COGR

Advancing Effective Research Policy

FEBRUARY 2025 UPDATE

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President's Message: Meeting the Moment

Dear Colleagues,

As noted in the November COGR Update, we anticipated there would be both policy threats and opportunities affecting research institutions given the changes in policy priorities of the new Administration and Congress. Both have manifested themselves in executive orders for example, the orders Ending Radical and Wasteful Government DEI Programs and Preferencing and Unleashing Prosperity Through Deregulation.

Here are some of COGR's recent actions to advance effective research policy and meet the moment:

- Letters to the new Administration offering recommendations to reduce red tape affecting research and noting the disruption and confusion new Executive Orders, and their subsequent implementation by federal agencies, have caused;
- Engagement with the media to explain and criticize the policy to cap NIH F&A research costs reimbursement at 15%;
- A new, and continuously updated, 2025 Administration Transition webpage that includes an Executive Order tracker, source documents, articles, and other resources to aid institutions;
- Release of a Transition Impact Survey (responses due February 24) to capture and quantify the financial, administrative, and personnel costs resulting from the payment pause and project cancellations;
- A new F&A Costs Reimbursement Materials web page that includes new and updated resources, including a new one-pager, and updated infographic, and more;
- An update to COGR's Changes in Federal Requirements Since 1991, including the chart that illustrates the unsustainable trajectory;
- A new portal where COGR members can share real-world stories about the impacts on research resulting from the new Administration's Executive Orders (log in required).

COGR's strategy and efforts have been informed and guided by joint discussions of the association's committees and the Board of Directors.

The Board of Directors earlier this month appointed three new members to the Board: Mike Legrand of the University of California at Davis, Missy Peloso of the University of Pennsylvania, and Lori Schultz of the University of Texas San Antonio. We are grateful for their service. COGR is stronger for their appointments and better positioned to advance effective research policy in this challenging political and policy environment.

COGR's February 25-28 Virtual Membership Meeting includes sessions on F&A costs reimbursements, the recent Executive Orders affecting research, research security, and more. The featured speaker is Marcia McNutt, President of the National Academy of Sciences. We will also hear from the leaders of COGR's committees about current issues and initiatives, and from colleagues from our partner organizations about recent legislative activities and the outlook for the year. The Virtual Membership Meeting will be an opportunity to not just learn the latest developments but to inform our advocacy in weeks and months ahead.

As we face an unprecedented number of simultaneous threats to research institutions' ability to perform federally funded research, COGR is grounded in the missions of our members institutions and the association's mission "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."

It is not hyperbole to say that our advocacy is more important than ever. The threats are numerous and severe. The successful partnership between academic research institutions and the federal government in service to our nation's security, health, and economic competitiveness is in jeopardy. From my conversations with university leaders and our partner associations, it is clear to me that they share COGR's determination to meet the moment. Critical to our success is your engagement with COGR and our partner higher education and research organizations.

Matt Owens
President

Announcements

New COGR Member Institutions: Welcome!

Now 225 strong, we are thrilled to announce that COGR has welcomed eight 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.

COGR Virtual Meeting February 25-28, 2024

Registration for COGR's February 25-28, 2025 virtual membership meeting is still open and the agenda, along with other meeting materials is posted to COGR's website. Sessions will be held via Zoom, and attendees will receive their registration links a few days prior to the meeting. If your institution will be registering five or more individuals, please reach out to memberservices@Cogr.edu for a special discount code.

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

Welcome New Board Members

COGR is pleased to welcome to our Board of Directors Michael Legrand, Associate Controller & Finance Director, University of California, Davis, Lori Ann Schultz, Senior Associate Vice President for Research Administration, The University of Texas at San Antonio, and Elizabeth Peloso, Sr. Associate Vice Provost & Sr. Associate Vice President for Research, University of Pennsylvania.

Mike will continue his service on COGR's Costing and Financial Compliance (CFC) Committee, Lori will serve on COGR's Contracts & Grants Administration (CGA) Committee, and Elizabeth will serve on COGR's Research Security and Intellectual Property Committee.

We thank Mike, Lori, and Missy for their commitment and service to COGR!

COGR's Emerging Research Institutions Pilot Program: FY 25 Participating Institutions

COGR launched an Emerging Research Institutions (ERI) Pilot Program on August 1, 2024, and we are pleased 15 universities are participating in Year 1. 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.

Emerging Research Institutions Pilot Participants

More information on COGR's ERI Pilot can be found on our website here. Please contact ERIservices@cogr.edu with questions.

Updated: Changes in Federal Requirements Since 1991

COGR updated its "Changes in Federal Requirements Since 1991" document In January 2025. New for this update:

- 2024 regulations and policies have been updated to include new additions since August 2024
- Cumulative graphic updated to highlight that the number of new/changed policies and regulations in the past ten years represents 62% of the total implemented or

changed since 1991
- GDP numbers are updated with the most up to d ate information available
- Graphics now available for download (log in required)
- Annual updates to this document will occur on an end-of-year schedule, so that totals are reflective of the full calendar year. Check back on COGR's website for the latest version.

Upcoming Comment Due Dates

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

Reminders

COGR Volunteer Survey

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

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.

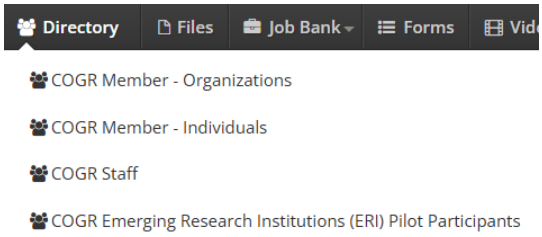
COGR Job Bank – New Opportunities Posted

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.

2025 Administration Transition Information and Resources

The Trump Administration implemented multiple Executive Orders (EOs) that had severe negative repercussions for research institutions, including termination of certain research grants and contracts, payment freezes, and unavailability of payment systems. These were followed by a late Friday, February 7th, NIH Grants Policy Notice drastically reducing the allowable F&A reimbursement rate for NIH grants. Multiple lawsuits were filed in response to both the payment freezes and NIH F&A rate reduction.

COGR has been closely following these events and quickly established the "2025 Administration Transition" webpage to provide members with easy access to resources and analysis regarding Whitehouse and agency actions. Additionally, members from all COGR Committees began jointly meeting to discuss developments, institutional responses, and advocacy efforts.

In addition to these efforts, COGR has:

- sent the new Administration on January 29th recommendations to reduce red tape affecting research and noting the disruption and confusion new Executive Orders, and their subsequent implementation by federal agencies, have caused;

- continuously updated the Summary of Executive Orders Tracker (latest version, V.5, released February 14, 2025);

- released a Transition Impact Survey (responses due February 24) to capture and quantify the financial, administrative, and personnel costs resulting from the payment pause and project cancellations;

- launched a new portal where COGR members can share real-world stories about the impacts on research resulting from the new Administration's Executive Orders (log in required).

Executive Orders

Between January 20 and February 14, 2025, the Trump Administration issued 106 EOs. Many of these EOs revoke prior EOs and focus on ending illegal immigration, promoting border security, withdrawing from certain international agreements and organizations, ending green energy and climate change initiatives, and imposing an "America First Trade Policy" including tariffs and export controls.

To assist institutions in understanding the EOs' impact, COGR published and regularly updates a Summary Tracker of Executive Orders ("Tracker"). The Tracker uses color-coding to indicate whether an EO has a high, moderate, or low level of impact on research or research funding. The EOs with the highest impact on research and research funding focus on the following broad areas:

- DEI: EOs in this area focus on halting the following activities by federal agencies, federally funded programs, and private entities: "illegal" diversity/equity/inclusion (DEI), diversity/equity/inclusion/accessibility (DEIA), and environmental justice activities (EJA). Major EOs in this category include:

    - Ending Radical and Wasteful Government DEI Programs and Preferencing (Jan. 20, 2025)
    - Initial Recission of Harmful Executive Orders and Actions (Jan. 20, 2025)

- Ending Illegal Discrimination and Restoring Merit-Based Opportunity (Jan. 21, 2025)

These EOs revoked prior EOs that established DEI/DEIA/EJA requirements for agencies, contractors and grantees, including the long-standing EO 11246 on equal employment opportunity, which dates to 1965. These "DEI EOs" also require OMB to coordinate termination of all DEI/DEIA/EJA related mandates, policies, programs, and activities in the federal government "under whatever name the appear."

Agencies were given 60 days to terminate all DEI/DEIA/EJA activities, including "equity-related" grants and contracts and performance requirements for federal employees, contractors, and grantees. Additionally, these EOs require federal grant recipients and contractors to certify that they do not operate any programs that promote DEI "in violation of federal law" and that compliance with federal anti-discrimination law is material to government payment decisions, thus setting the stage for future enforcement actions under the False Claims Act. Further, the EOs call on agencies to identify targets for compliance investigations of public corporations, non-profit corporations or associations, foundations with assets of $500 million or more, state and local bar and medical associations, and institutes of higher education with endowments of $1 billion or more.

