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President's Message: Fall Engagement

Dear Colleagues,

This fall is a key time for engagement on critical federal research policy issues affecting research institutions. From the impending proposal from OMB to make changes to the uniform guidance (2 CFR 200) including facilities and administrative costs policy, to proposals affecting patents and the Bayh-Dole Act, to the Administration's "deregulation" initiative, our engagement as an association and a community will be important in shaping effective federal research policy and the ability of academic institutions to perform research vital to our nation and the world.

Since the last COGR Update, COGR's engagement has included:

- a <u>joint statement</u> on the Joint Associations Group's FAIR model supporting the model and stating our readiness to work with policymakers;
- joint COGR-AAMC-AAU-APLU <u>comments</u> to NIH on its proposed options for the payment of article process charges and the publication of research results;
- a <u>statement</u> on the Executive Order "Improving Oversight of Federal Grantmaking";
- a <u>letter</u> to USDA Secretary Rollins seeking clarification on the USDA research security initiative outlined in the America First Memorandum for USDA Arrangements and Research Security; and
- a <u>letter</u> with partner organizations to NIH Director Jay Bhattacharya advocating for the full reinstatement of terminated NIH grants.

I wish to also note the release of NASEM's report <u>Simplifying Research Regulations and Policies:</u> <u>Optimizing American Science</u> and COGR's involvement, which is described in this report. The report and the Administration's deregulation initiative provide an opportunity to make progress toward eliminating, streamlining, and harmonizing federal requirements to remove unnecessary obstacles to research and innovation. I encourage you to review and promote the report. We will see in the weeks and months ahead if the Administration and Congress will act, and COGR will certainly work to support such efforts.

I hope you will also continue to engage with COGR, including by participating in the <u>COGR Forum V on September 30</u>. Next week's forum will include a focus on research security training and be followed by updates and discussion on recent and current federal research policy actions, including a potential government shutdown, facilities and administrative costs, and more.

Additionally, the next <u>COGR membership meeting on October 23-24</u> in Washington DC will provide opportunities for you to engage with colleagues on a host of timely and consequential issues. The agenda includes sessions on: the anticipated changes to the uniform guidance 2 CFR 200, including facilities and administrative costs; the use of AI in research misconduct compliance; the new NASEM report on federal research regulations; cybersecurity and research security; a legislative update & outlook; and an opportunity to meet in small groups to discuss the changing federal landscape. We look forward to seeing many of you – over 300 registrants to date – at the membership meeting.

Matt Owens President



Announcements

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October 23-24, 2025, COGR Membership Meeting Registration Still Open

Registration is <u>still open</u> for COGR's October 23-24, 2025, membership meeting in Washington D.C.!

Preliminary agenda topics have been announced, and other meeting materials, including the agenda, will soon be released via COGR's listserv. As a reminder, COGR has implemented an <u>Event Code of Conduct Policy</u>. By registering for the October meeting, attendees agree to abide by this policy.

Contact <u>memberservices@cogr.edu</u> with any questions. We hope to see you in Washington D.C. this October!



COGR FORUM V: Adapting to Change, Policy Shifts & Research Impact on September 30

Continuing the conversation from previous COGR Forums, attendees will hear from COGR leadership who will provide updates on latest federal policy developments, executive orders, and more, followed by an Issues Forum of topics and questions from the membership. The agenda for this complimentary webinar on September 30 is now available and posted on COGR's <u>website here.</u>

Register here (you must be logged into the COGR Portal to register. Don't yet have account? Request one here.) We strongly encourage attendees to read this Update prior to attending.



COGR Membership Annual Dues and ERI Pilot Participation Fee Invoices Available for Download

COGR membership annual dues and ERI Pilot Participation Fee invoices for FY 26 are available for download. The fiscal year runs August 1, 2025-July 31, 2026, and invoices were due August 1, 2025.

To download the invoice, the Primary Representative or billing contacts for the institution can log into the <u>COGR Portal</u>, and a gray renewal badge will appear. Follow the prompts to update your contact information, and then you can download the invoice. COGR membership invoices can be paid via check or ACH/EFT, and ERI Pilot invoices can be paid via credit card, check, or ACH/EFT. Please ensure payment is sent to the correct address. A copy of COGR's W-9 is <u>available here</u>.

If you have any questions or need assistance, please contact memberservices@cogr.edu.





Interested in becoming more involved with COGR? Complete the <u>COGR Volunteer Survey</u> 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 <u>four standing committees</u>, workgroups we convene from time to time on various topics, and more.

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 <u>COGR Member Benefits</u>? The Portal is where you can sign up for our listserv, browse our <u>video library</u>, view the <u>COGR Member Directory</u>, check out COGR's Job Bank, and view other members-only materials.

COGR Job Bank – New Opportunities Posted, Now Publicly Available

New job opportunities have been added to the COGR Job Bank. Did you know COGR hosts a <u>Job Bank</u> 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's Job Board is <u>publicly available</u> to assist those transitioning out of government service.

If you have a relevant position open, post it today on COGR's Job Bank. Contact memberservices@cogr.edu if you have any questions.

Follow COGR on LinkedIn

We invite you to follow <u>COGR on LinkedIn</u> and stay up to date on COGR's advocacy efforts, upcoming events, and more. We look forward to engaging with you on LinkedIn.

Potential For a Government Shutdown

Recent media reports (see <u>Politico</u> and <u>Punchbowl</u>) highlight the increasing possibility of a federal government shutdown. At this time, while there is little to no agency-level information on contingency operations (<u>OMB Agency Contingency Plans</u>), there are indications that the next shutdown may deviate substantially from prior ones. Notably, the



Office of Management and Budget has indicated the potential for mass layoffs of federal employees.

COGR has updated <u>Considerations for a Federal Government Shutdown</u>, a resource designed to help research institutions manage federally sponsored projects in the event of a lapse in appropriations. This document reflects lessons learned from past shutdowns and incorporates the information and guidance currently available. It does not represent official federal guidance.

We will continue to monitor developments closely and update this resource as warranted and as more information becomes available.

2025 Administration Transition Information and Resources

Agency Specific Actions (NEW)

Federal agencies have issued various directives and memoranda to implement the administration's 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 NIH, DOE, HHS, NASA, DOL, ED, USAID, NSF, GSA, DOJ, CDC, and others. As agencies continue to issue guidance, we encourage members to share relevant communications with COGR at memberservices@cogr.edu.

NIST: Several of our members reported receiving the following term in recent agreements pertaining to Executive Orders (EO):

Compliance with Executive Orders:

Incorporated by reference into this U.S. Department of Commerce financial assistance award are the policies set forth in all applicable Executive Orders currently in legal force and effect, including Executive Orders issued on or after January 20, 2025. A comprehensive list of Executive Orders may be found at: https://www.federalregister.gov/presidential-documents/executive-orders.

By accepting this Award Amendment and expending federal funding thereunder, the recipient agrees to the following conditions:

(A) Compliance with Executive Orders: The recipient agrees to comply with the policies and to further the objectives set forth in all applicable Executive Orders currently in



legal effect, including those issued on or after January 20, 2025, as well as Executive Orders that may be issued after the effective date of this award.

(B) Executive Order 14173, 90 FR 8633 (Jan. 21, 2025): The recipient:

- (1) Agrees that compliance in all respects with all applicable Federal antidiscrimination laws is material to the government's payment decisions for purposes of section 3729(b)(4)of Title 31 United States Code; and
- (2) Certifies to the Department that it does not operate any programs promoting diversity, equity, and inclusion that violate any applicable Federal anti-discrimination laws.
- (C) Affirmative Duty to Monitor for and to Report Potential Inconsistencies: The recipient must actively monitor its administration of this award to ensure that its activities do not violate the requirements of this award, including this SAC. At any time during the period of performance of this award, if the recipient believes that any of the activities in its approved scope of work may be inconsistent with the policies outlined in any applicable Executive Order, the recipient has an affirmative duty to immediately stop work on those potentially inconsistent activities and immediately contact the Grants Officer named in the Notice of Award (NoA) to determine whether the potentially inconsistent activities may proceed under this award. The performance of activities that violate or are otherwise inconsistent with requirements under any applicable Executive Order will result in appropriate enforcement action pursuant to 2 C.F.R. § 200.339, including the disallowance of costs and possible termination of a portion or all of this award.

Several of our members raised concerns about the following provision, which requires recipients to agree to comply with Executive Orders (EOs) before they are issued:

The recipient agrees to comply with the policies and to further the objectives set forth in all applicable Executive Orders currently in legal effect, including those issued on or after January 20, 2025, as well as Executive Orders that may be issued after the effective date of this award.

