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President's Message: Pushing Back & Pushing Forward

Dear Colleagues,

Changes to federal research policies and threats to the U.S. research and innovation enterprise have continued at a historical pace since the March COGR Update. From new caps on indirect costs reimbursement to expanded reporting requirements and deregulation initiatives, COGR remains actively engaged; is pushing back against harmful measures while pushing forward to advance effective research policy.

Pushing back and communicating the harmful consequences of new policies and requirements continues to be necessary and a core element of COGR's advocacy. From issuing <u>statements</u> on the 15% cap on indirect cost reimbursement policies issued by the Department of Energy, the National Science Foundation, and the Department of Defense, to joining amici briefs on the NIH/HHS grant terminations lawsuits filed by the <u>Commonwealth of Massachusetts</u>, et al. and the <u>American Public</u> <u>Health Association et al.</u>, we are elevating COGR's advocacy as the number of destructive policies and actions increase.

Pushing forward is also vital at this time. We must meet our responsibilities and obligations to execute high-quality, high-impact research on behalf of taxpayers and at the same time shape the future of the academic research enterprise. Pushing forward includes our continuous efforts to reduce red tape encumbering federally sponsored research. Building on <u>our January letters</u> to the Trump Administration, COGR developed <u>actionable ideas</u> to eliminate, streamline, and harmonize federal research regulations and requirements. These were shared with OMB, OSTP, and leaders in federal research agencies. Additionally, these actionable ideas formed the foundation for the association's <u>response</u> to the OMB's Deregulation RFI.

We are also pushing forward by developing new resources to help inform and guide COGR members in navigating the increasing number of new – and often duplicative and confusing – requirements that have been imposed by federal agencies in accordance with new Executive Orders and priorities. The new requirements have led to significant new burdens and inefficiencies. We hope you find the <u>Costing Points to Consider for Terminations and Suspensions</u>, <u>Points to Consider for</u> <u>Reimbursement of Expenses Under Active Grants</u>, and other resources helpful as your institution seeks to meet its compliance obligations.

Important to pushing back and pushing forward are the meaningful discussions taking place during COGR convenings. We launched a new COGR Forum series in late March, and we held the second forum in April. We will continue these convenings in the months ahead to share timely information, hear from the membership, and discuss pathways forward for COGR to provide resources and empower its advocacy. Our next convening is the June 5-6 Membership Meeting in Washington, DC. We look forward to a full house and a full agenda in which we will discuss key issues and COGR's continuing efforts to push back and to push forward. To help inform our discussion, we ask that each COGR member institution participate in our latest transition impacts <u>survey</u>. Preliminary results will be discussed at the meeting.

At this critical time, let me express the COGR team's gratitude for your engagement with association, and for your continuing resolve and efforts to maintain a strong academic research enterprise going forward.

Matt Owens President



Announcements

COGR Meeting June 5-6, 2025: Registration Still Open

Registration is still open for COGR's June 5-6, 2025, membership meeting in Washington D.C.!

The preliminary agenda is available on COGR's website, along with registration information and other <u>meeting materials</u>. Sessions will include:

- Joint Associations Group (JAG) on Indirect Costs: What's New and What's Next
- Legal Headwinds: Navigating Litigation, Policy Shifts, and Federal Pressure on Higher Ed
- Research Security in Focus: Updates and Priorities from NSF
- Fireside Chat with Dr. Jay Bhattacharya, Director, National Institutes of Health
- Securing Tomorrow, Today: Cybersecurity Updates from DARPA
- Exploring University-Industry Collaborations at a Pivotal Moment: From Basic Research to Clinical Trials
- Navigating the Storm: Institutional Perspectives on a Changing Federal Landscape
- On the Hill and in the Ledger: Legislative and Federal Budget Outlook
- Committee Reports and Hot Topics

New for this meeting, COGR has implemented a <u>COGR Event Code of Conduct Policy</u>. By registering for the June 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 June!

Meet the Committees: Contracts & Grants Administration Virtual Open House

Curious about what CGA (COGR's <u>Contracts & Grants Administration Committee</u>) does? Ever wonder who serves on the CGA Committee or how you can get involved? Have questions or issues you think CGA should consider? Then, join us at our (<u>virtual</u>) <u>Open House</u>!

CGA considers a <u>wide range of topics</u>, including award terms and conditions, 2 CFR 200, public access, subrecipient monitoring, disclosure requirements, data management and sharing, and more. If you have questions that you would like to be addressed, please send them to Krystal Toups at <u>ktoups@cogr.edu</u> by May 20. The committee will cover as many topics as possible during the session. You'll also have the chance to ask questions live — so bring your curiosity and join the conversation! <u>Register here</u> (you must be logged into the COGR Portal to register. Don't yet have account? Request <u>one here.</u>)





2025 Transition Impact Institutional Survey Part II: Responses Requested by 5/27

Earlier this year, COGR conducted a survey to assess the impacts of the Trump administration's executive orders and other research grants and contracts related activities on research institutions. [See <u>COGR Summary Tracker</u> for a list of the executive orders].

COGR is conducting this <u>second survey</u> as a continuation of these efforts. The data from this survey will assist COGR in its advocacy efforts.

If you answered the previous survey and would like to use your responses in answering this survey, you may request a copy of your responses by emailing <u>memberservices@cogr.edu</u>. Please be aware, if Part I was completed anonymously, we are not able to provide your institution's response.

<u>Please coordinate internally and submit only one response per institution to this survey.</u> **Please submit the survey by May 27, 2025**. Preliminary results will be presented during COGR's June membership meeting.

<u>Institutions may choose to complete this survey anonymously.</u> However, if you do choose to include your contact information, it will help COGR staff follow up as needed to ensure only one response per institution is submitted. In either case, all source data is confidential and will be reported in aggregate. No individual person or institution will be identified.



2025 Administration Transition Impacts on Research: Tell Us Your Story

COGR is collecting real-world stories about the impacts on research resulting from the new Administration's Executive Orders, subsequent agency implementation, and the policy to cap NIH F&A cost reimbursement at 15%. These stories may be used in communications and advocacy efforts as appropriate. You may share your story anonymously, and no individual or institution will be identified at any time (if you choose to identify yourself). Any communications or advocacy that incorporates information collected will be done in the aggregate. Log in to the COGR Portal required.

Tell Us Your Story



COGR membership annual dues and ERI Pilot Participation Fee invoices for FY 26 are now available for download. The fiscal year runs August 1, 2025-July 31, 2026, and invoices are 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 are 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 <u>memberservices@cogr.edu</u>.



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</u> <u>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 <u>sign up</u> 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 Job Bank in the COGR Portal? COGR members and ERI Pilot Institutions can submit a relevant job posting via the Portal from the Portal Dashboard and navigating to "Job Bank – Post and Manage Jobs". Under "Job Bank" you can also browse jobs posted by others. This service is complimentary.

COGR's Job Board is now <u>publicly available</u> in an effort to assist those transitioning out of government service.

If you have a relevant position open, post it today on COGR's Job Bank. Contact <u>memberservices@cogr.edu</u> 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.

2025 Administration Transition Information and Resources

Recent Executive Orders of Note (NEW)

COGR continues to track Executive Orders issued by the Whitehouse and identify those with the greatest impact on research activities and/or research funding. (See <u>COGR Summary of Executive</u> <u>Orders, v. 11</u>, released May 6, 2025). Many of the Trump Administration's Executive Orders are the subject of lawsuits and attendant temporary restraining order and preliminary injunctions. These matters are discussed below in the litigation update section.

Significant EOs issued since the <u>March COGR Update</u> including the following:

EO Impacting Biological Research – EO 14292, Improving the Safety and Security of Biological Research

Issued on May 5, 2025, <u>this EO</u> makes several important changes to the regulation of DURC/PEPP and other similar research. First, it requires federal agencies to immediately stop funding of all "dangerous gain-of-function" research conducted by foreign entities in countries of concern or "in countries where there is not adequate oversight to ensure that the countries are in compliance with United States oversight standards" ("Specified COCs/FCs") and end federal funding of "other lifescience research" in Specified COC/FCs "that could reasonably pose a threat to public health, public safety, and economic or national security" as determined by relevant agency heads. The EO defines "dangerous gain-of-function research" as:

[S]cientific research on an infectious agent or toxin with the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility. Covered research activities are those that could result in significant societal consequences and that seek or achieve one or more of the following outcomes:

- (a) enhancing the harmful consequences of the agent or toxin;
- (b) disrupting beneficial immunological response or the effectiveness of an immunization against the agent or toxin;

(c) conferring to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitating their ability to evade detection methodologies;

- (d) increasing the stability, transmissibility, or the ability to disseminate the agent or toxin;
- (e) altering the host range or tropism of the agent or toxin;
- (f) enhancing the susceptibility of a human host population to the agent or toxin; or
- (g) generating or reconstituting an eradicated or extinct agent or toxin.