- Ending "Gender Ideology"**:** EOs in this area focus on implementing the Trump Administration's policy of recognizing only two sexes – male and female – as determined at birth. Major EOs in this category include:

  - Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government
  - Keeping Men Out of Women's Sports
  - Protecting Children from Chemical and Surgical Mutilation

These EOs require federal agencies to identify and remove statements, policies, guidance, forms, and communications contrary to the EOs; end gender-identity access to sports and single-sex areas (e.g., restrooms, locker rooms); and align Title IX policies with this EO. They also prohibit "research or education grants to medical institutions, including medical schools and hospitals" that engage in any use of hormones, puberty blockers, or surgery to align a person's physical appearance with an identity that differs from their sex at birth.

- Suspending or Ending Certain Types of Foreign Assistance: The major EO in this area is "Reevaluating and Realigning United States Foreign Aid," which places a 90-day pause on foreign assistance, including new obligations and disbursement of

development assistance funds to foreign countries, non-governmental organizations, international organizations and contractors. During this pause, agencies are directed to evaluate the aid programs for efficiency and consistency with U.S. foreign policy and decide whether the assistance will continue, be modified, or cease altogether. Implementation of this (and other EOs) has resulted in the termination of a vast number of grants and contracts administered by USAID and the implementation of a plan to shut down this agency and move some of its functions to the State Department.

- Reducing Federal Regulations: EOs in this area focus on stemming new federal regulations. The two major EOs in this category are:

    - Regulatory Freeze Pending Review ("Freeze EO")
    - Unleashing Prosperity through Deregulation ("Deregulation EO").

The Freeze EO suspends the proposal or issuance of any new rule until it is reviewed and approved by a department or agency head appointment by the Trump Administration. It also instructs agencies to consider postponing until March 21, 2025, any rule (including certain guidance) that has been published in the Federal Register, or otherwise issued, but not yet taken effect. During this period, agencies can review these rules for "questions of law, fact, or policy" and can re-open the rule for further public comment.

The Deregulation EO requires an executive department or agency to identify at least ten regulations to be repealed when it promulgates a new regulation. It also sets forth certain requirements on incremental costs associated with new regulations, including a mandate that "the total incremental cost of all new regulations, including repealed regulations, being finalized . . . [in FY 2025], shall be significantly less than zero."

In addition to the foregoing EOs, on February 11, 2025, the Trump Administration issued an EO entitled Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative." Although this EO does not directly pertain to research or research funding, it is noted here because it will directly impact the federal workforce that oversees research funding. The EO calls on the Department of Government Efficiency (DOGE) to submit a plan to reduce the size of the federal work force that will require "each agency hire no more than one employee for every four employees that depart," excluding employees related to public safety, immigration, enforcement, or law enforcement. The EO also requires each agency to develop a plan that requires agency heads to approve the filling of any vacancies and to "undertake preparations to initiate large-scale reductions in force (RIFs), consistent with applicable law, and to separate from Federal service temporary employees and reemployed annuitants working in areas that

will likely be subject to RIFS." Offices that perform "functions not mandated by statute or other law" will be prioritized for RIFS.

Office of Management and Budget (OMB) and Agency Activity in Response to EOs and Ensuing Litigation

On January 27, 2025, OMB issued M-25-13, "Temporary Pause of Agency, Grant, Loan, and Other Financial Assistance Programs" ("M-25-13"). M-25-13 required federal agencies to "temporarily pause all activities related to obligation or disbursement of all Federal Financial assistance, and other relevant agency activities that may be implicated by the executive orders, including, but not limited to, financial assistance for foreign aid, nongovernmental organizations, DEI, woke gender ideology, and the green new deal." Agencies paused funding in response to M-25-13 and payment systems were taken off-line. Agencies also issued notices ordering funding recipients to immediately suspend all DEI/DEIA activities and stop incurring associated costs.

Institutions struggled with implementing these requirements because the EOs, M-25-13, and agency notices failed to provide concrete definitions of activities that would be considered illegal "DEI/DEIA" activities or guidance on how institutions should distinguish "illegal" DEI/DEIA activities from legal activities institutions must take to comply with current anti-discrimination statutes. Simultaneously, agencies implemented "communication holds," that prevented institutions and associations from using normal communications channels with agencies to gain clarification about the new requirements.

Two separate lawsuits were filed challenging M-25-13 and seeking a temporary restraining order (TRO) on implementation of the memorandum's payment freeze until the matter was fully litigated:

- State of New York v. Trump: This suit was filed by the attorney generals for 22 states and the District of Columbia in the federal District Court for Rhode Island. It sought a TRO halting the implementation of M-25-13 on the basis that this OMB Directive is unconstitutional and violates the Administrative Procedure Act (APA). Initially, the Trump Administration rescinded M-25-13 and sought to have this case dismissed as moot, but Administration statements that the EOs and payment pause remained in effect persuaded the court otherwise and it granted the TRO. To show its compliance with the TRO, the Department of Justice issued a Notice of Court Order ("Notice") to federal funding agencies advising them that per the TRO federal agencies "cannot pause, freeze, impede, block, cancel, or terminate any awards or obligations" on the basis of M-25-13 or the EOs. However, this Notice also stated that agencies "may exercise their own authority to pause awards or obligations, provided agencies do so

purely based on their own discretion" and not as a result of M-25-13 or the EOs. The Notice stated that it applies to all federal agencies, even those not named as defendants in the suits, as well as to all awards and obligations, not just those of the plaintiffs to the suits.

On February 7, the plaintiffs in this case filed a motion alleging that despite the Notice, the defendants were not adhering to the terms of the TRO, citing the continued freeze of federal grants. On February 10, the court held that the federal government had not followed the TRO and it ordered the government to immediately restore frozen federal funding and cease any further pause in funding while the litigation was pending. In response, the government appealed the TRO to the First Circuit and asked the District Court to stay the TRO until the appeal is decided. The First Circuit denied this request for a stay, and the TRO remains in force. Several institutions have notified COGR that CDC notified them that pursuant to the TRO, the following CDC communications have been rescinded:

- January 29, 2024: Cease DEI Activities on ALL CDC funded awards
- January 31, 2024: Cease ALL Activities Promoting Gender Ideology

- National Council of Nonprofits v. Office of Management and Budget: This suit, filed in the District Court for the District of Columbia, sought to have M-25-13 set aside and requested a TRO on its implementation until the court determines its legality. The court granted an administrative stay briefly halting the freeze, and the government sought to have the case dismissed as moot after M-25-13 was rescinded. The court did not dismiss the case and entered a TRO to prevent the government from freezing the disbursement of federal funds for all open awards. This case is now set for a hearing on February 20 on whether a preliminary injunction should be granted.

A third lawsuit was filed challenging the EOs underlying the funding freeze:

- National Association of Diversity Officers in Higher Education v. Trump: This suit was filed in the federal District Court of Maryland by the National Association of Diversity Officers in Higher Education and other plaintiffs, including the American Association of University Professors. The suit challenges the legality of the Trump Administration's Ending Radical Government DEI Programs and Preferencing and Ending Illegal Discrimination and Restoring Merit-Based Opportunity EOs and the funding freeze. Specifically, the suit alleges that these EOs are unconstitutional because they: (a) violate the separation of powers by ignoring Congress' spending powers; (b) are so vague that an ordinary person would not know what activities they

prohibit; and (c) they violate the First Amendment protections of free speech. The plaintiffs asked the court to declare the EOs unlawful and enjoin their enforcement.

Agency Specific Actions

Federal agencies have issued various directives and memoranda to implement the recent Executive Orders (EOs). Below is a summary of key agency actions.

- Agency Notices: COGR's 2025 Administration Transition Information & Resources includes a consolidated list of agency directives and memoranda issued in response to the EOs. Agencies that have released notices include the Department of Energy (DOE), Department of Health and Human Services (DHHS), National Aeronautics and Space Administration (NASA), Department of Labor (DOL), Department of Education (ED), United States Agency for International Development (USAID), National Science Foundation (NSF), General Services Administration (GSA), Department of Justice (DOJ), Centers for Disease Control and Prevention (CDC), and others. In some cases, members report receiving specific action notices for specific awards related to foreign aid or DEI. As agencies continue to issue guidance, we encourage members to share relevant communications with COGR at memberservices@cogr.edu.

- Communication with Agency Officials: As seen in previous administration transitions, some federal agencies initially suspended public communications, including study section meetings. Members have reported that communication with federal officials remains limited, with most interactions occurring through helpdesks, program officers, and grants management staff for specific projects. While there are reports that study section meetings have resumed, broader engagement on policy matters has yet to fully resume.

- Impact of EOs on Federal Awards: COGR has received multiple reports of agency actions affecting research and education projects involving DEI activities and foreign aid. Agencies, including the Department of State, USAID, United States Department of Agriculture (USDA), NIH, ED, NASA, and the Air Force Research Laboratory (AFRL), have issued stop-work orders and terminations. While these actions appear to be widespread across many federal agencies, NSF does not appear to be significantly impacted at this time.

  Additionally, NSF's Award Cash Management Service (ACM$) was temporarily down from January 27 to February 2 but has since been restored. NSF has also developed a webpage with FAQs on Executive Orders, which can be accessed here.

COGR has also received concerns regarding agency requests for institutions to certify compliance with DEI requirements, as seen in Department of State awards. In particular, the broad scope of these certifications appears to extend beyond individual projects, raising concerns. Members are working with their counsel offices to understand the requirements as there is no defined definition of DEI in the requirements.