Additionally, the term imposes an affirmative obligation to monitor for potential violations. A few members report unsuccessful attempts to negotiate the term with NIST.

COGR has contacted NIST regarding this term and will update the community as new information becomes available.



Recent Executive Orders of Note (UPDATE)

COGR continues to update the Summary of Executive Orders (V.17, released September 22, 2025), identifying those with the most significant impact on research activities and/or research funding. Many of the Trump Administration's Executive Orders remain the subject of lawsuits and attendant temporary restraining orders and preliminary injunctions. These matters are discussed in the litigation update section below.

While the most significant executive order since the June COGR Update is the "Improving Oversight of Federal Grantmaking" order, several additional EOs issued since the last COGR Update may have an impact on federal funding priorities, detailed below.

EO 14332, Improving Oversight of Federal Grantmaking (August 7, 2025) – This EO institutes a new layer of political and administrative oversight over discretionary federal grants. The order requires each agency to appoint a senior appointee charged with reviewing both new Funding Opportunity Announcements (FOAs) and discretionary grant awards to ensure alignment with agency priorities and the "national interest." It directs OMB to revise the Uniform Guidance and agency standard terms to require termination for convenience clauses, allowing agencies to end grants if they no longer advance priorities or national interest. The EO further instructs review of NOFOs and related forms to simplify requirements (plain language, eliminate unnecessary complexity), strengthen interagency coordination, avoid program duplication, and favor institutions with lower indirect cost rates. Finally, the order imposes new substantive constraints: discretionary awards may not promote racial preferences, challenge the sex binary doctrine, support illegal immigration, or undermine "public safety or anti-American values," and must demonstrably advance the President's priorities.

In response to the EO, <u>COGR issued a statement</u> on August 8, expressing concern over the potential for increased administrative burdens and the narrowing of research priorities. The statement emphasized the need for a balanced approach that maintains the integrity of the federal grantmaking process while ensuring alignment with national interests. COGR also called for ongoing dialogue between federal agencies and research institutions to address these challenges and uphold the principles of academic freedom and innovation.

EO 14351, The Gold Card (September 19, 2025) – This EO establishes a new "Gold Card" visa program offering expedited immigration benefits to foreign nationals or corporate entities that make substantial financial contributions aligned with U.S. priorities. Commerce, State, and DHS are tasked with establishing eligibility thresholds and ensuring contributions advance economic development, innovation, or strategic infrastructure goals.

While primarily an immigration and economic development initiative, the program may have some downstream implications on doctoral student sponsorship, particularly international students.



EO 14321, Ending Crime and Disorder on America's Streets (July 24, 2025) – This EO enshrines a federal policy to restore public order in U.S. cities by targeting vagrancy, disorder, and homelessness perceived as linked to mental illness or substance use. The order directs the Attorney General, in consultation with the Secretary of HHS, to pursue the reversal of judicial precedents and consent decrees that restrict the civil commitment of individuals who are homeless and unable to care for themselves or pose a public risk.

The EO further directs coordination among agencies (including DOJ, HUD, HHS, and Transportation) to reassess discretionary grant programs and give priority to states and municipalities that enforce prohibitions on urban camping, loitering, open illicit drug use, or "urban squatting."

It also mandates that federal homelessness assistance funds do not support drug injection sites or illicit drug use and prohibits housing sex offenders who receive homelessness assistance in the same units as children. On July 29, 2025, the Substance Abuse and Mental Health Services Administration issued a <u>"Dear Colleague" letter</u> to provide clarity on the Administration's position on harm reduction activities.

EO 14319, Preventing Woke AI in the Federal Government (July 23, 2025) – This EO mandates that federal agencies may only procure large language models (LLMs) that comply with two "Unbiased AI Principles": truth-seeking and ideological neutrality. The order states that LLMs reflecting frameworks such as systemic racism, critical race theory, intersectionality, or unconscious bias distort factual accuracy and erode trust. OMB must issue guidance by November 20, 2025, to incorporate these requirements into federal acquisition, and agency contracts must include enforceable terms that ensure compliance with possible termination or penalties for violations.

In addition to impacting universities that develop or license AI systems for federal use, the order could potentially indirectly affect university research in AI and data science, particularly in collaborations with agencies or contractors subject to these restrictions.

Ongoing Litigation Concerning Research and Research Funding (UPDATE)

COGR continues to track the progress of ongoing litigation challenging the Administration's actions to terminate and/or restrict research and research funding. Cases are regularly updated on the <u>COGR litigation tracker</u>. Notable cases since the July 2025 update are discussed below.

U.S. Supreme Court Rules that Court of Claims, not District Court, has Subject Matter Jurisdiction over Grant Termination Claims – <u>American Public Health Association v. NIH</u> and <u>Massachusetts v. RFK, Jr.</u>: The district court in these cases entered final judgment that vacated specified NIH directives based on Executive Orders concerning DEI and gender-ideology, along with grant terminations resulting from those directives. The



government appealed to First Circuit Court of Appeals, which denied the government's request for a stay of the district court's judgment pending appeal. The government then appealed to the U.S. Supreme Court.

The <u>Supreme Court held</u> that the district court did not have subject matter jurisdiction to adjudicate the plaintiffs' claims on research-related grants termination or to order relief designed to enforce any obligation to pay money in connection with those grants. It stayed the portions of the district court's order that (a) declared the NIH grant terminations to be unlawful, arbitrary, and capricious final agency actions under the Administrative Procedure Act (APA); and (b) set the terminations aside. This stay will remain in place until the government's appeal to the First Circuit Court of Appeals is decided and/or any Writ of Certiorari to the Supreme Court to hear the case is disposed of. This case has major implications for all cases concerning APA-based grant terminations claims because it holds that subject matter jurisdiction for such claims is under the U.S. Court of Claims, which cannot certify class actions or grant injunctive relief.

As a result of this decision, the district court in the <u>AAU v. DOD</u> case required the parties to provide briefs on the impact of the Supreme Court's decision on the district court's preliminary injunction that enjoined the government from giving effect to the 15% indirect cost cap. Similarly, the government cited the Supreme Court's decision in support of a motion for reconsideration that it filed with the Ninth Circuit in <u>Thakur v. Trump</u>, a class action challenging grant terminations brought by researchers in the University of California system.

The issue of subject matter jurisdiction can also be expected to be raised in the following rate cap cases where courts granted plaintiffs' motions for summary judgment or preliminary injunctions that the government then appealed to the First Circuit Court of Appeals: <u>AAU v. NSF, AAU v. DOE</u> and the consolidated cases of <u>AAU v. NIH, AAMC v. NIH</u> and Massachusetts v. NIH.

D.C. Court of Appeals Holds that Impoundment Control Act Can only be Enforced by Comptroller General – Global Health Council v. Trump: The D.C. Court of Appeals vacated the provisions of the district court's preliminary injunction that were based on violations of the Impoundment Control Act. It held that the APA cannot be used to enforce that Act, as the Act limits enforcement action to the Comptroller General. The court also held that the plaintiffs could not bring a freestanding constitutional claim if the underlying violation is statutory, nor could they reframe their claims as *ultra vires* (i.e., action taken beyond legal power or authority). However, the court allowed plaintiffs to pursue in the district court its claim that the government violated the APA by unilaterally deciding not to spend funds as Congress directed in relevant appropriation acts. On remand, the district court required the government to make foreign aid funds specified by Congress available for obligation and obligate them by September 30, 2025, unless Congress rescinds the funding.



Court Upholds Harvard's Claims that Grant Terminations and Payment Freezes Violated the First Amendment and Title VI – Harvard v. DHHS and AAUP (Harvard Faculty Chapt.) v. DOJ: The district court held the it had subject matter jurisdiction over the plaintiffs' claims that payment freezes and grant terminations violated the First Amendment and Title VI of the Civil Rights Act. It also held that it had jurisdiction over the plaintiffs' claims that freeze orders were arbitrary and capricious under the APA. However, the court also held that it did not have subject matter jurisdiction over arbitrary and capricious claims regarding grant terminations per the aforementioned Supreme Court decision. After establishing its jurisdiction, the court went on to state that the government used antisemitism as a "smokescreen" for a "targeted, ideologically-motivated assault." The court vacated the freeze and termination orders on several grounds, including violation of the First Amendment, and it enjoined the government from giving them any force or effect.

The district court is now waiting for the parties to work through implementation issues prior to entering a final judgment. Once a final judgment is entered, the government is likely to appeal.

Notably, the district court in <u>Rhode Island Latino Arts v. NEA</u> followed a similar path when it enjoined the government from evaluating plaintiffs' funding applications based on First Amendment grounds. Specifically, the court enjoined the government from assessing NEA funding applications under a "viewpoint based standard of review" that disfavors applications "deemed to promote gender ideology."

