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### President's Message: Summer in Overdrive

Dear Colleagues,

Thank you to all who were able to participate in the <u>June COGR Meeting</u> – our most attended inperson meeting. Being together to discuss the threats, challenges, and opportunities facing research institutions is critically important at this time. To that end, we look forward to <u>COGR Forum III</u> on July 23. We hope you are able to join us for this virtual convening and <u>welcome your questions</u> and suggestions in advance. COGR convenings guide and renew our collective efforts. I hope they provide you with a strong sense of purpose and togetherness as we defend our institutions' ability to conduct federally sponsored research and we advance effective research policy to bolster our nation's science and innovation enterprise.

Among COGR's top priorities is the threat posed by the policies imposed by four federal agencies placing a 15% cap on F&A cost reimbursement. COGR earlier this week hosted the fifth virtual townhall meeting on behalf of the <u>Joint Association Group on Indirect Costs</u> (JAG) to share the FAIR Model – a new approach to replace the current F&A cost structure and position the U.S. to remain the global science and innovation leader. This is critical effort in a highly charged political and policy environment. Your engagement with COGR and other JAG organizations in the legislative and regulatory processes in the weeks and months ahead is critical to achieving the best possible policy outcome. COGR member feedback and suggestions on the FAIR Model are particularly important to ensuring we nail down the nuances and details in the implementation of a new federal indirect costs policy. This issue is also playing out in the legal arena, and to that end, COGR co-led with NACUBO an amicus brief joined by 16 other organizations in support of the plaintiffs in the lawsuit to stop the NIH's 15% F&A reimbursement cap. We will consider other opportunities to weigh in on the lawsuits challenging other federal agencies' policies imposing a 15% cap.

Two other priorities I wish to highlight this month are: 1) pushing back on the duplicative and very burdensome "Defend the Spend" requirements, and 2) making the case for reducing red tape affecting federally sponsored research. In this month's COGR Update we are releasing a <u>new fact sheet</u> that not only identifies the problems with Defend the Spend, but solutions. Also, last month I spoke to the National Academies <u>panel</u> tasked with making recommendations to improve regulatory efficiency and reduce administrative burden. I shared COGR's <u>ideas</u> and <u>recommendations to OMB</u>.

While COGR's policy and advocacy efforts are in overdrive, we are also continuing efforts to strengthen the association. Since the <u>May COGR Update</u>, Howard University, Houston Methodist Academic Institute, Roswell Park Comprehensive Cancer Center, and Saint Louis University joined the association. COGR is also receiving applications for participation in the second year of the <u>Emerging</u> <u>Research Institutions Pilot Program</u> beginning August 1, and three institutions have been accepted – Kean University, Towson University, and University of North Carolina Wilmington – to join with the cohort of institutions that participated in year one of the pilot. Let me also note that we have completed the design phase to update the COGR website and we kickoff the development phase soon. Our target completion date is the end of the year.

Finally, I wish to recognize Theresa Colecchia of Johns Hopkins University for her six years of service on the COGR <u>Board of Directors</u> that will end this month. She has been critical contributor and invaluable collaborator while serving on the Board. We thank her for service on the Board and are grateful for her continuing contributions as a member of the Research Ethics & Compliance (REC) Committee.

Thank you for your engagement with COGR and for your continuing resolve and efforts in support of our collective agenda.

Matt Owens, President

#### July 2025 COGR Update



#### Announcements

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

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

Back for this meeting, we are pleased to offer a **\$125 discount for all registrations completed by September 5, 2025**. The discount will be automatically applied in the COGR Portal.

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

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

# COGR FORUM III: Adapting to Change, Policy Shifts & Research Impact on July 23

Continuing the conversation from COGR Forums I and II, attendees will hear from COGR leadership who will provide updates on litigation, executive orders, terminations and appeals, and more, followed by an Issues Forum of topics and questions from the membership. During the second hour, there will be a discussion on the FAIR model & the future of indirect cost reimbursement with time for QA. The agenda for this complimentary webinar on July 23 is now available and posted on COGR's <u>website here.</u>

<u>Register here</u> (you must be logged into the COGR Portal to register. Don't yet have account? Request <u>one here.</u>)

### Meet the Committees: Costing and Financial Compliance Committee Virtual EVENTS Open House on August 19

Curious about what CFC (COGR's <u>Costing & Financial Compliance Committee</u>) does? Ever wonder who serves on the CFC Committee or how you can get involved? Have questions or issues you think CFC should consider? Then, join us at our (virtual) Open House on August 19!

CFC considers a <u>wide range of topics</u>, including F&A cost reimbursement, single audit & compliance supplements, financial post award issues, 2 CFR 200, and more. If you have

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questions that you would like to be addressed, please send them to Cindy Hope at <u>chope@cogr.edu</u> by August 15. 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>)



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 is sent to the correct address. A copy of COGR's W-9 is <u>available here.</u>

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

### Reminders COGR Volunteer Survey

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

#### COGR Portal: Sign up for Access Today!

Did you know that all staff at COGR member institutions are eligible and encouraged to <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</u> <u>Member Directory</u>, check out COGR's Job Bank, and view other members-only materials.



#### COGR Job Bank – New Opportunities Posted, Now Publicly Available

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

COGR's Job Board is 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.

#### Upcoming Comment Due Dates

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

### 2025 Administration Transition Information and Resources

#### Recent Executive Orders of Note (UPDATE)

COGR continues to update the Summary of Executive Orders (<u>V.14, released July 14, 2025</u>), identifying those with the most significant impact on research activities and/or research funding. Many of the Trump Administration's Executive Orders are the subject of lawsuits and attendant temporary restraining orders and preliminary injunctions. These matters are discussed below in the <u>litigation update section</u>.

While the most significant EO to date were covered in the <u>May COGR Update</u>, several additional issued EOs issued since the Update may have an impact on federal funding priorities:

EO 14306, <u>Sustaining Select Efforts to Strengthen the Nation's Cybersecurity and</u> <u>Amending Executive Order 13694 and Executive Order 14144</u> (June 11, 2025) – This EO introduces a shift in the federal government's approach to cybersecurity, focusing on areas



such as secure software development, AI vulnerability management, and post-quantum cryptography, and away from areas like digital identity verification.

**EO 14307,** <u>Unleashing American Drone Dominance</u> (June 11, 2025) – This EO establishes a framework to accelerate U.S. leadership in both drone and electric vertical takeoff and landing (eVTOL) technologies. Specifically, for eVTOL technologies, the EO instructs the Secretary of Transportation to establish a pilot program to accelerate the deployment of aircraft.

**EO 14304** <u>Leading the World in Supersonic Flights</u> (June 11, 2025) – This EO instructs the FAA to repeal existing bans on overland supersonic flights and to issue a notice of proposed rulemaking to establish noise certification standards. The EO also instructs the Director of OSTP to coordinate supersonic research and development through NSTC with the goal of: (i) identifying research, development, testing, and evaluation (RDT&E) needs for regulatory development, commercial viability and operational integration into the National Airspace System; (ii) coordinating federally funded RDT&E at federal test sites; (iii) publishing RDT&E results to inform regulatory development and international science and technology engagement on civil supersonic matters.

**EO 14315, End Market Distorting Subsidies for Unreliable, Foreign Controlled Energy Sources (July 10, 2025)** – This EO requires the Secretary of the Interior to conduct a review of regulations, policies, guidance, and practices to determine whether any provide preferential treatment to wind and solar facilities in comparison to dispatchable energy sources, within 45 days of the enactment of the "Big Beautiful Bill" and to propose revisions to any regulations, guidance, polices, and practices that demonstrate preferences for wind and solar facilities.

In addition to the foregoing EOs, on May 23, 2025, the Trump Administration issued the following EO which has a significant impact on federal agencies' scientific integrity policies: **EO 14303,** <u>Restoring Gold Standard Science</u> ("RGSS EO") (May 23, 2025) – The RGSS EO's purpose is to ensure "that federally funded research is transparent, rigorous, and impactful, and that Federal decisions are informed by the most credible, reliable, and impartial scientific evidence available" to restore the public's trust in science. The purpose is similar to that set forth in the Biden's Administration's January 2021, "Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking," and both the RGSS EO and the 2021 Memorandum require(d) agencies to review and revamp their scientific integrity policies. However, the RGSS EO requires agencies to review actions taken between January 20, 2021, and January 20, 2025, to ensure alignment with the RGSS EO. It also instructs agencies to ensure these new scientific integrity policies encourage the open exchange of ideas, consider "different or dissenting viewpoints," and protect "employees from efforts to prevent or deter consideration of alternative scientific opinions."



The RGSS EO notes the "politicization" of science, particularly with respect to prior actions taken to incorporate "diversity, equity, and inclusion considerations" into "science planning, execution, and communications. However, the RGSS EO lacks the 2021 Memorandum's express directive that agencies "establish and enforce scientific-integrity policies that ban improper political interference in the conduct of scientific research and in the collection of scientific or technological data, and that prevent the suppression or distortion of scientific or technological findings, data, information, conclusions, or technical results."

The RGSS EO begins with a definitions section, that includes a definition of "scientific misconduct" patterned after the Public Health Service (Office of Research Integrity) definition of "research misconduct" at 42 C.F.R. §93.234. This reference raised concerns that the RGSS EO might affect the Office of Research Integrity's 2024 final rule on research misconduct [42 C.F.R. Part 93], and COGR raised this concern with ORI Director Sheila Garrity at a meeting in June. Director Garrity advised that ORU did not anticipate the EO would impact 2024 final rule or the sample research misconduct policy and procedures ORI published on June 4, 2025.

The RGSS EO requires the Director of OSTP to issue guidance for agencies on the implementation of "Gold Standard Science" for intramural and extramural scientific activities to ensure these activities are conducted in accordance with the following tenets:

- Reproducibility
- Transparency
- Communicative of error and uncertainty
- Collaborative and interdisciplinary
- Skeptical of findings and assumptions
- Structured for falsifiability of hypotheses
- Subject to unbiased peer review
- Accepting of negative results as positive outcomes; and
- Without conflicts of interest

OSTP issued this guidance with its publication on June 23 of the memorandum entitled "Agency Guidance for Implementing Gold Standard Science in the Conduct & Management of Scientific Activities" ("Memo"). The Memo discusses each of the foregoing tenets and includes the following agency directives:

- Establish incentives "to encourage researchers and institutions to prioritize reproducibility and replicability."
- Promote transparency regarding methodologies/data/analytical tools through the adoption and support of "data-sharing platforms," when feasible, and prioritize disclosure of funding sources/conflicts of interest.

- Encourage standardized formats for reporting uncertainty.
- Provide funding for replication studies and statistical validation methods and prioritize research that "is structured for falsifiability of hypotheses" and accepts negative results as positive contributions to the scientific enterprise.
- Promote unbiased peer review of "both research proposals and manuscripts" including reviewer selection that prioritizes "expertise, independence, and viewpoint diversity."
- Ensure science is conducted "without conflicts of interest" by requiring "researchers, reviewers, and managers to disclose all relevant affiliations, funding sources, and relationships relevant to the science conducted, adhering to stringent ethical standards support by strong institutional oversight, transparent reporting systems, and independent expert review mechanisms." Although the RGSS EO and Memo state that science should be "without" conflicts of interest," the Memo does discuss the need for agencies to adopt "clear and standardized protocols to identify, mitigate, and manage potential biases." [Emphasis added.]

Agencies must submit reports on their plans for implementing the RGSS EO to OSTP by August 22, 2025, as well as posting these reports on their websites. Subsequent reports to OSTP are due annually on September 1.