- NIH No-Cost-Extensions (NCE): In early February, members reported that the NIH NCE module in eRA Commons was deactivated due to policy changes. We've received reports that the module was restored on February 12.

- Grants.gov Temporary Outage: On February 6, 2025, members reported a temporary outage of Grants.gov, accompanied by a message indicating the system would be restored by February 10. However, functionality was reinstated later that same day.

COGR continues to monitor agency responses to the EOs and broader administration directives. However, federal agency restrictions on communications and actions have delayed the flow of information, potentially impacting COGR's ability to provide timely updates.

Member input remains critical to our advocacy efforts. We encourage institutions to report agency communications regarding policy changes, stop-work orders, terminations, and other relevant actions by contacting memberservices@cogr.edu.

Impact of the Funding Pause and Project Terminations

Institutions were forced to use their own funds to meet institutional obligations on research projects while payments were suspended. Additionally, when agencies terminated awards that were specifically made for DEI/DEIA-related purposes and/or for foreign aid projects, institutions were forced to determine how to address faculty, staff, and students assigned to terminated research projects.

To capture and quantify the financial, administrative, and personnel costs resulting from the payment pause and project cancellations, COGR released an institutional survey. COGR urges each member institution to complete the survey, and submit only one response per institution. Importantly, institutions may complete the survey anonymously. Survey results will be vital to supporting COGR's advocacy efforts. Survey responses are due by February 24, 2025, and a preliminary report will be provided during the Committee Report session of the February membership meeting.

NIH Grants Policy Notice Reducing F&A Rate to 15%

On February 7, 2025, the NIH issued NOT-OD-25-068, "Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates ("Notice"). This Notice, issued without any forewarning to or consultation with the recipient community, stated that as of February 10, 2025, the government would no longer honor negotiated indirect costs rates and instead:

> *For any new grant issued, and for all existing grants to IHEs retroactive to the date this Supplemental Guidance, award recipients are subject to a 15 percent indirect cost rate.*

Three lawsuits were quickly filed seeking TROs to prevent implementation of this Notice:

- Commonwealth of Massachusetts v. National Institutes of Health: This suit, filed by the attorney generals of 21 states in the federal District Court of Massachusetts, alleged that the Notice is unlawful because it violates the APA and sought a TRO barring NIH from enforcing the Notice until the matter is fully litigated. The court granted the TRO and prohibited the government from taking any steps to implement or enforce the Notice with regard to the states that filed the suit. In response, the government provided a status report stating that NIH would not implement or enforce the rate change until further order from the court. There have also been press reports of internal NIH memos to this effect.

- Association of American Universities (AAU) v. Dept. of Health & Human Services: This suit was filed in the federal District Court for Massachusetts by AAU, the American Council on Education (ACE), the Association of Public and Land-Grant Universities, and several universities. It alleges that the Notice violates the APA and seeks to have court rule the Notice is invalid and enjoin its enforcement. The plaintiffs also filed a motion for a TRO, which is pending before the Court.

- American Association of Medical Colleges v. National Institutes of Health: This suit was filed by the Association of American Medical Colleges and other associations representing colleges of pharmacy, schools of public health, and hospitals in the federal District Court of Massachusetts. The plaintiffs allege that the Notice is unlawful based on several grounds and seek a TRO and permanent injunction. The court granted a nationwide TRO stating that:

  > *The Defendants and their officers, employees, servants, agents, appointees, and successors are hereby enjoined from taking any steps to implement, apply, or enforce the Supplemental Guidance to the 2024 NIH Grants Policy*

> *Statement: Indirect Cost Rates (NOTOD-25-068), issued by the Office of the Director of the National Institutes of Health on February 7, 2025 (the "Rate Change Notice"),* ***in any form with respect to institutions nationwide until further order is issued by this Court. [Emphasis added.]***

Given the similarity between the subject matter of the AAU and AAMC cases, the court has ordered the cases combined for argument.

Additional analysis of the Notice is provided in the CFC section of this update. For more information, visit COGR's webpage on the NIH 15% Cap which includes statements and article quotes from COGR and other higher education associations, litigation updates, and institutional communications.

Litigation Tracking

COGR's 2025 Administration Transition webpage includes links to the aforementioned TRO and NIH Notice cases, as well as other cases that impact research and research funding. One case of note is:

- Doctors for America v. Office of Personnel Management: In response to the EOs regarding gender ideology, Department of Health and Human Services agencies (DHHS), including CDC and FDA, removed from their websites health-related data and other resources that researchers and health professionals frequently use. The plaintiffs in this case (filed in the federal District Court for the District of Columbia) claim that these actions violate the APA and notice requirements under the Paperwork Reduction Act. The court granted the plaintiff's request for a TRO and ordered DHHS, CDC and FDA to restore their websites to the versions in place on January 30, 2025, and to consult with the plaintiff to identify any other information that is relied upon to provide medical care and was removed or substantially modified and restore that information to websites as well.

In addition to the cases tracked on the COGR site, there is an excellent publicly available resource for tracking all litigation concerning the Trump Administration EOS: the "Litigation Tracker: Legal Challenges to Trump Administration Actions." This webpage is published and regularly updated by JustSecurity, a non-profit, daily digital law and policy journal.

Science & Security: Cross-Cutting Issues

COGR Joins Other Higher Education Associations in Letter to Secretary of State Marco Rubio

On February 3, 2025, COGR joined thirty other higher education associations in writing to congratulate Secretary of State Marco Rubio on his confirmation. The letter emphasized the important role higher education plays in research and innovation. It highlighted the community's significant contribution to training a skilled workforce for the U.S.'s long-term economic prosperity and national security.

The letter raised concerns about delays and visa denials for international students, urging the State Department to improve processing times and consider waiving interviews for certain applicants to ensure the U.S. remains an attractive destination for global students.

The letter also underscored the ongoing collaboration between higher education and the federal government to address national security threats targeting the research and education sectors. It highlighted efforts such as the work with the previous administration on creating the NSPM-33 to address such threats while safeguarding the positive exchange of students and researchers. The letter concluded by expressing the community's desire "to continue to work with the State Department and the administration regarding these important issues impacting our exchange programs, international students, and research programs."

COGR Meets with Representatives of the Secure Center and Secure Analytics

COGR, AAU, APLU, and ACE met with leadership from the Safeguarding the Entire Community of the U.S. Research Ecosystem (SECURE) Program on January 28, 2025, for the group's first quarterly meeting. The meeting provided an update on SECURE's progress to date and discussed potential areas of collaboration among SECURE and the higher education associations in the research security policy space.

The SECURE Program, consisting of the SECURE Center and SECURE Analytics, was established this past summer with a five-year investment by the National Science Foundation. Led by the University of Washington, the Secure Center will provide members of the U.S. research community with a trustworthy platform to share needs and information on research security matters, it will act as a bridge between the research community and federal agencies, and it will provide training on research security. SECURE Analytics, led by Texas A&M University, will provide tools that support the analytic needs of the SECURE Center and the research security community as a whole.

FAR Controlled Unclassified Information Amendment (NEW)

The proposed rule on Controlled Unclassified Information (CUI), released on January 15, 2025, aims to amend the Federal Acquisition Regulation (FAR) to better align with the government's handling of sensitive but unclassified information across all agencies and federal contracts. The rule introduces requirements for contractors (and subcontractors) to safeguard and adequately manage CUI when performing work on government contracts in which sensitive, unclassified government data is either created or handled that must be protected from unauthorized.

Key elements of the proposed rule include:

1. **CUI Protection Requirements**: Contractors must implement controls for handling and storing CUI under the National Institute of Standards and Technology (NIST) Special Publication 800-171 revision 2, which outlines security standards for nonfederal systems. Key requirements of SP 800-171 r2 include access controls to limit who can view and handle CUI, data encryption during transmission and storage, routine monitoring and logging of system access and activity, and implementing incident response plans to address security breaches.
2. **Subcontractor Flowdown**: Prime contractors must ensure that any subcontractors handling CUI comply with the protection requirements.
3. **Reporting and Incident Management**: Contractors must promptly report any incidents of CUI breaches or mishandling and cooperate with the government to address and resolve security concerns.
4. **Training**: Contractors must train employees in handling CUI and document such for compliance purposes.

The proposed rule amends and introduces several new FAR clauses:

- FAR 52.204-21: Updated to establish a baseline for safeguarding CUI and aligns with the broader scope of the proposed rule.
- FAR 52.204-WW: Informs contractors about their CUI obligations and reporting responsibilities at the time of solicitation, including the requirement to notify the governmental contracting officer (GCO) within 8 hours of discovering any unmarked, improperly marked, or unidentified CUI and the safeguarding of such until further guidance can be provided.
- FAR 52.204-XX: Establishes the comprehensive requirements for identifying and safeguarding CUI, reporting incidents, and preserving data. It also specifies that contractors are only responsible for protecting CUI identified in the CUI Standard Form (see below), except unmarked or mismarked CUI, which must be safeguarded until the GCO clarifies.

