, the 2022 HERD results were released on November 30, 2023. Included were 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 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.

Changes to OMB Guidance Impacting Fixed-Amount Awards: COGR Continues to Advocate for Practical Solutions (ONGOING)

COGR continues to engage on the critical issues arising from the 2024 revisions to fixed-amount awards, as highlighted in COGR's technical corrections letter dated June 28, 2024. The revisions significantly depart from performance-based accountability and instead now create an over-emphasis on financial oversight,

reporting, and administrative requirements, ultimately disincentivizing the use of fixed-amount instruments. The revised language to 200.201(b)(4) specifying "incurred" significantly handicaps performance-based standards. Additionally, 200.201 (b)(1) replaced "adequate" with "accurate cost implies a (unintended) change to a higher standard of precision in costing as described in COGR's Fifth Look: Implementation and Readiness Guide for the OMB Guidance for Federal Financial Assistance.

During the October COGR meeting, CGA met with OMB Policy Analyst Steven Mackey, who acknowledged these challenges and expressed a commitment to finding solutions in collaboration with the community. COGR will continue engaging with OMB and updating members on developments.

Defense Federal Acquisition Regulation Supplement: Public Access to Results of Federally Funded Research (2020-D028) (NEW)

The Department of Defense (DoD) is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement public access policies. The rule, published on September 26, 2024, proposes changes to DFARS part 235 to add two clauses that require contractors to submit final peer-reviewed manuscripts to the Defense Technical Information Center's publicly accessible repository and to develop and maintain a data management plan. Comments are due on November 25, 2024.

COGR is drafting comments in response to the request and welcomes input from the community. Those interested in providing feedback can reach out to Krystal Toups at ktoups@cogr.edu.

Federal Acquisition Regulation: Clarification of System for Award Management Preaward Registration Requirements (NEW)

On November 11, 2024, The Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA) issued an interim rule clarifying preaward registration requirements under FAR 52.204-7. The revision specifies that SAM registration is required at the time of offer submission and contract award, though continuous registration between these points is not mandated. Comments are due by January 13, 2025. CGA 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.

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 continue to monitor community concerns and engage 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. 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.

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.

COGR-ARIO Survey: Due November 30 (NEW)

In response to the Office of Research Integrity's (ORI) new Research Misconduct regulations, COGR and ARIO have issued a joint survey to collect feedback from institutions as to which provisions of the new regulations they would like to see (a) ORI guidance; (b) community guidance; (c) both ORI and community guidance; or (d) no guidance.

COGR and ARIO will analyze responses and use the information to guide advocacy efforts with ORI and to develop materials to assist members with implementation. Please note that the survey uses a "drag and drop" format, which makes it easier and much less time consuming to respond. COGR estimates that it will take individuals who have basic familiarity with the new rule about 15 minutes to complete the survey. The link to the survey is available here and it includes a link to a Word copy of the survey for review. COGR urges member institutions to respond to this important survey. Responses are due by November 30, 2024.

Update on NIH's Implementation of OSTP DURC/PEPP Policy (UPDATE)

At COGR's October membership meeting, REC Committee members met with Association for Biosafety and Biosecurity (ABSA) President-elect Sherry Bohn to discuss questions and concerns regarding the OSTP's Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential ("New Policy") and associated Implementation Guidance. ABSA and COGR agreed to cooperate with each

other in analyzing NIH and other agencies' implementation of this Policy and in developing materials to assist institutions in developing and implementing policies and processes necessary to comply with the new requirements.

Since that meeting, NIH has provided important information concerning its planned implementation of the New Policy through conversations with COGR and other associations. First, NIH does not plan to issue an RFI on its implementation plans. Institutions should consult the above-referenced Implementation Guidance to develop their own implementation plans. Second, NIH plans to issue a summary of its implementation of the New Policy at the end of 2024. Third, NIH anticipates that it will apply the New Policy to both current and future protocols. REC members and biosafety professionals from COGR member institutions will work to develop a list of questions for NIH to aid in the development of FAQs and other materials explaining implementation of the New Policy. In the meantime, institutions should consider taking the following actions to determine the impact the New Policy may have on their institutions.

