COGR℠

Advancing Effective Research Policy

NOVEMBER 2025 UPDATE

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President's Message:
Giving Thanks: Shutdown's Over. Onward We Go.

Dear Colleagues,

Thank you to all who were able to join the COGR Membership Meeting last month. It was a welcome – and many of you said a "needed" – opportunity to reconnect and recharge amidst a tumultuous year and the government shutdown. From the session discussions to the conversations at the breaks and in the elevators, it was clear that despite the obstacles, COGR members and ERI Pilot Participants are finding pathways to keep research moving. This month's update provides summaries of some of the key sessions, along with other recent key updates on federal research policy.

Thankfully, the longest federal government shutdown is over. Federal research agencies are working to address their backlogs. The new continuing resolution will keep the government open through January 30, and Congress is now working to clear as many appropriations measures as it can before the end of the year and provide itself room to complete the appropriations early in the new year and head off a second shutdown or a partial shutdown.

Onward we go, as agencies resume full operations, we are closely monitoring and preparing for new policy proposals. Chief among them is the OMB's pending revision of the Uniform Guidance, including changes to facilities and administrative costs reimbursement. In light of the OMB memo M-25-36, we are also anticipating the release of proposals and changes consistent with the Administration's deregulation initiative. As we engage what is to come, our clear purpose is to advance and effectuate effective research policy.

Since the September COGR Update, we have continued ongoing efforts to strengthen service to the membership and ERI Pilot Participants through new tools and publications. We hope you have visited our newly redesigned website that includes improved navigability, organization, and search. We will be using the upgraded platform to better deliver information and communicate with the COGR community, policymakers, the media, and others with whom we engage.

Two new COGR publications for your attention, are: 1) Research Security Regulations: Practical Considerations Guide for Technology Transfer Professionals outlines the regulations and risk areas where research security and technology transfer intersect and offers practical considerations for TTOs to ensure secure and responsible transfers of innovation; and 2) The Single Audit - Updates and a Potential for Efficiency Never Fully Realized describes the changes and the current Single Audit environment. Thank you to the RSIP and CFC committees for these new useful resources.

On behalf of the COGR staff team, we hope everyone has a restful and much-deserved break over the Thanksgiving holiday. We are grateful for the opportunity to serve the COGR community.

Matt Owens
President

Announcements

Announcing COGR's New Website!

It's been a decade in the making, and after a year of behind the scenes work and a lot of caffeine, we are pleased to share with you COGR's newly redesigned website.

Still at www.cogr.edu, the new site includes improved organization, navigability, search, LinkedIn integration, upgraded mobile viewing, and visual presentation and identity. The new site also has new features including AI summaries of many of COGR letters, reports, matrices and other documents and products.

We've also included a new section under "Policy Issues" - Reducing Red Tape. A core COGR mission priority, the Reducing Red Tape page is where you'll find COGR statements, comment letters on deregulation, letters to the Administration, actionable ideas to reduce burden, COGR's litigation & executive summary trackers, COGR's Changes in Federal Research Requirements Since 1991 document, and much more.

We are grateful for suggestions and feedback we have received from you as we redesigned and constructed the site. Thank you especially to the volunteers who worked with the staff, designers, and developers:

- **Allen DiPalma**, University of Pittsburgh, COGR Board of Directors and RSIP Committee Member
- **Jeremy Forsberg**, University of Texas at Arlington, COGR Board of Directors & CFC Committee Chair
- **Stephanie Gray**, University of Florida, COGR Board of Directors and CGA Committee Member
- **Sophia Herbert-Peterson**, Georgia Tech, COGR Board of Directors & RSIP Committee Member
- **Vivian Holmes**, MIT, COGR Board of Directors and CFC Committee Member
- **Jennifer Lassner**, University of Iowa, COGR Board of Directors & REC Committee Member
- **Craig Reynolds**, Van Andel Research Institute, COGR Board of Directors and CGA Committee Member
- **Nate Rigel**, Kean University, Emerging Research Institutions Pilot Participant
- **Lori Schulz**, Colorado State University, COGR Board of Directors and CGA Committee Member
- **Maggie Swift**, University of Michigan, at-Large Member Representative

In the weeks and months ahead, we will be working to maximize the new website's functionality, search, and how COGR delivers and presents content in user-friendly ways.

We welcome your feedback on the new site and if you see ways we can continue to improve the site, please share this with us at web_inquiry@cogr.edu.

February 24-27, 2026, Virtual Meeting: Save the Date

Registration will open for COGR's February 24-27, 2026 Virtual meeting in December, and you can add the event to your calendar now via COGR's events page. Preliminary agenda topics will be announced in January, and other meeting materials, including the agenda, will soon be released via COGR's listserv and website. As a reminder, COGR has implemented an Event Code of Conduct Policy. By registering for the February meeting, attendees agree to abide by this policy.

Contact memberservices@cogr.edu with any questions. We hope you will 'save-the-date'!

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. **Please note, if your institutional membership dues are not yet paid, you will not be able to register for the February virtual meeting unless you have made prior arrangements with COGR staff.**

To download the invoice, the Primary Representative or billing contacts for the institution can log into the COGR Portal, 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 available here.

If you have any questions or need assistance, please contact memberservices@cogr.edu. Thank you for your institution's membership!

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.

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.

Resumption of Operations after the Government Shutdown

Following the 43-day federal shutdown, Congress has enacted a continuing resolution that funds the government through January 30, 2026. Federal agencies have now resumed normal operations, and several have issued initial reopening guidance.

Recent announcements include:

- Resumption of Operations at NSF
- Interim Guidance on Reopening of NIH Extramural Activities [NOT-OD-26-005]

OMB Memo M-25-36 Streamlining the Review of Deregulatory Actions

On October 21, the Office of Management and Budget (OMB) issued a Memorandum M-25-36, *Streamlining the Review of Deregulatory Actions*. The memo, directed to all Regulatory Policy Officers across federal departments and agencies, as well as managing and executive directors of commissions and boards, provides guidance on implementing key elements of the Administration's deregulatory agenda under Executive Order (EO) 14192 (Unleashing Prosperity Through Deregulation). EO 14192 directs agencies to pursue a "10:1" ratio of deregulatory to regulatory actions.

Per the memo, "*the goal of this Memorandum is to offer guidance to the agencies as to how to bolster, streamline, and speed both (1) the deregulation of facially unlawful prior government regulations and (2) those types of deregulatory activity that will continue to require the development of more extensive agency record-building.*" To accomplish this, OMB outlines two pathways. For rules the Administration views as "*facially unlawful*" determined by recent Supreme Court decisions referenced in April 9 Memo, including Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024), West Virginia v. EPA, 597 U.S. 697 (2022), SEC v. Jarkesy, 603 U.S. 109 (2024) and seven others, agencies are directed to move quickly to withdraw them, identify any unlawful regulatory requirements, and repeal facially unlawful regulations "without notice and comment" under the Administrative Procedure Act's "good cause" exception. Agencies may also classify rules as unlawful when the "best interpretation" of the statute does not support the regulation. All other deregulatory actions must proceed through the APA processes and require agencies to

develop a reasoned, evidence-based record, including analysis of alternatives, tradeoffs, and costs.

To expedite deregulation, OMB is establishing new significantly shorter OIRA review timelines: a 14-day presumptive review period for actions removing facially unlawful rules and a 28-day presumptive maximum for other deregulatory actions. This represents a departure from the 90-day review period under EO12866, Regulatory Planning and Review. OMB notes that extensions may still be necessary for technically complex or economically significant.