- FAR 52.204-YY: Assigns to the contractor the responsibility for identifying and reporting potential CUI and safeguarding it until the GCO. Contractors must report any suspected CUI incident to the GCO within 8 hours of a suspected incident and safeguard such information until the GCO determines whether such information is CUI. Additionally, contractors must appropriately label their own proprietary information when submitting it to the government. The government will decide if such information qualifies as CUI or warrants other protection mechanisms.
- FAR 53.204-2: Introduces Standard Form (SF) XXX, Controlled Unclassified Information Requirements (the CUI Standard Form). The form identifies the categories of CUI a contractor (or subcontractor) may handle during performance, requirements for handling, safeguarding, disseminating, decontrolling, and marking of CUI, and the compliance obligations for reporting CUI incidents. The CUI Standard Form will be included in solicitations and contracts to establish clear requirements from the outset.

RSIP is currently reviewing and plans to submit comments requesting clarification in the rule's text that will explicitly state that fundamental research is outside the scope of NIST 800-171 requirements and highlight other concerns. Comments were originally due March 17, 2025. RSIP has sought confirmation of this March 17th deadline considering the Presidential Memorandum "Regulatory Freeze Pending Review" issued on January 28, 2025.

Department of Justice (DOJ) Final Rule on Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons (UPDATE)

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 and with COC-affiliated persons or entities ("Covered Persons"). [Note: Covered Persons can include entities within the U.S. that meet certain ownership criteria or have been designated as Covered Persons by DOJ.]

COGR submitted comments on the DOJ ANPRM. The DOJ reviewed comments received in response to the ANPRM and issued an NPRM on October 29, 2024. COGR submitted comments on this NPRM, and COGR staff were interviewed by personnel from the Department of Justice and Department of Commerce regarding the Proposed Rule's impact on clinical research. In its comments, COGR emphasized the need for an overarching exemption for the conduct of non-federally funded research activities that did not qualify under the Proposed Rule's exemptions for federally funded research and certain clinical trials required for government approval of new drugs, devices, and biologics.

Although DOJ did not include such an exemption in the Final Rule, it did make modifications to the Final Rule that addressed several other COGR comments, as discussed below.

The major points of the Final Rule are summarized here:

Effective Date: To date, the Trump Administration has not revoked President Biden's Executive Order 14117, which formed the basis for the promulgation of the Final Rule. Further, DOJ has not published anything to indicate the that Final Rule is being re-reviewed or re-opened for public comment under the Trump Administration's Regulatory Freeze Pending Review EO, which calls for agencies to consider postponing for 60 days any rules published in the Federal Register that have not yet taken effect. **Accordingly, the Final Rule appears set to become effective on April 8, 2025, and it will cover all new and ongoing transactions on or after that date**.

General Overview of the Rule's Requirements: The Final Rule prohibits certain transfers of bulk sensitive personal data of U.S. persons and government-related data to a COC or Covered Person. 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. **There is no exemption for deidentified, anonymized, or pseudonymized data.** Government-related data consists of precise geolocation data for certain U.S. government facilities and current/former senior government personnel.

The Proposed Rule prohibits certain types of data transactions (i.e., Data Brokerage Transactions, and Transactions involving Human Genomic Data, Other 'Omic Data, and Human Biospecimens) 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 (i.e., Vendor, Employment, and Investment Agreements) and can be undertaken only if the U.S. person complies with detailed due diligence, compliance, and security (including cybersecurity) 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. [See COGR's November 2024 Update for a full discussion of the definitions of Covered Persons, Covered Data and Covered Transactions, the rule's scope, and pertinent exemptions.].

New Category of Data Added to Final Rule: The Final Rule added Other 'Omic Data' as a new category of Covered Data. Other 'Omic Data includes "human epigenomic data," "human proteomic data," and "human transcriptomic data (excluding pathogen-specific

data embedded in human omic data sets)," and the Final Rule defines each of these terms. The numeric threshold for Other 'Omic Data is 1,000 persons; the threshold for human genomic data/biospecimens remains at 100 persons.

Data Brokerage Transactions: The Final Rule retains its complete prohibition on a U.S. person knowingly engaging in the sale of, licensing access to, or "similar commercial transactions" that involve access to Covered 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. In its comments, COGR asked DOJ to clarify whether "Data Brokerage" includes the transfer of Covered Data to a researcher in a COC for collaboration on a paper/co-authorship. DOJ did not explicitly address this question, but it did state in the Final Rule's preamble that "without more, a mutual interest in conducting research together, or the possibility of research collaboration or co-authoring a paper, would not constitute the kind of valuable consideration needed to qualify as a Covered Data Transaction" and that "the rule does not preclude research in a country of concern, or research collaborations or partnerships with covered persons that do not involve any payment or other consideration as part of a covered data transaction." [90 F.R. at p, 1648-49]. Note however, that DOJ's subsequent commentary states that "the value and benefit derived from one's experience [from unpaid service on a volunteer board] can constitute 'other consideration' as part of an exchange for services rendered." [90 F.R. at p. 1671]. Finally, the Final Rule retains its requirement that any U.S. person who enters into a Data Brokerage Transaction involving Covered Data with any foreign person or entity must contractually require the foreign person/entity to refrain from entering into a subsequent, onward Covered Data transactions with a COC or Covered Person and report to the U.S. person any known or suspected violations of this contractual requirement.

Exemptions: The Final Rule provided clarifications regarding the following exemptions:

- **Government Activities Exemptions**: The "Government Activities Exemption," exempts the U.S. government's provision of access to its own data and encompasses the activities of government grantees and contractors. In response to COGR and others' comments, DOJ clarified that the exemption applies to "transactions conducted pursuant to a grant, contract, or other agreement with Federal departments and agencies . . . even if those transactions also involve funding from non-Federal entities." [90 F.R. at p. 1676]. DOJ also clarified that data, which at the time of the transaction, is "lawfully available to the public from a Federal, State, or local government record or in widely distributed media, including unrestricted and open-access data repositories" is excluded from the definition of "sensitive personal data." [90 F.R. at p. 1686].

- **Biospecimens**: The Final Rule revised the definition of biospecimen to exclude the transfer of biospecimens that are "intended by a recipient solely for use in diagnosing, treating, or preventing any disease or medical condition." [90 F.R. at p. 1687].

- **Drug, Biological Product, and Medical Device Authorizations Exemption**: DOJ clarified that this exemption extends to regulatory inspections that are necessary to maintain a product's marketing authorization, but it does not cover the release of unredacted, identifiable bulk U.S. sensitive personal data for such inspections. [90 F.R. at p. 1681]. DOJ also made clear that the exemption does not extend to the use of a contract research organization or similar persons/entities to organize or submit Covered Data to the drug regulatory authorities in a COC if the use of those persons/entities is not necessary to obtain or maintain the product's authorization. [90 F.R. at p. 1682].

- **Other Clinical Investigations and Post-Market Surveillance Data Exemption**: DOJ clarified that this exemption may apply to persons/entities that are involved in the research (e.g., IRBs), as well as to persons/entities actually performing the research. Further, DOJ advised that data submissions to global public health authority databases will likely be exempt unless the authorities are Covered Persons and/or potentially covered by general licenses. [90 F.R. at p. 1685].

- **Compliance Program and Due Diligence Requirements**: The Final Rule delays the effective date for the due diligence and audit requirements set forth in Subpart J of the rule until October 5, 2025. DOJ modified the Final Rule to permit U.S. persons to perform internal audits of compliance programs for restricted transactions provided the auditors are sufficiently independent. In discussing due diligence requirements for vetting individuals/entities to ensure that they are not "Covered Persons," DOJ stated that U.S. persons cannot simply rely on certification from those individual/entities that they are not Covered Persons, but that certifications "with supporting documentation" may be a reasonable approach. [90 F.R. at p. 1689].

- **Research Institutions Implementation of the Final Rule**: Although many research activities will fall under one of the Final Rule's exemptions, the rule has the potential to impact a wide variety of U.S. persons/entities' 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 located both in and outside the U.S. 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 Covered 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, as previously mentioned, institutions must amend any contacts with foreign persons/entities for Data Brokerage Transactions to include provisions prohibiting subsequent transactions involving Covered Data with COCs/Covered Persons and requiring the reporting of violations of these provisions.

Research Security & Intellectual Property (RSIP)

Select Committee activities related to the 2025 Administration Transition and 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 (UPDATE)

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 concern with the USDA Statement is that it appears to prescribe the disposition of intellectual property owned by universities under the Bayh-Dole Act, which could substantially affect an institution's ability to transfer technology to the private sector for commercialization and potentially affect future research endeavors.

APLU met with USDA representatives in December to discuss these concerns, which several higher education associations share. As part of that conversation, and despite assurances that the USDA Statement was not intended to prescribe how universities should effectively transfer intellectual property, APLU was encouraged to submit comments highlighting any concerns. On February 7, 2025, COGR, APLU, and AAU sent a joint letter to Dr. Manjit Misra, Director of the USDA National Institute of Food and Agriculture, encouraging the department to maintain its current practices and remain consistent with the Bayh-Dole Act.

NIH Intramural Research Program Access Planning Policy (UPDATE)

On January 10, 2025, the National Institutes of Health (NIH) issued the Intramural Research Program Policy: Promoting Equity Through Access Planning (Notice Number: NOT-OD-25-062). Under the Intramural Research Program Policy (IRP Policy or Policy), companies seeking a commercial license must first submit a plan outlining the steps they will actively take to promote patient access in underserved communities in the United States and the rest of the world (Access Plan). Once approved by NIH, the Access Plan will be incorporated into the license granted as part of the licensee's development plan. The Policy applies to any exclusive, co-exclusive, partially exclusive, or non-exclusive licenses granted by NIH for the commercial rights in a patent wholly owned by the federal government that would authorize the commercialization of drugs, biologics (including vaccines), or devices used for the prevention, diagnosis, or treatment of human disease.