Each plan must include the following elements.

- A description of how the agency is addressing each tenet in agency culture, funding opportunities, budgets, resource allocation, award selection, reporting, and other activities relevant to the conduct and management of scientific activities.
- Metrics and evaluation mechanisms the agency will use to assess adherence to the tenets and their impact on scientific quality.
- Plans for training agency personnel on the tenets, including use of A-I tools when practicable.
- Descriptions of how technology will be leveraged to implement the RGSS EO and of any implementation challenges.

The RGSS EO also contains requirements for "Improving the Use, Interpretation, and Communication of Scientific Data," which includes a directive that agencies make available the following information in their possession:

Data, analyses and conclusions associated with scientific and technological information produced or used by the agency that will have "a clear and substantial effect on important public policies or important private sector decisions" along with the models and analyses (including source code) used to produce such information, with the exception of risk models used to guide enforcement actions.

Finally, the RGSS EO requires that each agency head designate a "senior appointee" who will be responsible for overseeing "internal processes" that the agency must develop to evaluate alleged violations of the EO and agency policies regarding the use, generation, interpretation, and communication of scientific information. This designee, may, but is not required to, "consult appropriate official with scientific expertise when establishing such processes." The processes must include measures to correct scientific information and forward potential violations to appropriate human resources personnel for disciplinary action. Further, the EO states that these processes will be "the sole and exclusive means" of evaluating violations of this order and related agency policies, unless otherwise required by law.

COGR will review the agency policies and processes that are developed in response to the RGSS EO and provide additional information and analysis in future updates.

# 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>litigation tracker</u> on the <u>2025 Administration Transition Information &</u> <u>Resources webpage</u> for periodic updates.] New cases and key updates from continuing cases are summarized below.

Recent U.S. Supreme Court Cases with the Potential to Impact Cases Concerning Research and Research Funding

• **Case Restricting Nationwide Injunctions** – <u>Trump v. CASA, Inc.</u>: The Supreme Court held that federal district courts likely DO NOT have equitable jurisdiction to enter nationwide injunctions. The Supreme Court granted a partial stay of the nationwide injunction that the district court placed on the EO limiting birthright citizenship, holding that that injunctions must not be broader than necessary to provide relief for each plaintiff with standing to sue. Notably, Justice Alito and Thomas' concurrence in the decision discussed two related issues that may be addressed in future Supreme Court rulings: (a) class certification for class action lawsuits and the scope of injunctions in such suits; and (b) third-party standing, such as when state attorney generals sue on behalf of the citizens of their state.

As a result of this decision, the government will likely contest nationwide injunctions that have been granted in other research funding cases. For example, in <u>Chicago</u> <u>Women in Trades v. Trump</u>, the district court issued a nationwide injunction ordering the Department of Labor to refrain from requiring ANY grantee or contractor to make any certification or other representation that it is in compliance with the DEI



EOs. After the decision in Trump v. CASA, Inc., the government filed a motion in this case for an indicative ruling and a partial stay of the preliminary injunction to limit the injunction only to the plaintiff, or at most to the plaintiff and entities with which it contracts. Similarly, in the case of <u>AAU v. DOD</u> regarding DOD's 15% indirect rate cost cap, the court requested that the parties brief the court on the relevance of the CASA case.

 Case Allowing State Prohibitions on Gender Affirming Treatment for Transgender Minors – <u>U.S. v. Skrmetti</u>: The Supreme Court upheld the Tennessee law that prohibits healthcare providers from prescribing/administering gender affirming medical treatments to transgender minors finding that the law did not trigger heighted scrutiny under the Equal Protection Clause of the 14<sup>th</sup> Amendment. Appellate proceedings in the cases of <u>State of Washington v. Trump</u> and <u>PFLAG, Inc.</u> <u>v. Trump</u>, which challenged EOs prohibiting funding to institutions providing gender affirming care to minors, had been stayed/held in abeyance pending a decision in *Skrmetti*. These cases will now proceed, and the appellate courts will consider how the Skrmetti decision applies to the facts of the cases before them.

New and Continuing Cases Regarding the 15% Indirect Cost Repayment Cap

- <u>New York v. NSF</u> (NEW CASE) At the end of May, the attorney generals for the states of NY, NJ, IL, HI, WI, OR, DE, CA, MA, NM, RI, WA, MD, CO, NV and CN filed suit asking the court to hold unlawful and enjoin (a) the NSF directive calling for termination of certain grants because of changes in NSF priorities ("Priority Directive"); and (b) the 15% indirect rate cost cap ("Indirect Cost Directive"). After hearing arguments on July 9, 2025, the court denied the plaintiff's motion regarding the Indirect Cost Directive and reserved judgment on the Priority Directive.
- <u>AAU v. DOD</u> (NEW CASE) On June 16, 2025, AAU, ACE, APLU, and several institutions of higher education filed suit challenging DOD's imposition of a 15% indirect rate cost cap. The court entered a nationwide TRO, and as previously noted, has requested that the parties provide briefs on the impact of the U.S. Supreme's holding in CASA Inc. v. Trump regarding nationwide injunctions.
- <u>AAU v. NSF</u> On June 20, 2025, the court entered a final judgment holding that the NSF 15% rate cap is invalid and vacating NSF's policy notice implementing the cap.
- <u>AAU v. DOE</u> At the end of June, the court entered final judgment for the plaintiffs on Counts I, IV, and VI of the suit. The court held that by imposing the rate cap, DOE



acted arbitrarily and capriciously and violated 2 CFR §200.414. The court entered an order vacating DOE Policy Flash 2025-22, which imposed the rate cap.

 NIH Indirect Rate Cap Cases – <u>AAMC v. NIH</u>, <u>AAU v. NIH</u>, <u>MA v. NIH</u> – A nationwide permanent injunction and final judgment was entered in these cases, and the government <u>appealed</u> the lower court's ruling to the First Circuit Court of Appeals. The government filed its response brief on July 1, 2025, and the court will hold oral arguments, if they are deemed necessary.

#### New and Continuing Cases Regarding Grant Terminations

 <u>Thakur v. Trump</u> (NEW CASE) – The plaintiffs in this case sought class action certification and a preliminary injunction on behalf of University of California system researchers whose previously approved grants from NSF, NEH, EPA, USDA, Americorps, DOD, DOEd, HHS, CDC, FDA, NIH, IMLS, Dept. of State, Dept. of Interior, and Dept. of Transportation were (or were threatened to be) terminated or suspended pursuant to EOs implemented through DOGE and federal agencies.

The court certified two classes of plaintiffs: (a) the Form Termination Class consisting of all faculty, staff, academic appointees and employees across the University of California system who are named as PIs, researchers, or project leaders on grant applications for previously awarded research grants from EPA, NSF, or NEH that were terminated by a form termination notice that does not provide a grant-specific explanation for the termination; and (b) the Equity Termination Class consisting of all faculty, staff, academic appointees and employees across the University of California system who are named as PIs, researchers, or project leaders on grant applications for previously awarded research grants from EPA, NSF, or NEH that were terminated per EO 14151 or 14173 from and after January 20, 2025.

The court vacated "form" grant termination by EPA, NSF, or NEH for the Form Termination Class and grant terminations under <u>EO 14151</u>, <u>Ending Radical and</u> <u>Wasteful Government DEI Programs and Preferencing</u> and <u>EO 14173</u>, <u>Ending Illegal</u> <u>Discrimination and Restoring Merit-Based Opportunity for the Equity Termination</u> <u>Class</u>. It also ordered these grants reinstated and entered a preliminary injunction preventing similar terminations. The government appealed this ruling to the Ninth Circuit Court of Appeals and requested that the preliminary injunction be stayed pending appeal.

• <u>American Public Health Association v. NIH</u> and <u>Massachusetts v. Robert F. Kennedy,</u> <u>Jr.</u> – On July 2, 2025, the court entered findings of fact, rulings of law, and a final order



for partial, separate and final judgment in these cases, which were combined for argument. The court declined to stay its judgment pending the government's appeal of the decision to the First Circuit Court of Appeals. The court's memorandum detailed the administrative record and factual and legal support for the court's finding that specified government directives and resulting grant terminations (as listed in the judgment) were void and set aside.

Cases Concerning Harvard University Grant and Student and Exchange Visitor Program Terminations

- <u>President and Fellows of Harvard College v. Dept. of Homeland Security (DHS)</u> The court granted a preliminary injunction enjoining the government from implementing DHS' revocation of Harvard's Student and Exchange Visitor Program and any adverse actions taken on the basis of this revocation. The government <u>appealed</u> the court's grant of this preliminary injunction to the First Circuit Court of Appeals.
- <u>President and Fellows of Harvard College v. DHHS</u> and <u>American Association of</u> <u>University Professors v. DOJ</u> – A July 21, 2025, hearing is scheduled on plaintiff's motion to set aside the payment freeze and grant terminations against Harvard. The plaintiffs contend that these actions are part of a campaign to unconstitutionally force Harvard to submit to government control of its academic programs and in violation of mandated due process.

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

In the case of <u>American Association of Colleges for Teachers Education v. McMahon</u>, the Court of Appeals stayed the district court's entry of a preliminary injunction as to teacher training grants pending the appellate court's decision on the appeal. In another case involving teacher training grants – <u>California v. DOEd</u> – the plaintiffs dismissed their appeal to the First Circuit Court of Appeals. The case has returned to the <u>district court</u>, where the government filed a motion to dismiss for lack of jurisdiction, or alternatively, to transfer the case to the U.S. Court of Claims. This motion was based on the <u>Supreme Court's opinion</u> in this case that it is unlikely that a district court has jurisdiction to order the payment of money under the APA.

Ongoing Case Regarding Removal of Information on Government Websites

Doctors for America v. Office of Personnel Management (OPM), CDC, FDA, and HHS: On July 2, 2025, the district court granted plaintiffs' motion for summary judgment in part and vacated the OPM and HHS memoranda which required the removal from government websites of information about clinical trials that are vital to medical professionals. The court

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ordered the plaintiffs to provide a list of all HHS websites and data sets they relied upon, and the government must restore these sites to their status prior to January 29, 2025.

COGR will continue to track new cases and developments in ongoing litigation pertinent to academic research institutions and update its litigation tracker on a regular basis.

### Agency Specific Actions (NEW)

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

<u>Agency Notices</u>: <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 NIH, DOE, HHS, NASA, DOL, ED, USAID, NSF, GSA, DOJ, CDC, and others. As agencies continue to issue guidance, we encourage members to share relevant communications with COGR at <u>memberservices@cogr.edu</u>.

<u>NSF</u>: Several institutions report receiving NSF awards with the following language regarding pertaining to <u>NSF policy</u> on indirect cost reimbursement.

The recipient must use a rate no greater than 15 percent of MTDC, as defined in 2 CFR § 200.1, for the life of the award, including the award period prior to notification of the application of this term. Excess indirect costs charged to an NSF grant due to use of an incorrect rate will be disallowed. This term and condition supersedes any previously submitted and/or approved budget.

The new policy applies "only to new awards made to IHEs on or after May 5, 2025," however institutions report receiving this notice in existing awards, including continuations and supplements.

COGR has contacted NSF for clarification and received the following response.