Second, the EO revokes the 2024 United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential" ("2024 DURC PEPP Policy"; see COGR <u>February</u> and <u>March 2025 and November 2024 Updates</u> for details of this policy), and requires OSTP to revise or replace this policy within 120 days with a new policy ("New Policy") that increases oversight, enforcement, and transparency and clearly defines the scope of research subject to the New Policy. The aforementioned "pause" in funding of this research is set to remain

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in place "at least" until the completion of the New Policy. Note that this pause applies to covered research being conducted in the United States.

"Oversight and enforcement measures" include the requirement that contracts or grant awards for covered research include terms that specify compliance with the EO is material to the government's funding decision and certification that the contractor/awardee does not participate in any research that violates that EO. Violations of these terms can subject contractors/awardees to "immediate revocation of ongoing Federal funding, and up to a 5-year period of ineligibility for Federal life-sciences funding" from HHS or other relevant agencies.

Third, the EO also revokes the <u>2024 Framework for Nucleic Acid Synthesis Screening</u> (see <u>COGR</u> <u>September 2024 Update</u> for discussion of this Framework), and requires OSTP, within 90 days, to revise or replace this policy. The "new" policy must take "a commonsense approach" to requiring providers of synthetic nucleic acid sequences to screen recipients in a manner that minimizes the risk of misuse. (Note: Under the 2024 version of the framework, core facilities at research institutions that provide sequences to internal users were considered to be "providers" subject to the policy.)

Fourth, the EO calls for OSTP, in connection with OMB and other relevant agencies, to "develop and implement a strategy to govern, limit, and track dangerous gain-of function research across the United States that occurs **without Federal funding** and other life-science research that could cause significant societal consequences." (**Emphasis** added).

Finally, the EO calls for a requirement that federally funded research institutions report both federally and non-federally funded dangerous gain-of-function research and provide a publicly available source of information about this research, including any research subject to the funding pause. NIH issued a guide notice implementing this EO, which is discussed in the Research Ethics and Compliance section of this update.

EO Impacting Sec. 117 Reporting – EO 14282, Transparency Regarding Foreign Influence at American Universities

The Trump Administration issued <u>this EO</u> on April 23, 2025. The directive aims to expand the enforcement of Section 117 of the Higher Education Act of 1965 (<u>20 U.S.C. § 1011f</u>). The Secretary of Education is instructed to take all necessary steps to enforce the requirements of Section 117 to ensure complete and timely disclosure of foreign funding received by universities. With absolute "transparency" as the stated goal, the Secretary is instructed in EO 14282 to (i) rescind any policy or actions of prior administrations that allowed institutions to "obscure" foreign funding sources, (ii) require universities to provide more specific information about the foreign funds received, (iii) provide the public more access to information about foreign sources of funds received by universities, and (iv) to initiate audits and enforcement actions to ensure compliance with Section 117 requirements.

In addition, the Secretary and heads of the other agencies are directed to take steps to ensure certifications of compliance are **material** for the purposes of the False Claims Act (<u>31</u> <u>U.S.C. 3729</u>) and the receipt of grant funds.



This Presidential action is separate from the proposed DETERRENT Act (H.R. 1048). Applying to institutions of higher education, receiving \$50M or more in federal funding, the pending bill amends 20 U.S.C § 1011f by lowering the Section 117 reporting threshold for foreign gifts and contracts to \$50000, with a zero threshold for countries and entities of concern. The latest status of the DETERRENT Act can be found in the <u>March 2024 COGR Update</u>.

Procurement & Payment Related EOs

In late March and April, the Trump Administration issued the following EOs that have provisions regarding payment and procurement activities the impact research institutions:

- EO 14240, <u>Eliminating Waste and Saving Taxpayer Dollars by Consolidating</u> <u>Procurement</u> (Mar. 20, 2025) – This EO consolidates federal procurement activities with the General Services Administration.
- EO 14249, Protecting America's Bank Acct Against Fraud, Waste and Abuse (Mar. 25, 2025) This EO calls for the return of "disbursing functions" to the Department of Treasury when possible and for the consolidation/standardization of core federal financial systems. The EO also requires the development of guidance and systems that ensure that all payments made by Treasury on behalf of agencies "are subject to pre-certification verification processes."
- EO 14274, <u>Restoring Common Sense to Federal Procurement</u> (Apr. 15, 2025) This EO calls for the Office of Federal Public Procurement Policy to amend the Federal Acquisition Rules (FAR) to "ensure [they contain] only provisions that are required by statute or that are otherwise necessary."
- EO 14287, <u>Protecting American Communities from Criminal Aliens</u> (Apr. 28, 2025) This EO calls for the U.S. Attorney General and Secretary of Homeland Security to identify for termination any federal funding (including grants and contracts) to state and local jurisdictions that "obstruct" enforcement of federal immigration laws. It also calls for the development of rules to ensure that state/local laws do not favor aliens over American citizens, including laws that provide in-state higher education tuition rates to aliens, but not out-of-state American citizens.

Department of Education – EO 14242 Improving Education Outcomes by Empowering Parents, States, and Communities

Issued on March 20, 2024, <u>this EO</u> directs the Secretary of Education to take action to facilitate the closure of the Department of Education. It also requires the termination of the Department of Education's financial assistance for DEI or gender ideology programs.



EO Impacting the General Compliance Landscape – EO 14294, Fighting Overcriminalization in Federal Regulations

Issued on May 9, 2025, <u>this EO</u> states that strict liability offenses and criminal enforcement of criminal regulatory offenses are "disfavored" and regulatory criminal enforcement should focus on circumstances in which a defendant knew that their conduct was unlawful. The EO tasks each agency head, in consultation with that Attorney General and OMB Director to provide, within a year for publication, a report detailing all criminal regulatory offenses, including the range of criminal penalties and applicable criminal intent standards. It also calls for agencies to publish guidance in the Federal Register describing their plans to address regulations with criminal liability, and it sets forth standards for notices of proposed rulemaking that include rules with criminal liability.

Institutions should also note that Department of Justice (DOJ) recently announced a new <u>enforcement plan</u> that prioritizes prosecutorial efforts in certain areas, list factors that DOJ will consider in determining whether to criminally prosecute, and provides greater incentives to entities to voluntarily disclose violations and enter into corporate compliance programs.

Status of Litigation Concerning Previously Issued EOs and Other Administration Activities (UPDATE)

COGR is tracking the status of new and continuing litigation concerning the Trump Administration's EOs and other activities impacting research and federal research funding. [See COGR's <u>lawsuit tracker</u> on the <u>2025 Administration Transition Information & Resources webpage</u> for periodic updates.] New cases and updates from key continuing cases are summarized below.

Significant Jurisdictional Issue Raised in State of California v. Department of Education (DOEd)

In this case challenging the termination of DOEd grants to state institutions, the U.S. Supreme Court stayed the TRO granted by the district court while an appeal was pending in the First Circuit and encouraged the government to apply to the Supreme Court for a writ of certiorari, noting that the government was likely to succeed in showing that subject matter jurisdiction for this case was in the U.S. Court of Claims, not the federal District Courts. In response, the plaintiffs withdrew their motion for a preliminary injunction and the government dismissed its appeal, effectively halting this case. However, courts in several other cases challenging payment pauses and grant terminations quickly picked up on the Supreme Court's statements, and they have considered/or are now considering these jurisdictional concerns in the cases under their review (see, e.g., American Assoc. of Colleges for Teacher Education v. McMahon in which the 4th Circuit Court of Appeals stayed a previously granted preliminary injunction based on the Supreme Court's jurisdictional concerns). However, other district courts have distinguished the State of California v. DOE from cases and held that they did have subject matter jurisdiction (see, e.g., order of D.C. District Court in Global Health Council v. OMB and the order of the Massachusetts District Court in Massachusetts v. Robert F. Kennedy, Jr. per which both courts held that they had subject matter jurisdiction).

New Cases Concerning Termination of Federal Funding Based on Allegations that Civil Rights Laws were Violated

 <u>Harvard College v. Dept. of Health and Human Services</u> (DHHS) and <u>American Assoc. of</u> <u>University Professors (Harvard Faculty Chapter) v. Dept. of Justice</u>: These cases allege that the federal government has withheld/misused federal funding and/or civil rights enforcement authority to undermine academic freedom and free speech. A hearing is scheduled for both cases on July 21, 2025.

New Cases Concerning Dept. of Energy (DOE) and National Science Foundation's (NSF) 15% F&A Cap

 <u>Association of American Universities v. NSF</u> and <u>Association of American Universities v. DOE</u>: In each of these cases higher education associations and universities filed suit against DOE and NSF alleging that the 15% F&A rate cap violates the Administrative Procedures Act and seeking injunctive and other relief. The plaintiffs in the DOE case sought a temporary restraining order (TRO), which was granted on April 16, 2025. This TRO enjoins the government from implementing, instituting, maintaining, or giving effect to the DOE F&A rate cap policy or otherwise modifying indirect cost rates (except as permitted by statute or regulation) and from terminating any grants based on an awardee's refusal to accept the lower rate. A hearing on a preliminary injunction was held on April 28, 2025, and the court granted the preliminary injunction on May 15. The plaintiffs did not seek a TRO in the NSF case but rather filed a motion for a preliminary injunction. A hearing has not yet been set for this motion.