As a matter of clarification, the IRP Policy and the requirement for an Access Plan do not apply to licenses granting rights in patents owned by universities and other nonprofit organizations resulting from NIH research in compliance with 37 CFR Part 401. The Policy also does not apply to license applications submitted to NIH for the sale of reagents for research purposes only, provided that the use has no clinical or therapeutic scope.

Per the new policy, any license application submitted to NIH on or after June 1, 2025, must include an Access Plan for NIH's review and approval. The elements of a Plan need to include (i) a brief description of the licensed product, (ii) the anticipated patient population(s), (iii) other products, tools, or resources necessary for the use of the product, and (iv) strategies to be undertaken by the licensee to promote patient access that may include partnering with public health or patient advocacy organizations, addressing accessibility and promoting equitable access as a product design objective, and committing to sublicensing that promote and accelerate underserved population access. The potential licensee must also provide an update on the Plan's progress and submit a non-confidential version of the Plan within 3 months of FDA approval so that such a version may be published.

Failure to address compliance with the Access Plan can result in the license being amended to remove exclusivity or otherwise narrow the scope of the rights granted, increase royalties paid by the licensee, or terminate the license.

Despite sharing NIH's aspiration for broad access to innovation and products resulting from federally funded research, COGR submitted a comment letter to Deputy Director Tabak on July 22, 2024, expressing concerns with the proposed Policy, including the potential to increase uncertainty in the commercialization process and unnecessarily

hamper the introduction of products into the marketplace, as well as our concurrence with the comments submitted by AUTM.

DOD Cybersecurity Maturity Model Certification (UPDATE)

The revised set of cybersecurity standards, commonly called CMMC 2.0, was enacted on December 16, 2024. The CMMC framework is relevant for defense contractors and subcontractors, including universities performing research under a Department of Defense (DoD) contract, who have access to or are creating Controlled Unclassified Information (CUI) or Federal Contract Information (FCI) during the performance of the contract.

The new framework's requirements will be implemented in four phases over the next three years and are intended to simplify the process, making compliance easier for DoD contractors and subcontractors handling CUI or FCI.

The first phase of implementation commenced on the effective date of the final rule (December 16, 2024) and requires level 1 or level 2 self-assessment, as applicable. The second phase begins 12 months after the start of phase one. In addition to phase one requirements, solicitations will require level 2 certification, as applicable. Phase three begins twenty-three months after the start of the first phase and will add level 3 certification to solicitation requirements, as applicable. Thirty-six months after the start of phase one, all solicitations and contracts will include appropriate CMMC-level requirements as a condition of contract award in the final implementation phase.

An organization's cost of compliance will be largely determined by the CMMC compliance level required in the solicitation or contract terms. Still, it can also vary widely based on individual factors of the institution, including the need to update the institution's cybersecurity policies, the need for additional staff, additional training required, the size of the institution's IT infrastructure, efforts required to prepare for an assessment and any subsequent remediation activities, the cost of any required third-party assessment.

Joined by EDUCAUSE, AAU, APLU, and ACE starting in 2020, COGR has consistently urged the DoD to amend the regulation's text to unequivocally clarify that fundamental research is outside the scope of the CMMC assessment provisions. In the Final Rule, the DoD 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."

In January, COGR published a CMMC 2.0 overview document highlighting key updates to the framework, steps for compliance, the timeline for the phased implementation, and links to resources published by the DoD Chief Information Officer.

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.

NSF Intellectual Property Options (NEW)

On December 16, 2024, the National Science Foundation (NSF) issued a Request for Comments on Proposed Intellectual Property Options. The original deadline to submit comments was January 24, 2025. At the request of COGR and other stakeholders, NSF amended the original request for comments to extend the comment period to February 21, 2025, and provide additional information to clarify the scope of awards for which the Proposed Intellectual Property Options would be applied. The request seeks public comments on three proposed intellectual property (IP) options only for use in award agreements in which NSF and a third-party organization have an explicit agreement to co-fund the award before issuance of the grant.

In the original RFC, NSF states that the Bayh-Dole Act informed the proposed IP options and that pursuant to applicable laws and regulations, the right, title, and interest in intellectual property funded by NSF shall vest in the entity that created it.

As further clarification, NSF explicitly states in the amended RFC that the IP options will not apply to the rest of the agency's award portfolio and that the agency will not participate in negotiations between awardees and industry partners.

According to the RFC, the Directorate for Technology, Innovation and Partnership developed the proposed IP access options after receiving feedback at the 2023 NSF-Industry Partnership Summit and subsequent listening session to address a need to facilitate the negotiation of intellectual property access terms between industry and academia.

The three IP options described in the RFC are a Research License with a Commercial Option, a Convertible Commercial License, and a Research-Only License. In all cases, NSF retains for itself and on behalf of the federal government, a non-exclusive, irrevocable, paid-up license to practice (or have practiced on behalf of the government) a governmental purpose license.

Research License With Commercial Option. This schema provides a non-exclusive, royalty-free license for research purposes only to all project "partners" (R&D License). The term of the R&D License is for 18 months from the date of disclosure of any intellectual property resulting directly from research funded by NSF (Project IP). During the term of the R&D License, any "partner" shall have 12 months to indicate in writing to the Project IP owner its exercise of a right of first negotiation (RFON) for the exclusive commercial license. The parties shall have up to 6 months to negotiate the exclusive commercial license. If no

exclusive license is agreed upon, a perpetual, non-exclusive, royalty-free research license is granted to all "partners."

Convertible Commercial License. This schema entitles all "partners" to a non-exclusive, royalty-free license for research and commercial purposes for up to 18 months from the disclosure date. Similar to the Research License with a Commercial Option schema, any "partner" can exercise their RFON within the first twelve months of the license term by providing the Project IP owner written notification. The parties shall have up to 6 months to negotiate the exclusive commercial license. If an exclusive license is secured during the negotiation period, the rights of the other "partners" convert to a perpetual, non-exclusive, royalty-free research license. If no exclusive license is agreed upon, a perpetual, non-exclusive, royalty-free research license is granted to all "partners."

Research-Only License. This schema grants all "partners" a non-exclusive royalty-free license to Project IP for research purposes only.

NSF needs to clarify key aspects of the Proposed Intellectual Property Options, including but not limited to:

- Who is responsible for selecting which of the three IP schemas applies to a given award? It is unclear whether NSF will determine and publish the relevant option at the time of solicitation or if the awardee will have the latitude to choose the appropriate IP option.
- Who will bear the cost of patent expenses, if any, during the 18-month period following the invention's disclosure, and will the Project IP owner be required to elect title even under the schema(s) that could grant a perpetual, non-exclusive license to one or more "partners"?
- What is the obligation of the Project IP owner to negotiate when multiple "partners" assert their right to first negotiation? Does the university only have to negotiate with the party who submits its written exercise to negotiate first? Will the university need to negotiate for co-exclusive licenses?
- Are the exclusive commercial licenses for all fields of use and/or jurisdictions, or can the Project IP owner determine appropriate fields of use and jurisdictions?

These ambiguities, and others, suggest a need for further clarification at a minimum or, more likely, an outright abandonment of the proposal.

RSIP is currently drafting a response to NSF. If your institution would like to provide any comments to RSIP for potential inclusion in COGR's response, please contact Kevin Wozniak, Director of RSIP, at kwozniak@cogr.edu.

COGR Meets with GAO Representatives Regarding Process for Disclosing Federally Funded Inventions (NEW)

COGR met with representatives from the General Accountability Office (GAO) on January 30, 2025, to discuss the challenges U.S. research universities face in disclosing inventions and patents to federal agencies and complying with reporting requirements under the Bayh-Dole Act.

In addition, GAO was interested in understanding the impact the federal reporting requirements have on technology transfer office resources, the degree to which institutions of different sizes are affected, and the barriers this may have on U.S. competitiveness.

COGR emphasized the following points during the discussion:

- Our community's appreciation for the efforts undertaken by the National Institute of Standards and Technology (NIST) to update the iEdison reporting system.
- There is a need for a single reporting system that all federal funding agencies use exclusively for all invention and commercialization reporting requirements.
- The increase in resource expenditures by technology transfer offices to meet the changing utilization reporting requirements implemented by various federal agencies.
- There is a need to harmonize intra- and inter-agency reporting requirements with a defined approval process for deviations from baseline requirements.

Costing and Financial Compliance (CFC)

Select Committee activities related to the 2025 Administration Transition are reported above under the Cross Cutting Issues section of the COGR Update. Other items followed by CFC are covered below.