NASEM Committee Releases Report Simplifying Research Regulations and Policies: Optimizing American Science (NEW)

Earlier this month, the National Academies of Sciences, Engineering, and Medicine's (NASEM) Committee on Improving the Regulatory Efficiency and Reducing Administrative Workload to Strengthen Competitiveness and Productivity of U.S. Research issued a consensus report <u>Simplifying Research Regulations and Policies: Optimizing American Science</u>.

The <u>Committee</u> noted: "While regulations are crucial to ensuring the highest ethical standards and safety in research, the current regulatory ecosystem has ballooned in recent years, hindering productivity and increasing costs for research institutions without sufficient gains. At a time when U.S. leadership in science, technology, engineering, medicine, and mathematics is being challenged globally, optimizing this system is critical to ensuring the research enterprise can provide the greatest benefit to the country."

Three overarching principles are identified "to underpin a new national strategy for a more efficient research regulatory framework." They are:



- Harmonize regulations and requirements across federal and state agencies and research institutions.
- Take an approach where regulation and requirements are tiered to the nature, likelihood, and potential consequences of risks for the research being conducted.
- Use technology to increase efficiency and simplify the process of complying with regulations and requirements to the greatest extent possible.

To implement these principles, the report outlines options at a system-wide level and in seven areas of research and research administration: 1) human subjects research, 2) protecting research assets, 3) financial conflict of interest in research, 4) grant proposals and management, 5) research misconduct, 6) research involving biological agents, and 7) research using nonhuman animals. All told, the report identified 53 options for policymakers to consider.

In May, COGR <u>presented</u> to the Committee <u>actionable ideas</u> and the association's <u>recommendations</u> to the Trump Administration to eliminate, streamline, and harmonize federal research regulations and requirements. The Committee's cites COGR's ideas and recommendations in many of the 53 options outlined in the report.

Science & Security: Cross-Cutting Issues

NIH Issues Notice on Implementation of Research Security Policies (NEW)

On September 11, 2025, the National Institutes of Health (NIH) issued NOT-OD-25-154, "Implementation of NIH Research Security Policies," establishing enhanced research security requirements pursuant to the CHIPS and Science Act of 2022 and related federal directives, with specific obligations for covered institutions and designated senior/key personnel under NIH grants and cooperative agreements.

<u>Research security training certification</u>. Beginning January 25, 2026, NIH will require both institutional and individual certifications of research security training for all senior/key personnel on grant and cooperative proposals.

Authorized Organizational Representatives (AORs) must certify that senior/key personnel have completed training within 12 months prior to proposal submission via signature on the face page of the application. Additionally, senior/key personnel must individually certify completion of the requisite research training at the time of application by submitting a signed, flattened PDF file as an attachment. Beyond the initial application, senior/key personnel must annually recertify completion of training for the life of the award.



A university may use its own training program, provided that such training addresses cybersecurity, international collaboration, foreign interference, and rules for proper use of funds, disclosure, conflict of commitment, and conflict of interest.

Malign Foreign Talent Recruitment Programs. Effective September 11, 2025, NIH policy prohibits any individual participating in a Malign Foreign Talent Recruitment Program (MFTRP) from serving as senior/key personnel on a NIH grant or cooperative awards. AORs must certify that senior/key personnel are aware of this prohibition and that each individual has certified that he/she is not party to an MFTRP. Senior/key personnel certification is done via the Biographical Sketch Common Form.

For NIH awards with Research Performance Progress Reports due on or after January 25, 2026, senior/key personnel will be required to recertify annually for the life of the award.

COGR has submitted a list of member questions to NIH for clarification of the requirements.

COGR's Research Security Charts (UPDATE)

COGR has updated the <u>Matrix of Science and Security Laws, Regulations, and Policies</u> and the <u>Quick Reference Table of Current and Upcoming Federal Research Security Requirements</u> to reflect the foregoing NIH requirements and any other research security developments that occurred since the charts were last updated in August 2025.

Select Committee on the CCP Issues Two Reports (NEW)

The House Select Committee on Strategic Competition with the Chinese Communist Party (CCP Committee) recently released two reports examining China's influence on U.S. university research: *Joint Institutes, Divided Loyalties* and *Fox in the Henhouse. Joint Institutes, Divided Loyalties* focuses on how Chinese joint institutes with U.S. universities are used by the CCP to advance technological, military, and political objectives. These partnerships, often heavily financed by Chinese government entities with minimal U.S. contributions, operate under PRC law and governance structures and frequently prioritize fields with dual-use or national security applications. The report highlights significant concerns regarding the inadequate disclosure of foreign gifts and contracts under Section 117 of the Higher Education Act, noting delays, omissions, and inaccuracies across institutions. Enforcement of these requirements has intensified, particularly following Executive Order 14282, which links inaccurate or incomplete disclosures to potential liability under the False Claims Act and risks to federal funding.

Fox in the Henhouse examines similar concerns in the context of Department of Defense (DOD)-funded research, documenting how taxpayer-funded projects are being exploited by Chinese entities, including those directly tied to the People's Liberation Army and China's defense industrial base. Between June 2023 and June 2025, roughly 1,400 DOD-funded publications acknowledged collaboration with Chinese organizations, over 700 of



which involved entities affiliated with China's defense research and industrial complex. These collaborations encompass sensitive areas such as hypersonics, quantum sensing, semiconductors, artificial intelligence, advanced materials, cyber warfare, intelligence, surveillance, and reconnaissance systems, as well as next-generation propulsion technologies. The report notes that DOD oversight has been insufficient to prevent these collaborations, even when partner institutions appear on U.S. government entity lists due to military affiliations or human rights concerns, underscoring both national security and ethical risks.

Despite concerns raised regarding the accuracy of the data underpinning these reports, taken together, they underscore a growing expectation that U.S. universities must proactively manage foreign research collaborations. Federal agencies are steadily increasing requirements related to the disclosure, oversight, and risk assessment of international collaborations, particularly those involving countries of concern or sensitive research areas. As legislative and regulatory scrutiny continues to intensify, universities should anticipate additional federal mandates and heightened oversight.

ODNI Releases Research Security Bulletin (NEW)

The <u>Safeguarding Academia</u> bulletin, released by the National Counterintelligence and Security Center (NCSC) on August 22, 2025, aims to help U.S. universities and research institutions strike a balance between their commitment to openness and collaboration and the growing need to protect research, technology, and talent from foreign intelligence threats. It is directed toward faculty, research administrators, compliance staff, and others responsible for managing research programs, grants, international collaborations, and institutional security.

The bulletin highlights that certain areas of cutting-edge research, such as artificial intelligence, quantum technologies, semiconductors, optics, hypersonics, and biotechnology, are particularly vulnerable to exploitation by foreign adversaries. These adversaries seek to gain economic and military advantages by targeting faculty, researchers, and students through recruitment efforts, talent programs, undisclosed collaborations, and even espionage. Non-transparent relationships with foreign entities, failure to disclose funding or affiliations in grant proposals, and participation in foreign talent recruitment programs pose significant risks to both individual researchers and their institutions.

Institutions also face insider threats, cyber intrusions, and social engineering attempts, often delivered through phishing campaigns, social media contacts, or expert networks. Students may be approached directly, either recruited or coerced into gathering sensitive information. Warning signs can include unusual requests for access to research outside one's role, undisclosed financial ties, or overly generous offers from foreign institutions.



The risks of failing to safeguard academic research are significant. Institutions may suffer reputational damage, loss of intellectual property, reduced funding opportunities, and exposure to legal liabilities such as export control violations or fraud. At a national level, adversarial states can use compromised research to close technology gaps and undermine U.S. competitiveness and security.

To mitigate these risks while preserving the open exchange of ideas, the bulletin recommends the following best practices for academic institutions:

- <u>Education & training</u>: Integrate research security into existing responsible conduct of research training and use real-world case studies to highlight risks.
- <u>Policies & transparency</u>: Require full disclosure of foreign funding, affiliations, conflicts of interest, and participation in foreign talent recruitment programs.
- <u>Cybersecurity & data protection</u>: Maintain strong cyber hygiene, secure data storage, restrict access to sensitive materials, and safeguard devices, especially during international travel.
- <u>Travel & collaboration protocols</u>: Provide clear guidance on protecting sensitive data during foreign travel, assess risks of international partnerships, and limit the sharing of pre-publication or proprietary information.
- <u>Review & oversight</u>: Use institutional offices (e.g., research security, sponsored programs, compliance) to evaluate risks in proposals, collaborations, and agreements, and conduct regular audits.

