COGR

MAY 2024 UPDATE

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COGR

President's Message

New Initiatives and Continued Advocacy

Dear Colleagues,

With spring in full swing, COGR is pursuing new initiatives and persisting in our advocacy to rebalance the partnership between the federal government and research institutions.

Later this month we welcome Kevin Wozniak as COGR's next Director for Research Security & Intellectual Property. A former COGR Board and RSIP Committee member, he brings deep experience and expertise from his service at Georgia Tech and the University of Georgia. Also this month, we are starting a new COGR Committee "Open House" series. The Research Ethics & Compliance Committee will host on May 28 "Knock Knock – Who's there? It's REC." We hope you will join this virtual session aimed at providing insights into the committee's efforts and soliciting ideas for its work.

Another new initiative underway is COGR's membership survey. Thank you to everyone who participated. It's not too late if you have not taken the 10-minute survey. We are exploring your perceptions of the association and your membership experience. We will be working with Brodeur Partners, a strategic communications consultancy, to assess the responses and inform actions we will take to strengthen COGR's brand, communications, and advocacy.

Next month's Membership Meeting provides an excellent opportunity to advance our collective understanding and advocacy on research administrative issues, such as the new OMB guidance on federal financial assistance, research security, and more. We are piloting a new session format in which your questions will be live-polled. A panel of COGR staff and committee Chairs will facilitate an audience discussion focused on brainstorming and benchmarking effective research administration and compliance solutions. Please send us your questions in advance. At the Membership Meeting, we will also recognize our colleagues Bob Hardy and Dave Kennedy for their years of service to COGR.

This spring has been an active one for advocacy. I wish to highlight just three recent advocacy efforts. First, we responded to the Centers for Medicare & Medicaid Services (CMS) request for information on research data requests and access policy changes. COGR's letter explained some of the harmful impacts the proposed changes would have on important research vital to improving patient outcomes and lowering healthcare costs.

Second, COGR and AAU wrote USPTO about its request for comments on *Unlocking the Full Potential of Intellectual Property by Translating More Innovation to the Marketplace*. We took the opportunity to weigh in on the misguided draft framework for march-in rights and to express our views about efforts to increase translation of innovation to commercialization. The letter notes our agreement with AUTM in these areas.

Third, some of the fruits of advocacy were realized in the updated Uniform Guidance, now referred to as OMB's Guidance for Federal Financial Assistance. The final version reflects several important COGR recommendations. At the same time, the updated guidance includes new directions of concern, including the removal of the explicit statement in the guidance that "[t]he principles are designed to provide that Federal awards bear their fair share of cost recognized under these principles except where restricted or prohibited by statute." This and other changes will be among our key advocacy priorities in our continuing efforts to restore balance to the partnership.

Matt Owens
President

Announcements

Registration Still Open: June 6-7, 2024, COGR Meeting in Washington D.C.

COGR's next meeting will be in-person on June 6-7, 2024 at the Washington Marriott in Georgetown. Registration is now open and the preliminary agenda is available on COGR's website.

If you do not already have access to the COGR Portal and are interested in registering for the upcoming meeting, please request access here.

Contact memberservices@cogr.edu with any questions, and we hope to see you there!

COGR's 2024 Membership Survey (Responses Due May 22)

COGR is interested in exploring your perceptions of the association as well as your membership experience. We invite you to participate in our brief survey.

This survey is being administered in collaboration with Brodeur Partners, a strategic communications consultancy. You may answer this survey anonymously, but if you include your name and email address, it will allow COGR to follow up with you directly if needed.

Individual survey responses will remain confidential, and results will be aggregated. The survey should take no more than 10 minutes of your time. Information collected from the survey will help inform COGR's efforts to serve its member institutions and representatives. To complete this survey, click here and submit by May 22.

COGR is Hiring: Costing and Financial Compliance Director (Applications Due May 31)

COGR is seeking its next Director for Costing and Financial Compliance. The Director for Costing and Financial Compliance leads COGR's research policy efforts in a wide range of areas associated with research costing, financial compliance, federal payments systems, and facilities and administrative (F&A) cost reimbursement. The Director is responsible for monitoring the regulatory landscape and leading in the preparation of COGR policy perspectives and activities related to the administration of and compliance with federal regulations and policies within the position's issue portfolio. The Director is the lead staff for the COGR's Costing and Financial Compliance Committee and works closely with the committee chair and members to execute the responsibilities of this position.

More information can be found in the position announcement and job description.

For full consideration, please submit a letter of interest, resume, references, and salary requirements to careers@cogr.edu by **May 31, 2024**.

Coming August 2024: Emerging Research Institutions Pilot Program

As announced in COGR's 2022-2023 Year in Review, COGR is launching an Emerging Research Institutions (ERI) Pilot Program in August 2024. This program will provide an opportunity for institutions that do not yet meet COGR's membership threshold[1] to formally engage with COGR and participate in COGR activities. The ERI Pilot Program aims to provide a pathway for COGR's direct engagement with ERIs. We hope the program will strengthen the totality of the U.S. research ecosystem by providing resources, information, and opportunities for networking across the wide spectrum of research institutions, many of which collaborate with each other through subawards and other projects.

Additionally, engagement with ERIs will help support and strengthen COGR's advocacy efforts with federal agencies especially on the cost and administrative burden of complying with research regulations and policies. Participation in the ERI Pilot Program will be limited. The ERI Pilot application process, eligibility criteria, and annual participation fee will be announced during the Summer of 2024.

Please note: *Smaller public institutions that have staff on COGR's listservs or have participated in COGR events over the years based on their flagship campus's membership will be invited to apply for the ERI Pilot Program in the Summer of 2024.*

If you have any questions about this program, please reach out to Toni Russo, Assistant Director of Member Engagement & Policy at trusso@cogr.edu.

Upcoming Comment Due Dates

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

Reminders

COGR Volunteer Survey

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

COGR Has Moved

COGR has moved into a new location. As of January 1, COGR's new physical and mailing address is:

COGR
601 13th Street NW 12th Floor
Washington DC 20005

[1] *At least $15M in annual federal research expenditures as reported in the most recently published NSF HERD survey or equivalent.*

If you are your institution's Primary Representative and/or Billing Contact, please ensure your institutional records are updated now to reflect our new address. Invoices for FY 25 (August 1, 2024-July 31, 2025) are expected to be ready by June 1, 2024. As a reminder, COGR accepts annual institutional dues payments via check payment or EFT/ACH. An updated W-9 is available on COGR's website here.

If you have questions, need institutional forms updated, and/or would like to set up EFT/ACH payments, please reach out to memberservices@cogr.edu now and allow for additional processing time.

Follow COGR on LinkedIn

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

COGR Portal: Sign up for Access Today!

Did you know that all staff at COGR member institutions are eligible and encouraged to sign up for access to the COGR Portal as part of the institution's COGR Member Benefits? The Portal is where you can sign up for our listserv, browse our video library, view the COGR Member Directory, check out COGR's Job Board, and view other members-only materials.