Threats to F&A Cost Reimbursement. NIH Grants Policy Notice. (UPDATE)

As described in the 2025 Administration Transition section, above, on February 7, 2025, the NIH issued NOT-OD-25-068, "Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates ("Notice"). This Notice, issued without any forewarning to or consultation with the recipient community, stated that as of February 10, 2025, the government would no longer honor negotiated indirect cost rates and instead:

> *For any new grant issued, and for all existing grants to IHEs retroactive to the date of issuance of this Supplemental Guidance, award recipients are subject to a 15 percent indirect cost rate."*

As the CFC Committee follows the lawsuits, TROs, and any forthcoming legal actions impacting implementation of a 15 percent indirect cost reimbursement rate for NIH grants, and potentially other awards, it is assessing both the potential financial impact and the administrative burden. Institutions are, understandably, confused and concerned about how to implement, in part because the NIH Grants Policy Notice conflates indirect/facilities and administrative (F&A) cost rates with the percentage of the award budgeted and charged as F&A cost:

> *Yet the average indirect cost rate reported by NIH has averaged between 27% and 28% over time.[2] And many organizations are much higher—charging indirect rates of over 50% and in some cases over 60%."*

"27% and 28%" represent the percentage of total funds directed toward F&A cost reimbursement while "over 50% and in some cases over 60%" are examples of F&A cost rates, which are applied to Modified Total Direct Costs (MTDC). F&A cost rates, on average across institutions, applied to MTDC result in 27-28% of the total funds used for reimbursement of F&A costs. Further, the Notice calls out foundation rates of 10-15%, with no acknowledgment that they typically allow F&A cost reimbursement rates to be applied to a larger, Total Direct Cost (TDC) base.

Institutions are not certain whether to continue preparing while a TRO is in place. Many have prepared impact analyses for advocacy and financial impact planning. But many assumptions are involved, including the appropriate application base, as the Notice does not state whether the 15% rate should apply to MTDC, TDC, or perhaps even total cost. If applicable to TDC, a 15% rate would result in just over 13% of the total

Administrators and researchers are uncertain about the future of equitable cost reimbursement and the impact of the other administrative actions described in the above 2025 Administration Transition section. Administrators are attempting to prepare, while also being asked to estimate the financial impact and provide clarifications and solutions that do not exist. This impedes progress and creates additional burden.

If the lawsuits are successful, it will be a battle won but we anticipate the war will continue. In previous updates, May 2024 Update and July 2024 Update, we reported on legislative attempts to eliminate or further cap F&A costs reimbursement. While some in Congress are criticizing the Notice, we anticipate continued legislative threats to equitable reimbursement.

COGR will continue to work with our partner 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. COGR's F&A cost reimbursement materials include several recent additions and updates and we are continuing to develop more effective communications. COGR recommends using the Guide to Updating Websites (Log in Required) to assist in 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. It is also important to note that our Institutions are not fully reimbursed and are already subsidizing federally funded research.

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

Changes to OMB Guidance Impacting F&A Cost Rates: COGR Continues to Advocate for Practical Solutions (UPDATE)

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.

On January 15, 2025 the COFFA issued Additional Implementation Information, "2 CFR Implementation and Flexibilities For Emergencies or Major Disasters," including section II. Flexibilities for Existing Awards Made Under the Prior Version of the Uniform Grants Guidance. This Memorandum grants two OMB class exceptions "applicable to awards applying the prior version of the Uniform Grants Guidance." One exception allows, with written agency notice or approval,

> *"recipients of both active and expired Federal awards, and subrecipients of both active and expired subawards, which applied the prior version of the Uniform Grants Guidance," to "instead use the revised equipment thresholds of $10,000 provided in the 2024 Revisions."*

While this guidance might be interpreted to apply only to the 2 CFR 200 Property Standards, but the Memorandum further states,

> *"Supplementary information in COFFA's August 2024 Memorandum … stated that "Federal agencies may also engage with recipients to address questions on*

whether systematic changes made by a recipient … could impact compliance with the terms and conditions of existing Federal awards." COFFA now clarifies, through this memorandum, that OMB's prior statement does not require recipients to receive formal approval from Federal agencies to implement systems changes to comply with the 2024 Revisions."

As significant systematic changes are required to make equipment inventory threshold changes, another interpretation is that changes that impact compliance with Property Standards do not require prior approval and changes that impact thresholds for MTDC purposes do require prior approval, but are possible.

COGR has not yet been in contact with OMB about the above guidance but will continue to pursue clarifications that will provide adequate flexibility for institutions to compliantly increase thresholds as allowed by revisions to 2 CFR 200 that went into effect October 1, 2024. Without flexibility, implementing compliantly is impractical given the various dates to be considered and local system constraints. We are hopeful that the above guidance is in response to OMB's engagement with COGR, including during the October COGR membership meeting when members of the CFC and CGA committees met with OMB and shared specific examples of situations with no practical solution. 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.

As a reminder, 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.

Accrued Leave Payouts (UPDATE)

On January 15, 2025, COFFA issued 2 CFR 200: Frequently Asked Questions, replacing the previous version, applicable to the previous version of 2 CFR 200. Included in these FAQs is:

§ 200.431 Compensation – fringe benefits.

83. Is it allowable for a recipient, using cash basis accounting with unfunded or unrecorded leave liabilities, to charge unused leave for employees that retire or are terminated?

No, this would not align with § 200.431(b)(3)(i). Charging all unused leave costs for

separating employees in the same manner as it had charged the employees' salary costs (i.e., directly to the activities on which the employees were working at the time of their separation) would result in inequitable distribution of the unused leave costs, because the leave costs were accumulated over the entire period of employment while working on various programs. In addition, having the last program bear the burden of these unbudgeted costs creates an unfair distribution of costs to this program. Therefore, **any state, Local or Tribal government** using the cash basis of accounting should allocate payments for unused leave, when an employee retires or terminates employment, in the year of payment as a general administrative expense to all activities of the governmental unit or component or, with the approval of the cognizant agency for indirect costs, the costs can
be included in fringe benefit rates. (emphasis added)

COGR is assessing whether this clarification is specific to "any state, Local or Tribal government or should be considered more broadly.

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.

Requirement to Adjust F&A Cost Pools (REMINDER)

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. The cap may also impact fringe benefit rates and service center rates.

COGR participated in an NCURA Webinar on this topic, which was recorded and available to everyone at no cost. An SRAI Webinar was also provided to the grants community at no cost.

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.

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

The fiscal year 2023 HERD survey results were released on schedule in November 2024. COGR frequently uses information from the annual HERD results in its advocacy for

equitable cost reimbursement regulation, policy, and practice and included analysis of some results in the December 2024 F&A Survey Capstone: Cost Reimbursement Rates, Actual Reimbursement, and Growing Regulatory Burden.

The survey results were accompanied by an InfoBrief, which reported a total increase in Higher Education research and development (R&D) expenditures of 11.2 percent. Of particular interest to COGR is Figure 2 of the InfoBrief, showing that of the $108.7 billion reported by participants reporting $1 million or more in R&D expenditures, unrecovered F&A cost totaled almost $6.8 billion. Of note, this number does not include amounts unreimbursed because of the 26% cap on the administrative component of the F&A cost reimbursement rate, as the survey instructs participants not to include those amounts. It also does not include voluntary uncommitted cost sharing and amounts over salary rate limitations, which may, instead be reported by participants in the Institutionally funded R&D expenditures category. COGR's F&A Survey Capstone also includes a comparison of the 2023 to 2010 survey results by funding source, which shows that the institutional share increased by 6 percentage points (from 19.5 to 25.5 percent) while the federal government share decreased by 6.4 percentage points (from 61.2 to 54.8 percent).

COGR will continue to use HERD survey data, its survey data, and other resources to demonstrate the continually increasing institutional share of critical financial investment in the nation's R&D.

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.

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 the 2025 Administration Transition 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)

As previously reported, 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. The revisions significantly depart from performance-based accountability and instead create an over-emphasis on financial oversight, reporting, and administrative requirements, ultimately disincentivizing the use of fixed-amount instruments. The certification requirement in 200.201(b)(4), which previously addressed only project completion, was revised to add "and that all expenditures were incurred in accordance with 200.403." In particular, specifying that costs were "incurred" significantly handicaps reliance on performance-based standards. Additionally, in 200.201 (b)(1), the replacement of "adequate" with "accurate" cost implies a (unintended) change to a higher standard of precision in costing is required, as described in COGR's Fifth Look: Implementation and Readiness Guide for the OMB Guidance for Federal Financial Assistance.

As mentioned above, on January 15, 2025, OMB released updated 2 CFR 200: Frequently Asked Questions (FAQs).

For fixed amount awards, OMB retained three of the seven FAQs from May 3, 2021 FAQs, and introduced one new FAQ in the January 15, 2025 FAQs.

FAQ #6 (previously Q-33, May 3, 2021 FAQ) reinforces the understanding of Section 200.201(b)(1) and "adequate" cost in relation to 2024 revisions of "accurate" costs.

> *6. What standards are used when deciding to use a fixed amount award, particularly when a project scope is specific and what constitutes adequate cost, historical, or unit price data?*
>
> *Fixed amount (fixed price) awards are* ***appropriate*** *when the work that is to be performed can be priced with a reasonable degree of certainty…Examples of mechanisms to establish an appropriate amount for a fixed amount award include the recipient's past experience with similar types of work for which outcomes and the award's costs can be reliably predicted, or the recipient can easily obtain estimates* (e.g., bids, quotes, catalog pricing) for significant cost elements to establish an amount…"

FAQ #7 [NEW] clarifies that salary costs exceeding a Federal agency's salary cap do not constitute mandatory cost-sharing when determining eligibility for fixed-amount awards or subawards.