Ongoing Cases Regarding NIH 15% Rate Cap

 <u>Commonwealth of Mass. v. NIH</u>, <u>Association of American Universities v. DHHS</u>, and <u>Association of American Medical Colleges v. NIH</u>: These ongoing cases concerning the NIH 15% F&A Cap are subject to a final judgment and permanent injunction that the government has appealed to the First Circuit Court of Appeals.

Ongoing Cases Regarding the Federal Payment Freeze

 In <u>National Assoc. of Diversity Officers in Higher Education v. Trump</u> and <u>National Council of</u> <u>Nonprofits v. Office of Management and Budget</u> the preliminary injunctions initially issued by the district courts were later stayed while the governments' appeals are pending. However, in <u>State of New York v. Trump</u>, the First Circuit Court of Appeals denied the government's motion for a stay of a the preliminary injunction while the appeal is being heard.

New Cases Regarding Grant Terminations for Not Effectuating Agency Priorities

• <u>Massachusetts v. Robert F. Kennedy, Jr.</u> and <u>American Public Health Association v. NIH</u>: The plaintiffs in these cases challenged NIH termination of grants and discontinued solicitation of funding applications based on claims that the grants/grant solicitations did not "effectuate agency priorities." COGR joined with other higher education and research



associations to file an *amicus* brief in *Massachusetts v. RFK*, *Jr.* On May 12, the court in that case issued an order holding that it has subject matter jurisdiction and setting a case management conference for May 13. <u>Permission</u> was also sought to file an *amicus* brief in the American Public Health Association case, and COGR and the other associations on the brief are waiting for the court's decision on this request.

New Case Regarding Termination of Grants Funded Through COVID-19 Related Laws

• <u>Colorado v. DHHS</u>: In this case, the states of Colorado, Rhode Island, California, Minnesota, Washington, Arizona, Connecticut, Delaware, Hawaii, Illinois, Kentucky, Maine, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Wisconsin, and the District of Columbia brought suit against DHHS for the termination of grants and cooperative agreements funded through laws related to the COVID-19 pandemic. The government stated that the grants were terminated for cause because they were issued for the limited purpose of ameliorating the pandemic, and the pandemic is now over, so the grants are no longer yesterday. On May 16, 2025, the federal District Court for Rhode Island granted a preliminary injunction preventing the government from implementing the March 24, 2025 decision that "numerous health programs and appropriations responsible for \$11 billion of critical federal financial assistance were 'no longer necessary' because 'the COVID-19 pandemic is over.'" The injunction is limited to the states that brought the suit, including their "local health jurisdictions."

New and Ongoing Cases Regarding the DEI EOs and Conditions Imposed on Grants

• Courts have come to differing conclusions in evaluating claims that the DEI EOs are unconstitutional. In <u>National Urban League v. Trump</u>, the D.C. District Court denied the plaintiffs' motion for a preliminary injunction based on lack of standing and the conclusion that the plaintiffs were unlikely to prevail on their claims that the DEI orders violate either the 1st or 5th Amendments. Alternatively, the court in <u>Chicago Women in Trades v. Trump</u> held that the plaintiffs' challenging the termination of Department of Labor grant established that the DEI EOs are likely to violate the 1st Amendment and granted a preliminary injunction, in part. Similarly, in the case of <u>King County v. Turner</u>, the District Court for the Western District of Washington granted a TRO prohibiting HUD from adding new conditions to awards regarding DEI, gender ideology, and immigration enforcement. The plaintiffs in this case alleged that these new conditions violate 5th Amendment due process protections, as well as the Constitution's separation of powers and spending provisions. Notably, the court also held that it, not the Court of Claims, had subject matter jurisdiction over the matter.

Cases on Prohibition on Provision of Gender-Affirming Care to Minors – State of Washington v. Trump and PFLAG, Inc. v. Trump

- In <u>State of Washington v. Trump</u>, the District Court granted a limited stay of proceedings while the government appealed the preliminary injunction to the 9th Circuit. The district court noted that this stay **does not** prohibit the plaintiffs from enforcing the preliminary injunction (which the 9th Circuit declined to stay). Further, the court is considering the plaintiffs' motion to compel discovery, which asserts that the government is disregarding the preliminary injunction by continuing to withhold funds under the challenged EOs.
- In <u>PFLAG, Inc. v. Trump</u> the federal District Court for Maryland issued a nationwide injunction preventing enforcement of EO provisions prohibiting the provision of medical services to transgendered individuals. The government appealed this injunction to the 4th Circuit. The Maryland District Court entered a limited stay of proceedings, similar to the one in place in the State of Washington case.

Actionable Ideas and COGR's Response to the OMB RFI on Deregulation (NEW)

In April 2025, COGR developed a table listing <u>actionable ideas</u> that the federal government can take to improve government efficiency and the regulation affecting the performance of federally supported fundamental research. This table included references to specific regulations, policy, and guidance statement, a summary statement of associated issues, and recommendations for improving efficiency. COGR shared the table with federal officials and the <u>National Academies of</u> <u>Sciences</u>, <u>Engineering</u>, and <u>Medicine's committee on Improving the Regulatory Efficiency and</u> <u>Reducing Administrative Workload to Strengthen Competitiveness and Productivity of U.S.</u> <u>Research</u>.

COGR used the table as the basis for its <u>response</u> to <u>OMB's RFI</u> soliciting ideas for deregulation and identification of regulations that are unnecessary, unlawful, unduly burdensome, or unsound.

National Academies' Committee on Improving Regulatory Efficiency and Reducing Administrative Workload to Strengthen Competitiveness and Productivity of U.S. Research (NEW)

This <u>Committee</u> (which includes a COGR Committee member) is tasked with implementing a "fasttrack consensus study" to review and prioritize federal actions to improve regulatory efficiency. As a part of its work, the Committee has developed a survey aimed at seeking feedback from persons working in the academic research community on administrative burden and research areas most in need of reform. The survey is available at this <u>link</u>, and COGR member are encouraged to participate.



Administration Transition Impact – Second Survey (NEW)

Between February 10 and March 11, 2025, COGR conducted a survey of its members to assess the impacts of the Trump Administration's payment freeze and termination/suspension of grants and contracts carried out pursuant to the Administration's EOs. Preliminary results from the survey were presented at the February COGR Meeting and in the <u>March COGR Update</u>.

On May 13, COGR launched a second survey to gather additional information about the impact that continuing payment pauses and grant terminations are having on research institutions. Respondents are once again asked to submit a single response per institution and responses may be submitted anonymously. The <u>survey link</u> was emailed to the COGR Listserv on May 13 and institutions are requested to respond by May 27, 2025. Preliminary results from the survey will be presented at COGR's June membership meeting.

Agency Specific Actions

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: <u>COGR's 2025 Administration Transition Information & Resources</u> includes a consolidated list of agency directives and memoranda issued in response to the EOs. Agencies that have released notices include the Department of Energy (DOE), Department of Health and Human Services (DHHS), National Aeronautics and Space Administration (NASA), Department of Labor (DOL), Department of Education (ED), United States Agency for International Development (USAID), National Science Foundation (NSF), General Services Administration (GSA), Department of Justice (DOJ), Centers for Disease Control and Prevention (CDC), and others. In some cases, members report receiving specific action notices for specific awards related to foreign aid or DEI. As agencies continue to issue guidance, we encourage members to share relevant communications with COGR at memberservices@cogr.edu.
- Impact of EOs on Federal Awards: COGR has received multiple reports of agency actions affecting research and education projects involving DEI activities and foreign aid. Agencies, including the Department of State, USAID, United States Department of Agriculture (USDA), NIH, ED, NASA, and the Air Force Research Laboratory (AFRL), have issued stop-work orders and terminations.
- NSF Award Terminations: More recently, starting in mid-April, NSF began terminating awards in weekly phases, stating that these awards "are not in alignment with current NSF priorities." NSF has identified that awards related to DEI, environmental justice, and misinformation/disinformation do not align with program goals or agency priorities and have been terminated. NSF termination letters state, "this is the final agency decision and not subject to appeal." However, this is inconsistent with <u>2 CFR 200.342</u>, <u>PAPPG Chapter XII</u>:



<u>Award Administration Disputes and Misconduct</u>, and (NSF) Grant General Conditions (GC-1) <u>Oct. 1, 2024</u> and <u>May 20, 2024</u>. As such, many recipients are proceeding with filing a formal dispute in accordance with NSF procedures for terminations. NSF maintains a webpage, <u>Updates on NSF Priorities</u>, with FAQs.