The memo also narrows when agencies must conduct consultation with communities. OMB instructs agencies to presume that consultation requirements related to states [EO 13132], tribes [EO 13175], small businesses [EO 13272], energy [EO 13211], or property rights [EO 12630] do not apply when removing or reducing regulatory burdens, unless the deregulatory action itself imposes new burdens. When consultation is necessary, agencies may rely on the standard APA notice and comment process rather than conducting separate outreach, potentially reducing opportunities for stakeholder engagement.

M-25-36 represents a significant shift in federal regulatory practice with broad implications for agencies, regulated entities, and the research community. The Administration's approach to identifying "unlawful" regulations may be consequential and lead to agency inconsistencies. Reduced consultation requirements and shorter OIRA timelines may affect the degree and quality of external input into regulatory decisions.

COGR will continue to monitor the implementation of M-25-36, assess its implications, and leverage opportunities for deregulation that benefit research.

2025 Administration Transition Information and Resources

COGR has developed a dedicated site, COGR's 2025 Administration Transition Information & Resources, a centralized hub designed to help members navigate executive actions and policy changes affecting federally funded research. The site features a consolidated list of agency directives and memoranda, EO tracker, COGR analyses and communications, litigation tracker, and other key resources. The page is updated periodically as new information becomes available. Members are encouraged to share relevant communications with COGR at memberservices@cogr.edu.

Summary of Emerging Federal Terms and Conditions (NEW)

COGR has developed this Summary of Emerging Federal Terms and Conditions (T&Cs) [COGR Portal Login Required] to assist member institutions with monitoring newly introduced or evolving federal award terms in connection with the Administration's priorities and the implementation of recent Executive Orders (EOs). These new priorities

have influenced agency award requirements, compliance expectations, and institutional obligations.

This summary consolidates observations from agency announcements and award documents to provide an overview of current trends, areas of concern, and examples of emerging federal requirements that may warrant institutional review or discussion.

The table is organized to include: Topic; Issuing Agency; Specific/Cited Term or Condition; and Notes or Comments. Institutional responses to these terms will vary based on structure, governance, and risk tolerance, and as such, COGR does not recommend a single approach. Instead, this summary serves as a reference and coordination tool, enabling members to benchmark their awareness and inform internal discussions.

COGR will maintain and periodically update this summary to reflect new developments and member input. We encourage members to review the information and share examples of new or emerging T&Cs, agency communications, or other documentation that could inform future updates. Contributions or questions may be directed to **memberservices@cogr.edu**.

Results from the "Navigating the Storm" Discussion Session at the October Membership Meeting (NEW)

Attendees at COGR's October membership meeting participated in COGR's second table topics discussion forum to share ideas and information on key topics in a variety of research administration areas. During this meeting session, attendees "assigned" themselves to sit at a table where a table placard was displayed indicating which of the following topics areas would be discussed:

- Grant/Contract Terminations and Appeals
- Future of Research
- F&A and Costing Issues
- Compliance During Uncertainty
- Research Security

Each table was provided with a list of "discussion starter questions," and asked to submit (via Poll Everywhere) the top three to five points that surfaced during the group's discussion. COGR directors (with the assistance of AI) then summarized key points for each of the discussion topics and reported out to the entire audience.

A summary of the key points for each broad discussion topic is shown in the charts below.

Grant Termination and Appeals	
Subtopic	**Key Points for Subtopics**
Reinstatements Tied to Litigation, not to Appeals	●Some institutions that appealed terminations never received responses from agencies. ●In cases where appeals were filed and grants reinstated, the agency cited court decisions mandating reinstatement, as opposed to the appeal itself. ●States whose institutions were not parties to lawsuits did not see their grants reinstated, leading to great variability across institutions.
Terminations Cause Operational Strain	●Mid-award terminations cause great operational strains (e.g., workforce retention, determining which compliance obligations remain after cancellation). ●Institutions have limited negotiation leverage with agencies. ●Some institutions are adding internal certifications to manage risk. ●Terminations for convenience are a major threat to research continuity, faculty confidence, and the researcher pipeline.

The Future of Research	
Subtopic	**Key Points for Subtopics**
Future of Federal Research Funding and Need for Institutional Change	●At present, federal support is cost-effective, but institutions must prepare for significant long-term changes, including increasing politicization. Federal research funding will become scarcer, especially for basic research. ●Institutions must become nimbler and more proactive and consider increased centralization of certain services/functions; narrowing research focus; and developing longer term strategic plans.
Need for Funding Diversification & Alignment with Stakeholder Needs	●Diversification is critical but challenging because of long-standing dependence on federal funds and systems built to accommodate that funding source. ●Institutions must explore diversifying research funding streams including industry partnerships, monetizing university assets (e.g., allowing industry access to facilities), developing new training programs, and permitting investors to earn returns on research. ●Institutions should conduct "customer discovery" to understand community and industry needs. ●Institutions must improve public perception of higher education and academic research through advocacy; better "story telling" about the

	need for research, research benefits and how funds are used; and cultivation of champions.
Changing Academic Models	●Tenure systems may require re-thinking. Dual or concurrent appointments with industry or international institutions may increase. ●Institutions may need to place more emphasis on technical staff support and non-degree training programs, but there are concerns about tilting too far in the direction of "for-profit" behaviors.
Developing Collaborations and Increasing Resilience	●Institutions need to develop collaborations that cut across multiple institutions, industry partners, and international partners. ●Although policy changes seem aimed at dividing academic institutions, they must collaborate and work together to succeed. ●Institutions may need to sharpen their mission focus and reject opportunities that are not clearly aligned with that focus. ●New costing polices may threaten some institutions' continued viability, particularly those with limited internal resources.
Role of AI	●AI will drive both science and operation. Potential uses include: ●Analysis of researcher "portfolios" to establish research teams. ●Assessment of commercialization potential ●Streamlining research administration operations.

F&A Cost and Other Costing Issues	
Subtopic	**Key Points for Subtopics**
Redefining Direct & Indirect Costs	●Institutions are exploring how to maximize direct charging by reducing/eliminating voluntary cost share, identifying indirect costs that may be shifted to direct costs (e.g., data management, compliance/regulatory functions such as IRB and IACUC costs), and expanding recharge centers. ●Institutions are considering new service center models to centralize more functions and reduce redundancies.
Preparing for Caps or a New Reimbursement Model	There is a widespread expectation that institutions will need to engage in complete financial and administrative restructuring, including: ●Pooling and redistribution of costs based on award activity. ●Moving toward permanent/central funding for certain services. ●Revisiting policies for allocation of IDC reimbursement.

Cost Controls & Return on Investment (ROI)	●Institutions are examining program ROI to identify areas for cuts. Some institutions have already implemented budget cuts and RIFs. ●Institutions are implementing cost controls such as elimination of F&A rate waivers, providing smaller faculty start-up packages, and negotiating higher F&A rates for state sponsored projects.
Drawdowns, Invoicing & "Defend the Spend"	●Institutions are facing significant challenges in addressing burdensome and inconsistent requirements for federal/non-federal drawdowns and invoices and "defend the spend" requirements. ●Institutions recognize that large write-offs are detrimental and are increasingly focused on accounts receivable.
Managing Award Delays/Terminations and Bridge Funding	Institutions are employing strategies to avoid delays and terminations including: ●Reviewing non-competing awards well in advance. ●Providing temporary pre-award spending with non-grant back-up accounts and creating bridge accounts/funds for delayed or at-risk awards. ●Consideration of possible furlough plans.
Termination Costs	●Institutions continue to face a lack of clear guidance on "allowable termination costs" and may employ an expansive interpretation of "non-cancellable commitments."
Institutional Modeling & Analysis Efforts	●Institutions have started engaging in early modeling efforts to understand the impact of (a) 15% IDC rate; and (b) potential FAIR model. ●Institutions are assessing FTE needs to manage potential new charge structures. ●Institutions are forming work groups to understand the drivers of an effective F&A cost rate and performing more detailed and more frequent "true-ups." ●Institutions recognize that new models will require major cultural shifts that require extensive training and the ability to clearly define those projects an institution is willing to support and those that are too expensive to subsidize.