2 CFR 200 "Uniform Guidance" Cross-Cutting Issues

The New "Uniform Guidance" is Available (NEW)

The OMB Guidance for Federal Financial Assistance (Title 2, Code of Federal Regulations; i.e., 2 CFR) was posted to the Federal Register on April 22 and will be effective on October 1, 2024. The OMB Guidance covers the following:

- Part 1 – About Title 2 CFR
- Part 25 – Unique Entity Identifier and System for Award Management
- Part 170 – Reporting Subaward and Executive Compensation
- Part 175 – Award Term for Trafficking in Persons
- Part 180 – Guidelines to Agencies on Debarment and Suspension
- Part 183 – Never Contract with the Enemy
- Part 184 – Buy America
- Part 200 – Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

2 CFR Part 200 is what has commonly come to be known as the "Uniform Guidance." While COGR's work and advocacy addresses the entirety of Title 2, our primary focus is on Part 200 (the Uniform Guidance). As OMB previously announced, public comments will not be considered. ***However, OMB has indicated that they will be open to observations and comments related to technical corrections, significant concerns, implementation processes, and other clarifications (which COGR believes includes addressing the status of the current FAQs, dated May 3, 2021).*** Accordingly, COGR expects to engage with OMB over the next several months and present our observations and comments.

Also of note is the availability of a redline version of the OMB Guidance. This version tracks changes between the current version (published in 2020) and the new version made available on April 22. In addition, COGR's Uniform Guidance Resource Page will continue to be an excellent resource and we will keep this page updated with new and helpful material. If you have any questions or comments, please contact Krystal Toups at ktoups@cogr.edu and David Kennedy at dkennedy@cogr.edu.

The Uniform Guidance: Continuous COGR Analyses and "Looks" (NEW)

COGR is conducting deep-dive analyses and corresponding education and advocacy to support the membership as we lead up to the October 1, 2024 implementation of the Uniform Guidance. Our current plan is as follows:

- *First Look: COGR Preliminary Assessment of Selected Items (April 24).* Covers major changes, including items for which COGR advocated, but were not accepted by OMB. This is meant only to be a "first look" and not to address all changes, nor to address changes in detail.

- *Second Look: Webinar on the Final OMB Guidance for Federal Financial Assistance (May 15).* Leaders from the Contracts & Grants Administration (CGA) and Costing and Financial Compliance (CFC) committees address some of the most significant changes, with a focus on implementation and how they will impact institutions. Panelists for this session included:

    - **Stephanie Endy**, *Associate Vice President for Research, Brown University (COGR Board & CGA Committee Member)*
    - **Jeremy Forsberg**, *Associate Vice President, Research and Innovation, University of Texas at Arlington (COGR Board & CFC Committee Member)*
    - **Twila Reighley,** *Associate Vice President for Research, Sponsored Programs, Michigan State University (COGR Board Alumni & CGA Committee Member)*
    - **Jeffrey Silber**, *Senior Director, Sponsored Financial Services, Cornell University (COGR Board Chair)*

    The slides and video of the webinar are available to all members via the COGR Portal Video Library (log in required).

- *Third Look: Thursday, June 6 COGR Meeting – Final OMB Guidance for Federal Financial Assistance, What's Next?* OMB leaders Deidre Harrison, Deputy Controller, and Steve Mackey, Policy Analyst, will provide additional insights and respond to questions from the membership. If you have advance questions for OMB, please contact Dave Kennedy at dkennedy@cogr.edu or Krystal Toups at ktoups@cogr.edu by May 29.

- *Fourth Look: Implementation Guide.* We expect this will be available later this summer in advance of the October 1 effective date. The design of this COGR publication will be to address all changes and provide points to consider as institutions prepare to implement the Uniform Guidance.

Other important events include formal adoption of all Parts of the OMB Guidance by federal agencies. We understand that agency plans – including proposed agency deviations – were due to OMB by May 15. Agency plans should be made available to the public in coordination with the October 1, 2024 effective date. Note, at the June COGR Meeting, we have scheduled a session with leaders from NIH and NSF so that they can speak to their respective agency plans.

Finally, as described in the previous section and based on OMB's invitation, ***COGR will provide OMB with observations and comments related to technical corrections, significant concerns, implementation processes, and other clarifications (including the status of the current FAQs, dated May 3, 2021).*** We will communicate this over the summer so that OMB has sufficient time to respond well in advance of the October 1, 2024 implementation date. We will keep the membership updated on all COGR activities and advocacy.

OMB Establishes Council on Federal Financial Assistance (REMINDER)

At the October 2023 COGR Meeting, Deidre Harrison reminded us of the recently established Council on Federal Financial Assistance (COFFA) – as specified in OMB Memorandum M-23-19, dated August 9, 2023 – and its mission:

> *[To provide] oversight and management of Federal financial assistance. The COFFA will create a partnership among Federal grant-making agencies, providing a single forum to inform Federal financial assistance policy, oversight, and technology activities. The COFFA will be responsible for providing strategic direction, policy recommendations, and priority-setting for other Government-wide grant-related activities.*

In addition, the Memorandum is clear in stating: "*The Biden-Harris Administration is committed to ensuring that Federal agencies have the tools they need to deliver Federal financial assistance programs in an efficient, effective, and equitable manner,* ***while also reducing administrative burdens on Federal financial assistance applicants and recipients" [emphasis added*****]**. Ms. Harrison encouraged engagement with COFFA. COGR views the COFFA as a great opportunity to address issues important to the research community. We will stay closely connected to all COFFA developments.

Science & Security: Cross-Cutting Issues

NSF Risk Assessment and Mitigation Process (NEW)

COGR representatives attended a meeting at which NSF presented on its proposed process for risk assessment of research proposals and the associated development of risk mitigations plans. The process, which will be known as Trusted Research Using Safeguards and Transparency (TRUST), is being finalized, and COGR will ask NSF representatives to provide a status update at the June COGR Membership Meeting.

Associations Foreign Financial Disclosure Report Meeting (FFDR) with NSF (NEW)

COGR and other higher education associations (AAU, APLU, ACE, and others) were invited to meet with NSF officials from the Office of the Chief of Research Security Strategy and Policy. The meeting provided

an overview and demonstration of the Foreign Financial Disclosure Report (FFDR) site. The FFDR is a new module in Research.gov (in Manage Financials) to address reporting requirements specified by Section 10339B of the CHIPS and Science Act of 2022, which requires institutions of higher education (IHEs) to report gifts and contracts ≥$50,000 (received from a source associated with a country of concern (i.e., People's Republic of China, Islamic Republic of Iran, Democratic Republic of Korea, and Russian Federation). The FFDR requirement applies to IHEs that receive a new award or funding amendment on or after May 20, 2024.

Below is a summary of the major highlights from the meeting.

- **Deadline Extended**: In response to community concerns, NSF is providing a one-time grace period for the initial report, extending the deadline to September 3, 2024, at 5:00 p.m. (the submitting organization's local time). The Year 1 report will open on July 1, 2023, for the reporting period July 1, 2023 through June 30, 2024.

- **FFDR Clarifications on Legal Name/Address of Foreign Source**: In response to feedback from the community, NSF removed the street address as a requirement for reporting the foreign source and added an option to provide either DBA or legal name of the foreign source.

- **New FFDR Preparer Role Added to Research.gov**: A new role has been added to research.gov in response to the community's feedback requesting the ability for non-AORs (such as those who typically complete Dept of Ed Section 117) to complete FFDR. All active AORs will automatically be assigned the new FFDR preparer role and can create a report, edit an existing report, or submit a report created by another FFDR preparer. Research.gov Organizational Administrators can add/remove the FFDR preparer role in their organization's Account Management.