- DOD Memorandum Implementing 15% Indirect Cost Cap for IHEs: On May 14, 2025, a <u>memorandum</u> was issued for senior Pentagon leadership to implement a 15% cap on indirect costs for assistance awards to Institutions of Higher Education (IHEs). Effective immediately DoD Departments will limit indirect costs to 15% for all new financial assistance awards for IHEs. Within 21 days of the memorandum's issuance, the Under Secretary of Defense for Research and Engineering must notify OMB about the intent to cap IDC to 15%. Additionally, the Under Secretary must develop and publish formal policy guidance, revise all upcoming grant solicitations, including NOFOs, and ensure new awards to IHEs are limited to the 15% IDC cap. For existing awards, DoD is directed to renegotiate the indirect cost rates to the 15% cap. If a bilateral agreement is not achievable, DoD is instructed to terminate and reissue the award under the revised 15% indirect cost cap. COGR released a statement expressing concern about the impact of this policy on national security and urged the administration to stop issuing misguided policies.
- DOE Policy Flash PF 2025-28:_On May 15, 2025, the Department of Energy issued a policy . notice titled Secretarial Policy on Ensuring Responsibility in Financial Assistance (PF 2025-28). The notice outlines DOE's intent to conduct focused reviews of existing financial assistance awards and other forms of support for alignment with the Administration's policies and priorities. According to the notice, DOE may request written responses and supporting documentation from recipients to facilitate these reviews. While the policy does not detail the specific scope or methodology of the reviews, it states that projects that fail to meet certain "Standards" may be subject to modification or termination. The policy defines "Standards" as ensuring "financial assistance award recipients and the individual projects are, among other things, financially sound and economically viable, aligned with national and economic security interests, and consistent with Federal law and this Administration's policies and priorities and program goals and priorities." Although the notice does not explicitly list criteria for determining alignment with Administration priorities, prior actions and statements by federal agencies indicate that certain types of projects such as those focused on diversity, equity, and inclusion (DEI), environmental justice, foreign aid, misinformation/disinformation, or COVID-19 as aligning with this Administration's priorities.
- NIH No-Cost Extensions & RPPRs:
 - <u>No-Cost-Extensions (NCE)</u>: As previously reported (<u>February 2025</u>), in early February, NIH temporarily disabled the No-Cost Extension module in eRA Commons for approximately ten days. More recently, on May 7, 2025, NIH issued policy <u>NOT-OD-25-110</u>, effective immediately, once again disabling the No-Cost Extension functionality. All NCEs must be submitted as prior approval requests. See the section below for additional information.



 <u>Research Performance Progress Reporting (RPPR)</u>: NIH published an updated version of the RPPR Instruction Guide <u>May 2025</u>. The updated Instruction Guide removes "diversity" from the Instruction Guide and any diversity-related reporting requirements (Trainee Diversity Report).

COGR continues to monitor agency responses to the EOs and broader administration directives. We continue to engage with federal agencies to advocate for clarity, consistency, and fairness in the implementation of EOs affecting the research community.

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

COGR Letter to New NIH Director Requesting Clarifications on Policy Changes (NEW)

On April 9, 2025, COGR sent a <u>letter</u> to newly confirmed NIH Director Dr. Jay Bhattacharya addressing multiple concerns from the research community regarding recent NIH policy changes. The letter sought clarification on several key issues, including "NIH's policy priorities" that have introduced "confusion and uncertainty within the research community."

Key Issues Addressed:

- <u>Terminations</u>: Clarification on the criteria and processes NIH employs to make termination decisions and how scientific priorities are determined.
- <u>Appeals of Terminations</u>: Details on the procedure for institutions to appeal terminations, including points of contact and expected timelines for decisions.
- <u>Orderly Closeout</u>: Requested that NIH issue AQs outlining allowable cost items for orderly closeout, in alignment with 2 CFR 200 requirements.
- <u>Funding Disruptions</u>: Immediate attention to funding disruptions and delays, with a request for NIH to clarify agency priorities and identify programs that no longer align with these priorities.
- <u>Centralized Peer Review</u>: Clarification on how complex funding mechanisms, such as centers, program projects, cooperative agreements, training grants, and career development awards, will continue to receive subject-specific expertise under the new centralized peer review process, and how institute-specific funding strategies will be maintained.
- <u>No-Cost Extensions (NCEs) and Expanded Authority</u>: Clarification on whether expanded authorities will be maintained for NCEs.
- <u>Temporary Restraining Orders (TROs) and Preliminary Injunctions</u>: Request for NIH to provide a centralized resource detailing the implementation of court directives to ensure consistent funding policies across NIH Institutes and Centers.
- <u>Award Terms and Stakeholder Engagement</u>: Clarification on NIH's approach to obtaining input from stakeholders and taxpayers on policies that impact the research community.



• <u>Payment Management System (PMS) Draw Requirement</u>: Inquiry into how NIH is assessing the impact of recent PMS changes on administrative burden and what measures are being taken to prevent undue duplication of efforts while maintaining efficient oversight.

COGR expressed a willingness to engage in dialogue with NIH leadership to address these concerns and emphasized the importance of collaborative efforts to develop effective solutions. COGR remains committed to advocating for clarity and consistency in NIH policies to support the research community.

Science & Security: Cross-Cutting Issues

Executive Order 14282 – "Transparency Regarding Foreign Influence at American Universities" (NEW)

See discussion of this Executive Order under the "2025 Administration Transition Information and <u>Resources</u>" section of this Report.

GAO Issues Genomic Data Security Report (UPDATE)

The General Accountability Office (GAO) published its report "<u>Human Genomic Data: HHS Could</u> <u>Better Track Use of Foreign Testing Entities and Strengthen Oversight of Security Measures</u>" on April 30, 2025. GAO was directed under the <u>Consolidated Appropriations Act of 2023</u> to evaluate the risks posed by countries of concern gaining access to U.S. human genomic data and the security measures in place by the Department of Health and Human Services (HHS) to protect such data.

The report concluded that HHS has strategies to mitigate the risks associated with countries of concern harvesting human genomic data but has not taken certain steps deemed necessary to address the risks associated with such data entirely.

In light of its findings, GAO made four recommendations:

- (i) The HHS Office of National Security needs to develop training and guidance on supply chain risk assessment standards to support HHS divisions in effectively managing risks concerning genomic data security.
- (ii) NIH needs to track the use of genetic service providers with ties to countries of concern by both intramural and extramural researchers.
- (iii) NIH needs to develop procedures to monitor researchers' compliance with data security management for human genomic data.
- (iv) In addition to developing its own data security management procedure, CDC needs to establish procedures to maintain restricted-access repositories with human genomic information across its enterprise.

In its written comments to GAO regarding the draft report, HHS generally agreed with the recommendations made in the report; however, the agency requested that the final report acknowledge the update HHS made to its security standards for restricted-access data repositories.



GAO agreed to do so but concluded that the updated standards did not impact their findings or recommendations.

Highlighted in the <u>September 2024 COGR Update</u>, Kris West, Director of REC, and Kevin Wozniak, Director of RSIP, met with GAO representatives in August 2024 and emphasized the necessity of scientific information sharing and the need to find an approach that balances the needs for scientific advancement, public health, individual privacy rights, and national security.

DOD Updates Research Security Decision Matrix (NEW)

On May 5, 2025, the U.S. Department of Defense (DOD) released an updated version of its <u>Decision</u> <u>Matrix to Inform Fundamental Research Proposal Mitigation Decisions</u> (Updated Matrix). The revised risk matrix maintains its focus on four primary risk factors:

(i)Participation in malign foreign talent recruitment programs (MFTRP).

- (ii) Funding from countries of concern.
- (iii) Patent activities in non-U.S. jurisdictions.
- (iv) Collaborations with individuals or entities on U.S. government restricted lists.

The Updated Matrix introduces changes to the timeframes used for evaluating risk and any associated mitigation requirements. For example, the qualifier "For the Period after 9 Aug 2024" has been removed from the description of prohibited activities as it relates to participation in the MFTRP. Instead, mitigation measures are now expected from the "period between October 10, 2019 and August 9, 2024."

A substantial update is the new prohibition on collaborations with entities on the most recent <u>list</u> <u>published by the DOD</u> in response to Section 1286 of the FY2019 NDAA in fundamental research proposals.

The Updated Matrix is in effect for all proposals submitted after May 9, 2025.

COGR Engages with NSF SECURE Program Leadership (NEW)

On April 30, 2025, representatives from COGR, AAU, APLU, AAMC, and ACE convened with leadership from the Safeguarding the Entire Community in the U.S. Research Ecosystem (SECURE) Program for the group's quarterly meeting. The NSF-funded SECURE Center's Principal Investigator and Director, Mark Haselkorn, Co-Director Lynette Arias, and Senior Advisor Lisa Nichols provided updates on Center activities and shared anticipated timelines for the release of initial resources. Additionally, the NSF SECURE Analytics PI/Director, Kevin Gamache, reported on progress and developments within the SECURE Analytics initiative.

<u>SECURE Center Update.</u> During the first six months of Year 1 (beginning September 1, 2024) the Center team was primarily focused on organizational setup, advisory board recruitment, staffing, training, establishing operational models, and early outreach. In Quarter 3, the Center has focused on building the Regional Center community through Co-Creation Stakeholder Activities (CSAs), co-

designing solutions previously prioritized by stakeholders. Features and content being developed support challenge areas such as risk assessment tools, managing federal risk matrices, developing foreign travel briefings, secure virtual community forums, and navigating agency risk expectations and mitigation strategies. As part of its research community resource rollout, the SECURE Center will launch a consolidated training module (CTM 1.0) by June 2025.