Compliance During Uncertainty	
Subtopic	**Key Points for Subtopics**
"Other Support" Documentation & Record-Keeping Challenges	●Institutions face continuing challenges with decentralization, particularly with regard to record-keeping functions spread across multiple programs (e.g., sponsored programs and COI systems) making it difficult to ensure "other support" disclosure accuracy and completeness. ●Decentralized systems and workflows also cause issues, and institutions are working to better integrate and automate these systems/processes. ●Institutions are using new strategies to meet other support documentation/document retention requirements, including integrating other support disclosure requirements into annual reporting requirements and modifying reporting form (e.g., COI forms) to include paid/unpaid activities. ●There is increased utilization of LMS systems to track completion of required compliance training.
Research Security Requirements	●Many institutions noted the significant challenges arising from the differing ways in which agencies assess the risk associated with foreign collaborations and the difficulty in advising faculty on those collaborations. ●Institutions are also facing challenges in implementing research security training and ensuring subrecipient compliance with training requirements. ●Inconsistent and rapidly changing agency requirements create a heavy administrative workload and make it difficult to accurately advise researchers; however, these inconsistencies have fostered the need for cross-unit collaboration and improved research engagement.
System Failures, Shutdowns & Federal Capacity Issues	●Government shutdowns and outages in federal reporting systems such as iEdison and ClinicalTrials.gov disrupt reporting, award setup, and compliance checks. ●Massive layoffs and attrition in the federal agency workforce have led to lost expertise and corporate knowledge, and institutions must spend more time educating federal staff on requirements. ●During shutdowns, institutions are forced to rely on internal documentation and "shadow" tracking systems until federal systems are back up.

Institutional Staffing Losses & Operational Efficiency	●At the same time that federal agencies are losing staff, institutions are also facing staff cuts and hiring freezes resulting in increased consolidation of workload among fewer employees. ●Institutions are revisiting workflows to achieve more efficiency.
Building a Resilient Compliance Infrastructure	●Institutions are placing a greater emphasis on documentation and process clarity including better use of SOPs and manuals; better employee transition procedures and succession planning; and greater use of FAQs.

Research Security	
Subtopics	**Key Points for Subtopics**
Training Approaches & Challenges	●Many institutions rely on a 1-hour consolidated research security (RS) training module, although some institutions (particularly those with more regulated research) provide more extensive RS training. ●Institutional leadership may be reluctant to mandate requirements above those specified in the federal rules. ●Faculty may view RS training as a "check-the-box" requirement and training is frequently redundant for faculty who take multiple trainings. ●For institutions that use the CITI training platform, changes in training requirements can be difficult to communicate and training may be inconsistent across institutions due to varied CITI platform configurations.
Cybersecurity Readiness (NIST & CMMC)	Institutions reported varying stages of readiness: ●Several institutions reported they have NIST compliant enclaves and are aiming for CMMC Level 2 compliance within months or by the end of 2025. ●Several other institutions reported compliant enclaves with no current plans to move to CMMC Level 2. ●Some institutions at CMMC Level 1 reported pressure from award requirements to move to Level 2. Many institutions are implementing compliance incrementally. ●Many institutions reported that they are interviewing CMMC auditors. ●Cybersecurity in general, and CMMC in particular, pose a major compliance challenges because of unclear federal requirements, difficulties in coordinating roles and responsibilities between IT and research admin. units, and high costs.

Export Control & Specialized Training	●NSPM-33 requires export control training for those on export-controlled projects, but NSF appears to require this training as a part of RECR. ●It can be difficult to capture personnel who require export control training when they join a controlled project after it is underway. ●Institutions use varied screening procedures for personnel and external entities screening and escalation/certification processes for identified risks.

Ongoing Litigation Concerning Research and Research Funding (UPDATE)

COGR continues to track the progress of ongoing litigation challenging the Trump administration's actions to terminate and/or restrict research and research funding. Cases are regularly updated on the COGR litigation tracker. Notable developments in cases since the September 2025 update are discussed below.

Litigation Paused During Government Shutdown: In response to the government shutdown, the Department of Justice filed motions in pending cases asking for proceedings to be stayed or delayed due to lack of appropriations to continue prosecution of the litigation. Most courts placed proceedings on hold, but with the end of the shutdown on November 12, courts are now rescheduling deadlines for postponed filings and hearings.

Oral Arguments Heard in Appeal of Cases Enjoining NIH's 15% Rate Cap: Despite the shutdown, on November 5, 2025, the First Circuit Court of Appeals heard oral arguments in the AAU/AAMC/states' attorney generals consolidated cases in which the government appealed the district court's permanent injunction against the NIH rate cap. The appeals court has not yet issued a ruling in these cases.

Continuing Fallout from Cases Addressing the Issue of Whether District Courts or the Federal Court of Claims has Jurisdiction to Hear Federal Grant Termination Cases – In California v. Department of Education (DOEd) ("California Case"), the district court issued a temporary restraining order (TRO) blocking DOEd from terminating grants due to violations of the Administrative Procedure Act (APA) and the Constitution. The government initially asked the First Circuit to stay the TRO pending appeal, which the First Circuit denied. The government then applied to the U.S. Supreme Court for a stay. The Supreme Court stayed the TRO pending the First Circuit's disposition of the appeal on the basis that jurisdiction for the case was likely in the federal Court of Claims.

In response to this ruling, the plaintiffs withdrew their motion for a preliminary injunction (PI), and the appeal to the First Circuit was voluntarily dismissed. The plaintiffs then filed an amended complaint in the district court, which added claims that the government violated the Constitution's spending clause and separation of powers

provisions and took actions outside the scope of its statutory authority. The complaint also sought a declaratory judgment to clarify the parties' rights and obligations regarding the termination of grants under the Uniform Guidance.

The district court in the California Case considered this amended complaint in light of another relevant Supreme Court decision in the case of NIH v. American Public Health Association ("American Public Health Case"). In that case, the U.S. Supreme Court stayed the district court's order setting aside certain NIH grant terminations as violating the APA on the basis that the Court of Claims, not the district court, has subject matter jurisdiction over claims related to research grant termination and ordering relief to enforce any obligation to pay money.

Following the Supreme Court's decision, the district court judge in the California Case held that the case should follow a "two-track litigation" process that involves both the district court and the Court of Claims. Under this process, the district court will decide whether the government's actions were unlawful under the APA and the Constitution. If the district court determines that that government violated the APA or Constitution, the plaintiffs can then file suit in the Court of Claims to request money damages for the terminated grants.

It remains to be seen whether the government will appeal the district court's latest ruling in the California Case. However, if this two-track process is ultimately adopted by the courts, institutions will be required to conduct costly litigation in two court systems to receive a complete remedy for grant terminations.