... The NSF policy notice on IDC rates for Institutes of Higher Education only applies to proposals and awards submitted after May 5, 2025. This policy does not apply to award administered prior to May 5, 2025, and since the same IDC rate applied to the initial award is also applied to supplements and continuations, the IDC rate will not change for supplements and continuations issued for awards originally administered prior to May 5, 2025. Please also note that as of May 19, 2025, NSF has paused implementation of the 15% IDC rate cap (outlined in NSF-25-034) pursuant to a consent agreement with the court. This pause will remain in place pending the outcome of a court hearing scheduled for June 13, 2025. During this period, NSF has



stated it will continue issuing awards based on institutions' federally negotiated IDC rates, not the 15% cap. A term that provides information on the deferred implementation is being added to awards issued during the pause...

NSF has stated this information is included in all NOAs for informational purpose. COGR has requested NSF to provide an FAQ on this point on the <u>NSF Priorities Webpage</u> for documentation purposes. COGR will update the community as new information is received.

NIH Closeout Requirements During Appeal of Termination (NEW)

On July 7, 2025, NIH issued Guidance on Enforcement of Closeout Requirements During the Appeals Process (NOT-OD-25-128). This guidance states that NIH will not initiate unilateral closeout while a recipient is waiting for a response to an appeal of a termination and directs recipients to, "disregard language within the termination letters and/or subsequent Notice of Awards requiring recipients to comply with closeout timelines that do not align with NIHs standard processes found in the NIH Grants Policy Statement, 8.6 Closeout that requires recipients to submit the final Federal Financial Report, final Research Performance Progress Report, and Final Invention Statement and Certification within 120 calendar of the end of the period of performance."

Additional costing considerations are discussed below in the Costing and Financial Compliance section.

Department of Education Notification to Grantees and Subgrantees of Assistance Under the Higher Education Act of 1965 of Updated PRWORA Interpretation of Federal Public Benefits (NEW)

Members report receiving a letter from the Department of Education ("2025 Letter") notifying grantees and subgrantees of the Departments interpretation of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA, P.L. 104-193). PRWORA is a 1996 law that established uniform eligibility criteria for many federal benefits that restricts the eligibility of "non-qualified aliens" (e.g., lawful permanent residents, asylees) to receive those benefits. [See, <u>Congressional Research Service</u>, "<u>PRWORA's Restrictions on Noncitizen Eligibility for Federal Public Benefits</u>: Legal Issues" (Sept. 3, 2020) ("CRS PRWORA Article")].

The 2025 Letter states:

The Department will issue a Notice of Interpretation rescinding portions of a 1997 Dear Colleague Letter that incorrectly classified certain programs as outside the



scope of PRWORA. The Notice of Interpretation clarifies that Federal programs administered by the Department that provide postsecondary education and other similar benefits to an "individual, household, or family eligibility unit," including the vast majority of postsecondary education programs authorized under the Higher Education Act of 1965, as amended; CTE programs under Perkins V; and adult education programs authorized under AEFLA are Federal public benefits subject to the citizenship verification requirements of PRWORA.

Notably, the 2025 Letter did not provide a citation to or link for the referenced 1997 letter, and the letter was not available on the Department of Education's website of historical Dear Colleague Letters for 1997 when accessed on July 17, 2025. [See, <u>U.S. Dept. of Education</u>, <u>Federal Student Aid</u>, <u>Dear Colleague Letters (Historical, 1997</u>)]. However, PRWORA's application to certain federal benefit programs can be unclear with regard to (a) laws in existence prior to PRWORA that contained specific eligibility criteria (e.g., federal student aid program under the Higher Education Act (HEA) ) that were not specifically repealed by PRWORA; (b) federal programs that provides benefit of a type not specifically referenced in PRWORA, but similar to reference benefit programs: and (c) benefits that were created after PRWORA's enactment. [CRS PRWORA Article, Summary section].

Accordingly, the 2025 Letter provides the current Department of Education interpretation of PRWORA's applicability. It states that PRWORA broadly applies to "Federal programs administered by the Department that "provide postsecondary and other similar benefits" to individual, household, and family "eligibility" units under the HEA. Further it states that PRWORA applies to postsecondary education authorized under the Strengthening Career and Technical Education for the 21<sup>st</sup> Century Act (Pub. L. 115-224 (2018), referred in the 2025 letter as "Perkins V") and adult education programs under the Adult Education and Family Literacy Act (Pub. L. 105-220 (1997) at Title II). Per this interpretation, institutions will be required to verify that recipients are U.S. citizens or "qualified alien," as described in the 2025 letters directive below:

As grantees and subgrantees of assistance authorized under the HEA who are engaged in the administration of Federal public benefits, your organization is responsible for ensuring that your programs are operating in compliance with the citizenship verification requirements of PRWORA. These verification requirements require that your agency or organization ensure that non-qualified aliens do not receive payment under your program, are not provided or receiving services funded by the program, and that non-qualified aliens are not able to access any Federal public benefit that may be imparted via these programs.

2025 Letter goes on to acknowledge that Dear Colleague Letters do not have the force of laws or regulations when it states:



While the interpretive rule is not binding on grantees, subgrantees, or the Department, it represents the Department's current interpretation of the law and may be used when taking enforcement actions.... The interpretive rule represents the Department's current position on the issue and **may be** referenced when enforcing or monitoring grantee and subgrantee compliance with PRWORA. The Department **may exercise** its enforcement discretion to seek to ensure that this citizenship verification is in use across all postsecondary education and other similar benefit programs covered under PRWORA. In general, the **Department does not have any plans to take enforcement actions against any grantee or subgrantee under PRWORA prior to August 9, 2025...**. The Department notes that, unless it is required by Departmental regulations, grantees have no **affirmative obligation to report on verification to the Department**. As an **interpretive rule, this guidance is not binding nor does it have an effective date**; rather, it informs the public, in addition to relevant stakeholders, of the Department's interpretation of the law. **[emphasis added]** 

Accordingly, institutions should consult with their general counsel prior in determining appropriate actions to take with respect to the 2025 Letter.

Questions on this notice can be directed to <u>Memberservices@cogr.edu</u>.

"Defend the Spend" – Inefficiencies in Federal Payment Processes Increase as a Consequence of EO 14222 (UPDATE)

As previously reported, changes to federal payment systems, processes, and requirements implementing <u>Executive Order 14222</u> — Implementing the President's "Department of <u>Government Efficiency</u>" <u>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.

COGR <u>developed an infographic</u> to highlight the excessive redundancy of "Defend the Spend" to assist with advocacy efforts. The fact sheet: Defend the Spend, *Waste and Inefficiencies Due to the New Grant Requirements*, addresses the problem of DOGE's implementation of Defend the Spend. It highlights approximately 53,749 hours of redundant work for recipients and agencies for information that is already accessible to agencies, documenting in detail where this information resides. The fact sheet highlights

tangible solutions the government can take to reduce burden, lower barriers, and engage with the community.

The Fact Sheet is the first in a series by COGR that will feature the significant issues posed by new policies established by the administration. This and future fact sheets are intended for use by COGR members in their discussions within the community and policymaker to communicate the significance of new requirements and their impacts on research.

Please direct questions, feedback, and/or suggestions for new fact sheets to Krystal Toups at <u>ktoups@cogr.edu</u>.

# Administration Transition Impact Survey, Part II – Final Survey Results (UPDATE)

At the June 2025 COGR meeting, COGR provided preliminary results from its Transition Impact Survey, Part II. The survey remained open for an additional two weeks after the meeting, and the final survey results are detailed in the slide deck posted on the <u>COGR</u> <u>website</u>. These slides include detailed breakdowns of survey responses shown in graphs, tables, and infographics. Key findings from the survey are summarized below:

**Survey Demographics:** The survey was open for response by COGR member institutions from May 20 to June 23, 2025, and 63 complete responses were received. Sixty-five percent of responders are public institutions. Thirty percent (30%) are located in the Northeast, with the remainder being fairly evenly distributed across the Southeast, Midwest, and West and a small number in the Southwest. Nearly 60% of responders had between \$51 - \$499M in annual federal R&D expenditures on the 2023 NSF HERD Survey and 27% had over \$500M.

#### **Major Survey Themes:**

Prevalence of Grant/Contract Terminations – Nearly 100% of responders reported: (a) receiving a request from one or more federal agencies to provide additional information for a payment request on a grant or contract; and (b) having a grant and/or contract terminated by the government "for convenience." Over one-half of responders reported that such terminations encompassed 21 to over 50 grants, and almost 60% responded that the total balance remaining on terminated grants/contract was over \$5 million. NIH led the pack in terminations, with NSF and USAID coming in second and third. Eighty-five (85%) percent of responders appealed/objected to/sought waivers for terminations, and 64% used institutional funds to continue the research supported by the terminated awards. The most common appeals strategies focused on providing justification for how awards support agency priorities, challenging the application of the termination, and eliminating problematic key words or elements.

- **Prevalence of Payment Rejections**: In addition to terminations, nearly 80% of responders reported that a grant or contract payment was paused/rejected/not reimbursed "due to insufficient detailed justification for payment." Of the institutions that received rejections, 37% spent 15-45 hours and 28% spent more than 45 hours responding.
- **15% Indirect Cost Cap Will Harm Federally Funded Research**: Ninety-one (91%) percent of responders reported that the rate cap will "definitely" or "likely" impact their engagement in federally funded research with 77% reporting an anticipated reduction in their federal research portfolio.
- Federal Grant/Contract Terminations, Rate Reductions, and Other Recent Federal Research Funding Changes will have Substantial Negative Impacts on Research Institutions: Forty-two (42%) percent of responders have implemented or plan to implement Reductions in Force (RIFs). Of those institutions, 45% anticipated that RIFs would impact less than 5% of the research/administrative workforce, while 40% expect RIFs will affect 5-10% of their research/administrative workforce. Thirty-five percent (35%) of responders reported recent federal actions have had other substantive impacts including program/project terminations, budget reductions, hiring freezes, fewer graduate students and post-docs, and travel restrictions.

COGR will continue to closely monitor the nature and extent of these impacts on academic research institutions and use the information it collects in its advocacy efforts.

### **Science & Security: Cross-Cutting Issues**

NSF Issues Notice on Updates to Research Security Polices (NEW)

On July 10, the National Science Foundation (NSF) Office of the Chief of Research Security Strategy and Policy issued <u>Important Notice No. 149</u>, "Updates to NSF Research Security Policies," outlining new and revised requirements for awardee institutions. These updates respond to Congressional mandates and Executive Orders and build on prior research security initiatives that NSF notes are already showing positive results.

#### Three of the six policies covered by the Notice take effect on October 10, 2025.

**Research security assessments**. NSF may conduct research security assessments of proposals and awards to assess the accuracy and completeness of senior/key personnel's (Key Personnel) disclosures related to current and other pending support. Supporting documentation, including contracts, grants, and other agreements related to foreign appointments, employment with foreign institutions, participation in foreign talent

programs, and all other "current and pending" support must be maintained by the university and provided to NSF upon request.

**Research security training.** NSF will require research security training certification for Key Personnel. A university may use training of its choice provided that such training addresses cybersecurity, international collaboration, foreign interference, conflicts of interest and commitment, and proper use of funds and disclosure.

Authorized Organizational Representatives (AORs) must certify that Key Personnel completed training within 12 months prior to proposal submission. The NSF SECURE Center has developed an <u>updated and condensed version of the research security training (RST)</u> modules that is designed to meet the government-wide RST requirements.

For Institutions of Higher Education (IHE), AORs will continue to be required to certify that the institution has a procedure to provide responsible and ethical conduct of research (RERC) training to any personnel conducting NSF-supported research. Such training must address mentor training and mentorship, awareness of potential research security threats, and Federal export control requirements.