(1) Understand the Differences between the New Policy and the current U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern ("Current DURC Policy") and the current Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens ("Current P3CO Policy").

The charts on the following pages summarize the major differences between current and upcoming policies.

	Current DURC Policy	New DURC (Category 1 Research) Policy
Regulated Agents	**15 agents and toxins[1]**	**91 agents and toxins[2]**
Regulated Experimental Outcomes	**7 categories of experimental outcomes:** 1) Enhances the harmful consequences of the agent or toxin; 2) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification; 3) Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies; 4) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin; 5) Alters the host range or tropism of the agent or toxin; 6) Enhances the susceptibility of a host population to the agent or toxin; 7) Generates or reconstitutes an eradicated or extinct agent or toxin listed in Section (III.1) above.	**9 categories of experimental outcomes:** 1) Increases transmissibility of a pathogen within or between host species; 2) Increases the virulence of a pathogen or conveys virulence to a non-pathogen; 3) Increases the toxicity of a known toxin or produces a novel toxin; 4) Increases the stability of a pathogen or toxin in the environment, or increases the ability to disseminate a pathogen or toxin; 5) Alters the host range or tropism of a pathogen or toxin; 6) Decreases the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods; 7) Increases resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions; 8) Alters a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin; 9) Enhances the susceptibility of a host population to a pathogen or toxin.
Review Process	**2 levels of review and approval:** • Institutional review by IRE • Funding agency review	**2 levels of review and approval:** • Institutional Review by IRE • Funding agency review[3]

[1]Avian influenza virus (highly pathogenic); Bacillus anthracis; Botulinum neurotoxin; Burkholderia mallei; Burkholderia pseudomallei; Ebola virus; Foot-and-mouth disease virus; Francisella tularensis; Marburg virus; Reconstructed 1918 Influenza virus; Rinderpest virus; Toxin-producing strains of Clostridium botulinum; Variola major virus; Variola minor virus; and Yersinia pestis. Excludes toxins that are ≤ permissible amounts for certain toxins specified by CDC and USDA.

[2] Agents are listed on pages 63-66 of the Implementation Guidance ("Implementation Guidance List").

[3] See the full review process diagramed in the chart on p. 25 of the Implementation Guidance. This chart outlines a series of communications between the PI and funding agency at the proposal stage. NIH has suggested that it will work with institutions on whether the PI or biosafety office/committee

	Current P3CO Policy	Current PEPP (Category 2) Research
Regulated Agents	1) Pathogen of pandemic potential (PPP) that is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and it is likely highly virulent and likely to cause significant morbidity and/or mortality in humans. 2) Enhanced PPP (EPPP), which are PPPs resulting from the enhancement of the transmissibility and/or virulence of a pathogen (excluding naturally occurring pathogens that are circulating in or that have been recovered from nature regardless of their pandemic potential). However, if a PPP's transmissibility and/or virulence is modified by surveillance activities or activities associated with developing and producing vaccines, the resulting pathogens are not considered to be EPPPs.[4]	• Research that involves or is reasonably anticipated to result in a pathogen of pandemic potential (PPP)[5]; and is reasonably anticipated to result in, or does result in one or more of four regulated experimental outcomes; and • Based on current understanding, the institution, agency, or agency's department review entity determines the research is reasonably anticipated to result in the development, use or transfer of a Pathogen with Enhanced Pandemic Potential (PEPP)[6] or an eradicated or extinct PPP (EE PP)[7] that may pose a significant threat to public health, the capacity of health systems to function, or national security.
Regulated Experimental Outcomes	Research that a funding agency has determined is reasonably anticipated to create, transfer, or use EPPPs.	Research that: 1) Enhances the transmissibility of the pathogen in humans. 2) Enhances the virulence of the pathogens in humans. 3) Enhances the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection. 4) Generates, uses, reconstitutes, or transfers an EE PP or a previously identified PEPP. [8]
Review Process	**3 levels of review and approval:** • Institutional review • Funding agency review • Agency Departmental review by multidisciplinary committee	**3 levels of review and approval:** • Institutional review • Funding agency review • Agency Departmental review by multidisciplinary committee