*Additional Proceedings Regarding the American Public Health Case (*Update) – Oral argument in the government's appeal of the district court's decision in the American Public Health Case and its consolidated case Massachusetts v. RFK, Jr. was originally set for October 14, 2025. Argument was delayed because of the government shutdown and is being rescheduled. COGR joined with other associations in an amicus brief filed in this case and in a supplemental amicus brief that was filed on November 19, 2025 in the U.S. Court of Appeals Fifth Circuit.

Harvard v. Dept. of Homeland Security (DHS) (NEW) – In this case, Harvard successfully challenged DHS' actions to revoke Harvard's ability to participate in the federal Student & Exchange Visitor Program (SEVP) and to terminate federal grants based on charges that Harvard was not doing enough to combat antisemitism. The district court held that these actions were unlawful punishment for Harvard's exercise of its 1st Amendment rights. The court entered a preliminary injunction and granted summary judgment for Harvard. The government has appealed the district court's ruling to the First Circuit Court of Appeals. COGR plans to join with other associations in filing an amicus brief with the Court of Appeals.

American Association of University Professors v. Trump (NEW) – Associations and unions representing faculty, staff, and students at University of California (UC) components filed a complaint alleging that the government used alleged violations of U.S. Civil Rights laws by UC as a pretext for punishing plaintiffs for exercising their rights under the U.S. Constitution.

The district court entered a broad preliminary injunction enjoining the government from suspending, terminating, or withholding research grants to UC based on allegations of Civil Rights law violations without following all of the processes set forth for such terminations under the applicable laws/regulations, and as set forth in the court's order.

Science & Security: Cross-Cutting Issues

NIH Requirement for Disclosure Training (ONGOING)

As previously reported, on July 17, NIH issued NOT-OD-25-133, "NIH Announces a New Policy Requirement to Train Senior/Key Personnel on Other Support Disclosure Requirements." 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."

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. More information on this is available on the NSF SECURE Center SECURE Center Consolidated Training Module (CTM), which specifies:

> *The National Institutes of Health (NIH) has indicated in NOT-OD-25-155 that this training will be required as of January 25, 2026. In addition, training on other support, which can be satisfied by taking the original 4 modules or the SECURE Center's CTM, is effective for Research Performance Progress Reports and just-in-time submitted on or after October 1, 2025 per NOT-OD-25-133 and additional guidance provided during the September 2025 FDP virtual meeting.*

Joint Committee Meeting with NSF SECURE Center (UPDATE)

At the October COGR membership meeting, members of the Contract & Grant Administration (CGA), Research Ethics & Compliance (REC), and Research Security & Intellectual Property (RSIP) Committees participated in a joint discussion with the new Director, Dr. Beth Kolko, and additional representatives from the NSF's SECURE Center (Center). The session offered committee members the opportunity to hear directly from Dr. Kolko about the Center's priorities and vision.

Additionally, participants received an update on the Center's Shared Virtual Environment, including progress to date and planned enhancements to support the community's needs. The NSF SECURE team also highlighted the consolidated research security training module and its regular research security briefings. Dr. Kolko also emphasized the importance of

ensuring that the Center becomes self-sustaining over time and noted that the team is actively exploring options to support long-term sustainability.

RSIP Committee Updated on NSF SECURE Analytics (UPDATE)

A representative from NSF SECURE Analytics (Analytics) briefed the Research Security & Intellectual Property (RSIP) Committee during the October COGR membership meeting, providing an overview of its progress and upcoming milestones. The update included information on the planned beta-testing of Argus, Analytics' flagship data collection, analysis, and reporting platform. RSIP was informed that initial testing is ready to begin and that access to the platform is expected to expand to a broader set of accredited users in Spring 2026. The representative also highlighted Analytics' second published advisory, "Iran's S&T Ecosystem: A Primer for Research Security Professionals."

To help ensure that the Argus and related analytics tools are responsive to the community's needs, Analytics is conducting a stakeholder survey. Feedback gathered through this process will inform the development roadmap and guide future platform enhancements.

HHS's OIG Issues Cybersecurity Audit Findings (NEW)

On November 14, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) publicly released its audit titled "The National Institutes of Health Needs to Improve the Cybersecurity of the All of US Research Program to Protect Participant Data." The audit assessed whether the National Institutes of Health (NIH) effectively oversaw the cybersecurity and data-protection practices of the All of Us Research Program's Data and Research Center (DRC), which stores the personal health information of more than a million participants.

Specifically, OIG evaluated whether NIH ensured that the DRC limited access to sensitive information, implemented required federal information security and privacy controls, and remediated identified vulnerabilities in a timely manner. OIG found that while the DRC awardee had implemented some foundational cybersecurity measures, NIH's oversight did not fully address several critical gaps. To address these findings, the report highlighted five recommendations that needed to be implemented. NIH agreed with all findings and committed to implementing corrective actions.

Key Findings of the HHS OIG Audit:

- Insufficient controls over international system access: The DRC did not enforce technical controls to prevent access from foreign locations without documented approval.
- Inadequate restrictions on downloading sensitive participant data: System controls did not prevent authorized users from downloading detailed participant information,

including genomic, demographic, and health-related data, contrary to the program's policy.

- Insufficient communication and assessment of genomic data risks: NIH had not adequately communicated to the DRC the national-security considerations associated with storing and managing large-scale genomic data, leading to a potential underestimation of risk and mis-categorization.
- Delayed remediation of known security and privacy weaknesses: Several critical and high-risk issues remained open beyond required deadlines.

Recommendations Made by the OIG:

- Strengthen international access controls: Require the DRC awardee to enforce technical restrictions on foreign systems access unless formal approval is obtained, and ensure monitoring detects unauthorized activity.
- Prevent unauthorized data downloads: Direct the DRC to deploy system-level protections, or compensating controls, to block or tightly restrict downloads of detailed participant data, in accordance with All of Us program policy and federal regulations.
- Address national-security risks of genomic data: Notify the DRC of the national-security implications of genomic datasets and require controls proportionate to these risks, including reassessing data sensitivity and security posture.
- Align system security with data sensitivity: Require the DRC to reevaluate system security categorization for genomic and other high-risk data, ensuring protections meet federal standards for sensitive biological and participant information.
- Enforce timely remediation of vulnerabilities: Mandate updates to system security plans and remediation timelines, with oversight to promptly and consistently address critical or high-risk weaknesses.

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.

COGR Publishes Practical Considerations Guide for TTOs (NEW)

At the direction of National Security Presidential Memorandum (NSPM) -33 and the CHIPS and Science Act of 2022 (CHIPS Act), federal agencies continue to expand research security requirements for disclosure, export control, data protection, and foreign engagement. As a result, technology transfer offices (TTOs) are taking on a more active role in safeguarding

the research enterprise. In addition to their core mission of supporting the responsible protection and commercialization of university innovations, TTOs must now ensure that research outcomes, including materials, data, and intellectual property arising from federally funded research, are transferred in accordance with increasing federal regulations. While their core mission remains advancing the responsible protection and deployment of university innovations, TTOs must ensure that materials, data, and intellectual property from federally funded research are transferred in line with evolving federal expectations. By integrating research security considerations into licensing, foreign patent filings, data and material transfers, startup support, and due diligence activities, TTOs help institutions maintain compliance, protect sensitive technologies, and preserve the openness and integrity of academic research.

COGR's "Research Security Regulations: Practical Considerations for Technology Transfer Professionals" outlines the regulations and risk areas where research security and technology transfer intersect most directly, offering practical considerations for technology transfer professionals to ensure secure, responsible transfers of innovation.