The bulletin also emphasizes the importance of reporting suspicious activities to appropriate channels, whether through institutional security offices, compliance staff, or federal partners such as the FBI. Universities are encouraged to leverage federal resources, including those from NCSC, NSF, NIST, and DCSA, which provide frameworks, training tools, and data analysis to strengthen institutional safeguards.

For research administrators, the key takeaway is that vigilance must be embedded into daily operations—grant reviews, international collaborations, compliance checks, and training initiatives. By implementing these measures, institutions can reduce vulnerabilities while continuing to support a thriving and open academic research environment.

NIH Requirement for Disclosure Training (UPDATE)

As previously <u>reported</u>, on July 17, NIH issued <u>NOT-OD-25-133</u>, "NIH Announces a New Policy <u>Requirement to Train Senior/Key Personnel on Other Support Disclosure Requirements."</u> The notices state, effective October 1, 2025, NIH award recipients must have a written and enforced policy on Other Support disclosure requirements and provide faculty and



researchers identified as Senior/Key Personnel with training "on the requirement to disclose all research activities and affiliations (active and pending) in Other Support."

NIH has updated the corresponding <u>Other Support webpage</u> and recently issued a new FAQ:

33. Does NOT-OD-25-133 (policy requirement to train senior/key personnel on other support disclosure requirements) place a new training requirement on the extramural community? New

No, NIH has not placed a new training requirement on the extramural community. <u>NOT-OD-25-133</u>: NIH Announces a New Policy Requirement to Train Senior/Key Personnel on Other Support Disclosure Requirements was intended to remind institutions that when policies are developed for Current/Pending (Other Support) disclosures, institutions must ensure that their implementation includes training for senior/key personnel on the internal policies and procedures that the institution developed. **This does not relate to the Research Security Program.**

At the September FDP meeting, NIH further clarified that, beginning October 1, 2025, Senior/Key Personnel who submit Other Support (typically at JIT or RPPR) are expected to complete training. Institutions may use the NSF Research Security Training Modules (full or condensed) or an equivalent program to satisfy this requirement.

With the additional clarification from NIH, here are some key takeaways for consideration:

- **Training expectation**: Effective October 1, 2025, Senior/Key Personnel submitting Other Support are expected to complete training. Typically, other support information for NIH is submitted at JIT or RPPR. Note that Other Support for applications is requested at JIT.
- **Training options**: The NSF Research Security Training Modules (full or condensed) may be used to meet the requirement. Because these modules cover the broader research security framework, completion would also fulfill the research security training requirement that takes effect January 25, 2026 (NOT-OD-25-154).
- Institutional policies: The notice also specifies that, effective October 1, 2025, recipients must maintain a written and enforced policy on requirements for the disclosure of other support. Institutions should review existing policies on disclosures (e.g., COI/COC, disclosure, and training policies) to determine if they satisfy the requirement, with consideration of whether they can be leveraged to satisfy the requirement.

COGR will host an institutional panel at the upcoming <u>COGR Forum V</u> on September 30 to discuss approaches to implementing research security training.



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.

DOD Reaffirms Commitment to NSDD-189 (NEW)

In its <u>Fundamental Research Guidance</u>, cleared for public release on August 2, 2025, the Department of Defense (DOD) reaffirms its commitment to supporting fundamental research and its importance to the mission of providing technological superiority to the U.S. military. per NSDD 189, is "basic and applied research in science and engineering" whose results are intended to be published and shared broadly, and that agencies should avoid imposing restrictions like publication reviews or export control constraints (EAR/ITAR) on such work unless explicitly mandated by statute or regulation. The guidance also explains how the DOD implements this via the 2010 "Carter Memo," DODI 5200.48, and other policies. Specifically, projects funded under budget activity 6.1 (and 6.2 when conducted on university campuses) are presumptively considered fundamental research, unless controls are required.

For program managers and contract/grant officers, the Guidance provides a decision tool to assist them in determining whether research should be designated as fundamental, recommends avoiding inappropriate restrictions for fundamental portions of multiperformer awards, and advises that security reviews should be risk-based, limited, and not extend to student or non-senior personnel (except where specifically required). Non-compliance risks reducing the openness that underpins many university research partnerships and could limit eligibility for certain awards or create legal exposure.

This Guidance and its reaffirmation for fundamental research are especially significant as research institutions prepare for new CMMC requirements and await the forthcoming FAR rewrite on handling Controlled Unclassified Information (CUI), both of which could otherwise blur the line between fundamental and otherwise controlled research.

SBIR & STTR Reauthorization Legislation (NEW)

On September 16, 2025, the U.S. House of Representatives passed H.R. 5100, approving a one-year "clean" extension of the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. The measure now heads to the Senate for consideration, with reauthorization required by September 30 to avoid program expiration. Unlike more comprehensive proposals currently under debate, this stopgap bill extends the programs without introducing new reforms.



The one-year extension was advanced as an alternative to two broader reauthorization efforts: the INNOVATE Act and the SBIR/STTR Reauthorization Act of 2025. Both bills would reshape the programs with implications for universities and research institutions engaged in federally funded collaborations with small businesses.

The INNOVATE Act, introduced by Chairwoman Joni Ernst (R-IA), would maintain current SBIR set-aside percentages but substantially reduce the share allocated to STTR, potentially limiting funding for university–small business partnerships. The bill also includes "anti-SBIR mill" provisions, such as limits on the number of proposals individuals may submit, a lifetime cap on cumulative award funding, and additional restrictions aimed at addressing concerns about foreign influence.

The SBIR/STTR Reauthorization Act of 2025, introduced by Ranking Member Ed Markey (D-MA), would move in the opposite direction by requiring agencies to increase their SBIR/STTR set-asides and would impose expanded reporting requirements, potentially increasing administrative obligations for both small businesses and their university partners.

AAU, AUTM, APLU, ACE, and AAMC sent a <u>joint letter</u> to the House Committee on Small Business expressing support for the one-year extension, noting the need for stability while longer-term reforms are debated.

USPTO Developments (UPDATES)

New USPTO Director is Confirmed. The U.S. Senate confirmed John Squires as Director of the USPTO on September 19, 2025, by a 51–47 vote. His nomination was approved "en bloc" with 47 others after Senate Republicans amended chamber rules to expedite confirmation of President Trump's sub-cabinet nominees.

Expedited Examination for Design Patent Final Rule. On April 17, 2025, the U.S. Patent and Trademark Office (USPTO) suspended its expedited examination program for design patent applications. The agency has now issued a <u>final rule</u>, effective August 14, 2025, permanently eliminating this option as part of broader efforts to combat fraud, reduce examination backlogs, and shorten processing times. According to the USPTO, the office has seen a 560% increase in expedited examination requests in recent years, which it links to fraudulent filings.

While the general expedited examination route is being discontinued, design patent applicants may still qualify for faster review under certain conditions. The Accelerated Examination program will remain available for cases where applicants file a petition to make special, provided it is supported by the required showing and associated fee.



DOD Issues CMMC 2.0 Final Rule (UPDATE)

On September 10, 2025, the Department of Defense (DOD) published the <u>final rule</u> amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement the Cybersecurity Maturity Model Certification (CMMC) program in DOD contracts and solicitations. The rule becomes effective November 10, 2025, at which point the CMMC clause (DFARS 252.204-7021) may be included in solicitations and contracts, and a new notice provision (DFARS 252.204-7025) must be used in solicitations. This change requires contractors and subcontractors that process, store, or transmit Federal Contract Information (FCI) or Controlled Unclassified Information (CUI) on covered contractor information systems to achieve and maintain a "current CMMC status," including flowing down requirements to relevant subcontractors.

The Cybersecurity Maturity Model Certification (CMMC) framework outlines three levels of requirements, each tied to the type of federal information a contractor handles. Level 1 ("Foundational") applies to contractors working only with Federal Contract Information (FCI) and requires compliance with 15 basic practices specified in FAR 52.204-21. Contractors at this level must complete an annual self-assessment and submit an affirmation of compliance. Level 2 ("Advanced") applies to contracts involving Controlled Unclassified Information (CUI) and requires full implementation of the 110 controls outlined in NIST SP 800-171 Rev. 2. Depending on the sensitivity of the work to be performed under the contract, organizations will either self-assess annually or undergo a certification review by a Certified Third-Party Assessor Organization (C3PAO) every three years, with an annual affirmation of compliance. Level 3 ("Expert") is reserved for the highest-risk contracts. It builds on Level 2 by requiring additional safeguards drawn from NIST SP 800-172 and is assessed every three years by government-led teams or equivalent high-level assessors.