**Confucius Institute Certifications.** NSF prohibits funding to institutions maintaining contracts with Confucius Institutes, unless a waiver is granted. To qualify, institutions must demonstrate: (1) protection of academic freedom, (2) no application of foreign law on any campus, (3) complete institutional control of the Confucius Institute, and (4) separation from the institution's Chinese language, history, and cultural programs.

AORs must certify the absence of any contract or agreement between the institution and a Confucius Institute, unless a waiver has been obtained. Institutions seeking a waiver or renewal must submit a request to <u>researchsecurity@nsf.gov</u>, including a description of the Confucius Institute and how each of the four criteria is met.

The Notice also covered three policies already in effect.

Malign Foreign Talent Recruitment Program (MFTRP) Prohibition. Individuals currently associated with MFTRPs are ineligible as senior/key personnel on an NSF proposal or any NSF award made after May 20, 2024.

**MFTRP Certification.** AORs are required to certify that all individuals on a proposal identified as Key Personnel have been made aware of their responsibility to certify that they are not, individually, a party to an MFTRP. Key Personnel must also make a pre-award certification that they are not party to an MFTRP.

Key Personnel serving as principal investigators or co-PI must resubmit annual post-award certifications via Research.gov.

**Foreign Financial Disclosure Reporting.** NSF implemented its annual Foreign Financial Disclosure Reporting (FFDR) requirement last year. Under the FFDR, IHEs receiving direct funding support from NSF must report all foreign financial support of \$50,000 or more from countries of concern, including gifts and contracts, received directly or indirectly. Reporting covers all affiliated entities, with tuition payments excluded unless structured as grants or contracts.

<u>Reports from July 1, 2024, through June 30, 2025, are due in Research.gov between</u> <u>September 1 and October 31, 2025</u>. Records must be retained for three years following the date of submission, unless otherwise specified by the award terms and conditions or required due to a pending audit or investigation. NSF may request supporting documentation and intends to make disclosure data publicly available, except for protected fields under federal law.

### GAO Publishes OSTP Open Recommendations (NEW)

On June 10, 2025, the General Accountability Office (GAO) sent a <u>letter</u> to Michael Kratsios, the Director of the Office of Science and Technology Policy (OSTP), highlighting four areas of concern tied to open priority recommendations: strengthening advanced manufacturing, ensuring access to critical materials, **addressing research security risks**, and fostering infrastructure resilience.

In the letter, GAO referenced its January 2024 report titled <u>Research Security:</u> <u>Strengthening Interagency Collaboration Could Help Agencies Safeguard Federal</u> <u>Funding from Foreign Threats</u>. The report included a single recommendation calling on OSTP, in coordination with federal research and development awarding agencies, to improve interagency information sharing related to foreign ownership, control, or influence (FOCI). GAO suggested this effort could build upon OSTP's then-existing efforts to implement National Security Presidential Memorandum 33 (NSPM-33).

As of February 2025, GAO reported that OSTP has not provided an update on the status of this recommendation.

### Congressional Research Service Report on Federal Research Security (NEW)

The May 2025 Congressional Research Service (CRS) report, <u>Federal Research Security</u> <u>Policies: Background and Issues for Congress</u>, outlines a key challenge in U.S. science and technology policy: how to safeguard national interests while maintaining the openness and international collaboration that have long characterized the U.S. research system. As the report clearly states, this openness, marked by an effective peer review process, public access to federally funded research, and robust international collaborations, has solidified the nation's status as a global leader in innovation and the destination of choice for top scientific talent worldwide.

However, the report also describes how heightened concerns about malign foreign influence, particularly from countries of concern, have led U.S. policymakers to reassess the vulnerabilities associated with this openness, prompting increased policy action. The report notes risks such as intellectual property theft, espionage, and efforts to exert undue foreign influence over research activities. In response, the federal government has introduced a series of research security policies, including disclosure requirements, restrictions on foreign talent programs, and expanded reporting obligations.

CRS emphasizes that this is not a zero-sum choice between national security and scientific freedom. Instead, the report advocates for a more balanced approach, one that mitigates foreign risks without undermining the collaborative, open environment essential to scientific discovery. CRS outlines several challenges associated with these evolving policies. Chief among them is the lack of clarity and consistency in disclosure requirements across federal agencies, which creates confusion among researchers and administrative burdens for institutions. The report notes that without clear, standardized expectations, researchers may inadvertently under- or over-disclose, and institutions may struggle to maintain compliance across a fragmented regulatory landscape. In addition, the administrative burden of interpreting and implementing these requirements falls heavily on universities, which must develop internal systems, train personnel, and ensure ongoing compliance with federal policies that are often inconsistent or not harmonized across agencies. CRS also flags concerns about the potential chilling effect these policies may have on legitimate international collaboration, especially if researchers fear misinterpretation or punitive responses to appropriate partnerships.

To address these challenges, CRS offers several considerations for Congress. First, it suggests refining rather than expanding existing research security frameworks, emphasizing the need for clear guidance, consistent standards, and risk-based implementation. CRS encourages Congress to evaluate whether current agency policies are appropriately tailored to specific fields, research stages, or technology areas, and whether those policies are proportional to the risks they aim to mitigate. Additionally, the report recommends that federal agencies be equipped with the necessary administrative capacity and technical infrastructure to manage compliance effectively.

The report also calls for ongoing congressional oversight to monitor the effects of these policies. This includes examining how disclosure and security requirements impact institutional operations, researcher behavior, and international collaborations. CRS suggests that independent evaluations and stakeholder input from universities, researchers, and professional associations are critical to ensuring that policy goals are being met without undermining scientific progress. Policymakers are encouraged to consider the perspectives of the research community when shaping future legislation.

The sustainability of U.S. scientific leadership, the report argues, will depend on federal efforts to safeguard national interests while still supporting the open, collaborative environment that has driven decades of innovation.

#### USDA Research Security Memorandum (NEW)

On July 8, 2025, the Secretary of Agriculture published <u>Secretary's Memorandum SM 1078-014</u>, <u>America First Memorandum for USDA Arrangements and Research Security</u>. The memorandum outlines requirements for a USDA-wide review of all arrangements/sub-arrangements with foreign persons/entities; lists prohibitions regarding relations with foreign countries/entities for USDA employees and affiliates; and sets forth research-security related disclosure and certification requirements for recipients of USDA R&D and science and technology (S&T) awards, similar to those in place at other federal agencies.

The memorandum directs all USDA units to identify and compile a list of any arrangements (including sub-arrangements) with "any foreign person or entity or any U.S. citizen or entity subject to foreign ownership, control, or influence (as defined in 32 CFR 117.11 and 20004.34)" ("Foreign Arrangements") for submission to the USDA Office for Homeland Security, Office of the General Counsel, and Office of the Chief Scientist ("Offices"). The list must include the details and objectives of each project, along with a justification as to why a U.S. recipient was not selected. Once the list is received, the Office recommendation will provide recommendations to the Secretary of Agriculture as to whether an arrangement should be terminated. Additionally, USDA units are prohibited from entering into any Foreign Arrangements "or extending letters of invitation" to participate in a Foreign Arrangement unless and until a justification for the Foreign Arrangement is approved by the Offices. The justification must including information about how the arrangement will benefit the US, whether there is a qualified US person/entity to carry out the project, and if so why they were not selected; the benefits afforded by the foreign recipient; whether the foreign recipient "received any funding from a country of concern or other foreign adversary for the proposed activity or related area in the last five years."

The memorandum places certain requirements on USDA recipients of R&D or S&T funding that are similar to research security requirements put in place by NIH, NSF, and other research funding agencies. The USDA memorandum requires the "employing entity of a recipient entering into an arrangement with USDA related to R&D or S&T" to:

- Prohibit applicants who are currently participating, or have within the past 10 years participated in malign foreign talent recruitment programs (FTRPs) from working on USDA-funded awards;
- Certify each employee applicant listed on the funding application has been made aware of the memorandum's requirements and has completed required research security training.



- For all applicants in an application, provide USDA with any supporting documentation (e.g., copies of grants, contracts) specific to foreign appointments, employment with a foreign institution, participation in a FTRP, and/or information reported as current and pending support.
- Review any documents required under this memorandum for compliance with USDA award terms and conditions, including guidance on conflicts of interest/commitment.

Failure to follow these requirements may result in termination of funding and/or other enforcement actions.

Finally, the memorandum prohibits USDA employees and affiliates from entering into any relations or arrangements with foreign adversaries and specified countries of concern, including "providing material or non-material benefits through the provision of funded or unfunded work" to any foreign person/entity or U.S. person/entity subject to ownership, control, or influence by a country of concern or foreign adversary (COC/FA) without Secretarial approval. It also restricts USDA employees/affiliates from certain activities including participation in FTRPs, travel to a COC/FA or acceptance of funding for such travel, and authoring/co-authoring scholarly publications in their official capacity with a foreign national without prior USDA approval.

# NSF SECURE Center Launches New Website and Initial Research Security Products (NEW)

As highlighted in COGR's <u>May Update</u>, the SECURE Center launched its consolidated training module (CTM 1.0) in June. The one-hour research security training module consolidates and combines the four federal modules, expanding on information related to malign foreign talent recruitment programs and foreign travel security. It incorporates details on cybersecurity and insider threats, while also enhancing design consistency and usability. This training module is explicitly referenced in NSF's Important Notice No. 149 as a training module that meets all the government-wide research security training requirements (see above for a summary of the Notice). CTM 1.0 can be accessed at <u>www.secure-center.org</u>.

In addition to the new training module, Research Security Briefings are now available at the SECURE Center website. The briefings are meant to serve as a "one-stop shop" for research security-related information, including new statutory requirements, federal agency notifications, community resources, any significant news, and relevant scholarly works. The first briefing was published on June 25<sup>th,</sup> with a second issue posted on July 10, 2025. It is anticipated that issues will be posted between 2 and 4 times a month unless pertinent information dictates a special publication.

The SECURE Center is also developing a shared virtual environment (SVE) that will house resources addressing challenge areas, including risk assessment tools, managing federal risk matrices, developing foreign travel briefings, secure virtual community forums, and navigating agency risk expectations and mitigation strategies. The SVE will be available to a small cohort of research security officers, researchers, and other subject matter experts for testing in September 2024.

#### NIH Requirement for Disclosure Training (NEW)

On July 17, NIH issued <u>NOT-OD-25-133</u>, "NIH Announces a New Policy Requirement to Train <u>Senior/Key Personnel on Other Support Disclosure Requirements.</u>" Effective October 1, 2025, NIH award recipients must have a written and enforced policy on Other Support disclosure requirements and provide faculty and researchers identified as Senior/Key Personnel with training "on the requirement to disclose all research activities and affiliations (active and pending) in Other Support." The notice states that Senior/Key Personnel must "fully understand their responsibility to disclose all resources made available to the researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant." The notice does not specifically state that the <u>NSF developed research security training modules</u> will suffice to meet this training requirement, but it does list those modules (which encompass disclosures in Module 2) as a resource.

### **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)

Accelerated Examination for Utility Applications Discounted. Beginning July 10, 2025, the U.S. Patent and Trademark Office (USPTO) will no longer accept petitions under the <u>accelerated examination program</u> for utility applications. According to the USPTO, the office received fewer than 100 applicants between 2014 and 2024, and this action will free up resources to focus on older, unexamined utility applications. The expedited process will remain in effect for design patent applications.

**Statutory Penalties for False Certifications of Small or Micro Entity Status.** The <u>USPTO</u> <u>announced</u> in June that it had begun implementing a comprehensive enforcement system for false assertions of small entity and micro entity fee status. Legislation passed in

2023 added penalty provisions to  $35 \text{ USC } \S 41(j)$  for small entity violations and  $35 \text{ USC } \S 123(f)$  for micro entity violations. The statute provides for a penalty of not less than three times the amount the patent applicant failed to pay as a result of the false certification.