Summary of Key Regulatory Areas TTOs Should Be Aware:

- Institutional Disclosure Requirements: TTO-led transactions, including licenses, material transfer agreements, data use agreements, and equity arrangements, may trigger reporting thresholds with respect to the Department of Education's Section 117 foreign gift and contract reporting requirements and the National Science Foundation's Foreign Financial Disclosure Reporting (FFDR) requirements.
- Export Control: Before transferring research outcomes that the fundamental research exclusion may no longer cover, TTOs should coordinate with the appropriate compliance office to ensure export control reviews are completed and any required licenses or restrictions are addressed.
- Restricted CUI & FCI: TTOs often play a key role in preventing unauthorized transfers of Controlled Unclassified Information or Federal Contracting Information. This includes obtaining agency authorization when required and incorporating mandatory security terms and dissemination restrictions into agreements with third parties, including subrecipients and collaborators.
- Restrictions on Sensitive Information: Transfers of human genomic data or biospecimens, particularly to foreign collaborators or parties affiliated with countries of concern, must comply with the Department of Justice's *Data Security Program* and the NIH *Biospecimen Security Policy*.
- Patents & Foreign Filings: TTOs should ensure that foreign patent filings comply with export-control and national security requirements, including obtaining a USPTO foreign filing license and reviewing draft applications for controlled technical data. Under the Department of Defense's *Component Decision Matrix*, foreign patenting

activities of key personnel may require mitigation measures when federally funded inventions are pursued in countries of concern.

- Foreign Investments: When foreign investors engage with university startups, TTOs should assess whether the transaction could trigger a review by the Committee on Foreign Investment in the United States (CFIUS) pursuant to the Foreign Investment Risk Review Modernization Act (FIRRMA), especially when the licensed technology involves export-controlled items or sensitive personal data.

COGR Submits Comments on BIS Interim Final Rule (NEW)

On September 30, the Department of Commerce's Bureau of Industry and Security (BIS) issued an interim final rule titled "Expansion of End-User Controls to Cover Affiliates of Certain Listed Entities" (the "Affiliates Rule"). The rule expands BIS's end-user controls by extending restrictions that apply to listed entities to certain affiliates under common ownership, control, or significant influence. BIS's stated goal is to prevent restricted entities from evading export controls through subsidiaries or affiliates not explicitly named on the Entity List.

While intended to strengthen national security protections, the Affiliates Rule introduces significant new compliance obligations for the higher education research community. Universities must now conduct ownership and control analyses to determine whether research collaborators, subrecipients, or vendors qualify as "affiliates" of restricted entities—a responsibility that previously rested with BIS. This shift represents a major expansion of institutional compliance workloads and requires specialized due diligence capabilities that many academic compliance offices are not resourced to support.

COGR, joined by the Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU), submitted a joint comment letter expressing concern that the Affiliates Rule creates substantial and uncertain compliance burdens and lacks sufficient clarity, transparency, and implementation support. The organizations emphasized that the rule shifts administrative responsibility from BIS to individual institutions without providing the tools, data access, or guidance necessary to perform complex ownership assessments effectively.

The associations recommend that BIS revise and clarify the rule to mitigate the undue burden on universities while maintaining its national security objectives. It highlights several key issues:

- The rule transfers complex ownership verification responsibilities to universities without providing a centralized database of BIS determinations or exemptions, leading to duplicative and inconsistent analyses.

- The rule introduces obligations that exceed traditional research compliance expertise, requiring deeper investigations into opaque ownership structures without clear due diligence standards.
- Ambiguity surrounding "red flag" determinations and unknown ownership creates risk of liability even when universities act in good faith.
- Increased uncertainty will likely drive a surge in license applications, straining BIS processing capacity and delaying time-sensitive research.
- The burden of implementation will fall disproportionately on smaller or teaching-focused institutions with limited compliance infrastructure.

The associations also recommend that BIS:

1. Define clear, objective due diligence standards for ownership verification and documentation.
2. Publish affiliate determinations, negative findings, and petition outcomes in a searchable database.
3. Create a safe-harbor provision protecting institutions that act in good faith and follow published standards.
4. Provide transition relief for existing collaborations predating the rule's effective date.
5. Narrow the "red flag" presumption to apply only to credible indicators of affiliation.
6. Offer robust implementation guidance, illustrative examples, and training tailored to university settings.

In addition, COGR, AAU, and APLU expressed support for the recommendations submitted by the Association of University Export Control Officers (AUECO) in their separate comment letter, which provides additional technical recommendations to enhance clarity, consistency, and fairness in the Affiliates Rule's implementation.

BIS Quickly Suspends Implementation of "Affiliates Rule" (NEW)

After issuing the interim final rule "Expansion of End-User Controls to Cover Affiliates of Certain Listed Entities" (the "Affiliates Rule") on September 30th, BIS announced a twelve-month suspension of the interim final rule, effective November 10, 2025. The suspension is scheduled to conclude on November 9, 2026, unless the Administration takes action to extend it.

John Squires Named Director of USPTO (NEW)

On September 18, the U.S. Senate confirmed John Squires as Director of the United States Patent and Trademark Office (USPTO). Since assuming the role, he has moved quickly to strengthen oversight of post-grant review proceedings at the Patent Trial and Appeal

Board (PTAB). In October, Director Squires introduced a new process in which he, together with a panel of at least three PTAB judges, now makes the final determination on whether to institute inter partes review or post-grant review. This change is intended to promote greater consistency and more uniform application of USPTO standards. Because the new process also imposes a higher, more centralized level of scrutiny, it may result in fewer decisions to allow petitions for inter partes review (IPR) or post-grant review (PGR) to move forward in the review process, particularly in emerging and applied-technology fields where the evolving prior-art landscape and rapid technical development have historically led to greater variability in PTAB review outcomes.

CMMC Institutional Implementation Panel (NEW)

Attendees at COGR's October membership meeting participated in a focused session on institutional readiness for the Department of Defense's Cybersecurity Maturity Model Certification (CMMC) requirements. The panel featured three Research Security & Intellectual Property (RSIP) committee members who shared institutional experiences, implementation strategies, and lessons learned. The session started with real-time audience polling that captured the broader community's experience. Six poll questions provided a snapshot of current readiness, planned approaches, and the challenges institutions face as they prepare for compliance. Overall, the results reflected strong engagement with CMMC planning but significant variation in institutional preparedness and strategy.

The following are the questions and results of the poll:

1. The level of CMMC requirements that their institutions intended to meet:
   - 28% - Level 1 only,
   - 31% - Level 2 self-certification,
   - 34% -Level 2 third-party assessment, and
   - 7% -Level 3, eventually.
2. To characterize their institution's current readiness for compliance:
   - 72% - active planning or assessment stage,
   - 15% - aware of the requirements, but have not taken any action,
   - 9% - institution is fully ready, and
   - 4% - unsure how CMMC applies to their institution.
3. How their university anticipates implementing Level 1 requirements:
   - 23% - dedicated enclave,
   - 21% - dedicated cloud environment,
   - 17% - contract or project-specific plans,
   - 15% - institution-wide, and
   - 22% - more than one mechanism, and
   - 1% - won't accept CMMC requirements.

4. How many CMMC Level 1 environments do they expect to register in the Supplier Performance Risk System (SPRS):
   - 33% - One,
   - 12% - Two to five,
   - 3% - Five to ten, and
   - 51% - Unsure.
5. To identify the biggest challenge in preparing for implementation:
   - 45% - Coordination across departments,
   - 37% - Funding and resources,
   - 9% - Understanding applicability,
   - 4% - Staff expertise in cybersecurity standards, and
   - 5% - Communicating requirements to researchers.
6. Where ownership of CMMC compliance resides:
   - 53% - Central IT or information security office,
   - 16% - Research compliance or sponsored programs,
   - 23% - Not yet designated, and
   - 7% - Unsure.