> *7. Section 200.201(b)(2) states that a fixed amount award (or subaward) cannot be used in programs that require a mandatory cost share. Do salary costs that exceed a Federal agency's salary cap constitute "mandatory cost-sharing" for the purpose of determining whether a fixed amount award or subaward can be used?*
>
> *No, salary costs above a Federal agency's cap are not a mandatory cost share or match but, instead, are the result of limitations on the amount of salary costs that may be charged to the Federal award, and are paid at the discretion of the recipient. Since these salary costs above a Federal agency's cap are not a mandatory cost share or match, a fixed amount award or subaward can be used.*

FAQ #8 (previously Q-34, May 3, 2021 FAQ) reinforces the understanding of certification requirements. There is additional clarification that recipients and subrecipients must maintain records for audit purposes.

> 8. What reporting and documentation requirements should the recipient provide to the awarding agency to fulfill the certification requirement for Fixed Amount Awards?
>
> The Federal agency or pass-through entity may specify the form or format required to certify completion or that the level of effort was expended. If no format is specified, the recipient should certify completion to the Federal agency (or the subrecipient should certify to the pass-through entity) as a part of the closeout process. **The 2024 Revisions clarify that records should be maintained and made available for audits. 2 CFR 200.201(b)(1) provides that recipients and subrecipients of fixed amount awards are subject to record retention requirements contained in 2 CFR §§ 200.334 through 200.338. It also explains that fixed amount awards do not absolve the recipient or subrecipient of the responsibilities of making records available for review during an audit**.

FAQ #9 (previously Q-38, May 3, 2021 FAQ) reinforces the understanding that cost principles should be used as a guide when pricing fixed-amount awards but do not serve as compliance requirements once an award is issued. Payments are based on achievement of milestones rather than actual costs incurred.

> *49. How do the Cost Principles in subpart E apply to fixed amount awards and subawards?*
>
> *For fixed amount awards… the cost principles should be used as a guide when proposing (pricing) the work that will be performed but are not formally used as compliance requirements for these types of awards. In other words, the recipient and*

the Federal agency… will use the principles along with historic information about the work to be performed to establish the amount that should be paid for the work to be performed. Once the price is established and the fixed amount award or subaward is issued, payments are based on achievement of milestones… and not on the actual costs incurred.

While there have been no formal discussions with OMB under the current administration, COGR will continue to advocate for solutions to address concerns raised by the research community. OMB has previously indicated willingness to collaborate with stakeholders and COGR will persist in engaging on this critical issue.

Transition of FSRS Subaward Reporting to SAM.gov (NEW)

The General Services Administration (GSA) has announced plans to retire the Federal Funding Accountability and Transparency Act (FFATA) Subaward Reporting System (FSRS.gov) and transition subaward reporting to the System for Award Management (SAM.gov). The transition aims to streamline reporting processes and integrate subaward data into a centralized federal system. For the latest information about the upcoming move see SAM.gov/FSRS.

To facilitate this transition, GSA has provided an Application Programming Interface **(API)** for bulk uploading subaward reports. Detailed information about the API is accessible here. During a recent meeting, GSA highlighted access to the API will be important for institutions managing high volumes of subaward data. Institutions should consult with their IT offices on system requirements.

Some important considerations for the API include:

- *You must have an alpha.SAM.gov system account with reporting permissions and a system account API key to use this API to report subcontracts and subawards.*
- *You can use the same system account for an entity and any of its child entities. You do not need separate system accounts for each child entity.*
- *You need separate system accounts to bulk report for entities not in the same hierarchy.*
- *API requests must use a REST API connection type.*
- *API requests must come from the IP address(es) listed on your system account application.*

At the request of COFFA several COGR members have volunteered to participate in User Acceptance Testing (UAT) for the new system. Their feedback will help refine the implementation process before the full transition. Institutions interested in participating in UAT can provide feedback through GSA's UAT form.

For ongoing updates, discussions, and open houses, institutions can refer to the GSA Interact Community here.

COGR Responds to Request for Comment on PAPPG 26-1 (NEW)

The National Science Foundation (NSF) issued a request for comment on the Proposal & Award Policies & Procedures Guide (PAPPG) 26-1. Key revisions include updates to align with the revised 2 CFR Part 200, implementation of NSF's public access policy, and modifications to various research security requirements, including Foreign Financial Disclosure Requirements (FFDR). PAPPG 26-1 is set to take effect in October 2025.

COGR submitted a response letter to NSF outlining key recommendations. For the updated NSF ID requirements, COGR recommended limiting their application to NSF systems and requiring multifactor authentication only for financial roles. In research security, COGR requested clarification on when research security training is required and urged NSF to maintain the current FFDR reporting period (July 1 – June 30). Additionally, COGR identified sections of the PAPPG that should be updated to align with 2 CFR 200 and requested clarifications on aspects of NSF's public access requirements. Further clarification was also requested regarding reliance on NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules. Lastly, COGR sought clarification on recipient obligations related to NSF Brand Standards for equipment.

Requests for Comment Under Review (NEW)

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

- NIH Persistent Identifier (PID) RFI **[Due: 2/21/25], Link**
  The National Institutes of Health (NIH) is seeking public input on a plan to enhance the findability and transparency of research results through the use of metadata and persistent identifiers (PIDs). This initiative aims to improve research tracking and accessibility.
- Interim Final Rule (IFR): DOE Other Transaction Agreements (OTA) **[Due: 3/4/25], Link**
  The Department of Energy (DOE) has proposed updates to its regulations governing Other Transaction Agreements (OTAs), which provide flexible funding mechanisms for research and technology investments. The rule seeks to modernize and relocate these regulations within the Code of Federal Regulations.
- NSF Research Infrastructure Guide (RIG) **[Due: 3/10/25], Link**
  The National Science Foundation (NSF) is requesting comments on its Research

Infrastructure Guide, which provides policies and procedures for large-scale research infrastructure projects. Updates may affect funding, reporting, and oversight requirements for recipients.

- Proposed Rule: Federal Acquisition Regulation – Controlled Unclassified Information (CUI) **[Due: 3/17/25], Link**
  This proposed rule would amend the Federal Acquisition Regulation (FAR) to establish uniform requirements for handling Controlled Unclassified Information (CUI) in federal contracts. The rule aims to improve security and compliance across agencies and contractors.
- Proposed Rule: FAR Preventing Organizational Conflicts of Interest in Federal Acquisition **[Due: 3/17/25], Link**
  DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement the Preventing Organizational Conflicts of Interest in Federal Acquisition Act. The statute requires the FAR to provide and update definitions, guidance, and examples related to organizational conflicts of interest, including the creation of solicitation provisions and contract clauses to avoid or mitigate organizational conflicts of interest.

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 previously (September 2023, February 2024, March 2024, and the presentation Overview of System for Award Management (SAM) Registration Process – Challenges & Tips), COGR continues to monitor community concerns and engage with GSA on the challenges members report with SAM.gov renewals/registration. 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 Ethics & Compliance (REC)

Select Committee activities related to the 2025 Administration Transition and Science & Security are reported above under the Cross-Cutting Issues section of the COGR Update. Other items followed by REC are covered below.

Results from COGR ARIO Survey Regarding Final PHS Research Misconduct Regulations (NEW)

COGR and the Association of Research Integrity Officers (ARIO) issued a survey to their members in response to the new PHS Research Misconduct regulations , published by the department of Health and Human Services (DHHS) Office of Research Integrity (ORI) in September 2024. The survey was designed to collect feedback from institutions as to which provisions of the new regulations they would like to see (a) ORI guidance; (b) RIO community guidance; (c) both ORI and RIO community guidance; or (d) no guidance. The survey took place between October 31 to November 30, 2024, and responders were asked to provide one response per institution. One hundred seventy-seven total responses were received consisting of 91 complete responses and 86 partial responses.

COGR and ARIO published a report with a full analysis of survey demographics and results. Key findings from the survey included:

- Responders called for additional guidance on six of the eleven newly defined terms added to the new regulations.
- The provision on maintaining a research integrity assurance and making research misconduct policies publicly available was the only institutional and policy requirement for which Responders did not request additional guidance.
- Responders were fairly evenly split on whether guidance regarding the new formalized Assessment phase of research misconduct proceedings should come from ORI, the RIO community, or both.
- The new regulations' requirements for institutional records and the requirement to pursue leads were the top Inquiry/Investigation requirements for which responders requested ORI and/or RIO community guidance.
- The majority of institutions do not plan to implement the new regulations before their provisions take full effect on January 1, 2026.

COGR and ARIO will communicate the survey results to ORI. They also plan to work together to develop tools and materials to address those items noted in the survey for which RIO community guidance was requested.

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

On January 10, 2025, NIH issued guide notice NOT-OD-25-061, NIH Implementation of the U.S. Government Policy for Oversight of Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) ("Notice"). This Notice provided additional details on NIH's implementation of OSTP's Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential ("New Policy") and associated Implementation Guidance. [See COGR's November 2024 Update for a full discussion of the New Policy.] The Notice applies the New Policy to both new and competing grant and cooperative agreements as of May 6, 2025.