When the USPTO makes a preliminary determination that a pending patent application or issued patent includes a false claim of entitlement to reduced fees, resulting in at least one improperly reduced payment, it will issue a combined notice of payment deficiency and an order to show cause explaining why a fine should not be imposed. After considering any timely responses from the applicant, the USPTO will issue a final notice specifying the amount of the fine, as applicable.

**Increase in Requests for Prioritized Examination Final Rule Issued.** Under the America Invents Act, the USPTO established a prioritized examination program for patent applications commonly referred to as "Track One". Under Track One, applicants typically receive a first office action within 2 to 4 months, with the goal of a final disposition determination within one year of the prioritized status being granted by the USPTO.

In response to receiving over 15,000 requests for prioritized status in FY2024, the USPTO will raise the limit to 20,000 requests per fiscal year starting in FY2025 (note: FY2025 ends on September 30, 2025). This increase is the third time that the USPTO has raised the request cap, doubling the initial limit of 10,000 requests that was in place until 2019.

The USPTO determined that this increase in the limit is a procedural change that does not affect the criteria of patent matter eligibility and, as such, does not require a public notice or comment period under the Administrative Procedure Act. The <u>final rule</u> was issued on July 8, 2025.

### GAO Issues Report on the Bureau of Industry and Security (NEW)

On June 26, 2025, the Government Accountability Office (GAO) released a report titled "*Export Controls: Commerce Should Improve Workforce Planning and Information Sharing.*" The report found that the Bureau of Industry and Security (BIS) lacks a comprehensive long-term strategy to assess its workforce resource needs. Additionally, the GAO identified ongoing challenges with information sharing during interagency export license reviews conducted by the Departments of Defense, Energy, and State, which undermine the overall integrity and effectiveness of the review process.

According to the report, the success of interagency reviews relies heavily on the timely, complete, and seamless sharing of information—a key internal control principle outlined in the Export Control Reform Act of 2018. Ensuring that all reviewing agencies have prompt access to all relevant information improves the quality and consistency of evaluations.

The report also emphasized the importance of BIS consulting with the reviewing agencies before modifying or removing license conditions. Moreover, issuing updated guidance on the appropriate use of license conditions would reduce ambiguity, improve procedural efficiency, and limit the number of disputes that require escalation.

Based on these findings, GAO issued four recommendations as part of the report:

- (i) The Department of Commerce should conduct a long-term assessment of BIS's workforce requirements.
- (ii) BIS should ensure that the reviewing agencies have full access to all relevant information during the interagency review process.
- (iii) BIS should consult with the reviewing agencies before modifying or removing any export license conditions recommended by them.
- (iv) BIS should collaborate with the reviewing agencies to establish clear, written guidance for the use of export license conditions.

The report states that the Department of Commerce agreed with all four recommendations.

# Federal Acquisition Regulation: SBIR & STTR Proposed Rule Withdrawn (UPDATE)

On April 7, 2023, the Department of Defense, General Services Administration, and National Aeronautics and Space Administration proposed amendments to the Federal Acquisition Regulation (FAR) to clarify and harmonize data rights provisions under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs (<u>88</u> <u>FR 20822</u>). The proposed changes were intended to address concerns about the data rights afforded to grant awardees.

However, following the issuance of <u>Executive Order 14275</u> on April 15, 2025, the proposed rule was withdrawn on June 12, 2025. EO 14275 instructs the Administrator of the Office of the Federal Public Procurement Policy, in coordination with the FAR Council, to review and revise the FAR to ensure it includes only provisions that are required by statute or that serve to enhance simplicity, usability, procurement efficiency, or national and economic security.

The <u>withdrawal notice</u> indicated that any future amendments will depend on the reform actions taken under Executive Order 14275.

### NSF Issues Information Collection and Innovation Announcements (NEW)

**Directorate for Technology, Innovation and Partnerships Core Technology Areas.** NSF issued a <u>Request for Information</u> (RFI) soliciting input from stakeholders to support the review and potential update of the key technology focus areas prioritized by the NSF's Directorate for Technology, Innovation, and Partnerships (NSF TIP).

Established under the CHIPS and Science Act of 2022, the TIP Directorate is tasked with advancing U.S. leadership in critical and emerging technologies. The legislation identified ten initial focus areas for TIP investment and directed the directorate to review and update these priorities annually, as needed.

Through this RFI, the NSF is requesting feedback on three key questions: (1) should any of the ten current technology areas be refined or revised; (2) are there any areas that should be removed from the list; and (3) are there additional areas that merit inclusion. Respondents are encouraged to consider these questions in the context of achieving specific goals related to global competitiveness, economic growth, national security, workforce development, and technology transfer.

The RSIP committee is reviewing the RFI and is in discussion with our partner associations about a joint letter of support for the current core technology areas. The deadline for interested COGR members to respond is July 21, 2025.

**Breakthrough Innovations Initiative Application.** NSF TIP is also implementing a new data collection process tied to the application form for its new program, the Breakthrough Innovations Initiative ("Initiative"). The application form will gather key applicant information, such as contact details, professional affiliation, and a technical proposal, to support funding decisions. Applicants will also be asked to submit a description of their proposed idea, addressing how it aligns with the Initiative's technical goals, potential integration into broader systems, the current maturity of the technology, along with a budget, timetable, and biographical details describing the team's expertise.

Applicants must also complete a certification section disclosing any affiliations with foreign talent recruitment programs or funding from foreign countries of concern. The notice states that all collected data will be used solely for decision-making, due diligence, auditing, and legal oversight.

This Initiative is modeled after the process used by the German Federal Agency for Disruptive Innovation (SPRIND) for their challenge prize program, with the hope of reducing administrative burden and accelerating timelines for selecting translational research projects.

In October of last year, NSF TIP and SPRIND signed a <u>Memorandum of Understanding</u> to collaborate on accelerating the selection and performance of translational research projects using the SPRIND Challenge Model.

<u>Comments</u> on the application form for the Breakthrough Innovation Initiative are due September 2, 2025. The RSIP committee is reviewing the RFC to determine if a comment letter is warranted. COGR members are welcome to contact Kevin Wozniak, Director, Research Security & Intellectual Property at <u>kwozniak@cogr.edu</u> in the interim with any comments or concerns on the proposed application form.

#### July 2025 COGR Update



**Innovation Corps Program RFC.** NSF issued a notice of intent and request for comment (RFC) seeking approval to renew its information collection for the Innovation Corps (I-Corps) Program (Document Number 2025-11079). The purpose of this collection is to monitor and evaluate the outcomes of I-Corps-funded teams, assessing the program's impact on training an entrepreneurial workforce, translating technologies from academic laboratories to the marketplace, nurturing an innovation ecosystem, and facilitating regional economic development.

The data collection will include surveys, interviews, focus groups, and other methods to gather information about team composition, customer discovery, technology demonstrations, funding sources, patents, licenses, and other commercialization outcomes.

As RSIP reviews this RFC, COGR members are welcome to contact us with any comments or concerns about the information being collected and the renewal of this collection by the NSF I-Corps program. Comments are due August 15, 2025.

**SBIR/STTR Pre-Award Information RFC.** NSF is also seeking approval to renew its preaward information collection for the SBIR/STTR program. The data that NSF is seeking to continue to collect is from a subset of applicants who have already been reviewed and are being considered for funding. The collected information includes a list of company officers, associations with other companies, conflicts of interest, and locations of all research facilities to be used during the performance of the project. A list of questions related to foreign influence disclosure will also be included in the questionnaire.

Written comments in response to this <u>notice</u> are due September 2, 2025. The RSIP committee is currently reviewing the notice.

### DOD Updates Research Security Decision Matrix (UPDATE)

As reported in the <u>COGR May Update</u>, the DOD released an updated version of its <u>Decision</u> <u>Matrix to Inform Fundamental Research Proposal Mitigation Decisions</u>. 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.

During the COGR June meeting, members of the REC and RSIP Committees met with Jesse Watkins, Deputy Director, Security and Intelligence Directorate from the Defense Advanced Research Projects Agency (DARPA). During that conversation, he was able to

clarify that DARPA expects all qualifying patent activities in non-U.S. jurisdictions need to be disclosed during the pre-award process with any accompanying mitigation measures.

### Costing and Financial Compliance (CFC)

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

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

The Joint Associations Group on Indirect Costs (JAG) presented its Financial Accountability in Research (FAIR) model during a <u>townhall</u>, hosted by COGR on July 15. The JAG proposed the FAIR Model as an alternative to the current model for reimbursement of indirect costs. As background, the JAG was formed in April 2025, by ten "national organizations representing America's academic, medical, and independent research institutions." The JAG announced a <u>Joint Effort to Develop a New Indirect Costs Funding Model</u>, engaging a team of <u>Subject Matter Experts</u>, to explore other models for reimbursement and improvements to the current model. <u>Recordings</u> of this and four earlier webinars, held to share progress and receive feedback, are available.

The FAIR model uses three overarching categories for expenses:

- 1. Research Performance Costs (RPC) Expenses classified currently as direct costs, such as research personnel and supplies.
- 2. Essential Research Performance Support (ERPS) Expenses generally classified currently as indirect costs but that could, absent current restrictions, be allocated directly to awards. Four subcategories comprise the ERPS category:
  - Regulatory Compliance (RC)
  - Award Monitoring, Oversight and Reporting (AMOR)
  - Research Information Services (RIS)
  - Essential Research Performance Facilities (ERPF)
- 3. General Research Operations (GRO) Expenses generally classified currently as indirect costs and that continue to be impractical to allocate directly to awards, such as HR, payroll, procurement and other services necessary to conduct research but supporting all institutional activities.

The FAIR model offers a Base option, which provides funding for GRO at 15% of total budget/cost and RIS plus ERPF at 10% of total budget/cost. Under the Base option, institutions also may calculate and apply direct charge fees/rates for RC and AMOR. Under an Expanded option, institutions may calculate direct charge fees/rates for all ERPS categories, while receiving a flat 15% of total budget for GRO.

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A <u>summary</u> of the model and a set of <u>frequently asked questions</u> is available and a more detailed guidance document is under review by the JAG.

The JAG proposed its new model in recognition of 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.

While the ongoing legal challenges to recent attempts to cap Facilities and Administrative (F&A/indirect) cost reimbursement could succeed, the outcome is uncertain. Those attempts are described in the May <u>COGR Update</u> and the status of the litigation can be found in COGR's <u>lawsuit tracker</u>. Also, further attempts by the federal Administration to limit F&A cost reimbursement are anticipated. For example, as previously <u>reported</u>, OMB is working on revisions to 2 CFR 200, including language regarding indirect cost reimbursement, but has not yet provided a specific timeline for release of its revisions.

In support of legal challenges to caps on indirect cost reimbursement, on June 16, COGR joined NACUBO and sixteen other organizations in an <u>amicus brief</u>, "supporting community appeal of indirect cost reimbursement rate cap". COGR will continue to work with our partner associations to support research, dispel myths, and combat misinformation. Institutions should continue to communicate accurate information about the activities and costs necessary to support research and the required processes research institutions must follow to receive reimbursement of these F&A costs. COGR's <u>F&A Cost Reimbursement</u> <u>Materials</u> webpage is a compilation of information, resources, and tools created to assist with effective communication on F&A costs.