In December 2024, COGR published an <u>overview of CMMC 2.0</u> outlining the requirements of the updated regulation and highlighting resources available to help institutions understand the framework, evaluate its implications, and prepare for compliance.

FAR Part 27 – Patents, Data, and Copyrights Overhaul (NEW)

Initiated in accordance with <u>Executive Order 14275</u>, the Revolutionary FAR Overhaul (RFO) has released its rewrite of FAR Part 27: Patents, Data, and Copyrights. According to the U.S. General Services Administration, the proposed revision, published as <u>Class Deviation RFO-2025-27</u>, introduces a streamlined structure that eliminates outdated, duplicative, and non-statutory provisions that often contributed to confusion or overly rigid application. The rewrite aims to refocus Part 27 on the core legal requirements under existing patent and copyright statutes, thereby enhancing clarity for both contracting officers and contractors. Supposedly, the revised language is intended to provide greater flexibility in negotiating data rights and technical data deliverables, allowing for more nuanced agreements that



reflect the specific circumstances of each project while still preserving the government's essential rights.

COGR's RSIP committee is evaluating how the new provisions align (or potentially conflict) with obligations under the Bayh-Dole Act and the treatment of technical data, copyrights, and deliverables.

Department of Commerce Issues Bayh-Dole Compliance Letter and Introduces Possible Licensing Revenue Sharing Model (NEW)

Bayh-Dole Compliance Review at Harvard: On August 8, 2025, U.S. Commerce Secretary Howard W. Lutnick issued <u>a letter</u> to Harvard University announcing a "comprehensive review" of the university's compliance with the Bayh-Dole Act. The letter raises questions about whether the university fully met its obligations under the Bayh-Dole Act and related regulations. It formally notifies the institution that the Department of Commerce is initiating an immediate review of its federally funded intellectual property portfolio.

The review is focused on several core compliance requirements familiar to technology transfer offices:

- <u>Timely disclosure and election of title</u>: ensuring inventions resulting from federal funding ("Subject Inventions") are promptly disclosed to the funding agency and that the university properly elects title.
- <u>U.S. manufacturing requirement:</u> verifying that license agreements include provisions requiring substantial manufacture of products incorporating Subject Inventions in the United States.
- <u>Practical application</u>: assessing whether effective steps have been taken to commercialize inventions and deliver public benefit, consistent with Bayh-Dole's purpose.

Notably, Secretary Lutnick referenced the government's <u>march-in rights</u>, a rarely invoked authority under Bayh-Dole that permits the government to reclaim ownership of, or license out, patents if certain conditions are not met. These conditions include failure to commercialize, failure to meet public health or manufacturing needs, or failure to report use of federally funded inventions.

Commerce directed Harvard to provide a comprehensive list of all Subject Inventions by September 5, including disclosure dates, commercialization status, and licensing details.

Revenue-Sharing for Federally Funded Research: In a September 2025 <u>interview with Axios</u>, Secretary Lutnick expanded on his concerns with university technology transfer practices. He suggested that institutions benefiting from federally funded inventions



should share 50% of their licensing revenue with the federal government, arguing that taxpayers are the original investors in the research.

Framing the issues as one of accountability and fairness, Secretary Lutnick noted that while universities often generate substantial licensing revenue from Bayh-Dole inventions, the federal government currently receives no financial returns.

According to the <u>AUTM Licensing Survey</u> data, most U.S. universities spend more on maintaining their technology transfer operations than they earn in licensing revenue. Instead, they often deliver significant non-financial value in terms of innovation, startup creation, and societal impact.

Although no formal policy change has yet been proposed, Lutnick's remarks signal that Commerce may explore mechanisms to capture some share of licensing income. Such a change would represent a significant shift in the financial structure underpinning university technology transfer, potentially altering how institutions approach both licensing negotiations and overall commercialization strategies.

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.

Responding to Threats to F&A Cost Reimbursement (UPDATE)

The CFC committee continues to assess the Joint Associations Group on Indirect Costs (JAG) <u>Financial Accountability in Research (FAIR) model</u> to identify practical implementation approaches. The committee is also preparing to support the necessity of each category of facilities and administrative (F&A, Indirect) cost in anticipation of OMB changes to Uniform Guidance (2 CFR 200) that likely will include further limits to federal reimbursement of F&A costs.

As described in the July 2025 <u>COGR Update</u>, the JAG proposed the FAIR Model as an alternative to the current model for reimbursement of indirect costs in response to the current system's critics, including within the <u>new administration</u>. The current system ensures a research institution never, in total, overcharges the federal government for its allocable share of indirect costs. Cost allocations at the project level, however, may appear unreasonable when taken out of context and few understand the many internal controls built into the current system. The JAG was <u>formed in April 2025</u>, by ten "national organizations representing America's academic, medical, and independent research institutions." The JAG appointed a team of Subject Matter Experts (SMEs), to explore other models for reimbursement and improvements to the current model.



On behalf of the JAG, COGR hosted a series of virtual town halls. Two May 2025 town halls communicated the JAG's goals and plans for its initiative. In June 2025, the SMEs presented two provisional models. In response to community feedback, the SMEs developed a final FAIR model, which was presented by Dr. Kelvin Droegemeier, the SME team lead, and JAG organization representatives during a July 15 town hall. An overview of the FAIR model can be found in the July 2025 COGR Update and on the JAG webpage, where FAQs and additional resources can be found. JAG organizations issued a statement on September 5 promoting the FAIR model and stating they "stand ready to work with the federal government to make the changes necessary to sustain American science and innovation leadership."

During the July 23 COGR Forum III on Adapting to Change, Policy Shifts & Research Impact, the CFC committee presented additional analysis of the FAIR model. COGR then hosted a members-only webinar on August 15, during which SME representatives provided additional information about the FAIR model and CFC committee members discussed COGR's approach to interpreting the model and identifying practical implementation options. COGR assembled four working groups to begin these efforts, led by CFC committee members and including representatives from other COGR committees, consulting firms, and other cost accounting experts. These working groups are assessing the FAIR model cost allocation categories but also preparing to support the necessity of every category of facilities and administrative cost allocable to federally funded research.

Legal challenges to the administration's attempts to cap facilities and administrative (F&A/indirect) cost reimbursement, summarized in the COGR <u>litigation tracker</u>, have thus far been successful. The final legal outcomes are, however, uncertain and, as previously reported in the May 2025 <u>COGR Update</u>, OMB is working on revisions to 2 CFR 200, including changes to indirect cost reimbursement.

COGR anticipates OMB changes will include implementation of EO 14332 Improving Oversight of Federal Grantmaking (August 7, 2025), described in the Recent Executive Orders of Note section above. This EO claims that "[a] substantial portion of many Federal grants for university-led research goes not to scientific project applicants or groundbreaking research, but to university facilities and administrative costs." Among other problematic requirements, it directs all agencies to ensure, when assessing grant proposals, "[a]II else being equal, preference for discretionary awards should be given to institutions with lower indirect cost rate." (Sec 4(b)(iii)) And, of most relevance to anticipated 2 CFR 200 changes, it directs the OMB Director to revise the Uniform Guidance to "appropriately limit the use of discretionary grant funds for costs related to facilities and administration." (Sec 5(b))



COGR is following legislative actions, as tracked by APLU <u>here</u>, that would potentially prevent OMB from making changes to F&A cost reimbursement regulations prior to engaging with the community and considering the FAIR model. These actions to date are summarized in a Legislative Update section within the CFC portion of the July 2025 <u>COGR Update</u>. Additionally, over 160 organizations sent a <u>letter</u> to leaders of the House and Senate Appropriations Committees asking them to support the JAG's efforts by:

- Including appropriations bill language supporting the work of the JAG and the development and implementation of the FAIR model by the executive branch;
- Blocking any federal agency or OMB action to cap or otherwise change existing negotiated F&A rates until they have worked with the stakeholder community to develop a clear plan for implementation of a new system based on the FAIR model framework;
- Ensuring at least a two-year transition period for agencies and institutions to make the necessary changes to an alternative model; and
- Preserving continued support for F&A expenses at existing levels until the new model is fully implemented.

The impact of a continuing resolution or a government shutdown on the legislative approach to address reimbursement of F&A costs is impossible to predict with any confidence. Institutions, meanwhile, should continue to communicate accurate information about the facilities and administrative costs necessary to support research, the required processes research institutions must follow to receive reimbursement of these costs, and the probability of devastating impacts on research that would result from additional caps on reimbursement. COGR's F&A Cost Reimbursement Materials webpage is a compilation of information, resources, and tools created to assist with effective communication on F&A costs. COGR members also are encouraged to explore how the FAIR model might be efficiently implemented and provide suggestions to the CFC committee by emailing chope@cogr.edu.