- **FFDR Takeaways**: On July 1, 2024, all individuals designated as an FFDR preparer, will receive a system-generated email notifying them that the IHE must submit an FFDR. Every IHE must submit a report, including a negative report (nothing to report), on Research.gov. A submitted report can be edited up to the deadline. Once a report is submitted to NSF, it cannot be deleted or withdrawn. Requests must be submitted to the Office of the Chief of Research Security Strategy and Policy Office to amend the submitted report.

- **FFDR Demo & Resources:** A demo site is available on Research.gov (in Manage Financials) until June 28, 2024 (after June 28th, the demo site will be replaced by the actual site). NSF also expects to have a webinar to demo the new site in July and plans to host virtual office hours. NSF has developed a Resource Page, with FAQs.

As this is the initial year for the report and each entry will need to be entered (there is not an upload file option), we encourage institutions to review the demo site to start collecting information for the report early.

COGR will host NSF at the June membership meeting to provide an overview and updates on the FFDR.

HHS OIG Survey on Reporting of Monetary Donations that Support Research and Related COGR Questionnaire (UPDATE)

In January 2024, HHS OIG issued the *NIH Recipient Institutions' Reporting of Monetary Donations that Support Research Survey* (OEI-03-22-00570) to all U.S-based institutions that received NIH funding in 2022. The survey collected data concerning institutions' categorization of financial support as unrestricted gifts or current and pending support. COGR developed a questionnaire and invited institutions to provide information on how they answered the survey. An analysis of those responses can be found in the Committee Reports slides for the February 2024 meeting. COGR contacted HHS OIG to inquire about its timetable for issuing a survey report. HHS OIG responded that they are still conducting data analysis, and the estimated timeline for a final report is late 2024.

JASON Report – Safeguarding the Research Enterprise (UPDATE)

On March 21, 2024, the JASON group published Safeguarding the Research Enterprise ("SRE Report"), a report that offers recommendations for how NSF should identify projects that may require additional research security controls. A summary of the report is included in COGR's March Update. Report co-author Dr. Rachel Segalman will discuss the findings and recommendations of the report at COGR's June Membership Meeting.

COGR Survey on Research Institutions' Experiences with Department of Defense (DoD) Policy for Risk-Based Security Reviews of Fundamental Research (FR) and Follow-Up with DoD, Army Research Laboratory (ARL), and Defense Advanced Research Projects Agency (DARPA) (UPDATE)

COGR conducted a survey of its member institutions to gain information on their experiences in developing research security risk mitigation plans in response to the recent research security risk assessment and mitigation requirements implemented by DoD research funding components. Eighty-two (82) institutions submitted responses to the survey. Fifty percent of responding institutions received at least one request to submit a risk mitigation plan, with the majority of plan requests coming from the Army/ARL. Major findings from the survey are summarized below:

- DoD frequently did not identify the specific reason(s) a plan was necessary, with 58.6% of responders indicating that DoD provided a clear reason for the plan's necessity in less than 25% of requests.
- The initial development and negotiation of risk mitigation plans is time-consuming, with slightly over 46% of responders reporting that it takes from 11 to over 21 hours to develop a plan, and 47% of responders indicating that the negotiation process took four to six weeks.
- Common required plan elements include the following requirements for PIs and grant personnel: reporting of international travel, threat awareness training, reporting of suspicious contacts with foreign operatives, and reporting/restrictions on certain collaborations with persons/entities in countries of concern (CoCs).
- Over 65% of responders reported that they were able to successfully negotiate risk mitigation plans, but for the just over one-third of responders whose plans were rejected, DoD components did not provide a clear reason for the rejection in over 83% of those cases.

The full survey report can be found at this link. COGR provided copies of the survey report to DoD, ARL, and DARPA. Representatives from each these units will meet with members of COGR's REC, RSIP, and CGA Committees on June 5 to discuss the report's findings and ways in which institutions can work with funding agencies to better understand risk mitigation requirements and make the plan develop process more efficient. At COGR's invitation, a representative from the Federal Demonstration Project (FDP) will also attend this meeting to assist FDP in its work to develop a risk mitigation plan template.

DARPA Updated FAQs on Fundamental Research Risk-Based Security Review Program (FRR-BS) (NEW)

On May 3, 2024, DARPA published updated FAQs on its Fundamental Research Risk-Based Security Review Program (FRR-BS). FRR-BS (which DARPA also refers to as "Ferbs") is an "analytical risk review process focused on identifying and mitigating undue foreign influence in [DoD] Science and Technology (S&T) research grants and cooperative agreements." [FAQ 1]. DARPA adopted the DOD June 2023 policy on Risk-Based Security Review of Fundamental Research ("DoD Policy") and its associated risk evaluation matrix, and the FAQs will assist institutions in understanding DARPA's implementation of the policy. Some important points noted in the FAQs include:

- **Associations v. Affiliations**: The DOD Policy distinguishes between "associations" and "affiliations." For the period after October 10, 2019, indicators of "affiliations" with entities on specified lists require mitigation and rejection of a proposal if mitigation is not possible. "Associations," however, do not rise to this risk mitigation level until August 9, 2022. "Affiliations" include co-authorships where the co-author has received funding or been employed by a foreign entity/institution are viewed as an affiliation, while such arrangements that do not involve funding as considered to be "associations."

- **Consulting:** "Consulting the is permitted by an individual's appointment and consistent with the proposing organization's 'Outside Activities' policies and procedures may be excluded from reporting." [FAQ 9].

- **Countries Subject to a Risk Assessment**: At a minimum, DARPA performs a risk assessment of projects that involve a Country of Concern (COC), but it may also review projects that involve foreign countries that are not COCs.

Department of Justice (DOJ) Advanced Notice of Proposed Rulemaking (ANPRM) Regarding Access to American's Bulk Sensitive Personal Data and Government-Related Data by Countries of Concern (NEW)

On February 28, 2024, President Biden issued an Executive Order on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern instructing the Attorney General, in coordination with the Department of Homeland Security, to develop a rule to regulate the transfer of certain classes of American's sensitive personal information to designated countries of concern. In response, DOJ issued an ANPRM identifying three classes of restricted data transactions that involve the transmittal of certain categories of U.S. sensitive personal data to specified countries of concern (COCs) (i.e.,

China, Russia, Iran, Cuba, North Korea, and Venezuela). [*See* COGR's March Update for a more detailed summary of the ANPRM.].

COGR developed a response letter that emphasized the following points:

- COGR supports the proposed exemption for data transactions to the extent they are for "the conduct of the official business of the United States government by its employees, grantees, or contractors" and "transactions conducted pursuant to a grant, contract, or other agreement entered into with the United States government." This exemption would permit federal agencies, including the Department of Health and Human Services and NSF, to implement their own grant and contract-based conditions to address "risks that countries of concern can access sensitive personal data," thereby avoiding duplicative requirements from multiple agencies.

- COGR encourages DOJ to consider a similar exemption for non-federally funded international research, innovation, and development activities, which often augment funding from federal agencies. International biomedical, public health, and environmental concerns frequently require the exchange of genomic data, personal health data, and biospecimens across all countries, and this research is vital to achieving global health and scientific advancement. Further, as shown by the recent COVID pandemic this research may be very time sensitive, and cumbersome licensing processes may impede important scientific progress when it is most necessary.