Slides from the session, "Cybersecurity Implementation and Updates from the University Perspective," are available on COGR's website. Additionally, COGR's resource, "Overview of DOD Cybersecurity Model Certification 2.0," was updated in October to incorporate recent amendments made to the Defense Federal Acquisition Regulation Supplement (DFARS) that took effect on November 10, 2025.

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.

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

As previously reported (COGR September 2025 Update), on September 4, 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 Biosketch (generated either through SciENcv or NIH Form Library.docx templates) and Other Support 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 NIH Forms 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 ORCID iD topic in the eRA Commons 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.

In conjunction with the preview of the NIH Common Form, NIH published an updated table on activities that should be reported in the biosketch, other support, or annual progress reports, NIH Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Other Support [September 5, 2025]. The revised table consolidates NIH's prior disclosure table with the activity categories outlined in the NSPM-33 Implementation Guidance Pre- and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending (Other) Support (May 20, 2024), with several notable changes.

Of particular significance, the table adds a new category of activities requiring disclosure as other support: "*Monetary donations that support an investigator's research activities, that are given with an expectation. See examples at https://grants.nih.gov/grants-process/write-application/formsdirectory/other-support.*" The linked reference, Example Scenarios: Monetary Donations as Other Support vs. Gifts, provides illustrative cases and appears to expand on the NSTC definition of "gift." This appears to be NIH's response to the OIG report, NIH Recipient Institutions' Reporting of Monetary Donations That Support Research.

At this time, NIH has not clarified the effective date for the revised table or whether the previous table remains applicable to existing awards.

COGR will continue to engage with NIH to seek clarification on these issues and welcomes member feedback regarding concerns related to the NIH Common Forms.

NIH Guide Notices (NEW)

COGR would like to make members aware of several recent NIH Guide Notices.

- Reminder of Compliance Requirements for NIH Extramural Recipients Related to Renegotiated Aims, Objectives, Titles, and Abstracts [NOT-OD-26-007]: Published on November 18, 2025, as a *reminder to NIH awardees that changes in scope represent new terms and conditions, with which recipients must comply. This reminder applies to grants, cooperative agreements, and other transactions.*

- Updated Terms and Conditions of Award – Termination and Compliance with Court Orders [NOT-OD-26-009]: Published on November 18, 2025, implementing a new award term effective October 1, 2025:

  This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, by accepting an NIH award, the recipient agrees that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates the program goals or agency priorities, in line with 2 CFR 200.340(a)(4).

  Any term or condition in this Notice of Award, including those incorporated by reference, that NIH is enjoined by court order from imposing or enforcing, shall not apply or be enforced as to any recipient or subrecipient to which that court order applies and while that court order is in effect.

- Notice of Early Expiration of NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Notices of Funding Opportunity and Guidance for Existing Recipients [NOT-OD-26-006]: Published on November 17, 2025. The notice specifies that legislative authority for SBIR/STTR programs expired on October 1, 2025. As such, NIH expired all SBIR/STTR NOFOs effective immediately. All active NIH SBIR and STTR awards can continue. However, NIH will not issue any noncompeting continuation awards until the program is reauthorized.

Revolutionary FAR Overhaul Initiative (ONGOING)

As COGR reported previously (May 2025 and July 2025 COGR Update), the Integrated Award Environment (IAE) 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 Acquisition.gov serves as a central hub for updates, including FAR Parts and Deviations 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 ktoups@cogr.edu.

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

As previously reported, Effective October 1, 2025, the Department of Health and Human Services (HHS) released Version 2.0 of the Grants Policy Statement, which supersedes prior versions and applies to new awards and award modifications that add funding (including supplements and competing or non-competing continuations). The GPS applies to all HHS discretionary recipients except NIH, and its requirements flow down to subrecipients.

HHS outlined the following changes from the previous version 1.0:

- In this update, HHS adopts 2 CFR 200 with HHS-specific modifications at 2 CFR 300.
- 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.
- Minor plain language changes to grammar, syntax, and consistency in citations and links.

Upon further review, COGR highlights the following additional significant changes noted:

- Chapter 2.6.1: Accepting the Award, HHS may now take action to amend or withdraw an award if recipients fail to draw down funds in a timely manner or cannot justify delays in acceptance.
- Chapter 2.6.2: Periods of Performance, language has been updated to reflect, "funding is based on adequate performance, availability of funding, and program goals and agency priorities."
- Chapter 3.1.2.2: Significant Budget Changes, lowers the prior approval threshold from 25% to 10% of the total budget to transfer between direct cost categories.
- Chapter 3.1.4: Extensions to Awards, reduces the notification timeline from 30 days to 10 days before the period of performance ends to notify the HHS agency in writing with the supporting reasons and a recommendation for a revised period of performance.

- Chapter 3.6.4: Termination, a new provision authorizes termination when an award no longer effectuates program goals or agency priorities, consistent with 2 CFR 200.340(a)(4).
- Chapter 4.4: Audit Responsibilities, the GPS now requires recipients to submit audits within 30 days of receiving the auditor's report or within nine months after the fiscal year-end—whichever comes first.
- Appendix D: Administrative and National Policy Requirements, includes general statements regarding compliance with federal laws and policies. Notably, the language appears to misstate SAM.gov requirements by indicating adherence to "all federal laws" rather than "all applicable federal laws," which is the operative language in the SAM.gov Financial Assistance Certifications and Representations. This inconsistency may have implications for recipient obligations and risk exposure.

COGR will continue to analyze the implications of these changes and will engage HHS to seek clarification on areas of concern. COGR welcomes member feedback to inform these discussions.

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)

During the October COGR membership meeting, a panel of CFC committee members and one guest consultant spoke about the uncertain future of the facilities and administrative (F&A/indirect) cost reimbursement process and the potential for reduced indirect, and direct, funding. This conversation was part of the session, Uniform Guidance Revisions—Then, Now and When October 2025. Panelists reported that some institutions are assessing the potential impact of a reduction in reimbursement of indirect costs, less total funding, and opportunities for expanded direct charging. This was supported by responses from meeting attendees during the Friday morning "Navigating the Storm" discussion session, detailed in the above "2025 Administration Transition Information and Resources" section.

While most direct charging of normally indirect costs is restricted for colleges and universities by Uniform Guidance (UG, 2 CFR 200) Appendix III, C. 8., the panel discussed normally direct costs that are frequently not charged to federal projects to the full extent allowable. For example, many institutions do not require faculty researchers to allocate their salary and related fringe benefits to projects during the academic year, most provide some level of subsidization of recharge centers benefiting research, and some provide institution

funded graduate research assistant positions. There are also new types of compliance costs that did not exist when the 26% administrative cap and related restrictions on shifting costs from indirect to direct and from capped to uncapped cost pools were issued in 1991. Further the Joint Associations Group on Indirect Costs (JAG) Financial Accountability in Research (FAIR) model includes the opportunity for universities and other non-profit research organizations to directly charge many of the facilities and administrative costs that they currently charge through application of their indirect cost reimbursement rates.