Inefficiencies in Federal Payment Processes - EO 14222 and EO 14332 (UPDATE)

COGR's CFC committee updated its, *Points to Consider for Reimbursement of Expenses Under Active Grants*, found in COGR's <u>Framework for Navigating the 2025 Administration Transition</u>, on August 5. Subsequently, the White House issued a new Executive Order, EO 14332 <u>Improving Oversight of Federal Grantmaking</u> (August 7, 2025), that may further burden the federal payment process.

As described in the May and July <u>COGR Updates</u>, changes to federal payment systems, processes, and requirements implementing <u>Executive Order 14222</u> — <u>Implementing the President's "Department of Government Efficiency" Cost Efficiency</u>, issued February 26, 2025,



have significantly increased recipient and federal burden for requesting and routing payments. While many institutions have developed processes for more efficiently complying with the new requirements, varying agency systems and processes inhibit efficiency.

EO 14332, described in the <u>Recent Executive Orders of Note</u> section above, includes language that may further increase burden:

- (c) To the extent practicable and consistent with applicable law, agency heads shall insert in future discretionary grant agreements terms and conditions that:
 - (i) prohibit recipients from directly drawing down general grant funds for specific projects <u>without the affirmative</u> authorization of the agency; and
 - (ii) require grantees to provide written explanations or support, <u>with specificity</u>, for requests for each drawdown.

The new requirements in EO 14222 and EO 14332 ignore the numerous audits that recipients undergo to ensure they have adequate internal controls, confirming their systems and processes comply with federal regulations requiring allowability, allocability, reasonableness, and consistent treatment of costs. The additional requirements result in no savings, reduction in improper payments, or other cost benefits to the government as they are not triggered by audit findings or other signs of risk. In July, COGR developed an infographic to highlight the excessive redundancy of "Defend the Spend." COGR's *Defend the Spend, Waste and Inefficiencies Due to the New Grant Requirements* infographic confronts the problem created by DOGE's Defend the Spend implementation of EO 14222. We will report any additional requirements resulting from EO 14332 and encourage members to share relevant information with COGR at memberservices@cogr.edu.

Costing Points to Consider for Terminations and Suspensions (UPDATE)

On August 20, 2025 COGR's CFC committee updated the Costing Points to Consider for Terminations and Suspensions in COGR's Framework for Navigating the 2025 Administration Transition. COGR developed this section of the Framework in response to terminations and suspension notices and related communications from federal agencies that appeared inconsistent with sponsor policies and Uniform Guidance. It provides examples of problematic federal actions and notices, a review of the relevant sections of Uniform Guidance, and a list of items for institutions to consider when following sponsor instructions and in determining best practices. Problematic agency instructions include restrictions on reimbursement of allowable expenses, such as closeout costs and noncancellable commitments, after the date of termination. For example, NIH guidance, Payment Management System (PMS) Payment Request Process Used for NIH Awards, includes multiple statements that only payment requests "related to human subjects or



animal welfare" will be approved under terminated awards. Other language in the guidance seems to contradict this restriction.

Members report similar issues with suspension and stop-work orders. While agreements that are not subsequently terminated do not incur closeout costs until project end, they may have other costs that they would not have incurred had work continued as planned and they may have noncancellable costs during the period between suspension/stop-work notice and cancellation or expiration of the suspension/stop-work order. Members should consider taking steps similar to those suggested for terminations, including documenting the institution's definition, or examples, of eligible termination costs and non-cancellable commitments and steps taken to mitigate costs.

OMB Compliance Supplement (NEW)

OMB recently provided the AICPA and NASACT a "final draft version" of the 2025 Compliance Supplement, which can be downloaded from the AICPA website here (free AICPA account required). COGR has not reviewed this draft yet but will provide the membership with an update if it includes anything noteworthy and will also report when the final version is released.

OMB last published a <u>Compliance Supplement</u> in May 2024. As stated in <u>Part 1 — Background</u>, <u>Purpose</u>, <u>and Applicability</u>, the Compliance Supplement "is based on the requirements of 31 USC Chapter 75 and 2 CFR Part 200, Subpart F. The Supplement is a document that identifies existing compliance requirements that the federal government expects to be considered as part of an audit required by the 1996 Amendments to the Single Audit Act. Without the Supplement, auditors would need to research many laws and regulations for each program under audit to determine which compliance requirements are important to the federal government and could have both a direct and material effect on a program."

The AICPA webpage states that the draft version of the supplement was provided to its Governmental Audit Quality Center "so that auditors can use it to begin planning their 2025 single audit engagements."



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.

New Application Structure for NIH-Funded International Collaborations (NEW)

On September 12, 2025, the NIH issued notice <u>NOT-OD-25-155</u>, *New Application Structure* for NIH-Funded International Collaborations. The notice outlines the award structure first announced on May 1, 2025 (<u>NOT-OD-25-104</u>), which prohibits foreign subawards from being nested under the parent award. The new structure is expected to be implemented by September 30, 2025, and will apply prospectively to all NIH grants and cooperative agreements involving foreign subawards, including new, renewal, and non-competing

Under this policy, for grants requesting NIH funding for one or more foreign components, NIH will leverage NIH's <u>multi-component or complex application</u> package and require that competing applications submit applications to a Notice of Funding Opportunity (NOFO) that supports the new PF5 Activity Code for grants, new UF5 Activity Code for cooperative agreements, or another complex mechanism activity code that supports the International Project component type. The notice further outlines implications for application submission, peer review, award issuance, and reporting.

It remains unclear whether the new NOFOs and activity codes will be available starting September 30, 2025. However, NIH has indicated that further details are forthcoming and will release additional resources, including training, FAQs, and guidance, to support the transition to the new application structure.

Request for Information on Maximizing Research Funds by Limiting Allowable Publishing Costs (NEW)

As previously <u>reported</u>, on July 8, the National Institutes of Health (NIH) <u>announced</u> plans to implement a new policy to cap publishers' fees, limiting allowable publication costs. On July 30, 2025, NIH issued a <u>Request for Information</u> (RFI), outlining five proposed options:

- Option 1: Disallow all publication costs
- Option 2: Set a limit on allowable costs per publication
- Option 3: Set a limit on allowable costs per publication and allow a higher amount to be paid when peer reviewers are compensated
- Option 4: Set a limit on the total amount of an award that can be spent on publication costs



• Option 5: Set a limit on both the per publication cost and the total amount of an award that can be spent on publications

The proposed policy would apply to all new and competing awards and proposals for contracts submitted to NIH for receipt dates on or after January 1, 2026, or Other Transactions executed on or after January 1, 2026.

The comment period closed on September 15, 2025. COGR, in collaboration with AAMC, AAU, and APLU, submitted a joint <u>response</u> urging NIH to avoid arbitrary caps, preserve flexibility for investigators, and provide adequate time for implementation.

Revolutionary FAR Overhaul Initiative (ONGOING)

As COGR reported previously (May 2025 and July 2025 COGR Update), the Integrated Award Environment (IAE) Industry announced a comprehensive initiative to overhaul the Federal Acquisition Regulation (FAR), aligning with Executive Order 14275, Restoring Common Sense to Federal Procurement, and OMB Memorandum M-25-26 Overhauling the Federal Acquisition Regulation. The initiative aims to modernize federal procurement processes, enhancing efficiency and reducing administrative burdens.

The FAR Overhaul Page at <u>Acquisition.gov</u> serves as a central hub for updates, including FAR <u>Parts and Deviations</u> currently under review for public comment or awaiting overhaul. If you have feedback on any of the proposed parts or deviations, please contact Krystal Toups at <u>ktoups@cogr.edu</u>.

Preview of NIH Common Forms for Biographical Sketch and Current and Pending (Other) Support Coming Soon to SciENcv (NEW)

On September 4, 2025, the NIH released NOT-OD-25-152, announcing the availability of preview versions of the NIH Common Forms for Biographical Sketch, Current and Pending (Other) Support, and the Biosketch Supplement. This preview period is intended to familiarize applicants and recipients with the updated form structure and functionality, not to collect feedback or use for real submissions. During this preview period, applicants and recipients must continue to use the current NIH <u>Biosketch</u> (generated either through <u>SciENcv</u> or NIH Form Library.docx templates) and <u>Other Support</u> Format Pages for all submissions to NIH until NIH's official implementation of the Common Forms.