The third COGR Forum on Adapting to Change, Policy Shifts & Research Impact, on July 23, 2025, will include additional time to allow for a discussion devoted to COGR's approach to assessing the FAIR model and identifying practical implementation options. COGR members are encouraged to assess how the FAIR model might be implemented, including 2 CFR 200 language that could ensure OMB and federal funding agency acceptance of practical approaches to implementation.

While the FAIR model took just a few months to develop, implementation details will take much longer. COGR will remain alert to opportunities to improve on the FAIR model, including through implementing language. To that end, COGR will continue to seek input from the membership and keep it posted on new developments.



F&A Cost Reimbursement – Legislative Update: The Senate Armed Services Committee addresses F&A cost reimbursement as it works on the FY26 National Defense Authorization Act. The bill language prohibits the Secretary of Defense from changing F&A cost rates for DOD grants and contracts until such time the Secretary certifies that department has worked with extramural research community to develop an alternative indirect cost model. The bill (S. 2296) states:

SEC. 226. PROHIBITION ON MODIFICATION OF INDIRECT COST RATES FOR INSTITUTIONS OF HIGHER EDUCATION AND NONPROFIT ORGANIZATIONS.

(a) PROHIBITION.—The Secretary of Defense may not change or modify indirect cost rates (otherwise known as facilities and administration cost rates) for Department of Defense grants and contracts awarded to institutions of higher education and nonprofit organizations (as those terms are defined in part 200 of title 2, Code of Federal Regulations) until the Secretary makes the certification described under subsection (b).

(b) CERTIFICATION.—A certification under this sub-section is a certification to the congressional defense committees that the Department of Defense—

(1) working with the extramural research community, including representatives from universities, university associations, independent research institutes, and private foundations, has developed an alternative indirect cost model that has—

(A) reduced the indirect cost rate for all applicable institutions of higher education and nonprofit organizations (compared to indirect rates for fiscal year 2025); and

(B) optimized payment of legitimate and essential indirect costs involved in conducting Department of Defense research to ensure transparency and efficiency for Department of Defense-funded grants and contracts; and

(2) established an implementation plan with adequate transition time to change budgeting and accounting processes for affected institutions of higher education and nonprofit organizations.

Additionally, some of the House and Senate FY26 appropriations measures include language addressing F&A cost reimbursement. The Senate Commerce, Justice, Science Appropriations Subcommittee included both report language and a provision in its FY26 appropriations bill. The <u>report</u> (S. Rpt 119-44) accompanying the bill states:

INDIRECT COST RATE The Committee recognizes that indirect cost recovery has been essential for supporting federally-funded research at university and private laboratories, enabling critical institutional functions such as Federal



compliance, research facility operations, and administrative support. The Committee acknowledges that optimizing indirect cost rates can further enhance the efficiency of funding allocation for direct research and programmatic activities, benefiting early-career researchers, smaller institutions, and community-based organizations. Ensuring an effective balance in indirect costs is key to sustaining U.S. leadership in scientific research and technological innovation. The Committee notes the academic research community's efforts to develop a consensus proposal to refine this balance. In anticipation of that effort, the Committee introduces a new Title V General Provision on indirect cost rates.

The <u>bill</u> (S. 2354) includes the following provision:

SEC. 542. In making Federal financial assistance, the Department of Commerce, the National Aeronautics and Space Administration, and the National Science Foundation shall continue to apply the negotiated indirect cost rates for Institutions of Higher Education in section 200.414 of title 2, Code of Federal Regulations, including with respect to the approval of deviations from negotiated indirect cost rates, to the same extent and in the same manner as such negotiated indirect cost rates were applied in fiscal year 2024: Provided, That none of the funds appropriated in this or prior Commerce, Justice, Science, and Related Agencies Appropriations Acts, or otherwise made available to the Department of Commerce, the National Aeronautics and Space Administration, and the National Science Foundation may be used to develop, modify, or implement changes to such fiscal year 2024 negotiated indirect cost rates.

The House Energy & Water Appropriations Subcommittee also included language in its <u>report</u> accompanying its FY26 appropriations bill. The report states:

Indirect Cost Rates.—The Committee is aware of the Department's recent policy flashes addressing maximum indirect cost rates for institutions of higher education, state and local governments, for-profit entities, and nonprofit entities. The Committee supports the Administration's efforts to increase the accountability of taxpayer resources and provide further transparency of facilities and administrative costs of the Department's grants. The Committee notes that the Department supports research and development efforts across a vast range of scientific and technological pursuits. These pursuits often require specialized, proprietary, and cuttingedge equipment. A blanket indirect cost rates policy, while well-intentioned, does not fully address the unique nature of the Department's research and development work. The Committee directs the Department to work with



stakeholders to develop new indirect cost rates policies for each of the affected groups stated above that better reflect the unique capabilities of entities that support the Department's research goals. The new policies shall take into account previous indirect cost rates negotiations that have been approved by the Department. The Committee directs the Department to pause implementation of its previously announced changes while it works to make these updates.

The House Defense Appropriations Subcommittee included in its report (<u>S. Rpt 119-162</u>) accompanying its FY26 Department of Defense Appropriations bill the following:

FACILITIES AND ADMINISTRATIVE COSTS OF RESEARCH INSTITUTIONS The Committee recognizes the Department's effort to identify new mechanisms that reduce administrative burdens, increase transparency, and save taxpayer dollars. We encourage the Department to work closely with the extramural research community to develop an optimized Facilities and Administrative (F&A) cost reimbursement solution for all parties that ensures the nation remains a world leader in innovation.

COGR is closely tracking these provisions and working with the JAG organizations to help inform these, and potentially other legislative provisions, that would effectuate the FAIR Model and provide academic research institutions sufficient time to transition to it.

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

Additional guidance for navigating the NIH/DOGE Defend the Spend process was added recently to the NIH Grants and Funding Information Status <u>webpage</u>. In the Payments section is a link to <u>Payment Management System (PMS) Payment Request Process Used for NIH Awards</u>, which includes recommendations for avoiding, "a request for additional clarification in DTS." The guidance provides "examples of appropriate payment justifications" and recommends not combining requests from multiple agencies or requests for payments on terminated awards. More information on requests under terminated awards is provided below. The guidance also provides information on the NIH DTS process and the timing of the flow of payment requests, from submission through all approvals.

As described in the May <u>COGR Update</u> and discussed during the June COGR membership meeting, changes such as the above to federal payment systems, processes, and requirements implementing <u>Executive Order 14222</u> — <u>Implementing the President's</u> <u>"Department of Government Efficiency"</u> Cost Efficiency, issued February 26, 2025, have significantly increased recipient and federal burden for requesting and routing payments. It

should be noted that costs are approved by the agency at the time of award and the additional requirements result in no savings, reduction in improper payments, or other cost benefits to the government. The new requirement ignores the numerous audits that recipients undergo to ensure their systems and processes comply with federal regulations requiring allocability, reasonableness, and consistent treatment of costs. The requests for additional supporting details, none of which have undergone a federal rule-making process, add no value and, therefore, are a waste of taxpayer dollars.

As described in the Agency Specific Actions section above, COGR developed an infographic to highlight the excessive redundancy of "Defend the Spend", Defend the Spend, Waste and Inefficiencies Due to the New Grant Requirements, that confronts the problem created by DOGE's Defend the Spend implementation of EO 14222. Further, COGR's CFC committee is updating, Points to Consider for Reimbursement of Expenses Under Active Grants, found in COGR's Framework for Navigating the 2025 Administration Transition, adding more recent examples and experiences. A summary of the current document and additional background is included in the May COGR Update.

#### Costing Points to Consider for Terminations and Suspensions (UPDATE)

As noted in the above section for Cross Cutting issues, on July 7, NIH issued closeout guidance for recipients that have appealed terminations but have not received decisions. CFC will be updating the Costing Points to Consider for Terminations and Suspensions in COGR's Framework for Navigating the 2025 Administration Transition for this new guidance and other new information since the document was posted, April 28, 2025. COGR developed this section of the Framework in response to terminations and suspension notices and related communications from federal agencies that appeared inconsistent with sponsor policies and Uniform Guidance. It provides examples of problematic federal actions and notices, a review of the relevant sections of Uniform Guidance, and a list of items for institutions to consider when following sponsor instructions and in determining best practices. Problematic agency instructions include restrictions on reimbursement of allowable expenses, such as closeout costs and noncancellable commitments, after the date of termination. For example, the recently posted NIH guidance, Payment Management System (PMS) Payment Request Process Used for NIH Awards, includes multiple statements that only payment requests "related to human subjects or animal welfare" will be approved under terminated awards. Other language in the guidance seems to contradict this restriction.



### **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 Implementation Guidance of NIH Policy on Foreign Subawards for Active Projects (NEW)

On July 18, 2025, NIH released Updated Implementation Guidance of NIH Policy on Foreign Subawards for Active Projects, NOT-OD-25-130. The implementation guidance pertains to NIH's policy, Updated NIH Policy on Foreign Subawards (NOT-OD-25-104), which establishes a new award structure that prohibits foreign subawards from being nested under the parent award to be implemented by September 30, 2025. The new structure will apply prospectively to all NIH grants and cooperative agreements involving foreign subawards, including new, renewal, and non-competing continuation awards (see COGR's May 2025 Update for more information).

NIH notice <u>NOT-OD-25-130</u> applies to applications submitted before May 1, 2025, and projects active on or before May 1, 2025. Below are key aspects of the policy:

- Applies to existing grants and cooperative agreements involving human subjects research (e.g., clinical trials and clinical research).
- NIH Institutes, Centers, and Offices (ICOs) will have the option to renegotiate with recipients the award structure for foreign subawards to remove the award from the prime award and reissue/award it as an administrative supplement (i.e., Type 3)
- Each supplement will be for a single foreign entity.
- Streamlined non-competing award process (SNAP) and automatic carryover authority will be removed from both the primary award and the foreign supplement(s).
- The primary award and each foreign supplement will have its own distinct document number and will need to submit separately Federal Financial Reports (FFR, SF-425).
- Rebudgeting is not allowed between the primary award and the supplement within a budget period. However, the RPPR may be used to request reallocation for future year commitments.

NIH specified that the supplement option is meant to be a short-term solution and is not the new award structure. The supplement structure is an additional option to the other options outlined in <u>NOT-OD-25-104</u> for foreign subawards:
- ICOs may renegotiate with the primary recipients to move activities to a domestic organization,
- Remove the scope of the foreign component from the overall project scope, or
- Bilaterally terminate the award.

Also of note, NIH has clarified in public forums that proposals submitted on or after May 1, 2025, involving foreign subawards will not be accepted until the new structure is implemented. Applicants have been advised to hold these submissions. However, this guidance has not yet been formally issued in a Notice or included in the NIH FAQs.

COGR continues to engage NIH on the issue and will keep the community informed on developments. We are interested in hearing from members navigating this issue and the impacts on research, specifically any terminations or funding delays. Individuals interested in providing feedback or sharing information are encouraged to contact Krystal Toups at <u>ktoups@cogr.edu</u>.

# NIH to Crack Down on Excessive Publisher Fees for Publicly Funded Research (NEW)

On July 8, the National Institutes of Health (NIH) <u>announced</u> plans to implement a new policy to cap publishers fees, limiting how much publishers can charge NIH supported research. The cap is expected to be introduced on allowable publication costs starting in Fiscal Year 2026.

NIH has not provided any indication on: the amount of the cap, whether or not this is a prospective policy, and when the policy will be made available. It is also unclear at this time if there will be an opportunity for the community to comment on the policy before implementation.