As described in COGR Updates earlier this year, the JAG was formed in April 2025, by ten "national organizations representing America's academic, medical, and independent research institutions." The JAG proposed the FAIR model of cost reimbursement in response to critics of the current system, including within the current administration. The longstanding system for F&A cost reimbursement prescribed in the UG ensures a research institution never, in total, overcharges the federal government for its allocable share of costs. At the project level, however, cost allocations may appear unreasonable given the widely different supporting infrastructure and other resource needs of one project compared to another. Further, the many internal controls built into the system are often overlooked or ignored, as discussed in a new COGR communication, The Single Audit - Updates and a Potential for Efficiency Never Fully Realized.

As previously reported, COGR understands that OMB is working on revisions to the UG, including language regarding indirect cost reimbursement, that will not likely align with the FAIR model but may allow for direct charging of some types of costs currently classified as normally indirect. Legal challenges to the administration's attempts to cap Facilities and Administrative (F&A/indirect) cost reimbursement, summarized in the COGR litigation tracker, have thus far been successful. The timing and substance of the OMB revisions are unknown, and legislative efforts, as tracked by APLU here, could potentially prevent OMB from making changes to F&A cost reimbursement regulations prior to engaging with the community and considering the FAIR model.

Under the FAIR model, and potentially under the OMB model, additional direct charging of currently indirect cost would be the only method for reimbursement of more than a set, flat rate for facilities and administrative expenses supporting research. It, therefore, may not be too early for institutions to begin exploring new cost allocation models. The CFC committee continues to assess the Joint Associations Group on Indirect Costs (JAG) Financial Accountability in Research (FAIR) model to identify practical implementation approaches and is also preparing to support the necessity of each category of facilities and administrative cost, in anticipation of OMB changes to 2 CFR 200. 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.

Institutions should also continue to share information about the total cost of research, including necessary facilities and administrative costs, and the negative consequences of any reduction in federal funding, such as a limit on reimbursement of indirect costs. 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.

Update from COGR on Department of Energy Limitations on Reimbursement of Indirect Costs (NEW)

The Department of Energy (DOE) has recently begun incorporating new limitations on the reimbursement of indirect costs in certain solicitations and awards. As detailed in COGR's document, Update from COGR on Department of Energy Limitations on Reimbursement of Indirect Costs, Institutions of Higher Education (IHEs) are exempt from these restrictions. Documented through DOE award terms and pending suit AAU v. DOE, 1:25-cv-10912 (D. Mass.).

Members have identified several DOE FY 2026 Notice of Funding Opportunities (NOFOs) (ex., DE-FOA-0003600 and DE-FOA-0003583_11.14) that impose maximum indirect costs reimbursement levels at 10% or 15% of the total award for certain recipient types (state and local governments, for-profit organizations, and nonprofit organizations), without a clear indication that IHEs are exempt. Also of note, IHEs working with non-IHE collaborators (prime recipients from which IHEs are subrecipients and subrecipients to which IHEs are pass-through entities) may find those collaborators subject to one of these new limits. Making navigating these details more nuanced.

Given the ongoing litigation, many members continue to propose their full Negotiated Indirect Cost Rate Agreement (NICRA) rate in proposal submissions, consistent with instructions provided in the budget preparation sections of the NOFOs.

COGR is actively seeking clarification from DOE regarding the incomplete and inconsistent guidance for IDC reimbursement for IHEs.

If you have any questions, please contact Cindy Hope (chope@cogr.edu) or Krystal Toups (ktoups@cogr.edu).

OMB Compliance Supplement and Single Audit (UPDATE)

As previously reported, OMB provided the AICPA and NASACT a "final draft version" of the 2025 Compliance Supplement. The draft can be downloaded from the AICPA website here (free AICPA account required), where you will also find a two-hour presentation highlighting all of the changes. The final version was not published prior to the shutdown and was likely further delayed by it. OMB last published a Compliance Supplement in May 2024.

During an October COGR membership meeting presentation, Uniform Guidance Revisions—Then, Now and When October 2025, the CFC committee described the significant revisions found in the draft Compliance Supplement, primarily reflecting changes to Uniform Guidance that went into effect October 1, 2024. On November 13, 2025, the committee released The Single Audit - Updates and a Potential for Efficiency Never Fully Realized, further describing the changes and the current Single Audit environment. Continuing delay of the final supplement may impact members. As the new communication explains, "AICPA presenters state that the draft Compliance Supplement is for audit planning purposes and, therefore, Single Audit reports for years subject to the 2025 supplement will not be signed and issued prior to release of the final supplement." The Single Audit communication also describes the "revised AICPA guide to Government Auditing Standard (GAS) and Single Audits, and new requirements dictated by Executive Orders that seem to disregard the Single Audit entirely".

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.

Legislation Ending Government Shutdown Contains New Definition of "Hemp" (NEW)

The 2018 Farm Bill (Agriculture Improvement Act of 2018, Pub. L. 115-334) carved out "hemp" from the definition of "marijuana" under the Controlled Substances Act. Specifically, Section 10113 defined "Hemp" as "the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

One issue that researchers and others encountered in applying this definition was determining whether products produced by certain manufacturing processes and containing less than 0.3% delta-9 THC, but with a "total THC concentration in excess of

0.3%," come under the definition of "hemp" or constitute a synthetically derived product that falls outside of that definition. Courts interpreting this provision have arrived at different conclusions. [*See,* Congressional Research Service, "The 2018 Farm Bill's Hemp Definition and Legal Challenges to State Laws Restricting Certain THC Products. (Aug. 20, 1015)].

The "Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026" ("2026 Appropriations Act," H.R. 5371 signed by the President on Nov. 12, 2025, to end the government shutdown) contains a provision that addresses this "total THC" issue and substantially changes what products will meet the new definition of "hemp." Although Section 781 of the Act retains the general hemp definition stated above, it specifically excludes the following items from that definition:

(i) any viable seeds from a Cannabis sativa L. plant that exceeds a total tetrahydrocannabinols concentration (including tetrahydrocannabinolic acid) of 0.3 percent in the plant on a dry weight basis; or

(ii) any intermediate hemp-derived cannabinoid products containing—

(I) cannabinoids that are not capable of being naturally produced by a Cannabis sativa L. plant;

(II) cannabinoids that—

(aa) are capable of being naturally produced by a Cannabis sativa L. plant; and

(bb) were synthesized or manufactured outside the plant; or

(III) more than 0.3 percent combined total of—

(aa) total tetrahydrocannabinols (including tetrahydrocannabinolic acid); and

(bb) any other cannabinoids that have similar effects (or are marketed to have similar effects) on humans or animals as a tetrahydrocannabinol (as determined by the Secretary of Health and Human Services); or

(iii) any intermediate hemp-derived cannabinoid products which are marketed or sold as a final product or directly to an end consumer for personal or household use; or

(iv) any final hemp-derived cannabinoid products containing—

(I) cannabinoids that are not capable of being naturally produced by a Cannabis sativa L. plant;

(II) cannabinoids that—

(aa) are capable of being naturally produced by a Cannabis sativa L. plant; and

(bb) were synthesized or manufactured outside the plant; or

(III) greater than 0.4 milligrams combined total per container of—

(aa) total tetrahydrocannabinols (including tetrahydrocannabinolic acid); and

(bb) any other cannabinoids that have similar effects (or are marketed to have similar effects) on humans or animals as a tetrahydrocannabinol (as determined by the Secretary of Health and Human Services).

Subsection (iv)(III) addresses the total THC issue by excluding from the definition of hemp "any final hemp-derived cannabinoid products containing . . . greater than 0.4 milligrams combined total per container of . . .

total tetrahydrocannabinols (including tetrahydrocannabinolic acid)." To put this issue in context, a typical hemp gummy has 2.5 to 10 milligrams of delta9-THC. [C. Small, Clark Hill, Hemp Industry Alert: Federal Ban on Hemp-Derived THC Products – Immediate Action Required (Nov. 14, 2025)).