Preview versions of the NIH Common Form instructions can be found in the <u>NIH Forms</u> Directory:

- (PREVIEW) Biographical Sketch Common Form
- (PREVIEW) Biographical Sketch Supplement
- (PREVIEW) Current and Pending (Other) Support (CPOS) Common Form



To prepare for using the previews and adoption of the Common Forms, NIH recommends that users:

- Obtain an Open Researcher and Contributor Identifier (ORCID iD).
- Associate your ORCID iD account and eRA Commons account with SciENcv.
- Link your ORCID iD to your eRA Commons Personal Profile prior to previewing the forms.
 - For information on linking an ORCID iD to the eRA Commons Personal Profile see the <u>ORCID iD topic in the eRA Commons</u> Online Help.

NIH plans to issue a future Guide Notice with final implementation of the Common Forms details after securing clearance from the Office of Information and Regulatory Affairs, Office of Management and Budget under the Paperwork Reduction Act.

Department of Energy (DOE) Requirements and Guidance for Digital Research Data Management (NEW)

Beginning October 1, 2025, the DOE will require all new research funding solicitations and invitations to include a Data Management and Sharing Plan (DMSP) in accordance with the <u>2023 DOE Public Access Plan</u>. All DOE-funded research and development awards and contracts are subject to a DOE approved DMSP. Each solicitation will specify how and when a DMSP should be submitted. DOE sponsoring research offices will have discretion regarding whether DMSP requirements are applied to existing awards.

This policy is likely to have practical impacts on project budgets and the dissemination of research findings. Institutions should notify DOE-funded researchers and review project plans to account for potential costs associated with data management, storage, and sharing, as well as implications for where research results may be published or archived.

For additional information on DOE requirements, visit the <u>DOE Requirements and Guidance for Digital Research Data Management</u>. Additional resources include <u>Frequently Asked Questions</u> and guidance on <u>Writing a Data Management and Sharing Plan</u>.

HHS Updates the Grants Policy Statement (GPS) (NEW)

Effective October 1, 2025, the Department of Health and Human Services (HHS) released Version 2.0 of the <u>Grants Policy Statement</u>, which supersedes previous versions. In this update, HHS adopts 2 CFR 200 with HHS-specific modifications at 2 CFR 300.



Other notable changes include:

- Chapter 2.5.4.3: Includes a Title IX certification requirement and updated nondiscrimination language.
- Chapter C.8.10.3: Updates to SBIR/STTR data rights language.
- Appendix D: Updates related to administrative and national policy requirements.

For additional information, visit the HHS Grants Policies and Regulations page.

Department of Commerce (DOC) Updates Award Terms, Conditions and Associated Regulations (NEW)

Effective September 22, 2025, the DOC released updates to award terms, conditions, and associated regulations, now available on the <u>Financial Assistance Policy page</u>. The revised <u>Department of Commerce Financial Assistance General Terms and Conditions</u> apply to awards and funded amendments made on or after September 22, 2025.

A key change is the update to Section A.07 Termination. The revised language now includes an option to terminate for convenience or based on national interest, with an exception for awards under the NDAA, Chips Act, Infrastructure Investment and Jobs Act, and non-discretionary grants.

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.

COGR-ARIO Materials on 2024 Research Misconduct Rule (NEW)

Over the summer, working groups composed of both COGR and ARIO members analyzed the 2024 PHS Research Misconduct Rules and compared it to the 2005 Rule. Based on this analysis, the groups developed several templates and checklists to assist institutions in reviewing and revising their existing PHS Research misconduct policies and procedures to ensure compliance with the 2024 Rule. The tools are listed below, and COGR and ARIO hosted a webinar on September 26, 2025 to review the tools and instructions for their use.

All tools are available on the COGR website at this <u>link</u>. Each tool can be downloaded and customized to meet an individual institution's needs.



| COGR and ARIO Tools for Finalizing Institutional Research Misconduct Policies and Procedures | | |
|--|---|--|
| Tool | Description | |
| Chart Comparing Regulatory Requirements Under 2005 and 2024 Rules and Comparing Key Features of Federal Agencies' Research Misconduct Policies | This tool has two separate sheets. The first sheet compares regulatory requirements from ORI's 2021 checklist of policy/procedure under the 2005 and 2024 Rules and color codes the nature of changes as requiring minor, moderate, or significant changes to existing policies & procedures. The second sheet compares key provisions of seven federal agencies' research misconduct policies. | |
| Decision Points Slides | These slides highlight flexibilities in the 2024 Rule that institutions will need to assess and determine how to address in revised policies and procedures. | |
| Institutional Assessment Result Template | This template provides a format that institutions can use to document the 2024 Rule's new "assessment" phase of research misconduct proceedings. | |
| Sample Inquiry Report Template | This template provides a format that institutions can use to document the results of the inquiry phase of research misconduct proceedings. | |
| Case Document Index Template | This template provides a format for creating an index of relevant case documents to satisfy the requirements of 42 CFR §93.204(b). | |
| Instructions for Use of Sample | This document describes how to use the three documents listed | |
| Sequestration Inventory Record Template | below for documenting the sequestration of evidence. | |
| Sequestration Inventory Record Template | This tool can be used to document research records and other evidence sequestered during a proceeding, including important metadata about the records and sequestration process. | |
| Sequestration Signature Log Template | This log can be used to collect the signatures of individuals from whom records/evidence are obtained and can serve as a record of receipt of these materials. | |
| Template Chain of Custody Log | This template can be used for tracking access to, and use of, records and other evidence throughout the course of a research misconduct proceeding. | |

Office of Research Integrity (ORI) Guidance Documents (NEW)

ORI released its second batch of new guidance documents to assist in clarifying key issues under the 2024 Research Misconduct Rule. Each of these new guidance documents is discussed below:

Honest Error Guidance: Honest error is an affirmative defense against allegations of research misconduct. Institutions need not prove the absence of honest error, but they do need to consider any evidence of honest error that is raised during the proceedings. This guidance document outlines "best practices" for how to review such evidence and consider it in context of allegations and research record and other evidence being examined during the proceedings.

Admissions Guidance: The 2024 Research Misconduct Rule sets forth detailed requirements for a respondent's statement of admission to allegations of research misconduct. [42 CFR §93.103]. This guidance details the elements that must be included in a written admission statement and notes that the statement "should not allude to honest error, difference of opinion, or mitigating factors" for the respondent's actions. It



also "recommends" that the respondent draft their own admission statement. The guidance makes clear that in addition to the respondent's statement, the institution must draft an accompanying written statement that describes how the institution "determined that the scope of the research misconduct was fully addressed" by the admission. This statement must also state how the admission "confirms the respondent's culpability," and it must be supported by the institutional record of the proceeding. Finally, the guidance outlines the need for institutions to consult with ORI prior to closing out a proceeding on the basis of an admission and examples of circumstances which may limit the institution's ability to close a proceeding based on an admission.

Pursuing Leads Guidance: In this guidance document, ORI describes examples of leads that may warrant additional review and possible expansion of an investigation. These examples include patterns of behavior across multiple papers/applications, repeated use of a technique that was used to generate the suspect data; and evidence that experiments were not performed, such as lack of lab notebooks or original data. The guidance makes clear that in evaluating whether there are instances of research misconduct beyond those set forth in the allegations, institutions may need to examine "a respondent's papers and grant applications that could include figures or other data elements which are similar to those in the initial allegations." Although the regulations only require that leads be pursued during the investigation phase [42 CFR §93.310(j)], the guidance encourages institutions "to remain alert for indications of significant issues or additional leads during all stages of the proceedings."

<u>Sub-Awardee Assurances Guidance</u>: The 2024 Research Misconduct Rule specifies that sub-awardees who receive PHS support must have an active research integrity assurance on file with ORI. This guidance discusses the Research Integrity Assurance Establishment form that awardees and sub-awardees must file and maintain with ORI, as well as the underlying compliance obligations (e.g., maintenance of and compliance policies and procedures that comply with 42 CFR Part 93).

Assessments Guidance: The 2024 Research Misconduct Rule sets forth the requirements for the newly prescribed "assessment" phase of research misconduct proceedings. This guidance outlines the purpose of the assessment phase, advice on how a research integrity officer should conduct and document the assessment, and the importance of separating the assessment from the inquiry. Notably, the guidance makes clear that a RIO may conduct an informal interview of the complainant during the assessment, but that assessment does not "involve interviewing the respondent." The guidance also notes that if the allegations involve multiple institutions, "the assessment period provides an opportunity to coordinate with" them prior to notification of the respondent and sequestration.



NIH Biosafety Initiative (NEW)

In September, NIH launched a new <u>Biosafety Modernization Initiative</u> to "strengthen biosafety policies, practices, and oversight." Currently, NIH's biosafety oversight policies are limited to research involving <u>recombinant or synthetic nucleic acid molecules.</u> NIH has indicated that it intends to expand the scope of its oversight policies to encompass additional research activities, while also considering whether there is adequate safety data to support reducing oversight for certain low-risk recombinant research and/or for research that is subject to regulation by other federal agencies. Note that this initiative is separate from, and in addition to, OSTP's activities on dangerous gain-of-function (DGOF) research taken in response to the directives contained in the <u>May 5, 2025, Executive Order on Improving the Safety and Security of Biological Research</u>.