The one-hour research security training module consolidates and combines the four federal modules, expands on information related to malign foreign talent recruitment programs and foreign travel security, incorporates details on cybersecurity and insider threat, and enhances design consistency and usability. CTM 1.0 was user tested this month with a stakeholder group consisting of approximately 50 VPRs, researchers, research administrators, SECURE Center and SECURE Analytics subject matter experts, and federal staff. To receive updates from the SECURE Center or get involved, COGR members may are asked to submit your request and interest via the Center's <u>contact form</u>. For questions, you may email the Center at <u>securecenter@uw.edu</u>.

<u>SECURE Analytics Update.</u> In its April 29th <u>announcement</u>, NSF SECURE Analytics named Argus as the official platform for data collection, analysis, and reporting for the NSF-funded initiative, along with details about its initial rollout. The first phase release of Argus is scheduled for Fall 2025 and will offer basic-level access to beta testers only. A broader second phase of the release is expected in Spring 2026, extending basic-level access to accredited users and introducing advanced-level features to the beta testers.

The SECURE Analytics inaugural advisory, which will be published this month, will focus on the emerging Chinese Science and Technology Infrastructure. COGR members are encouraged to suggest future advisory topics. You may submit your suggestions at <u>info@secure-analytics.org</u> or via <u>LinkedIn</u>.

DOJ Issues Guidance and FAQs on Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons and Announces 90-day Limited Enforcement Policy (UPDATE)

As discussed in COGR's <u>February 2025 Update</u>, the Department of Justice (DOJ) adopted its final rule on Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern [COCs]or Covered Persons, which it is referring to as a "Data Security Program." The rule prohibits certain transfers of bulk sensitive personal data (e.g., personal identifiers, health data, genomic data, financial data, biospecimens, 'omic' data) to China, Cuba, Iran, North Korea, Russia, and Venezuela and to certain COC-affiliated persons and entities (both inside and outside the U.S.) who have been designated by DOJ as Covered Persons or that meet certain ownership criteria (collectively "Covered Transactions"). The February Update provides additional details on information and transactions covered under the final rule, as well as certain exempt categories of data (e.g., federally funded research, clinical trials necessary to support marketing applications for new drugs). Notably, deidentified, anonymized, and pseudonymized data **ARE NOT** exempt from this rule, and it impacts flows of business and research-related covered



data with COCs **AND** with Covered Persons located inside the U.S. and non-COC affiliated foreign entities.

The final rule went into effect on April 8, 2025, but DOJ issued an <u>Implementation and Enforcement</u> <u>Policy</u> that states it will use "enforcement discretion" for the first 90 days. This policy states that entities must comply with all provisions of the final rule as of April 8, 2025, except for obligations related to certain due diligence, audit, and reporting requirements detailed in Subpart J, and sections 202.1103 – 1104 of the rule, which take effect October 6, 2025. However, until July 7, 2025, DOJ will pursue enforcement and penalties "as appropriate for egregious, willful violations."

DOJ also issued a <u>Compliance Guide</u> and <u>Frequently Asked Questions</u> that provide additional information about the rule's requirements. The Compliance Guide provides a thorough summary of the final rule including reporting and due diligence requirements. Notably, U.S. entities that engage in Covered Transactions are expected to establish a Data Compliance Program that includes the implementation of "risk-based procedures" for:

[Verifying data flows involved in any restricted transaction, including procedures to verify and log, in an auditable manner, the following: (1) the types and volumes of bulk U.S. sensitive personal data or government-related data involved in any restricted transactions; (2) the identity of the transaction parties, including any ownership of entities or citizenship or primary residence of individuals; and (3) the end-use of the data and the method of data transfer.

The compliance program must include procedures for initial and periodic vetting of vendors that receive Covered Data in Covered Transactions to determine if they are Covered Persons, as well as an overarching written policy that describes the compliance program and is annually certified by an "officer, executive, or other employee responsible for compliance." Although the Compliance Guide does not mandate training on the compliance program, it makes clear that such training should be considered. Finally, the Compliance Guide details the annual audit requirements for compliance programs.

Institutions should review and document their current business and research uses of each bulk category of sensitive data (both inside and outside the U.S.) to ensure that the flows are not considered Covered Transactions or that they fall under an appropriate exemption category. Institutions that engage in Covered Transactions must develop the required Data Compliance Program.

COGR Committee Members and Staff Will Participate in National Academies Workshop on Assessing Research Security (NEW)

The National Academies of Science Engineering and Medicine (NASEM) will hold the "Assessing Research Security Efforts in Higher Education" workshop and meeting of experts on May 22-23, 2025. The workshop will consider research security initiatives at NSF and other federal agencies, but its primary focus will be on Department of Defense efforts in this area and the development of metrics to assess effectiveness. COGR's President, members of the REC, CFC, and CGA Committees, and COGR staff will participate in the following panel presentations: The Impact of Research



Security Policies and Requirements on the Research Ecosystem, Advancing Research Security in the Research Community, and the Path Forward for the U.S. Dept. of Defense and Other Funding Agencies (see full <u>agenda</u>). The meeting is open to the public (online and in-person), and persons interested in attending can register at this <u>link</u>.

Update to COGR's Matrix of Science & Security Laws, Regulations, and Policies (UPDATE)

On May 12, 2024, COGR updated its <u>comprehensive matrix</u> of science and security laws, regulations and policies. This matrix summarizes and compares research security-related federal laws, regulations, and policies, including major federal-wide legislation/policy, agency-specific regulations and policies, and agency conflict of interest policies. COGR also updated its Quick Reference Table of Current and Upcoming Federal Research Security Requirements.

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.

USPTO Developments (NEW)

Interim Process for PTAB Workload Management. On March 26, 2025, the U.S. Patent and Trademark Office (USPTO) sent a memorandum to all Patent Trial and Appeal Board (PTAB) judges outlining significant changes to the board's practices. Citing "workload needs" for the changes, the USPTO director will now decide whether petitions challenging a patent should be denied for discretionary reasons before the PTAB considers the petition's merits.

The PTAB can exercise discretion to deny petitions challenging the validity of patents when an infringement trial occurs before the board's decision is due or when the office has already considered the invalidity argument.

The memo states that the new process is temporary but does not specify the duration it will remain in effect.

New Efforts to Target Fraud in Patent Applications. The USPTO has created a Patent Fraud Detection and Mitigation Working Group tasked with monitoring and reviewing "suspicious" filings, unauthentic signatures, and inaccurate entity discount certifications.

Many universities file as small entities, reducing USPTO fees by 50 percent. However, small entity status is revoked once the (pending) patent is licensed or rights are otherwise conveyed to an entity that does not qualify as a small business concern. It is important to note that non-exclusive, royalty-free licenses, options, or a right of first refusal granted to non-Federal sponsors likely disqualify a university from claiming small entity status when filing a patent application. It is important for the

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technology transfer office to verify with patent counsel the appropriate entity status at the time of the patent application.

Termination of Climate Change Mitigation Pilot Program. A <u>notice</u> was published in the Federal Register on April 18, 2025, formally terminating the USPTO Climate Change Mitigation Pilot Program. The pilot program was designed to accelerate the process from application to issuance of a patent for innovations combating climate change. In its first year, 244 patent applications were granted this no-cost opportunity to be fast-tracked through prosecution.

Petitions from applicants to participate in the pilot program received by the USPTO after 5 PM EST on January 28, 2025, will not be granted.

Two Bills Re-Introduced to Strengthen U.S. Patent System (UPDATE)

Senators Coons and Tillis have reintroduced two bills aimed at strengthening the U.S. Patent system post-American Invents Act (AIA).

Patent Eligibility Restoration Act. If passed, the Patent Eligibility Restoration Act (PERA) will clarify 35 U.S.C. § 101, the section of the Patent Act that defines what inventions are eligible for patent protection, following the Supreme Court's introduction of ambiguity to the scope of patent-eligible subject matter in some of its recent rulings. The Court's rulings, particularly in Mayo v. Prometheus, Myriad Genetics, and Alice v. CLS Bank, have significantly narrowed the scope of what is considered patent-eligible and introduced vague standards that the USPTO and lower courts have struggled to apply consistently.

The current interpretation of Section 101 has made it more difficult for university technology transfer offices to patent certain biotech, genetic, diagnostic, and software-related inventions because they are based on natural phenomena or abstract ideas.

Notably, the U.S. Court of Appeals for the Federal Circuit, which handles patent appeals, has urged Congressional action due to the Supreme Court's reluctance to provide additional guidance on this matter. The proposed legislation will codify clearer, more predictable standards for what is patent eligible.

Additionally, U.S. innovators will once again be on equal footing with their counterparts around the world. European and Asian countries generally maintain broader patent eligibility standards, providing a stronger and more predictable patent ecosystem.

Promoting and Respecting Economically Vital American Innovation Leadership Act. The Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL) addresses imbalances and inefficiencies in the U.S. patent challenge system, particularly within the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB). Created under the AIA, the PTAB was intended to be a faster and more cost-effective alternative to litigation for challenging patents. In practice, the process has been exploited by some. Patent owners can face multiple, duplicative PTAB proceedings, often accompanied by a corresponding legal challenge. Serial

challenges to patents make it hard for smaller innovators to defend their intellectual property and overwhelm the PTAB (see *Interim Process for PTAB Workload Management* above). To complicate matters for patent owners, the district courts and the PTAB are not always consistent in their decisions on patent validity.