- In developing a final rule, the DOJ should consider different requirements for anonymized, pseudonymized, deidentified, or encrypted data.

- The proposed bulk data thresholds for genomic and personal health data are very low, and DOJ should work with FDA, NIH, and other federal agencies involved in the funding of clinical research to identify appropriate bulk threshold levels that would facilitate the conduct of important clinical and public health research that requires the participation of sites in COCs. Alternatively, if these thresholds cannot be adjusted, DOJ should consider the development of general licenses to accommodate the conduct of this research.

DOJ has asked COGR to meet to further discuss the issue of appropriate bulk thresholds. REC is identifying institutional subject matter experts who may be able to assist in providing additional information on this issue in preparation for this meeting.

OSTP Issues Updated Guidance to Support a Secure and Fair Research Ecosystem (UPDATE)

COGR reported in February 2024 the release of the OSTP memorandum Policy Regarding Use of Common Disclosure Forms for the "Biographical Sketch" and the "Current and Pending (Other) Support" Sections of Applications by Federal Research Funding Agencies. The memorandum outlines the purpose and conditions for the use of the NSTC-developed common disclosure forms by federal research funding agencies. The memorandum specified that Federal research funding agencies with more than $100 million in annual extramural research expenditures must submit an implementation plan to OSTP within 90 days of the policy. The plan must

document the anticipated implementation date, plans for any deviations, and information regarding the electronic implementation of the Common Forms. COGR continues to follow and dialogue with agencies on adopting the common forms. In recent conversations with OSTP, individual agency plans are not expected to be made public. The expectation is that agencies will broadly adopt the common forms. Any deviations will require OMB/OIRA review and clearance.

CISA Cyber Incident Reporting Requirements for Critical Infrastructure (NEW)

On April 4 the Cybersecurity and Infrastructure Security Agency (CISA) issued a Notice of Proposed Rulemaking (NPRM; 89 FR 23644) for the Critical Infrastructure Act of 2022 (CIRCIA) cyber incident reporting requirements for covered entities. The requirements include Title IV-funded institutions of higher education in their scope as covered entities ("education facility;" 226.2(b)(9)(ii); p. 23768 in print version).

One concern is the potential for redundant reporting. For example, the DFARS 252.204-7012 clause requires cyber incident reporting for institutions with DOD contracts involving covered defense information. There are a number of other concerns relating to the content of reports, data preservation, and enforcement. Also in the past higher education has not been treated as a critical infrastructure sector. The appropriateness of using Title IV as the basis for extending the requirements to higher education entities appears questionable,

COGR expects to join EDUCASE, and possibly other higher education associations, in comments on the NPRM. Comments are due July 3.

NIST Issues Final Version of Updated CUI Security Requirements (NEW)

On May 14 NIST published the final versions of Special Publication (SP) 800-171r3 (Revision 3), *Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations*, and SP 800-171Ar3, *Assessing Security Requirements for Controlled Unclassified Information.*

See NIST Finalizes Updated Guidelines for Protecting Sensitive Information for the NIST news release and description.

The primary change is to restructure the requirements to directly align with NIST SP 800-53r5 source catalogue controls. The safeguards are now available in machine-readable formats. New tailoring criteria are included. A helpful supplement maps the changes from the previous version, which do not appear extensive. It may be helpful to begin with this supplement in analyzing the new version.

U.S. Department of Commerce Announces New Additions to the Entity List (NEW)

On May 14, the U.S. Department of Commerce announced the addition of 37 new Chinese entities to its Entity List. Each of the newly added entities has some nexus with China's development of critical technologies like quantum computing, artificial intelligence, and microelectronics. The scope of export restrictions appliable to each entity includes "all items subject to the Export Administration Regulations (EAR)" with a "presumption of denial" for all license requests. These are among the most severe restrictions the Department of Commerce can apply to an entity.

COGR member institutions should also be aware that multiple locations at the Chinese Academy of Sciences were among the 37 entities added to this list as well as the prolific University of Science and Technology of China (USTC). Schools should work through their export controls offices to locate and analyze engagements involving any of these newly added entities to determine the extent to which these new restrictions will affect ongoing engagements and activities.

Research Security & Intellectual Property (RSIP)

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

COGR/AAU Submit Comments on PTO Request for Comment (UPDATE)

The COGR March Update mentioned the United States Patent and Technology Office (USPTO) request for comments (RFC) on *Unlocking the Full Potential of Intellectual Property By Translating More Innovation to the Marketplace* (89 FR 18907). On May 14 COGR and AAU jointly submitted comments.

Previous COGR Updates discussed the Framework proposed by NIST for agencies consideration of requests for exercise of march-in rights under the Bayh-Dole Act (see February Update). It also was discussed in a panel at the February COGR Meeting. The RFC suggested that this topic was beyond the scope for comment. USPTO does not have direct responsibility for the draft Framework. However, according to the RFC, the focus was on "opportunities for positive public impact by bringing innovation to market through commercialization, for example via the licensing of IP rights." Given this focus, we believed it was imperative to address the march-in issue. Our comments expressed the view that the draft march-in Framework if implemented would constitute a difficult if not impossible barrier to the achievement of this goal.

The COGR/AAU comments generally concurred with the comments submitted by AUTM on the RFC. We cited AUTM's comments that the "Framework will have a crippling impact on the ability of universities and others to find licensees and investors willing to invest in high-risk, early-stage technologies. The framework will harm the ability of research institutions to license patents vital to new products, processes, and technologies that start-up companies and others rely on to commercialize products and services that benefit our nation's health, security, and economy." We also cited our previous comments to NIST that the Framework "will cause irrevocable damage to the 40+ year success story of the Bayh-Dole Act, and our nation's successfully tried and true technology transfer practices will be undermined."

From conversations and convenings throughout the COGR/AAU membership and the wider innovation ecosystem, it is apparent that the draft Framework already is having a chilling effect on technology transfer. It is crucial to convey the concerns to government policymakers and relevant agencies wherever possible.

The COGR/AAU comments also addressed several other areas that we viewed as particularly important and highlighted some of the AUTM recommendations. These included patent eligibility, exclusivity and Patent Trial and Appeal Board operations; patent prosecution, examination, and use of patent databases; and growing concerns

over the licensing of biological materials and data. Finally, our comments stressed the importance of USPTO leadership to promote and support patenting and technology transfer at HBCUs.

It is encouraging that USPTO is seeking to directly address technology transfer and innovation. Hopefully this will lead to initiatives that we can support and participate in.

Congressional Request for GAO Study of the Impact of the NIST Framework (NEW)

In a May 1 letter Sens. Coons (D-DE) and Tillis (R-NC) joined by Reps. Issa (R-CA) and Auchincloss (D-MA) requested GAO conduct a study of the impact of the implementation of the NIST March-In Framework on drug prices and innovation. The letter cited the success of the Bayh-Dole Act, and a number of previous studies that showed exercise of march-in would have limited impact on drug prices.

The letter expressed concerns that the Framework would impact all technologies and harm innovation, noting the large number of comments submitted to NIST opposing the Framework. The letter posed a series of questions, including whether NIST had conducted an analysis of the economic impact, the full range of potential effects, whether the Framework provides clarity for potential licensees and investors, and the expected impact on the U.S. economy, innovation, and the value of intellectual property. The letter includes a large number of footnotes and citations.