Institutions should notify NIH-funded researchers of this new policy as it is likely to have impacts on project budgets and it may impact where researchers publish results. A major concern about the policy is the cap (to be determined) may be too low and therefore insufficient to cover all publication costs. This shortfall will need to be covered and is likely to result in an unfunded mandate.

COGR is following this issue and identifying members' concerns on the implications of a publication cap and will keep the community informed on developments. Individuals interested in providing feedback or sharing information are encouraged to contact Krystal Toups at <u>ktoups@cogr.edu</u>.



### NIH Supporting Fairness and Originality in NIH Research Applications (NEW)

On July 17, 2025, NIH announced a new policy, <u>Supporting Fairness and Originality in NIH</u> <u>Research Applications (NOT-OD-25-132)</u>, addressing the use of artificial intelligence (AI) in research applications. The notice specifies that NIH will not consider applications that are either substantially developed by AI or contain sections substantially developed by AI. If the detection of AI is identified post award the matter may be referred to the Office of Research Integrity for review of research misconduct.

The notice also announced a new policy limiting the number of applications a principal investigator/program director or multiple principle investigator may submit in a calendar year to six, new renewal, resubmission, or revision applications for all council rounds. The policy applies to all activity codes except Ts and R13 conference applications.

The policy is effective for applications submitted on or after September 25, 2025.

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

As reported previously, 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-</u><u>25-047</u>), moving the effective date from December 31, 2025, to July 1, 2025 superseding the 2008 Public Access Policy. COGR expressed concerns regarding the expedited timeline, issuing a <u>statement</u> urging NIH to reinstate the original implementation deadline.

As of July 1, 2025, the new public access require all NIH recipients to deposit research articles upon acceptance, for immediate public availability on the date of publication.

In collaboration with other associations, COGR continue to actively review potential impacts and share resources with our members. We like to highlight a <u>resource</u> by Authors Alliance on Q&A for Authors. Of particular note is the <u>FAQ</u> for <u>authors</u> for navigating publication agreements that may conflict with the NIH Public Access Policy. Additionally NIH updated FAQs on the Public Access Policy located <u>here</u>.Additionally NIH updated FAQSs on the Public Access Policy located <u>https://grants.nih.gov/faqs#/public-access-policy</u>

### Revolutionary FAR Overhaul (RFO) Initiative (ONGOING)

As COGR reported in the <u>May 2025 Update</u>, 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</u> <u>Federal Procurement</u> and OMB Memorandum <u>M-25-26 Overhauling the Federal</u>



<u>Acquisition Regulation</u>. The initiative aims to modernize federal procurement processes, enhancing efficiency and reducing administrative burdens. Comments on the proposed changes for FAR <u>Part I</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>.

### **Research Ethics & Compliance (REC)**

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

## COGR Response to Dept. of Health and Human Services RFI on Deregulation (NEW)

In May 2025, DHHS published "Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make American (sic) Healthy Again" [<u>90 F.R. 20478</u>]. COGR's <u>response</u> to this RFI emphasized several of the recommendations COGR previously provided in its response to OMB's RFI on Deregulation including:

- Facilitating harmonization between the Common Rule on FDA regulations on human subjects research and designating FDA as the sole federal agency regulating human subjects research for DHHS funded clinical research that is subject to FDA jurisdiction.
- Aligning the NIH Grants Policy Statement's requirements for registration of all NIHfunded clinical trials in ClinicalTrials.gov with the narrower category of "applicable clinical trials" that are required to be registered under Section 801 of the Food and Drug Administration Amendments Act of 2007, the statutory authority for ClinicalTrials.gov; and
- Deferring to USDA as the as the sole regulator for research using animal species covered by the Animal Welfare Act.

The response also set forth the following new recommendations: (a) revising the PHS Policy on the Humane Care and Use of Laboratory Animals ("PHS Policy") to clarify that the Guide for the Care and Use of Laboratory Animals ("Guide") is an informational resource, as opposed to a set of regulatory requirements; (b) provide a clear definition of "departure from the Guide" that excludes IACUC-approved departures from "should statements" in the Guide; and (c) streamline the existing Animal Welfare Assurance form and filing process, using the OHRP Federalwide Assurance form and portal as a model.

REC Meeting with ORI Director and ORI's Publication of Sample Policy and Procedures for Responding to Research Misconduct Allegation and First Phase of Final Rule Guidance Documents (NEW)

- **Meeting with ORI Director:** REC members met with ORI Director Sheila Garrity and Deputy Director Loc Nguyen-Khoa on June 4, 2025, to discuss implementation of the final research misconduct rule and hear other ORI updates. ORI announced that it published its <u>Sample Policy & Procedures for Responding to Research Allegations</u> (see discussion below), and as previously noted, did not anticipate that the final rule or the sample policy would be impacted by the <u>Gold Standard Science EO</u>. Ms. Garrity and Mr. Nyguyen-Khoa advised that ORI planned to issue guidance documents on the following topics:
  - Writing policies and procedures to comply with updated regulation
  - Sample policies and procedures
  - Small institution guidance
  - Implementation guidance
  - Honest error
  - Admissions
  - Levels of intent
  - Multiple institutions and respondents
  - Pursuing leads
  - Institution assessments

They did not have a specific timeline for when these guidance documents would be issued, but as discussed below, ORI issued guidance on the first four highlighted topics on June 23.

Additional key points from the discussion are noted below:

- **Case Processing Time**: ORI has implemented internal processes and templates to cut case processing time. These new processes enabled the agency to close 150 cases in the first quarter of 2025. ORI also noted that it is developing triage teams to quickly review institutional case reports and get back to the institution on obvious issues, such as failure to assign culpability or neglecting to include supporting grants.
- ORI Retains Jurisdiction over Terminated Grants: ORI noted that under the regulations, its jurisdiction begins at that time a funding proposal is submitted for PHS support, and it retains jurisdiction over allegations of research misconduct



concerning a PHS-supported project or program even after the support is terminated.

- **Review of Institutional Research Misconduct Policies:** ORI will begin reviewing institutions' new research misconduct policies at the end of April 2026, when institutions must submit their policies with their annual reports. ORI will work with institutions to correct any noted deficiencies.
- **RIO Boot Camps**: ORI has revised its RIO boot camps to address the new research misconduct regulations and will test the new format in August.
- Sample Research Misconduct Policy and Procedures and Guidance for Writing Policies and Procedures: As noted, the ORI Sample Policy and Procedures were published on June 4, 2024. Notably, the policy was labeled as a "sample," not "model" policy, to clarify that institutions are not required to use it. In reviewing the sample policy and deciding how to use it, institutions should begin by reading ORI's new <u>Guidance for Writing Policies and Procedures for Addressing Allegations of Research Misconduct</u>. Notably this guidance states:

If your institution adapts ORI's Sample Policies and Procedures to create your own institutional policies and procedures, keep in mind that your final document must comply with 42 CFR part 93. Also, using ORI's Sample Policies and Procedures for your own policies and procedures does not guarantee that ORI will find your institution compliant with 42 CFR Part 93 should your institution address an allegation of research misconduct. [Guidance at p. 4].

The guidance goes on to clearly state that "ORI does not mandate that policies and procedures be written verbatim from the PHS regulation" and if an institution "simply restate[s]" the relevant portions of the regulations "they may not provide sufficient detail to be practically used for the institutional officials conducting research misconduct proceedings." [Guidance at p. 4]. Instead, the institution's policy and procedures must involve "a comprehensive and critical assessment of the institution's unique mission, operations, and organizational structure" AND follow the requirements at 42 CFR Part 93. [*Id.*]. The Guidance goes onto list required elements for policies and procedures [*Id.*] and discusses how to incorporate those elements in a policy, including addressing regulatory provisions for which institutions have discretion. [Guidance at p. 6]. Finally, although ORI did not provide a detailed discussion of the Sample Policy at its June meeting with REC members, it did note that with respect to the policy provision on providing respondents a copy of the



investigation report for review, this applies to the portion of the report that applies to a particular respondent in cases with multiple respondents.

• Implementation Guidance and Small Institution Guidance: ORI also published Guidance for Implementing the Revised Regulation which outlines when the 2024 research misconduct regulations apply and when the 2005 version of those regulations apply. In sum, the 2024 regulations will apply to all allegations received on or after January 1, 2026. For allegations received before that date, the 2005 regulations will apply even if the proceeding continues beyond January 1, 2026, **unless** both the institution and respondent elect in writing to follow the 2024 regulations.

Finally, <u>ORI's Guidance for Small Institutions</u> outlines the criteria for qualification as an institution "that is too small to conduct research misconduct proceedings without an actual or apparent conflict of interest." It also discusses the process for submitting a "Small Institution Statement," in lieu of written policies and procedures that comply with 42 CFR Part 93. If ORI approves the Small Institution Statement, the institution agrees to report all research misconduct allegations to ORI, whereupon ORI (or another HHS entity) will work with the institution to handle the allegations in manner appropriate to the institutional setting.

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

The Association of Research Integrity Officers (ARIO) and COGR working groups continue to meet to develop materials (i.e., templates, checklists, decision point lists) to assist institutions in complying with the new PHS Research Misconduct Regulations. The groups plan to share materials as they are developed by publishing them on COGR and ARIO websites over the summer.

## NIH and USDA Notices Requiring Reporting of "Dangerous Gain of Function" (DGOF) Research (UPDATE)

The <u>May 2025 Update</u> discussed the NIH's implementation of <u>Executive Order 14292</u>, <u>Improving the Safety and Security of Biological Research</u> via NIH Notice <u>NOT-OD-25-061</u>, <u>Recission of NIH Implementation of the U.S. Government Policy for the Oversight of Dual</u> <u>Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential</u> (<u>PEPP</u>) and <u>NOT-OD-25-112</u>, <u>Implementation Update</u>: <u>Improving the Safety and Security of</u> <u>Biological Research</u>. In June, both NIH and USDA continued their implementation of the EO by sending out notices advising institutions to review ongoing research activities that may constitute DGOF research and to notify the agencies of these activities.



NIH Notice <u>NOT-OD-25-127</u>, <u>Implementation Update: Terminating or Suspending</u> Dangerous Gain-of-Function Research in Accordance with Executive Order on Improving the Safety and Security of Biological Research, states that NIH will terminate funding and other support for projects "including unfunded collaboration/projects" that meet the DGOF research definition and that are conducted by foreign entities in countries of concern or "foreign countries where there is not adequate oversight." Additionally, NIH stated that it will suspend funding and "other support" for domestic NIH funded projects including unfunded collaborations/projects that meet the DGOF research definition "at least" until implementation of the new policy described in the EO. NIH instructed awardees to complete a review of ongoing research activities "to identify NIH funding and other support for projects, including unfunded collaborations/projects" and **immediately** notify the NIH funding institute, center, or office (ICO) of such activities that meet the DGOF definition. Institutions were required to complete this review and notification process by June 30, 2025.

what COGR contacted NIH for additional information about "unfunded collaborations/projects" were encompassed by the notice, considering there must be an NIH nexus for the agency to have jurisdiction. NIH advised that they included this text to ensure the agency was reviewing all relevant NIH-supported activities, including projects/collaborations that receive significant non-monetary NIH support. Given that such projects/collaborations may not have a funding ICO point-of-contact, NIH recommended that institutions notify the appropriate NIH point-of-contact involved with, or supporting, the project/collaboration. NIH also cautioned that institutions should err on the side of reporting if they are unsure whether research activities meet the DGOF definition.