PREVAIL seeks to limit repetitive challenges by requiring all PTAB petitions be filed within a reasonable timeframe, implement procedural reforms at the PTAB, and improve coordination between PTAB proceedings and the courts to ensure patent validity decisions are not conflicting.

AAU, AUTM, and other higher education associations have endorsed both PREVAIL and PERA.

NIST High-Performance Computing Security Overlay (NEW)

Developed by the High-Performance Computing (HPC) Security Working Group, NIST published the draft <u>Special Publication 800-234</u> on May 1, 2025. The publication provides a security framework specifically designed for high-performance computing systems, recognizing their unique performance demands and architectural complexity. Building on <u>NIST SP 800-53B</u> (Control Baselines for Information Systems and Organizations), the overlay modifies 60 security controls by incorporating supplemental implementation guidance and contextual clarifications to align with the performance constraints and architectural nuances of HPC systems. The overlay is purported to offer a technically sound, performance-optimized security posture that is both implementable and extensible. The guidance was reportedly developed to provide a comprehensive foundation for securing HPC infrastructures while accommodating specific organizational differences, including variations in threat models and system architectures.

The COGR RSIP Committee is discussing the extent to which these guidelines impact research activities and whether comments are warranted. The deadline to submit comments is July 3, 2025.

GAO Releases Patent Quality Report (NEW)

A recent <u>GAO review</u> of the U.S. Patent and Trademark Office (USPTO) found that patent examiners continue to prioritize the processing of large volumes of patent applications over the quality of their reviews. Examiners interviewed by GAO reported that performance expectations are heavily focused on quantity, and that this pressure, combined with increasingly complex applications and time constraints, undermines the depth and accuracy of the examination process. These concerns are consistent with issues raised in earlier GAO reports from 2016 (<u>GAO-16-490</u> and <u>GAO-16-479</u>). *Key findings of the review included*:

- Time constraints and application complexity limit the thoroughness of prior art search performed by the USPTO.
- Applicants can exploit these pressures by submitting lengthy and complex amended applications in response to the initial office action.
- Primary tools used by the USPTO for prior art searches and other tasks are often unreliable.
- There is a lack of sufficient technology-specific training and limited sharing of training resources.
- Current quality assessment processes do not adequately validate the quality of metrics used.

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GAO made eight recommendations, urging the USPTO Director to:

- 1. Review and improve current patent quality initiatives by applying evidence-based policymaking, setting clear goals and metrics, and collecting data for evaluation.
- 2. Establish a structured framework for developing, managing, and evaluating pilot programs, based on best practices.
- 3. Update guidance to ensure that supervisory quality reviews accurately reflect examiner performance.
- 4. Create policies to improve the documentation and transparency of changes to random quality review outcomes made during the Office of Patent Quality Assurance (OPQA) data integrity reviews. These policies should include a clear record of modifications and justifications.
- 5. Ensure OPQA's data integrity reviews include a sufficient number of compliant cases from random quality reviews.
- 6. Set a clear statutory goal for patent quality compliance and explain how it supports the issuance of high-quality patents.
- 7. Better explain the reasons behind patent reversals by the Patent Trial and Appeal Board.
- 8. Develop patent quality metrics that reflect the economic or scientific value of patents, to inform strategic planning and improve performance reporting.

NCCIH Rescinds Previous Policy Change to Budget Limits for SBIR/STTR Phase I and II Applications (NEW)

On May 8, 2025, the National Center for Complementary and Integrative Health (NCCIH) issued a notice (<u>NOT-AT-25-004</u>) rescinding the previous announcement it made on July 29, 2020. Through the published rescission, NCCIH's funding limits for Phase I and Phase II SBIR/STTR applications will now align with the <u>NIH SBA budget policy</u>.

U.S. Copyright Office Releases Pre-Publication Report on AI Training (NEW)

On May 9, 2025, the U.S. Copyright Office released a pre-publication version of Part 3 of its <u>Report</u> on <u>Copyright and Artificial Intelligence</u>. Focused on AI training, the publication emphasizes that while some uses of third-party copyrighted material may qualify as fair use, large-scale, commercial "scraping" of content for AI training likely falls outside the scope of the fair use doctrine. In Part 3 of the report, the Copyright Office advocates for the development of licensing mechanisms to allow AI developers to legally access and use copyrighted material while compensating creators. It also reaffirms the principle established in Part 2 of the report, published in January, that works generated entirely by artificial intelligence are not eligible for copyright protection. However, AIassisted works may qualify if there is meaningful human authorship.

The Copyright Office concludes the report with a call for clearer legal standards to strike a balance between technological advancement and the protection of an individual's creative rights.



Costing and Financial Compliance (CFC)

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

Threats to F&A Cost Reimbursement (UPDATE)

In April 2025, COGR and nine other "national organizations representing America's academic, medical, and independent research institutions" announced a <u>Joint Effort to Develop a New</u> <u>Indirect Costs Funding Model</u>. Engaging a team of <u>Subject Matter Experts</u>, the Joint Associations Group (JAG) on Indirect Costs is exploring other models for reimbursement and improvements to the current model. Two <u>Town Hall</u> webinars, open to the public, were held May 8th and May 12th, and <u>recordings</u> of each are available.

While legal challenges to recent attempts to cap Facilities and Administrative (F&A/indirect) cost reimbursement continue, the JAG also recognizes the need to respond to critics of the current system. The current system is fair in that it ensures the federal government is never overcharged by an institution for its allocable share of indirect costs, in total, but perceptions of inequity at the project level and a general lack of understanding of the controls built into the system persist.

COGR and JAG leadership met with OMB on May 14, 2025, to share the <u>JAG process</u>, <u>plans</u>, <u>and</u> <u>activities to-date</u>. OMB acknowledged that it is working on revisions to 2 CFR 200, including language regarding indirect cost reimbursement. OMB was unable to provide a specific timeline for release of its revisions.

As of this Update, three federal funding agencies have announced 15% caps on indirect cost rates, though each is a bit different. In its <u>March Update</u>, COGR reported on <u>NOT-OD-25-068</u>, <u>"Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates</u>, released February 7, 2025. As described above and in COGR's <u>lawsuit tracker</u> on the <u>2025 Administration</u> <u>Transition Information & Resources</u> webpage, the Permanent Injunction the court granted currently stands but has been appealed by the government.

On April 11, 2025, the Department of Energy made an announcement, <u>Department of Energy</u> <u>Overhauls Policy for College and University Research, Saving \$405 Million Annually for American</u> <u>Taxpayers</u>, limiting "financial support of "indirect costs" of DOE research funding to 15%."

For the reasons set forth in this memorandum, hereinafter, the Department will no longer use the negotiated indirect cost rate for grants awarded to IHEs. Instead, it is setting a standardized 15 percent indirect cost rate for all grant awards to IHEs.

While the announcement does not specify that the 15% rate is to be applied to MTDC, it does refer to the de minimis rate of 15%, which Uniform Guidance directs recipients using it to apply to MTDC. It is unclear if it was intended to apply to all assistance agreements or only to "grants", the term used in the announcement.

As it did when NIH announced its cap, COGR released a <u>statement</u> criticizing DOE's new policy. As <u>reported above</u> and in COGR's <u>lawsuit tracker</u> on the <u>2025 Administration Transition Information &</u> <u>Resources</u> webpage, the court issued a Temporary Restraining Order on April 16, 2025.

The April 11 announcement by DOE targeted only colleges and universities (Institutions of Higher Education/IHEs), but in a subsequent announcement, <u>Energy Department Aligns Award Criteria for For-profit, Non-profit Organizations, and State and Local Governments, Saving \$935 Million Annually</u>, DOE broadened its application of caps on indirect cost reimbursement through three new policies. These policies, limiting indirect cost reimbursement for state and local governments to 10% and for nonprofit and for-profit organizations to 15%, apply only to assistance agreements (grants and cooperative agreements). The policies also state, "The percentage that will be reimbursable is inclusive of total indirect costs and fringe benefit costs."

On May 2, 2025, NSF became the third agency to <u>announce a 15% cap</u> on indirect cost reimbursement. The NSF policy notice is more precise, specifying applicability to "grants and cooperative agreements awarded to IHEs for which indirect costs are allowable" and the requirement to use MTDC as the base. The new policy applies "only to new awards made to IHEs on or after May 5, 2025." Because the new policy is to be applied prospectively, as <u>reported above</u> and in COGR's <u>lawsuit tracker</u> on the <u>2025</u> Administration Transition Information & Resources webpage, the May 5, 2025 filed Complaint asked for a permanent injunction rather than a restraining order, and the court has not yet ruled.

COGR issued a <u>statement</u> criticizing the policy as misguided, on the day it was issued.

On May 16, DoD became the fourth agency to <u>announce a 15% cap</u> on indirect cost reimbursement. COGR <u>issued a statement</u> calling on the Administration to stop issuing misguided policies and start working with the academic research community in good faith. See <u>'Agency Specific Actions</u>" in this Update for more information on this policy memo.