"Invent Here, Make Here" Legislation May Advance (UPDATE)

The COGR December Update discussed the "Invent Here, Make Here" legislation introduced by Sen. Baldwin (S. 1956). The bill strengthens the existing Bayh-Dole Act domestic manufacturing preference (35 USC 204) to make domestic manufacturing a requirement with stringent requirements for waiver requests.

The bill languished for several months. However it now is scheduled for markup by the Senate Commerce, Science and Transportation Committee. The bill amends Section 204 of the Bayh-Dole Act to require that all products related to a subject invention "be manufactured substantially in the U.S." Currently Section 204 applies only to exclusive licenses and sales in the U.S.

The most disturbing aspect of the bill is the manufactured substantially definition: "manufactured substantially from all articles, materials, or supplies mined, produced, or manufactured in the United States." The definition is unworkable, since there is no feasible way to assure compliance of all product components with all of these facets. Waivers could be granted by agencies only on a showing of lack of commercial feasibility or unsuccessful attempts to find licensees that would comply with the requirement. No waivers would be allowed for manufacturing in a "country of concern."

The Bayh-Dole Coalition is strongly opposed to the bill. In a letter to the Committee Co-Chairs, they pointed out that the burden would fall mostly on small businesses including SBIR firms that receive the majority of academic patent licenses. The letter also noted the current waiver process is already broken and the bill makes the process even more cumbersome. It made several suggestions for alternative approaches.

The intent of the bill is understandable. However, licensing federally-funded technologies is challenging and complex, and this bill would add additional burdens and complexities to the process. Unfortunately, the result probably would be for more technologies to "sit on the shelf" and not be developed into commercial products. This is the opposite of what Bayh-Dole was intended to achieve.

A mark-up on the bill was scheduled for May 16 but it was cancelled. Various redrafts of the bill have been circulating among Congressional staffers which would address our biggest concerns. We will keep the COGR membership informed.

Enhanced Export Controls for Artificial Intelligence (NEW)

A bipartisan bill (H.R. 8315) has been introduced that would "modernize" the 2018 Export Control Reform Act that would give the Bureau of Industry and Security more authority to impose export controls on Artificial Intelligence (AI). The bill, titled *Enhancing National Frameworks for Overseas Restriction of Critical Exports Act* or ENFORCE, expands BIS Authority to control the transfer of AI systems. This includes authority to use "U.S. person" controls for AI and require licenses for export of AI systems.

The bill was scheduled for markup on May 17 but was pulled. The implications for fundamental research are unclear.

Contracts & Grants Administration (CGA)

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

NIH Grants Policy Statement (NEW)

On May 2, 2024, NIH released (NOT-OD-24-115) the revised version of the NIH Grants Policy Statement (NIHGPS) applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2023. NIH noted that changes in response to the updated 2 CFR Part 200 will be included in the FY 2025 release of the NIHGPS.

NIH provides a table of Significant Changes to the GPS for FY 2024 for the following sections:

- In all sections, for consistency with the Uniform Guidance, replaced "prime recipient" with "pass-through recipient," replaced the terminology FOA (Funding Opportunity Announcement) with NOFO (Notice of Funding Opportunity), and replaced the term "commercial organization" with "for-profit."
- Added entries for Animal Welfare Assurance, For-Profit Organization, and Notice of Funding Opportunity to section 1.2 Glossary.
- Updates and revisions to section 2.3 Application Information and Processes. A new notice type, Notice of Intent to Publish, was added in subsection 2.3.5.1. In subsection 2.3.7 Policies Affecting Applications, clarified the definition of Early Stage Investigator in line with NOT-OD-19-072, added language regarding post-submission materials in line with NOT-OD-23-106, and updated the heading for NIH Genomic Data Sharing to NIH Data Management and Sharing and Genomic Data Sharing. Additionally, headings were changed for section 2.3.9.1 (now "Electronic Submission Requirements"), section 2.3.9.2

(now "On-time Application Submission"), and section 2.3.9.3 (now "Continuous Submission for Appointed Members of NIH Federal Advisory Committees"). New subheadings were added to 2.3.9.2.1 (Late Applications) and 2.3.9.6 (Natural Disasters and Other Emergencies)

- Updates and revisions to section 2.5 Completing the Pre-Award Process (2.5.1 JIT procedures and 2.5.2 Submitting revised project summary/abstracts, specific aims, and/or Public Health Relevance Statement).
- Provided clarifications, updates, and revisions to section 4.1 Public Policy Requirements and Objectives (see additional information above in REC for section 4.1.1 Animal Welfare Requirements and 4.1.10 Financial Conflict of Interest)
- Revised the language in section 8.1 Changes in Project and Budget to clarify that recipients must notify NIH of developments that significantly impact the award-supported activities as soon as they become known.
- Revisions to section 8.2 Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources. Revising subsection 8.2.3.1 to incorporate the current NIH DMS policy and moving genomic data sharing policy from section 8.2.3.5 to a new section 8.2.3.1.1. Also revised the government support clause to require the grant number and to specify NIH as the Federal awarding agency in subsection 8.2.4.
- Updates to section 8.4 Monitoring for subsections 8.4.1.5.2 Financial Expenditure Reports, updating the section to replace OFM with FFR-C and incorporating language in 8.4.1.5.3 (3 Revised Financial Reports and Expenditures) in line with NOT-OD-23-102 (Guidance for the Repayment of Grant Funds).
- Updates to section 8.6 Closeout in line with NOT-OD-23-102 (Guidance for the Repayment of Grant Funds) adding added language clarifying that recipients must submit a revised FFR when a refund of $20,000 or greater is due back to NIH and that refunds under $20,000 should be sent directly to PMS with instruction to post the funds to Miscellaneous Receipts.
- Updates and revisions to section 11.2 Individual Fellowships, revising predoctoral training to include *basic biomedical or clinical sciences, in behavioral or social sciences, or in health services research*. Also incorporated the reminder in NOT-OD-23-111 on NIH policies for NRSA stipends, compensation and other income and added language in line with NOT-OD-23-094.
- Updates and revisions to section 11.3 Institutional Research Training Grants. Incorporated NOT-OD-23-094 regarding the redesign of the xTrain Module in eRA Commons and requirements for trainees to sign reappointments and amendments. Also made editorial changes in section 11.3.3.3 and added clarifying language to define dual degree programs and eligibility for the predoctoral training program.
- Corrections and updates to section 14.10 Allowable and Unallowable Costs regarding costs for meals.
- Updates to section 15.2 Administrative and Other Requirements in subsection 15.2.1 Written Agreements to incorporate NOT-OD-23-182 final policy guidance for subaward/consortium written agreements stating there must be a written agreement signed by both parties and foreign subrecipients must provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes described in progress report no less than once per year.

NIH Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2024 (NEW)

NIH published on April 23, 2024, Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2024 (NOT-OD-24-104), superseding NOT-OD-23-076. Stipends were raised by 4% for predoctoral trainees ($28,2247 for FY 2024) and 8% for postdoctoral scholars (starting at $61,008 for FY 2024). NIH expressed commitment to reaching the $70,000 recommendation over the next 3-4 years as recommended in the Advisory Committee to the Director Working Group on Re-Envisioning NIH-Supported Postdoctoral Training report. The Training Related Expenses and Institutional Allowances for predoctoral and postdoctoral trainees and fellows reflect a moderate increase (increased by $200). The Tuition and Fees for all educational levels remain unchanged from the prior budget year.