In <u>materials</u> concerning the new initiative, NIH has stated that it plans on moving away from a technique-based to risk-based approach to regulation that encompasses "wild type agents and other possible biohazards." In terms of scope, NIH has posited the following three options for consideration as to the type of research to which the new requirements will apply:

- **NIH Guidelines Plus** Maintaining the current scope of recombinant and synthetic nucleic acids and adding other biohazards (e.g., wild-type agents such as toxins and prions).
- Harmonized with the CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL) Publication Encompassing infectious microorganisms and hazardous biological materials based on risk groups.
- **Life Sciences Research** Establishing a broad category of research encompassed by the requirements and issuing criteria and guidance on areas that require institutional or NIH oversight.

NIH also noted the following areas that may be eligible for less NIH or local oversight: (a) non-biomedical research with plants, agricultural animals, or certain microbes that fall under the purview of other federal agencies; (b) clinical research under the purview of FDA; and (c) low risk research such as that involving RG1 agents and some transgenic organisms.

During the autumn of 2025, NIH plans to solicit stakeholder input on the scope of the new policy and the possible options that it put forth. This input will not be gathered via the traditional mechanism of requesting comments on a published request for information. Rather, NIH plans to host six virtual engagement meetings to collect verbal comments on the initiative and options presented. The meetings will be organized by geographical region, with the Region 1 Meeting including northeastern and mid-Atlantic states. Although stakeholders from the states within a specific region will be given priority to attend their region's session, any stakeholder may attend any region's meeting if there is capacity to accommodate them. The Region 1 session is scheduled for September 30, 2025,



from 2:00 to 5:00 p.m. (ET). NIH has posted questions for comment at this session and plans to adjust the questions as the regional meetings progress.

After the information solicitation phase concludes, NIH will consider public input and develop a draft policy that it plans to publish in spring 2026. NIH will seek feedback on the draft policy during the spring and summer and publish a final policy in the autumn of 2026.

COGR has organized a group of biosafety professionals from member institutions to assist in developing verbal comments for regional meetings and written comments that will be provided to NIH. NIH has emphasized the need to obtain comments from a large number and variety of stakeholders, and COGR encourages institutions to participate in their regional sessions and send their own written comments. Toward this end, COGR will be providing materials on comments from its working group, along with template letters. COGR will also be coordinating with ABSA and other biosafety organizations to align comments in a manner designed to achieve optimal outcomes for academic research institutions.

New NIH Guide Notices Impacting Human and Animal Research (NEW)

Since the July 2025 update, NIH issued the following new guidance notices impacting the conduct of human and animal research:

NOT-OD-25-160, NIH Policy on Enhancing Security Measures for Human Biospecimens and NOT-OD-25-159, Required Security and Operational Standards for NIH Controlled-Access Data Repositories – The Department of Justice's regulations on Preventing Access to U.S. Persons Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons (28 CFR Part 202, "DOJ Regulations") included an exemption for "Official Business of the United States Government" (28 CFR §202.504) that encompassed research sponsored by federal agencies. This exception was included, in part, to permit agencies "to pursue grant-based and contract-based conditions to address risk that countries of concern can access sensitive personal data in transactions related to their agencies' own grants and contracts . . . without subjecting those grantees and contractors to dual regulation." [90 FR 1675]. With its issuance of these two guidance documents, NIH has now set forth its own security requirements concerning the transfer of certain biospecimens to Countries of Concern and imposing additional security requirements on its Controlled-Access Data Repositories (CADRs).

NOT-OD-25-160 sets forth the NIH Biospecimens Security Policy ("NIH Policy") for protecting U.S. persons biospecimens – a category of data under the DOJ rule. The NIH Policy encompasses "all human clinical and research biospecimens obtained from U.S. persons (regardless of identifiability) that are collected, obtained, stored, used or distributed and that are supported or funded by any on-going or new NIH funding mechanisms." The Policy prohibits direct or indirect distribution of such biospecimens to



institutions or parties located in countries of concern (COCs) as those countries are determined under the DOJ Regulations at 28 CFR §202.601. Currently, COCs include China (plus Hong Kong and Macau), Cuba, Iran, North Korea, Russia, and Venezuela.

Unlike the DOJ Regulations, the NIH Policy does not establish any "bulk thresholds" that trigger applicability; rather, the Policy applies to any number of biospecimens. The NIH Policy includes its own definition of "Human Biospecimens" but excludes from the Policy "cell derivative products or cell lines derived from human biospecimens of U.S. persons collected, obtained, stored, used, or distributed using on-going or new NIH funds that are commercially or publicly available" prior to the Policy's October 24, 2025, effective date.

The NIH Policy also sets forth limited exceptions to the Policy's distribution prohibitions, including distribution/sharing that is:

- Necessary to carry out "transactions required or authorized by Federal law or international agreements, or necessary for compliance with Federal law" as defined in the DOJ Regulations at 202.507;
- Needed in time-sensitive "rare and compelling circumstances where the facility and personnel" in the COC have expertise/capabilities that are unavailable elsewhere, provided the individual from whom the specimen was obtained consents to the transfer; or
- Made at the request of the individual form whom the biospecimen was collected, obtained, or stored using NIH funds, "for purposes of diagnosis, prevention, or treatment of that individual" and in compliance with "applicable Federal laws, regulations, and policies."

Entities must retain documentation regarding any biospecimens shared under these exceptions, including the quantity and content of the biospecimen that was shared. This documentation must be provided to NIH upon request.

NOT-OD-25-159, Required Security and Operational Standards for NIH-CADRs requires specified CADRS to follow the security requirements set forth in the "NIH Controlled-Access Data Repository Guidebook to Adhere to 'Required Security and Operational Standards for NIH Controlled-Access Data Repositories." As a part of these security standards, CADRS must implement NIH NOT-OD-25-083, Implementation Update: Enhancing Security Measures for NIH Controlled-Access Data, which became effective April 4, 2025. NOT-OD-25-083 prohibits "access to NIH Controlled-Access Data Repositories and associated data by institutions located in countries of concern" [emphasis added] including China (plus Hong Kong and Macau), Russia, Iran, North Korea, Cuba and Venezuela.

NIH has published a <u>list</u> of all CADRS that are subject to these requirements. CADRs that cannot satisfy these requirements may choose to migrate data to a compliant NIH CADR.



Implementation of categories of security requirements set forth in the Guidebook are being phased in between now and February 25, 2026, when all categories will be applicable.

NOT-OD-25-153, NIH Disposition of Biospecimens Collected from Tribal Populations – This guidance sets forth three options that NIH can follow to facilitate the transfer or return of de-identified biospecimens collected from "Tribal Populations" back to those populations, including transfer/returns initiated upon a tribe's request. The guidance applies to "biospecimens held at NIH facilities or at facilities on behalf of NIH," but it encourages all researchers to review and adopt the options "when practical."

NOT-OD-25-145, Notice of an Update to the OLAW Guidance Disclaimer – In July 2023, OLAW published a request for information (RFI) seeking stakeholder input on a proposed update to the OLAW Guidance Disclaimer statement. COGR submitted comments in response to this RFI, suggesting the OLAW pattern its disclaimer statement after those used by the FDA and OHRP. Although, OLAW did not adopt those disclaimer statements directly, it did modify its disclaimer statement language to specifically note that information in guidance documents "that is not contained within specific statutory or regulatory requirements represents OLAW's interpretations for meeting the outcome-based requirements in the PHS Policy" and that institutions may use alternative approaches that meet the PHS Policy "without compromising animal welfare."

OLAW Webpage on its Implementation of the 21st Century Cures Acts Mandat to Reduce Administrative Burden on Animal Research Without Negatively Impacting the Health, Safety or Welfare of Animals Used in Research: OLAW has published a new webpage that assembles in one place the guidance documents it has issued and other activities it has undertaken in conjunction with the Cures Act mandate. COGR commented on all of these guide notices, which for the most part restate long-standing flexibilities available to IACUCs and animal care and use programs, without adding much in the way of new burden-reducing members. The site also contains the results of OLAW's survey of IACUC Administrators on whether its efforts resulted in burden reduction. Notably, the survey results demonstrated that 40% of responders found the efforts to be ineffective in reducing the workload of researchers, while just over 50% stated the efforts were very to extremely effective in reducing IACUC workload.



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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