[4] This exemption is not carried over to the new DURC PEPP Policy.
[5] A Pathogen with Pandemic Potential (PPP) is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans (may be estimated by comparing case hospitalization or fatality rates).
[6] A Pathogen with Enhanced Pandemic Potential (PEPP) is a type of PPP resulting from experiments that enhance the PPP's transmissibility or virulence or disrupt the effectiveness of pre-existing immunity, regardless of progenitor agent, such that it may post a significant threat to public health, national security, or the capacity of health systems to function
[7] An eradicated or extinct PPP (EE PP) comes from experiments that generate, use, reconstitute, or transfer an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security, regardless of whether the experiment enhances the PPP.
[8] See, Table 3 on p. 15 of the Implementation Guidance.

(2) Assess How Many Researchers at Your Institution have Research Projects that may Require at least Initial Review to Determine if they Include Category 1 or Category 2 Research:

In comparing the current and new policies, it is likely that some institutions will have additional research projects that require DURC review[9] (e.g., research protocols that used select agents that were not among the 15 agents listed under the current policy, or research using toxins that were previously exempt because they were not used at threshold amounts that triggered applicability of the DURC policy). Accordingly, institutions should consider working through their biosafety offices to survey researchers with currently active protocols to determine if they use any of the agents on the Implementation Guide List at any amount.

Additionally, depending on how your institution handles registration with USDA/HHS for possessing/using/transferring select agents or toxins and/or the purchasing of those materials, biosafety personnel may want to consider reviewing registration/purchasing records over the past year to identity other potentially affected researchers, including researchers who may possess covered agents below current threshold amounts. Identifying and reviewing IACUC protocols requiring biosafety review may be another avenue to identify researchers who may be impacted by the New Policy.

Once researchers have been identified, institutions should consider providing them with a questionnaire that asks the researchers to:

(a) Identify which of the agents/toxins on the Implementation Guide List they are currently using or planning to use in 2025 and whether the agents/toxins are being used in current research or proposed.
(b) For each such agent/toxin, identify whether the research project in which the agent is being used/or will be used is reasonably anticipated to result, or will result, in one or more of the listed nine experimental outcomes, and if so, which outcomes.
(c) Identify for each project that has both a listed agent and listed experimental outcome, the actual or proposed source of funding for that project.

The information collected can be used to estimate the anticipated institutional review burden for projects that were not previously subject to DURC review and to help the researcher begin consideration of required risk/benefit assessments and any risk necessary risk mitigation plans.

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[9] *Protocols requiring PEPP review are anticipated to remain relatively rare.*

Appendix A – Upcoming Comment Due Dates

Agency	Description	Due Date	Notes
Department of Defense (DoD), Defense Acquisition Regulations System	**Defense Federal Acquisition Regulation Supplement: Public Access to Results of Federally Funded Research (2020-D028)**	November 25, 2024	COGR is drafting comments.
Department of Justice (DOJ)	**NPRM on Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern**	November 29, 2024	COGR plans to submit comments.
Department of Homeland Security (DHS), Cybersecurity and Infrastructure Security Agency (CISA)	**Request for Comment on Security Requirements for Restricted Transactions Under Executive Order 14117**	November 29, 2024	COGR is not submitting comments.
Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA)	**Federal Acquisition Regulation: Clarification of System for Award Management Preaward Registration Requirements**	January 13, 2025	COGR is currently reviewing for potential comment.

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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