FAR Prohibition on Certain Semiconductor Products and Services (NEW)

DoD, GSA, and NASA issued an advanced notice of proposed rulemaking (89 FR 36738) to amend the Federal Acquisition Regulation (FAR) to implement paragraphs (a), (b), and (h) in section 5949 of the FY 2023 National Defense Authorization Act that prohibits executive agencies from procuring or obtaining certain products and services that include covered semiconductor products or services effective December 23, 2027. CGA is reviewing the ANPR to understand potential impacts fully and welcomes any feedback you may have by contacting Krystal Toups at ktoups@cogr.edu. Comments for the ANPR close on July 2, 2024.

FAR Federal Acquisition Supply Chain Security Act (FASCSA) /Orders (NEW)

The DoD, GSA, and NASA issued an interim rule, effective on December 4, 2023, amending the Federal Acquisition Regulation (FAR) to implement supply chain risk information sharing and exclusion or removal orders consistent with the Federal Acquisition Supply Chain Security Act of 2018 (Title II of the SECURE Technology Act, Pub. L. 115–390, Dec. 21, 2018) and a final rule issued by the Federal Acquisition Security Council (FASC). The rule creates three new Federal Acquisition Regulation (FAR) clauses, FAR 52.204-28 Governmentwide Acquisition Contracts, 52.204-29 Federal Acquisition Supply Chain Security Act Orders—Representation and Disclosures, and 52.204-30 Federal Acquisition Supply Chain Security Act Orders—Prohibition. The new FAR clause applies to all relevant solicitations and contracts, including contracts below the simplified acquisition threshold (SAT), contracts or orders for commercial products or services (including commercial off-the-shelf (COTS) items), and orders under indefinite delivery, indefinite quantity contracting vehicles. The rule requires contractors to monitor the issuance of FASCSA Orders on SAM.gov regularly. At this point, no FASCSA orders have been published. New or amended contracts should be for the new FAR clause to determine if there are any associated FASCSA orders. Contact Krystal Toups at ktoups@cogr.edu for questions.

Grant & Contract Administration: Other Issues (NEW & ONGOING)

The items below are issues that the CGA Committee has recently reported and/or issues that we continue to follow:

SAM.gov (ONGOING). As reported in September 2023, February 2024, and March 2024, COGR is actively engaged with GSA on the challenges members report with SAM.gov renewals/registration. COGR hosted Ms. Ivana Henry, Management and Program Analyst, U.S. General Services Administration, who presented an

Overview of System for Award Management (SAM) Registration Process – Challenges & Tips. She addressed the following key areas. COGR has engaged federal officials, including OMB, on the concerns of the community and will keep the COGR membership updated on all developments. Additionally, to assist with our advocacy efforts, COGR has established a workgroup with members from the community. We encourage COGR members to contact Krystal Toups at ktoups@cogr.edu if they are experiencing challenges or have comments or concerns to report related to SAM.gov registration.

NIH Data Management and Sharing (DMS) (ONGOING). NIH published NOT-OD-24-123 announcing changes planned to the Research Performance Report (RPPR) instructions to address DMS. NIH plans to implement new questions for the RPPRs submitted on or after October 1, 2024. CGA is following this update and will update the community accordingly.

Research Environment (ONGOING). CGA has been closely following developments related to the NSF OIG Review of award recipient compliance with NSF's harassment policies. As part of the FY 2024 Annual Audit Work Plan, NSF will assess whether the policies and procedures at a sample of 100 NSF-funded institutions comply with NSF's harassment terms and conditions. The report is expected to be issued by August 2024. CGA is gathering preliminary information on common themes and observations to present to COGR members. If you would like to share observations from a review, please contact Krystal Toups at ktoups@cogr.edu.

Costing and Financial Compliance (CFC)

Select CFC activities related to the Uniform Guidance are reported above under the Cross-Cutting Issues section of the COGR Update. Other issues followed by CFC are covered below.

F&A / Indirect Cost Caps Back in the News (NEW)

Inevitably, when higher education is elevated to front page news – most recently due to student protests – it seems indirect costs and endowments become targets for political gamesmanship. On May 2, the *No Subsidies for Wealthy Universities Act* was proposed by Sen. Mike Lee (R-UT) and Rep. Ben Cline (R-VA). The Senate version is co-sponsored by Sens. Roger Marshall (R-KS) and Josh Hawley (R-MO). The bill would eliminate facilities and administrative (F&A) costs reimbursement (*aka*: indirect costs) on grants for universities with endowments over $5 billion, cap reimbursements to 8% for universities with endowments between $2-$5 billion, and cap reimbursements at 15% for all other universities. The bill also would require reporting on federal funds used towards administrative and DEI staffing.

Our sister associations – AAU, APLU, and AIRI – are engaging leaders on Capitol Hill and monitoring the prospects of this legislation. To date, the sense is this legislation will not garner momentum. Nevertheless, the research community needs to stay diligent around this recurring issue. The reemergence of proposals to can F&A reimbursement costs provides an opportunity to dust off two important, and still relevant, COGR publications: Finances of Research Universities (June 2014) and Excellence in Research: The Funding Model, F&A Reimbursement, and Why the System Works (April 2019).

We will keep the membership posted on developments.

F&A Cost Rate Survey and Capstone Report (UPDATE)

The publication date for the 2024 F&A Capstone Report – an upcoming COGR report and analysis on F&A cost rate trends and other observations around F&A cost rates and reimbursement – has been moved to later in 2024. However, a third report will be added in June to the 2023 F&A Survey Report page (login required). The three reports that will be available are:

- F&A Cost Rates (and other demographics) by Institution
- Off-Campus / MTDC Definitions by Institution
- Summary of Responses to Selected Survey Questions

The Summary of Responses report contains charts and graphs documenting the results of the 120 institutional survey responses and addresses topics such as methodologies used in F&A proposals, negotiation experiences, institutional resources committed to the F&A process, and other areas of interest. These reports are meant to be used for institutional purposes only and should not be shared beyond the institution. In addition, both a June 2023 presentation and an October 2023 presentation at past COGR meetings featured analyses that may be of interest to the COGR membership.

Timeliness of F&A Cost Rate Negotiations: F&A Survey Results (REMINDER)

The timeliness of completing F&A cost rate negotiations (as well as fringe benefit rates) has been problematic for institutions over the past several years. Anecdotally, the time between submitting an F&A cost rate proposal and arriving at final negotiation of cost rates could exceed two years. We addressed the "timeliness" concern in the F&A Cost Rate Survey and crafted several survey questions around this topic. For one of the questions included in the survey, the results showed:

- 84 out of 120 survey respondents indicated their F&A cost rates were up-to-date and "all was good."
- For the remaining 36 survey respondents, 22 responses also suggested "all was good."
- However, 14 of the remaining 36 indicated some level of concern around timeliness – for example: *We have submitted a proposal and our rates have expired, we are officially concerned.*

The survey results suggest there may be a systematic problem around timeliness rather than anecdotal only. Still, the systematic problem may be more regionally based rather than national. In the case of institutions that work with the Northeast region of Cost Allocation Services, timeliness seems to be less of a concern. Whereas in other regions, the concern is heightened.