Under the process detailed in the Notice, institutions via their researchers and institutional review entities (IREs) must assess their research at the time of proposal (and throughout the project life cycle) to determine if it constitutes Category 1 (DURC) or Category 2 (PEPP) research, as described in the New Policy. At JIT (for new grants/cooperative agreements) or Research Performance Progress Report (RPPR) (for existing grants/cooperative agreements), the institution's Authorized Organizational Representative (AOR) must provide NIH with the following DURC PEPP Materials:

- Confirmation that the IRE (which may be the Institutional Biosafety Committee) has reviewed the research and made a category determination (including a determination that the research is neither Category 1 or 2 research).
- A risk-benefit assessment developed per consultation between the research and IRE; and
- A risk mitigation plan developed per consultation between the research and IRE, if the research is Category 1 or 2.

NIH plans to issue a future Guide Notice(s) with additional information about the content/format of these materials, submission requirements, and implementation timelines.

Upon NIH's receipt of the DURC PEPP Materials, it will determine if it concurs with the IRE's research categorization and the assessment and risk mitigation plan. NIH will refer any Category 2 research for HHS Department level review. Research may not proceed until NIH (and/or HHS) approval has been received. The NIH funding institute/center will make the final funding determination and add any applicable terms and conditions to the Notice of Award. Recipients must provide annual reports for Category 1 research and semi-annual reports for Category 2 research, as well as provide an annual assurance that the institution is operating in accordance with the New Policy.

In addition to having an IRE and AOR, the New Policy requires institutions to have an Institutional Contact for Dual Use Research (ICDUR). However, the AOR and ICDUR's respective roles under the Notice are not entirely clear. Specifically, the Notice refers to the New Policy's description of the ICDUR's role. The New Policy states that the ICDUR "is the official designated by the research institution to serve as an internal resource for application of this Policy as well as the liaison (as necessary) between the institution and the relevant federal funding agency." Yet, the Notice goes on to state that the DURC PEPP Materials must be submitted to NIH by the institution's AOR, not the ICDUR. COGR will work to obtain additional clarification about how the ICDUR and AOR roles align. Additionally, a panel of institutional biosafety officers will present on their campuses' implementation plans for the New Policy at COGR's February membership meeting.

NIH's Genomic Data Sharing (GDS) Policy (UPDATE)

In December, 2024, COGR published a Summary of Recent Significant Updates to the NIH Genomic Data Sharing Policy, which detailed NIH's application of stricter cybersecurity standards to individuals accessing controlled-access human genomic data stored in NIH controlled-access repositories ("Covered Data") and new terms of access for "developers." In January 2024, COGR updated this summary to reflect additional information issued by NIH subsequent to the document's initial publication. Key points from the updated summary include the following items:

- As of January 25, 2025, institutions must assess that their IT systems that will be used to store or access Covered Data against NIST SP 800-171 cybersecurity standard. The requirements of NIST SP 800-171 are much stricter than those of NIH's previous security guidance for genomic information and implementation costs may be substantial, particularly for institutions that do not have existing data enclaves or third-party/cloud service provider systems that meet this standard.

- NIH did not agree to extend the January 25th deadline, but it published new FAQS [GDS FAQs M.8 and M.9] that permit institutions to "deviate" from the NIST SP 800-171 security controls when "institutions have to the best of their ability, implemented security controls and where there is a Plan of Action and Milestones (POAM) to further mitigate the risk."

- NIH clarified that developer activities do not include research, and developer terms of access will apply only when individuals are conducting Developer Activities on a federally funded research project that relate to developing or maintaining an NIH controlled-access data repository appearing on this list. Researchers who access Covered Data to develop and share analytical tools that have no relationship to the

NIH controlled-access data repository as involved in research, as opposed to conducting Developer Activities. Going forward, NIH plans to include notices of when the Develop Access requirements apply in the terms of funding instruments.

COGR asked NIH whether the January 25, 2025, effective date would be impacted by the Trump Administration's Regulatory Freeze Pending Review EO, but a "communications hold" was in effect and NIH did not respond.

Response to Department of Commerce National Telecommunications and Information Administration's (NITA) Request for Public Comments Concerning Ethical Guidance for Research Using Pervasive Data (NEW)

In January, NITA sought public input on a long list of questions designed to gain information from stakeholders about whether DOC should issue non-binding guidelines on how researchers "can work with pervasive data while meeting ethical expectations of research and protecting individuals' privacy and other rights." The Request defined "pervasive data" as "data about people—user-contributed, observed, derived, or inferred—collected through online services regardless of the extent to which the data is publicly available, is aggregated, or could lead to the identification of an individual."

REC developed comments that were directed to the question on potential drawbacks of developing these guidelines. These comments questioned the helpfulness of adding another set of guidelines into an area that was already subject to a large and complex collection of existing laws, policies, and guidance. The comments also questioned whether NITA was the most appropriate agency to lead efforts to develop guidance in this area and suggested that DHHS was better equipped for this mission based on its research funding profile and explicit statutory authority to establish guidance regarding ethical issues associated with research involving human subjects.

Response to NSF RFI on CHIPS and Science Act, Section 10343 (NEW)

REC developed comments in response to this NSF request for input on ways in which "to incorporate ethical, social, safety, and security considerations into the agency's merit review process" and to develop strategies for improving the risk-benefit ratio of scientific research. These comments urged NSF to clearly define the terms "ethical, social, safety, and/or security risks" and to align these definitions with any currently existing federal definitions. The comments also encouraged NSF to inventory processes and frameworks currently in place at federal agencies for performing risk/benefit assessments for research projects and determine how those tools could be adapted to address emerging risks.

DHHS NPRM – HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information (NEW)

This NPRM proposes several key changes to the HIPAA Security Rule including more robust risk inventory, assessment, testing, and audit requirements. Key points of the NPRM include:

- Adoption of a broad definition of electronic media that encompasses telephone and fax systems and only excepts information handwritten on paper and mailed.
- Requirement for covered entities to create and maintain a thorough written technology asset inventory and network map of all electronic information systems and technology assets that must be updated at least annually.
- Requirement for encryption of all ePHI at rest and in transit, with limited exceptions.
- Requirement for multi-factor authentication, with limited exceptions.
- Requirement for annual compliance audits and/or reviews and testing of administrative, physical, technical safeguards.
- New security requirements for workstations (including mobile workstations) and additional controls for all mobile components, including removable media.

REC is evaluating the NPRM to determine its impacts on research and will decide whether to comment based on this assessment.

Recent FDA Guidance Documents of Note to IRBs and Investigators

- FDA Final Guidance – Institutional Review Boards FAQs (Feb. 2025) (NEW) The FDA has published a final set of FAQs that compiles answers to various questions regarding FDA regulation of IRBs, Informed Consent Process and Documentation, Clinical Investigations, and General Questions. The FAQs provide detailed information on both FDA regulatory requirements and FDA expectations in the absence of such requirement for IRB organization, membership, procedures, and records, and well as the informed consent policies, procedures, and documentation. The section on clinical investigation contains similar detailed FAQs on various aspects of the conduct of clinical investigations under INDs and IDEs.

- Joint FDA and DHHS Final Guidance – Institutional Review Board (IRB) Written Procedures (Feb. 2025) (NEW) This guidance was jointly developed by FDA and DHHS to set forth a Written Procedure Checklist that institutions can use in preparing and maintaining written procedures for IRB review and reporting processes, as required by FDA regulations and the Common Rule. The Checklist sets forth each applicable

regulatory requirement, followed by operational recommendations to consider in developing written policies and procedures.

- Joint FDA and DHHS Draft Guidance – Considerations for Including Tissue Biopsies in Clinical Trials (Jan. 2025) (NEW) This guidance was jointly developed by FDA and DHHS to set forth information that sponsors, research, and IRBs should consider in determining when biopsies should be required as part of a clinical trial protocol for trials involving adults and trials involving children. In general, the guidance calls for consideration of the reason for the biopsy (e.g., necessary to determine if treatment is successful v. evaluation solely for non-key secondary endpoints) in determining whether requiring the biopsy in the protocol presents reasonable risks in relation to the anticipated benefits from the information the biopsy will provide.

Appendix A – Upcoming Comment Due Dates

Agency	Description	Due Date	Notes
NIH	NIH Plan to Increase Findability and Transparency of Research Results Through the Use of Metadata and Persistent Identifiers (PID)	2/21/25	COGR is reviewing. Please send comments or input to CGA Director Krystal Toups at ktoups@cogr.edu
DOE	Update and Relocation of the Department of Energy Technology Investment Agreement Regulations	3/4/25	COGR is reviewing. Please send comments or input to CGA Director Krystal Toups at ktoups@cogr.edu
NSF	Agency Information Collection Activities: Comment Request; National Science Foundation Research Infrastructure Guide	3/10/25	COGR is reviewing. Please send comments or input to CGA Director Krystal Toups at ktoups@cogr.edu
DOD/GSA/NASA	Federal Acquisition Regulation: Preventing Organizational Conflicts of Interest in Federal Acquisition	3/17/25	COGR is reviewing. Please send comments or input to CGA Director Krystal Toups at ktoups@cogr.edu
DOD/GSA/NASA	Federal Acquisition Regulation: Controlled Unclassified Information	3/17/25	COGR plans to submit comments and has asked for clarification of the 3/17 deadline in light of the "Regulatory Freeze Pending Review" issued 1/28.

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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