Further attempts by the federal Administration to limit F&A cost reimbursement are anticipated. COGR also expects delays and complications due to the closure of two of four HHS <u>Cost Allocation</u> <u>Services</u> offices and staffing reductions within those office and ONR's <u>Indirect Cost Branch</u>.

COGR will continue to work with our partner associations to dispel myths and combat misinformation, as well as explore potential new models for reimbursement. Institutions should continue to communicate accurate information about the activities and costs necessary to support research and the required process research institutions must follow to receive reimbursement of these F&A costs. COGR's <u>F&A Cost Reimbursement Materials</u> webpage is a compilation of information, resources and tools created to assist with effective communication on F&A costs.

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

Inefficiencies in Federal Payment Processes Increase as a Consequence of EO 14222 (UPDATE)

Changes to federal payment systems, processes, and requirements implementing <u>Executive Order</u> <u>14222 — Implementing the President's "Department of Government Efficiency" Cost Efficiency</u>,



issued February 26, 2025, have significantly increased recipient and federal burden for routing payments to low risk institutions for projects and costs previously approved by the agency, offering no savings, reduction in improper payments, or other cost benefits to the government. The new requirement ignores the numerous cost and process audits that grantee institutions undergo to ensure its systems safeguard government assets and comply with federal regulations. The additional, ad hoc requests for supporting details, none of which have undergone a federal rule-making process add no value for the taxpayer.

A compilation of COGR's observations, *Points to Consider for Reimbursement of Expenses Under Active Grants*, was added May 13th to COGR's <u>Framework for Navigating the 2025 Administration</u> <u>Transition</u>. In summary, the EO directs Agency Heads to build systems that will record "*a brief*, *written justification*" for every payment by the agency employee approving the payment request. After the system is in place, Agency Heads must require written justification from the agency employee and, "to the maximum extent deemed practicable by the Agency Head," post the justifications publicly.

As described in the Points to Consider document, agency requirements implementing <u>EO 14222</u> vary widely. Members report increasingly impractical requests for additional details, including requests that appear to ignore rebudgeting authority. Requirements for increasingly detailed justifications also appear to be leading to other, unintentional, inefficiencies. For example, system limitations may not provide adequate space for justification details on each award's expenditures, unless each account/award is a separate draw. This could result in the need to perform hundreds of draws a month rather than a few.

The Points to Consider document also explores potential paths to challenge the new requirement. For example, it is not clear that the new requirement is exempt from OMB's Office of Information and Regulatory Affairs (OIRA) approval process or that all draws for which justification is requested are on "covered contracts and grants". It also does not appear that the <u>EO 14222</u> requirement for agencies "to build systems that will record "*a brief, written justification*" for every payment by the agency employee approving the payment request" was satisfied prior to agency implementation of the requirement for justification. As these additional detail requirements are unlikely to prevent improper payment, an exception, as provided for in the EO, should be granted by each Agency Head for institutions subject to the Single Audit requirement and receiving no findings of improper requests for payment. If necessary, to comply with <u>EO 14222</u>, the agency employee approving the payment requirement as, "Approved for low-risk recipient based on risk assessment dated XX/XX/XX and receipt of progress reports received xx/xx/xx."

Further discussion of this issue will be included during the upcoming "Navigating the Storm" session during the <u>COGR June membership meeting</u>.

Costing Points to Consider for Terminations and Suspensions (NEW)

In response to terminations and suspension notices and related communications from federal agencies that appear inconsistent with sponsor policies and Uniform Guidance, COGR posted to its <u>Framework for Navigating the 2025 Administration Transition</u> a section titled, Costing Points to

Consider for Terminations and Suspensions. 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. In some cases federal sponsors are limiting those to cost related to human subject protection or animal welfare and in some cases do not seem to acknowledge their allowability at all.

Further discussion of this issue will be included during the upcoming "Navigating the Storm" session during the <u>COGR June membership meeting</u>.

Accrued Leave Payouts (UPDATE)

In response to a request for clarification from COGR, OMB confirmed that the FAQ on unused leave charges, included in the January 15, 2025, <u>COFFA</u> issued <u>2 CFR 200: Frequently Asked Questions</u>, is not applicable to Universities or other entities not named in the answer. FAQ § 200.431 Compensation – fringe benefits asks:

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

The FAQ answer states, that it is not allowable and provides the rationale for the answer but goes on to say, "Therefore, **any state, Local or Tribal government** using the cash basis of accounting should allocate payments for unused leave, when an employee retires or terminates employment, in the year of payment as a general administrative expense to all activities of the governmental unit or component or, with the approval of the cognizant agency for indirect costs, the costs can be included in fringe benefit rates." (**emphasis** added)

COGR asked OMB whether this clarification is specific to "any state, Local or Tribal government" or should be considered more broadly. OMB stated that the COFFA memo makes it clear that OMB's guidance in 2 CFR prevails when there is a discrepancy between the it and the FAQs and that when an FAQ mentions specific entity-types, it only applies to those entities.

Additional background details are provided in the March 2025 COGR Update.

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

The fiscal year <u>2023 HERD survey results</u> were released on schedule in November 2024. COGR frequently uses information from the annual HERD results in its advocacy for equitable cost reimbursement regulation, policy, and practice and included analysis of some results in the December 2024 <u>F&A Survey Capstone: Cost Reimbursement Rates, Actual Reimbursement, and Growing Regulatory Burden</u>.



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

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

Contracts & Grants Administration (CGA)

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

Updated National Institute of Health (NIH) Policy on Foreign Subawards (NEW)

On May 1, 2025, NIH issued <u>NOT-OD-25-104</u>, *Updated NIH Policy on Foreign Subawards*, introducing a significant policy change regarding foreign subawards. The policy establishes a new award structure that prohibits foreign subawards from being nested under the parent award.

The research community has expressed significant concern regarding this new policy and proposed structure. The abrupt announcement, paired with the withholding of funding for projects with foreign subawards, has disrupted ongoing research and threatened project continuity, all without offering immediate solutions.

A central concern is the lack of detailed guidance, which raises significant questions about how recipients are expected to adapt their business processes and systems to ensure compliance, particularly given the time, resources, and coordination required for such transitions. The roles and responsibilities between the U.S. prime awardee and the linked foreign subaward also remain unclear. While the new structure suggests that foreign components should be treated as independent subprojects, there is considerable uncertainty about how this model will function in practice. It is unclear at this time how the roles and responsibilities are distributed between the prime awardee and the linked foreign subaward. It is unclear how key operational issues such as oversight of compliance activities (ex., IRB, IACUC), expectations around data sharing, publication, financial compliance, and more will be addressed. Moreover, it is unclear whether foreign subawardees will have the necessary infrastructure, administrative capacity, and systems in place to receive and manage NIH funding directly in compliance with NIH terms and conditions. Also, it is unclear how this policy will impact new proposals for upcoming NIH deadlines that include foreign components. While NIH has stated that foreign components may continue to be funded in the future as independent subprojects rather than subawards, critical details are lacking on how to proceed.

Key Aspects of the New Policy:

- **Independent Awarding of Foreign Subawards:** The new structure will award foreign subawards independently from the prime recipient, but the awards will be linked.
- Implementation Timeline: The new structure will 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 continuation awards.
- **Domestic Subawards:** NIH indicates that this structure will also apply to domestic subawards in the future, though specific timelines have not been provided.
- **Restriction on Awards with Foreign Subawards**: Effective with this policy, NIH will not issue awards to domestic or foreign entities (new, renewal, or non-competing continuation) that include a subaward to a foreign entity.
 - Essentially, withholding funding for awards with foreign subawards.
- **Prior Approval Requests**: NIH will no longer accept prior approval requests to add a new monetary foreign component or subaward to an ongoing project. However, prior approval requests for foreign components that do not involve funding can still be submitted.
- Scope of the Policy: The policy applies to all monetary foreign collaborations. It does not apply to funds provided to support foreign consultants, or purchasing unique equipment or supplies from foreign vendors. It also does not impact awards directly funded to foreign recipients.
- **Renegotiation of Awards:** NIH will permit NIH Institutes, Centers, and Offices (ICOs) to renegotiate awards (new, renewal, or non-competing) to remove subawards to foreign entities where the work can be performed domestically, allowing funds to be rebudgeted. If the project is no longer viable without the foreign subaward, NIH will permit recipients to negotiate a bilateral termination.

Considerations for Institutions:

- **Communication:** Notify impacted researchers of the new policy and develop a coordinated approach for communicating with NIH. Communicate early with Program Officers to discuss options for impacted awards and any instructions for addressing foreign subawards. Guidance may be provided to address in the RPPR.
- **Review & Inventory Portfolio:** Inventory the institution's award portfolio to identify impacted projects, particularly upcoming non-competing awards and associated Research Performance Progress Reports (RPPRs).
- **Develop Guidance for Ongoing Projects:** For ongoing projects, consider developing options for addressing the new policy. The guidance may include:
 - Evaluate whether the project can be performed with a domestic partner.
 - Consider options if the project can only be performed by the foreign subrecipient.
 - Explore restructuring the foreign subaward as a vendor or consultant, consistent with institutional policies.
- **Proposal Preparation:** Develop guidance for new proposals involving foreign subawards. Correspond early with Program Officers for instructions on including foreign subawards. Consider statements in the proposal to indicate that the project will follow NIH's policy and

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new structure for subprojects for foreign subawards. As the NIH policy did not specifically address proposals, it is unclear how the Center for Scientific Review (CSR) may evaluate proposals for compliance.