F&A cost rate negotiations are a fluid process and what was true one year ago may not be true today. As such, we are asking COGR members to keep COGR updated on concerns around timeliness. In December of 2022, COGR sent a letter to Mak Karim, the National Director for Cost Allocation Services at HHS, to address the concern. Over the past year, we have continued to lift the concern to OMB within the context of our Uniform Guidance responses. We are also considering a short survey of the membership as an update to COGR's F&A Cost Rate Survey from last year.

Please reach out to COGR if your institution is experiencing a problem around this topic. We will continue to advocate for solutions as long as this issue persists.

Costing & Financial Compliance: Audit and Other Topics (ONGOING & REMINDERS)

The items below are issues that the CFC Committee has recently reported and/or issues that we continue to follow:

New CAS Requirement to Adjust Indirect Cost Pools

We have reported in the past three COGR Updates (most recently, March 2024 Update, p. 22) on a Cost Allocation Services (CAS) position that required adjustments to me made to indirect cost pools for salaries exceeding the Executive Level II (NIH, HHS) salary cap. The genesis of this position was based on a finding in an HHS OIG report, Cost Allocation Services Needs to Update its Indirect Cost Rate Setting Guidance (see p. 23, Indirect Cost Rate Proposals Included Potentially Unallowable Compensations Costs). ***For now, the CAS/OIG position has been reversed and the salaries are not capped.*** However, OMB and HHS continue to review this case and we expect an update soon. Until then, we will remain in "wait-and-see" mode, and as appropriate, continue advocacy work with AIRI (Association of Independent Research Institutes) to bring this issue to a favorable closure.

Personal Information and Federal System Log-on Concerns

We provided an update in the March 2024 Update (pp. 21-22), in addition to prior updates going back to the fall of 2023. This issue intersects federal reporting systems, safe and secure system log-ons, federal policy, and other federal agency technology applications – all of which, combined, have created operational and administrative challenges at COGR member institutions. Primary examples of the challenge have been demonstrated by new security protocols required for logging into the Automated Standard Application for Payments (ASAP) and the Payment Management Services (PMS) federal payment systems, maintained by the Departments of Treasury and HHS, respectively. The concern is demonstrated by the personal identifying information (PII) required to log-in to these systems (e.g., ID.me to login to PMS). While ASAP and PMS are primary examples, ***COGR is on the look-out for other examples where one's PII is required to be used in the workplace.*** COGR has raised concerns to OMB, though the solution is not obvious. However, we will continue to research and engage this issue and will keep the COGR membership updated on all developments.

Financial Reporting Developments at NASA

We have reported on developments at NASA for the past year (most recently, March 2024 Update, pp. 23-24). Over the course of this period, COGR has developed a strong working relationship with NASA's Grants Policy and Compliance Team (GPC) led by Antanese Crank, Chief, and her team of four other individuals (see GPC webpage for complete point of contact information). The two financial compliance initiatives we have engaged are the *Transition from FCTR to FFR* and implementation of the *Routine Monitoring–Financial Transaction Testing Review program*. Prior COGR reports have detailed the issues, challenges, and advocacy around these

two topics, and while we have not achieved ideal resolutions, we have made progress. We will stay in communication with NASA and the GPC team, as needed, but also encourage COGR members to reach out to the GPC team when issues arise.

Single Audit & the 2024 Compliance Supplement

OMB expects the 2024 Compliance Support (CS) to be published soon. We were pleased with the OMB engagement and their rollout of the 2023 Compliance Supplement, and in particular, changes made to the Cash Management section (see page 3-C-3). While we don't expect any significant changes to the 2024 CS, we will closely review key sections when it is available. We welcome COGR members to contact us on audit issues that arise, including issues applicable to the Compliance Supplement. When appropriate, we will reach out to our contacts at the OMB and the audit firms and engage, accordingly.

Federal Office of Inspectors General (OIG) Developments

COGR members are encouraged to follow NIH-related audit activity posted in the HHS OIG Workplan, as well as completed reports posted under All Reports and Publications (select by HHS Agency). For activity from the NSF OIG, the NSF OIG Reports & Publications page lists recently completed reports. Further, the NSF Management Responses to an External Audits is a helpful resource for reviewing NSF OIG audit resolutions. COGR members are welcome to contact us when audit issues arise. When appropriate, we can connect institutions and/or provide feedback on the issues in question.

NSF Project Reporting Compliance Program

We first reported on this topic in the COGR September 2023 Update (p. 20). NSF introduced a pilot *Project Reporting Compliance* program for three participating NSF Divisions: Computing and Communication Foundations (CCF); Civil, Mechanical and Manufacturing Innovation (CMMI); and Information and Intelligent Systems (IIS). NSF will temporarily withhold payments for an award if the PI fails to submit annual project reports 90 days prior to the end of the annual budget period of the project. Several implementation concerns have emerged, and when reported to NSF, officials have been open to addressing them. We encourage COGR members to contact NSF and/or COGR when issues arise.

2022 NSF Higher Education Research & Development (HERD) Survey

The 2022 HERD results were released on November 30, 2023. Included are the InfoBrief and the complete suite of 2022 data tables (which contains the popular *Table 22 – Higher education R&D expenditures, ranked by all R&D expenditures, by source of funds: FY 2022*). Also of interest is Table 4 from the InfoBrief, which presents data on recovered and unrecovered indirect costs, in aggregate, for all institutions. For FY2022, the total recovered indirect costs were $16.1 billion (out of $22.3 billion incurred) and the total unrecovered indirect costs were $6.2 billion (up from $5.9 billion in FY2021).

Please contact David Kennedy at dkennedy@cogr.edu to discuss any of the issues above, or other items that you would like to address.

Research Ethics & Compliance (REC)

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

REC Open House (NEW)

On May 28, 2024, at 11:00 a.m. (ET), REC will host the first in a series of open houses with each of the COGR Committees. The event will offer a chance for representatives from COGR member institutions to meet with REC members to learn more about REC's portfolio, current projects, and how to become more involved with REC and COGR. Individuals who would like to attend the Open House should register via the COGR Portal here.

Certificates of Confidentiality (NEW)

Certificates of Confidentiality (Certificates) are deemed to be issued to NIH-funded research to protect identifiable sensitive information ("Covered Information"), and NIH may also issue Certificates to non-NIH funded research projects on request. Member institutions notified REC that they have received questions from NIH about how third parties involved in research projects (e.g., survey platforms, data storage platforms) would protect project data they received in accordance with the Certificate's requirements. In response, REC contacted NIH concerning its expectations for implementation of the following institutional assurance statement concerning Certificates of Confidentiality ("Certificate"):

> This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges. ***In addition, this institution will not utilize third parties or entities (e.g., contractors, online platform vendors) to collect or store information that cannot or will not protect against the compelled disclosure of the personally identifiable information.*** [Emphasis added.].

In particular, COGR asked NIH for clarification about the basis for subawardees, subcontractors, or vendors to assert the protections of a Certificate, given that the Certificate is issued/deemed to be issued to the prime awardee/contractor.