The new definition goes into effect Nov. 12, 2026. Investigators who are conducting or planning research that involves commercially available hemp products should evaluate those products to determine whether they will meet the new definition of "hemp," or effectively be prohibited once the new definition goes into effect.

Products that do not meet the new hemp definition by its effective date will be considered marijuana, a Schedule I substance under the Controlled Substances Act. Researchers face additional requirements when conducting research using Schedule I substances, however, Section 3 of the HALT Fentanyl Act (Pub. L. 119-26, Jul. 16, 2025) provides some relief from these requirements for practitioners conducting research pursuant to an FDA IND or research that is conducted or funded (in part or full) by DHHS, DOD, or the VA ("Covered Research").

Specifically, practitioners with current DEA Schedule I or II Research Registrations who conduct Covered Research can begin the research within 30 days after sending a notice to the DEA containing (a) the chemical name and quantity of the substance being used in the research; (b) establishing that the research is "Covered Research" (e.g., by providing name of research sponsor and grant/contract number or IND application number); and (c) verifying that the researcher is authorized to conduct the research under any applicable state laws (e.g., has any required state research registration). The Act includes a similar path for researchers without a current Schedule I or II DEA registration, provided, however, that DEA will treat a notice received from such an investigator as a request for a researcher registration. DEA will either process the request in 45 days or provide information about why it will not be processed.

The Act also contains the following additional provisions that serve to reduce other administrative burdens associated with conducting research using Schedule I or II substances:

- Separate registration is no longer required for an additional researcher at same institution who is an agent/employee of the institution and working under the registration of a registered practitioner who will take responsibility for their actions and notifies DEA that they are working under them. [Sec. 3(b)].
- A single registration may cover research conducted at multiple geographic sites if the research "occurs exclusively on sites" that are all within the same city/county and under the control of the same institution/agency/organization and DEA is notified of each site where the research is conducted or the controlled substances are stored. [Sec. 3(c)].
- A new DEA security inspection is no longer required if a registered practitioner seeks to conduct research with an additional controlled substance in the same or higher number schedule. [Sec. 3(d)].
- Researchers are permitted to engage in small manufacturing activities coincident to research. [Sec.3.(f)].

Letter to U.S. Army Medical Research and Development Command's Animal Care and Use Review Office on Limits to Protocol Review (NEW)

The U.S. Army Medical Research and Development Command's Animal Care and Use Review Office (ACURO) announced that as of January 1, 2026, it would limit ACURO protocol review to only protocols describing research projects that are fully-funded by the Department of Defense as a means of reducing administrative burden on ACURO staff. Given that many institutions' IACUC protocols routinely describe research funded by multiple sources, this change will require researchers and IACUCs to develop, review, and provide oversight for numerous additional protocols that encompass the same research. Accordingly, administrative burden will not be eliminated, but rather shifted onto institutions, who are already under tremendous strain from funding cuts and the threat of cuts to indirect cost rates. Notably, the policy change will be particularly onerous for ongoing protocols requiring triennial review because researchers will be forced to re-write existing protocols to segregate DOD-funded components.

After hearing directly from several COGR member institutions about their concerns with this policy change, COGR sent a letter to ACURO asking the agency to re-evaluate its current path. Specifically, COGR asked ACURO to consider taking one or more of the following options:

- Take steps to truly eliminate administrative burden by terminating the ACURO protocol review requirement and instead relying solely on institutional IACUC review of protocols, as most federal agencies do.
- Exempt any on-going protocols that involve multiple funding sources from the new policy.
- Extend the January 1, 2026, deadline for institutions to comply with the new policy.

Now that the government shutdown has ended, COGR plans to follow up with ACURO to see if it might be willing to engage in discussions regarding COGR's letter and the impact of the policy change on institutions.

NIH Biosafety Initiative (UPDATE)

As discussed in the September 2025 COGR Update, NIH launched a new Biosafety Modernization Initiative to "strengthen biosafety policies, practices, and oversight." 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.

REC convened a working group of institutional biosafety professionals to develop written comments in response to this initiative and specifically to respond to the following three scope expansion options that NIH posited for consideration:

- 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.

With input from this working group, REC drafted and provided a comment letter to NIH. The letter urges NIH to ensure that any new biosafety requirements are appropriately tailored to the level of risk presented by specified materials and experiments and to consider less stringent requirements for lower risk research. The letter also noted the problems that arise when different federal funding agencies adopt inconsistent biosafety regulations and advocated that NIH work with other agencies on a "Common Rule" approach to biosafety/biosecurity requirements. COGR's comments also stressed the

importance of building on local IBC and biosafety review entities, which are in the best position to review research and establish appropriate risk mitigation measures because they have the most concrete knowledge of the research and the context in which it is being conducted.

In terms of the options presented by NIH, COGR advocated for a hybrid approach that aligns risk assessment criteria and application of biosafety levels with the Biosafety in Microbiological and Biomedical Laboratories, while utilizing the NIH Guidelines to clearly describe research subject to the NIH policy and the roles/responsibilities of the IBC. In this regard, COGR encouraged NIH to empower the IBC to take on a role in the biosafety arena similar to that played by IRBs and IACUCs in the oversight of research involving human subjects and animal subjects. Finally, the letter suggested specific examples of research that may require less oversight (e.g., work with certain well-established model organisms, cell lines, and transgenic animal models that meet specified criteria).

Now that the government shutdown has ended, NIH is expected to proceed with its regional listening sessions on the initiative. COGR provided verbal comments at the first listening session and plans to attend subsequent sessions to gain information on the types of comments that are being submitted.

NIH Policy on Enhancing Security Measures for Human Biospecimens (NOT-OD-25-160) (Update)

As noted in the September 2025 COGR Update, NIH issued this notice setting forth the NIH Biospecimens Security Policy which encompasses **any number of** "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" and prohibits direct or indirect distribution of such biospecimens to institutions or parties located in countries of concern (COC) (currently, China [Hong Kong and Macau], Cuba, Iran, North Korea, Russia, and Venezuela).

REC members discussed several issues concerning implementation of the NIH Policy. First, the definition of "human biospecimen" ends at the cellular level vs. the molecular level, and thus plasmids do not appear to be within scope. Second, transfers prior to the policy effective date – October 24, 2025 – are not covered by the NIH Policy, but, depending on the number of specimens transferred and date of transfer, they may be subject to the DOJ's rules on Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern of Covered Persons ["DOJ Rule," 90 FR 1636 (Jan. 8, 2025)]. Third, regarding subawardees that received covered specimens prior to October 24, institutions may consider sending reminders to subawardees about restrictions on subsequent transfers. Finally, several institutions reported including transfer restrictions in pertinent MTAs.

FDA Guidance Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers (NEW)

The FDA recently published final guidance regarding expanded access to investigational drugs. The guidance discusses the three categories of expanded access: (a) access for individual patients, including emergency use; (b) access for intermediate-size populations; and (c) access for widespread treatment via a treatment IND or treatment protocol in FAQ format. The guidance replaces the 2016 and 2017 versions of this guidance and withdraws the 1998 information sheet Emergency Use of an Investigational Drug or Biologic. The guidance describes the information that must be submitted for each type of expanded access including a table listing the FDA forms that must be completed and details the requirements/timeline for FDA authorization and IRB approval of requests. IRBs should consider reviewing this new guidance and updating training materials and policies, as necessary.

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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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