• Impacts of the New Structure: Assess the impacts of the new structure on institutional subaward processes, policies, agreements, and systems. Determine what communication is needed to notify foreign subawardees. Consider potential impacts if the subawardee may not be able to support the infrastructure of a direct NIH award. Evaluate how budgets might be impacted.

COGR has initiated discussions with NIH on the issue and will keep the community informed on developments. At this time, it is unclear if NIH will release additional guidance, such as FAQs, or engage in formal dialogue with the community regarding the new structure. COGR is assessing the potential impacts of the policy and operational realities and will monitor its implementation. Individuals interested in providing feedback or sharing information are encouraged to contact Krystal Toups at <u>ktoups@cogr.edu</u>.

Updated NIH Processes for No-Cost Extensions (NEW)

NIH has issued <u>NOT-OD-25-110</u>, announcing a temporary change in the process for requesting No-Cost Extensions (NCEs). Effective immediately, the NCE module in eRA Commons has been disabled. All NCE requests must now be submitted as prior approval requests through the eRA Commons Prior Approval module. The NIH Director instructed NIH staff to review all existing grants and cooperative agreements to ensure that NIH awards do not fund "off-mission activities" or projects.

The community has previously <u>reported</u> the temporary disablement of the NCE module, and COGR addressed this issue in its April 9, 2025, <u>letter</u> to NIH Director Jay Bhattacharya.

The duration of this disablement and the timeline for reinstating the NCE module remain unclear. deviates from the NIH Grants Policy Statement Section 8.1.2.1, which allows recipients the authority for a one-time NCE of up to 12 months beyond the original completion date specified in the Notice of Award. COGR continues to seek clarification on this matter to ensure that institutions can effectively manage their NIH-funded projects.

Revision: Notice of Updated Effective Date for the 2024 NIH Public Access Policy (NEW)

On April 30, 2025, the National Institutes of Health (NIH) announced an accelerated implementation timeline for the 2024 NIH Public Access Policy (<u>NOT-OD-25-047</u>). , moving the effective date from December 31, 2025, to July 1, 2025 . This policy supersedes the 2008 Public Access Policy and aims to enhance transparency and accessibility of NIH-funded research.

COGR has expressed concern regarding the expedited timeline, emphasizing that the revised date does not adequately consider the extensive public <u>comments</u> solicited in August 2024. COGR

issued a <u>statement</u> urging NIH to reinstate the original implementation deadline of December 31, 2025, to allow institutions sufficient time to adapt their compliance processes effectively.

In collaboration with other associations, COGR is actively reviewing the potential impacts of this accelerated implementation and is committed to keeping the research community informed of any developments.

Revolutionary FAR Overhaul (RFO) Initiative (NEW)

On May 6, 2025, the Integrated Award Environment (IAE) Industry announced a comprehensive initiative to overhaul the Federal Acquisition Regulation (FAR), aligning with Executive Order 14275, <u>Restoring Common Sense to Federal Procurement</u> and OMB Memorandum <u>M-25-25 Overhauling</u> <u>the Federal Acquisition Regulation</u>. The initiative aims to modernize federal procurement processes, enhancing efficiency and reducing administrative burdens.

The General Services Administration (GSA) will host a webinar on May 28, 2025, from 1:00 - 2:45 p.m. to discuss the contract consolidation requirements under Executive Orders. Registration for the webinar <u>here</u>.

Comments on the proposed changes for FAR <u>Part 1</u> and <u>Part 34</u> are due by September 30, 2025. COGR is reviewing the request for potential comments and welcomes input from the community. Those interested in providing feedback can reach out to Krystal Toups at <u>ktoups@cogr.edu</u>.

DOE Transparency of Foreign Connections (UPDATE)

COGR has previously reported (<u>September 2023</u> and <u>June 2023</u>) on DOE's Office of Research, Technology & Economic Security (RTES) Transparency of Foreign Connections requirements. Recently, DOE RTES released a collection <u>form</u> accompanied by definitions and instructions in an effort to ensure consistency across DOE components.

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.

Recission of NIH Implementation of the U.S. Government Policy for Oversight of DURC/PEPP & Implementation Update (NEW)

In response to the May 5, 2025, Executive Order, <u>Improving the Safety and Security of Biological</u> <u>Research</u> (see discussion under Administration Transition section of this update), NIH issued <u>NOT-OD-25-061</u> and rescinded its prior implementation (<u>NOT-OD-25-112</u>) of the ("2024 Policy") and announced the action that it was taking in response to the EO. Specifically, NIH stated that it would

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no longer accept competitive applications for grants/cooperative agreements or contract proposals for "dangerous gain-of-function research" as defined in the EO. As previously noted, the EO encompasses dangerous gain-of-function research that takes place in countries of concern, other foreign countries, and in the United States.

NIH announced that it would suspend funding of such research in accordance with the instructions set forth in the EO. This suspension of funding encompasses dangerous gain-of-function research in the United States, "at least" until OSTP develops new policy and guidance to replace the 2024 Policy. NIH instructed awardees to "review ongoing research activities to proactively identify potential dangerous gain-of-function research and identify safe action to halt such research and to effectively comply" with forthcoming OSTP policy/guidance.

In conversations, NIH noted that safe shut-down of this type of research often requires a long lead time. It strongly encouraged institutions to begin reviewing research protocols that may meet the EO's definition ahead of any termination notices that it may send regarding the termination of specific protocols. With respect to the types of information covered under the definition, any DURC and P3CO research will be subject to the funding pause. However, institutions may also want to continue considering how the now-revoked 2024 Policy would have applied to their research portfolio in the event the new OSTP policy/guidance also takes the tack of encompassing a broader scope of research than was covered under the pre-2024 DURC and P3CO policies.

NIH Implementation Update: Promoting Maximal Transparency Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NEW)

On March 28, 2025, NIH published <u>NOT-OD-25-082</u> stating that the Office of Science Policy (OSP) would publicly post the roster of all active Institutional Biosafety Committees (IBCs) registered with OSP using the IBC-Registration Management System. Members must be identified by name and committee role, and contact information must be provided for the IBC Chair, Biological Safety Officer and IBC Contact. In addition, IBCs will be expected to post approved meeting minutes on publicly available institutional websites for IBC meetings that take place after June 1, 2025. Minutes must be posted immediately after approval and inclusion of any allowable redactions.

NIH Rescinds its Final Scientific Integrity Policy (NEW)

In <u>NOT-OD-25-080</u>, NIH has rescinded the scientific integrity policy that it issued under <u>NOT-OD-24-178</u> to "ensure alignment with the Administration's priorities." Importantly, other policies cited with the rescinded final policy remain in effect (e.g., Federal Research Misconduct Policy, Public Health Service Policies on Research Misconduct), and NIH will adhere to the <u>HHS Scientific Integrity</u> <u>Policy</u>.

ARIO COGR Activities Regarding the New PHS Research Misconduct Regulations (UPDATE)

ARIO and COGR members have formed working groups to develop materials (i.e., templates, checklists, decision point lists) to assist institutions in complying with the new PHS Research Misconduct Regulations. Seventeen COGR and/or ARIO members are staffing the committees, and the groups plan to share materials as they are developed by publishing them on COGR and ARIO websites over the summer.

NIH and FDA Prioritization of Human-Based Research Technologies (NEW)

Both NIH and FDA recently announced initiatives to reduce the use of animal models research under their purview. On April 10, 2025, <u>FDA announced</u> that it planned to phase out its animal testing requirement for monoclonal antibodies and other drugs by replacing it with a "range of approaches" including the use of AI computational models and organoids for toxicity testing. FDA noted that implementation of the plan will begin immediately for investigational new drug applications, and it published a "<u>roadmap</u>" for reducing animal testing in preclinical studies. In response to this announcement, a <u>citizen's petition</u> has been filed with the FDA seeking the reinstatement of animal testing requirements in compliance with the ethical principles set forth in the Nuremberg Code that mandate that human experiments be based on results from animal experiments.

In a similar vein, NIH <u>announced</u> it is adopting "a new initiative to expand innovative, human-based science while reducing animal use in research" through the development and use of alternative research models. To lead this initiative, NIH is establishing the Office of Research Innovation, Validation, and Application (ORIVA) within the NIH Director's Office to coordinate efforts "to develop, validate, and scale the use of non-animal approaches across the agency's biomedical research portfolio and serve as a hub for interagency coordination and regulatory translation for public health protection." Another notable part of this initiative, is "mitigation training" for NIH grant review staff "to address any possible bias towards animal studies and integrate experts on alternative methods into study sections."

COGR will continue to closely follow developments in this area and impacts on IACUC and IRB operations.

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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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