NIH advised that it had received an inquiry concerning a third-party platform that was unable to contractually agree to protect against compelled disclosure, as required per a Certificate. In response to this situation, NIH advised that it updated the institutional assurance statement to reinforce grantees' responsibility to protect Covered Information at all stages of the research, including stages where third-party platforms are used. NIH stated that institutions should consult with their legal counsel regarding the use of third-party platforms and their ability to adhere to the Certificate's requirements. NIH also stated that it likely will ask institutions about protections afforded by third-party platforms before issuing a

Certificate to non-NIH funded research. Finally, NIH encouraged institutions to consider ways in which to protect Covered Information provided to third-party platforms including providing only de-identifiable information, selecting platforms that automatically delete, or allow the institution to delete, Covered information after a very short time, or bring the third-party platform in-house as part of the institution's systems.

Updated NIH Grants Policy Statements Concerning Financial Conflicts of Interest and Animal Welfare (NEW)

The recent updates to the NIH Grants Policy Statement included the following additions to sections regarding financial conflict of interest (FCOI) and sections concerning animal welfare requirements at foreign institutions:

- **Section 4.1.10, FCOI**: This section was amended to reflect changes made to GPS Section 15.2.1 concerning written subaward agreements. Specifically, the agreements must specify whether subrecipients will apply their own FCOI policies or rely on those of the prime awardee, and in all cases include required significant financial interest disclosure, review, and FCOI reporting timelines to ensure compliance with the FCOI regulations.

- **Sections 4.1.1 – 4.1.1.4, Animal Welfare and Foreign Recipient/Performance Sites**: These sections were amended to clarify the Animal Welfare Assurance and IACUC (or in the case of a foreign site, an alternative oversight review body) approval requirements at foreign and domestic sites, along with the necessity for institutions to conduct a congruence review between the grant application and IACUC-approved protocol when the IACUC approval date is provided.

Final Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (NEW)

The proposed changes to the NIH Guidelines were published in on August 10, 2023 [88 F.R. 54332], and COGR submitted comments. NIH published its final changes to the NIH Guidelines on April 5, 2024. The final Guidelines retain the initially proposed definition of "gene drive" as "a technology whereby a particular heritable element biases inheritance in its favor, resulting in heritable element becoming more prevalent than predicted by Mendelian laws of inheritance in a population over successive generations." As suggested by COGR and other commenters, the final Guidelines were modified to reference different containment practices for arthropods, as well as to include sources of containment practices for additional species. Finally, the final Guidelines clarify the two instances where transgenic rodents are specifically exempted from the Guidelines' application: (a) the purpose or transfer of transgenic rodents under Appendix C-VII; and (b) the generation of BL1 rodents by breeding. The final Guidelines also state that the use of exempt rodents remains exempt *unless* the subsequent research involves the use of recombinant or synthetic nucleic acid molecules.

HHS/USDA Notices of Proposed Rulemaking – Select Agent Regulations (UPDATE)

COGR submitted comments in response to the CDC's proposed rules and USDA's proposed rules regarding the current list of select agents and toxin. (See, 89 FR 5823 [HHS] & 89 FR 5795 [USDA]). The proposed rules, which are part of a biennial review process, remove certain select agents from the lists and make changes to certain definitions, exemptions, and training requirements.

COGR's response to the proposed rules expressed concerns about the overbreadth and ambiguity of the definition of "release" and provisions regarding the scope of personnel who would be required to take select agent and toxin related training. COGR provided suggested clarifications in each of these areas that would make implementation of these requirements easier for institutions.

Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (NEW)

In May 2024, OSTP published guidance regarding oversight for Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP). Each agency will be responsible for implementing the Guidance, which has an effective date of May 6, 2025. This Guidance supersedes the 2012 U.S. Government Policy for Oversight of Life Sciences Dual Use Research of Concern, the 2014 U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, and the 2017 Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO). OSTP previously issued an RFI to collect input on proposed changes in October 2023, and COGR submitted comments at that time.

The final version of the Guidance refers to DURC as Category 1 research and research involving PEPP as Category 2 research. The Guidance broadens the scope of agents that potentially fall under Category 1 and Category 2 research.

Under the new review process outlined in the Guidance, the Principal Investigator must assess whether proposed or ongoing research constitutes Category 1 or 2 research, and if so, notify the federal funding agency at the time of proposal. Each institution must have an "institutional review entity" (IRE) that then assesses whether the research meets Category 1 or Category 2 criteria. Institutions may use existing biosafety and/or DURC review committees to fulfill this IRE role.

The IRE must then notify the funding agency of its determination, and if the funding agency agrees that the research is Category 1, then the IRE and PI must develop and submit a risk assessment and risk mitigation plan to the federal funding agency for review and approval. For Category 2 research, the risk assessment and risk mitigation plan must be reviewed by a multidisciplinary review entity that is convened by the federal department funding the research.

Dr. Michael Lauer, Deputy Director for Extramural Research at NIH, will meet with REC members on June 5, 2024, to discuss NIH's plans for implementing the Guidance, which is expected to add significantly to the number of research protocols that require review, as well as the time required for that review.

Centers for Medicare & Medicaid (CMS) Request for Information (RFI): Research Data Request and Access Policy Changes (UPDATE)

COGR submitted comments in response to this RFI regarding changes to the manner in which researchers can access request identifiable claims data for their research. Currently, researchers can request physical data extracts that they can use at their institutions, provided certain cybersecurity requirements are met, or they can access the data via CMS' virtual data center. Physical data extracts permit researchers to link the CMS data with other data sets and utilize institutionally based analysis tools. CMS, however, plans to eliminate the option for physical data extracts for new studies in 2024 and transition existing studies that use extracts to the virtual data center in 2025. Additionally, CMS plans to make changes to the existing pricing structure for accessing data.

COGR's response letter highlighted the need for researchers to maintain continuing access to physical data extracts to ensure CMS data can be linked to other large patient and outcomes data sets that are not available in CMS' virtual data environment. COGR noted that institutions and federal funding agencies have made substantial investments in ensuring that existing data enclaves that house CMS data are secure, and these investments should not be disregarded. COGR also emphasized that the dramatically increased seat fees and project fees may price many institutions out of doing research with CMS data, or substantially limit the number of researchers who can access the data, thus causing substantial harm to early-stage researchers.

COGR also joined other institutions in meeting with CMS on May 10, 2024, to discuss institutions' concerns regarding the RFI. During the meeting, CMS acknowledged the importance of the research that is conducted using its data. It also emphasized the need to ensure that the research data was secure and that its fee structure was both equitable and adequate to cover expenses for providing the data. The meeting was very productive, and CMS expressed its willingness to continue discussions with the research community after it reviews the RFI responses.

OLAW Webinar on Research Using Agricultural Animal Species (NEW)

In March, OLAW conducted a webinar regarding research using agricultural animal species. The webinar discussed when the Animal Welfare Act (AWA) applies to such research. Institutions raised concerns to REC that the webinar's statements regarding the application of the AWA to some types of research were much broader than previous interpretations. COGR is working with NABR to look into these concerns and obtain clarification as to whether USDA's interpretation of the AWA's scope has changed.

Appendix A – Upcoming Comment Due Dates

Agency	Description	Due Date	Notes
DOD/GSA/NASA	FAR Prohibition on Certain Semiconductor Products and Services ANPR	July 2	COGR is reviewing for potential impacts.
CISA	Cyber Incident Reporting for Critical Infrastructure Act (CIRCIA)	July 3	COGR expects to submit joint association letter.

COGR would like to thank COGR Board Chair Jeffrey Silber (Cornell 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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