Shortly after the reporting period ended, NIH began sending "pause" notices to researchers that it believed were conducting projects meeting the DGOF definition based on the agency's review. Several institutions have reported receiving letters from an NIH ICO, advising that the ICO determined a specific project is encompassed by the EO, pausing the work, and requesting a quick response (e.g., one or two days) to the notice. Some institutions that received the notices reported to COGR that they were no longer conducting the project referenced in the NIH letter or that they believed the NIH determination that the project fell under the DGOF definition was inaccurate. [See, J. Cohen & J. Kaiser, "Exclusive: NIH suspends dozens of pathogen studies over 'gain-of-function' concerns," Science (Jul. 11, 2025) for additional information about the types of projects that were suspended.]

Similar to NIH, USDA APHIS sent out a broad listserv notification and made a website posting entitled "<u>Implementation Update: Improving the Safety and Security of Biological Research</u>." This notice stated that USDA would not accept competitive applications for grants/cooperative agreements with post-June 20, 2025, due dates for DGOF research and

that it would "suspend ongoing funding" for such research. USDA instructed its awardees to "review active or ongoing research activities to proactively identify potential" DGOF research and "identify safe actions to halt such research and to effectively comply with guidance once established." USDA provided an Excel spreadsheet template for institutions to use in notifying USDA of any "USDA-funded projects, inclusive of all source(s) or type(s) of funding, including in-kind support that is believed to meet or has the potential to meet" the DGOF research definition. USDA provided the following example of a reportable project that does not receive direct USDA funding: "non-funded agreements (including material transfers) and any use of employee time commitments." Researchers were advised to submit a single consolidated spreadsheet if they receive funding from multiple USDA agencies, and responses were due by June 27, 2025.

Based on the information provided by NIH and contained in the USDA spreadsheet, it appears that these agencies are viewing "other support" from agencies for non-directly funded research in the broad sense that the term is used in the "other support/current and pending support" disclosure arena.

COGR is working with partner associations to collect additional information from institutions about (a) the processes that the institutions used to review projects to identify DGOF research; and (b) research subjected to a pause notice that the institution did not believe fell within the EO's scope because it was no longer being conducted and/or did not meet the DGOF research. COGR will use this information for follow-on communications with NIH regarding EO implementation at the institutional level. Please contact Kris West at <u>kwest@cogr.edu</u> if you have information that you would like to contribute to this effort.

### NIH FDA Meeting Regarding New Approach Methodologies (NEW)

In April 2025, FDA announced that it would move to replace animal testing for drug and monoclonal antibody therapies with "New Approach Methodologies" (NAMS) such as "Albased computational modes of toxicity and cell lines and organoid toxicity testing in a laboratory setting." FDA advised that it would immediately begin encouraging the use of NAMS in Investigational New Drug applications and set forth a <u>roadmap</u> for reduced animal toxicity testing over the next three years.

In its announcement, FDA advised that it was working with NIH and other federal partners to accelerate the development and validation of NAMS. On July 10, 2025, NIH followed on with a similar <u>announcement</u> that stated it would "prioritize human-focused research and reduc[e] animal use in research." Toward this end, NIH stated that it "would no longer issue NOFOs exclusively supporting animal models or limit/specify the types of models that must be used," and permit NOFOs that exclude any animal use proposals.

On July 7, 2025, FDA and NIH held a joint workshop for NIH, FDA, and other government employees on reducing animal testing. This workshop was recorded and can be viewed at

this <u>link</u>, along with the <u>agenda</u>. The meeting included useful information on NAMS for toxicology testing, as well as perspectives of persons involved with European, Australian, and Japanese drug regulatory authorities. However, some of the language used during the workshop to describe the current U.S. animal research arena did not accurately reflect the great care that institutions take to ensure this research is conducted ethically and humanely.

COGR continues to monitor this area closely, along with partner associations such as the National Association for Biomedical Research. These efforts are part of larger federal effort to scale back the use of animal models and/or limit/prohibit the use of "sensitive" species (e.g., dogs, cats, non-human primates) in federally funded research. [See, e.g., EPA, <u>EPA</u> <u>New Approach Methods: Efforts to Reduce Use of Vertebrate Animals in Chemical Testing</u> (updated Jun. 16, 2025); <u>L. Hersey, "Navy ends experiments using cats and dogs as test subjects," Stars and Stripes (May 30, 2025)].</u>

Updated NIH Processes for Proposed Projects Involving Chimpanzees or Chimpanzee Biomaterials (NEW)

NIH previously prohibited invasive research on chimpanzees (NOT-OD-14-024, Update to the Interim Agency Policy, NIH Extramural and Intramural Research Involving Chimpanzees (Nov. 25, 2013)) and permits only limited research using noninvasive methods (NOT-OD-16-095, NIH Research Involving Chimpanzees (May 26, 2016)). Previously, researchers who wanted to apply for NIH funding or submit other requests for research involving chimpanzees or their biomaterials submitted these requests via the NIH's Chimpanzee Research Use (CRU) Reporting System under the NIH Office of the Director's Division of Program Coordination, Planning, and Strategic Initiatives.

<u>NIH NOT-OD-25-123</u> (July 17, 2025) notes that the CRU was decommissioned in June 2025 and details the new process for the review of requests regarding non-invasive research on chimps. Researchers will continue to complete a CRU form at just-in-time, but the review of the information on that form will now be conducted by the Office of Laboratory Animal Welfare to determine if the research is/is not consistent with the definition of "noninvasive" research a <u>42 CFR Sec. 9.2</u>.

Revised NIH Policy and Guidelines on Including Women and Minorities in Clinical Research (NEW)

On July 17, NIH issued Notice <u>NOT-OD-25-131</u>, <u>Revision: NIH Policy and Guidelines on the</u> <u>Inclusion of Women and Minorities as Subjects in Clinical Research</u> ("Inclusion Policy"). The notice sets forth changes to the Inclusion Policy, which was originally <u>announced in 2001</u> and amended in 2017 by <u>NIH NOT-OD-18-014</u>, <u>Amendment: NIH Policy and Guidelines on</u> <u>the Inclusion of Women and Minorities as Subject in Clinical Research</u> to require reporting

of "valid analyses" of Phase III clinical trials by "sex/gender, race, and/or ethnicity" in ClinicalTrials.gov.

The 2025 revised policy is substantively very similar to the 2001 version of the policy (as amended), but it contains some changes to terminology and definitions to align wording with <u>EO 14168</u>, <u>Defending Women from Gender Ideology Extremism and Restoring</u> <u>Biological Truth to the Federal Government</u>." These revisions are described below:

- Eliminates references to "gender" by deleting the phrase "sex/gender racial/ethnic and relevant subpopulations" contained in the 2001 policy and replacing it with "sex, race, and/or ethnicity and relevant subgroup."
- Replaces references to "minorities" with references to "racial and/or ethnic minority groups."
- Replaces references to "clinically important sex/gender and race/ethnicity differences" with "clinically important sex, race and/or ethnicity differences."
- Replaces references to "men and women" and with "males and females."
- Adds a new section entitled "Guidelines for Reporting Results of Valid Analysis in ClinicalTrials.gov" that reflects the requirements of <u>NIH NOT-OD-18-014</u>, <u>Amendment:</u> <u>NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subject in</u> <u>Clinical Research</u>.
- Removes the reference to the NIH Outreach Notebook on the Inclusion of Women and Minorities in Biomedical and Behavioral Research and accompanying FAQs.
- Removes the reference to FDA Guidelines for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs [58 FR 39406].
- Removes specific definitions for ethnic categories (i.e., Hispanic or Latino, Not Hispanic or Latino, American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander and Majority Group White), but retains the reference to OMB Directive 15, which defines "minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal Reporting and the use of its categories, along with a statement that "NIH considers racial and/or ethnic minority populations to include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Middle Eastern or North African, and Native Hawaiian or Pacific Islander."

### NIH Indefinitely Extends Certain Flexibilities for Results Reporting for Certain Basic Studies with Human Subjects (NEW)

On July 17, NIH published <u>NOT-OD-25-134</u>, <u>Flexibilities for Registration and Results</u> <u>Reporting of Prospective Basic Experimental Studies with Human Participants</u> (BESH). The notice rescinds several previous notices issued between 2018 and 2024 that provided for delayed enforcement for registration and results reporting in ClinicalTrials.gov. Although these notices were rescinded, this notice indefinitely extends "policy flexibilities regarding registration and results reporting [for BESH] per the <u>NIH Policy on the Dissemination of</u> <u>NIH-Funded Clinical Trial Information (NOT-OD-16-149)</u>." BESH studies are defined as

"prospective basic science studies involving human participants" that (a) meet the NIH definition of clinical trial per <u>NOT-OD-15-015</u>; (b) meet the definition of <u>basic research</u>; and (c) are submitted in response to a NOFO designated as BESH.

Under these flexibilities, BESH studies can be registered and report results in ClinicalTrials.gov OR an alternative publicly available platform. If an alternative platform is used, plans for meeting registration and results reporting must be included in the funding application and provide the unique study identifier from the alternative platform in annual progress reports. The notice also states that all personnel involved in the conduct, management, or oversight of BESH studies must complete Good Clinical Practice training (see <u>NOT-OD-16-148</u>) and that informed consent forms be posted (see <u>NOT-OD-19-110</u>).

Message from HRSA HIV Bureau Regarding Pre-publication Review (NEW)

COGR is aware that some institutions have received a message from the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau concerning "journal articles and/or conference presentations resulting from initiatives funded by Health Resources and Services Administration (HRSA), Ryan White HIV/AID Program, Part F Special Projects of National Significance and the Department for Health [SPNS] and Human Services Secretary's Minority HIV/AIDS Fund (MHAF)." Specifically, the notice stated that if a researcher plans to submit a paper, abstract, or conference presentation to journal or conference based on a SPNS or MHAF project, it must first be reviewed by HRSA "to ensure alignment with Administration priorities." Further, prior to "writing papers based on a HRSA-funded initiative" the researcher must submit a "concept proposal for HRSA approval" via the project officer. The notice goes on to state that if papers/materials based on a SPNS or MHAF project were submitted **without** this clearance, the project must be withdrawn until clearance is obtained, whether or not the papers have HRSA authors.

COGR plans to follow up with HRSA to ascertain the specific grant terms and conditions supporting this request.



### Appendix A – Upcoming Comment Due Dates

AGENCY	DESCRIPTION	DUE DATE	STATUS
National Science	Request for	July 21, 2025	RSIP Committee is reviewing –
Foundation	Information:		potential joint letter with partner
	Innovation and		associations.
	Partnership Core		
	<u>Technology Areas</u>		
National Science	<u>Request for</u>	August 15,	RSIP Committee is reviewing.
Foundation	<u>Comment –</u>	2025	
Innovation Corps	<u>Renewal of Info</u>		
Program	Collection for I-		
	<u>Corps</u>		
National Science	Application form for	September 2,	RSIP is reviewing.
Foundation (TIP)	<u>the Breakthrough</u>	2025	
	Innovation Initiative		
National Science	Approval to Renew	September 2,	RSIP is reviewing.
Foundation –	Pre-Award Info	2025	
SBIR/STTR Program	<u>Collection</u>		
Federal Acquisition	Revolutionary FAR	September 30,	CGA Committee is reviewing.
Regulation	Overhaul – <u>Parts 1</u>	2025	
	and <u>34</u>		

### **JULY 2025 UPDATE**



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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601 13TH ST. N.W. 12TH FLOOR WASHINGTON D.C. 20005 (202) 289-6655 \* <u>WWW.COGR.EDU</u> \* <u>COGR ON LINKEDIN</u>