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## COGR

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#### President's Message

Dear Colleagues,

Next month we will celebrate COGR's 75th anniversary during our October 26-27 meeting in Washington D.C. From a NACUBO committee to an independent nonprofit organization, COGR continues to be a dynamic organization that serves its members' interests.

COGR also continues to grow in size and stature. We welcomed the University of Texas San Antonio, the University of Texas El Paso, and the University at Albany SUNY to the association over the summer. COGR's new members further strengthen our standing as a leading voice for sound, efficient, and effective regulation that safeguards research and minimizes administrative and cost burdens. COGR now comprises 215 research institutions in 48 states with over \$45 billion in combined annual federal research expenditures.

Over the summer, our advocacy efforts yielded positive outcomes. First, NASA issued a new financial conflict of interest (FCOI) policy that was very responsive to comments provided by COGR and other associations and institutions. Unlike the originally proposed NASA policy, the new policy is patterned after NSF's current FCOI policy, which will enable institutions to leverage their existing FCOI processes to comply. Second, the Department of Energy (DOE) expressed appreciation for COGR's notification of a potential error in recent funding opportunity announcements concerning implementation of DOE's interim FCOI policy and noted that the provisions would be corrected. These are just two recent examples of how our collective efforts make a difference. Thank you.

As the federal fiscal year ends this week, we watch with great frustration and disappointment as Congress once again has failed to complete the appropriations process on time. A federal government shutdown looks all but certain. Everyone loses when this happens.

The uncertainty and disruption that the threat of an actual shutdown causes at our institutions wastes energy, time, and resources that would otherwise be focused on teaching and research. To aid your efforts, COGR has pulled together a "<u>Considerations when Preparing for the Federal Government Shutdown</u>" document that draws from past shutdown experiences and outlines matters and actions institutions should consider. We will continue to provide updates and resources about the appropriations impasse and a shutdown should it come to pass. COGR members will effectively manage whatever comes our way, even if Congress doesn't.

I hope you are able to join us as we recognize COGR's 75<sup>th</sup> anniversary next month. I look forward to seeing many of you then.

Matt Owens, President



#### Announcements

## <u>Registration Still Open: COGR's October 26-27, 2023, Meeting in Washington D.C. & 75<sup>th</sup></u> <u>Anniversary Celebration (REMINDER)</u>

COGR will celebrate its 75<sup>th</sup> anniversary during the October 26-27, 2023, meeting in Washington, D.C. Originally a standing committee in what is now the National Association of College and University Business Officers (<u>NACUBO</u>), COGR began operating as an independent organization in 1994 and today has a membership of over 200 of the most research-intensive institutions in the U.S.

October's <u>preliminary agenda</u> is now available, and <u>registration is still open</u>. Meeting materials are available on COGR's website, including our health and safety protocol. Be sure to <u>book your hotel room</u> by 10/3 for special COGR pricing.

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

#### June Meeting Session Recordings Now Available in COGR Video Library (NEW)

Recordings of several June 2023 COGR meeting sessions are now available for all COGR members to view via the <u>COGR Video Library</u>. In addition, several webinars and past meeting session recordings are available for view and sorted by year and tagged by keywords. Session registration is not required to view, but you do need to be logged into the COGR Portal.

#### September 2023 Update Appendix on Upcoming Comment Due Dates (REMINDER)

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>). We hope this list is a helpful brief supplement to the detail and analysis provided within this Update on each of these topical areas.

#### Did You Know? COGR Is Now on LinkedIn (REMINDER)

We invite you to follow <u>COGR on LinkedIn</u> and stay up to date on COGR's advocacy efforts, upcoming events, joint initiatives with other higher education associations, and more. You can find colleagues to connect with and interact with COGR's content by "liking" and commenting on COGR's posts.

In addition to providing a new engagement platform for COGR members, we also use LinkedIn to help elevate COGR's effectiveness in affecting federal research policy and practices, amplify our advocacy with key federal agencies by providing an additional avenue to share information, and build relationships with federal partners. We look forward to engaging with you on LinkedIn.

#### COGR Portal: Sign Up for Access Today! (REMINDER)

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> (that includes recordings of past COGR webinars and meetings), view the <u>COGR Member Directory</u>, check out <u>COGR's Job Board</u>, where member institutions can submit relevant job postings at their institutions, and view COGR members- only materials. In addition, the Portal is where Primary Representatives and financial billing contacts can manage their institutional dues invoices each year<sup>1</sup>. Encourage your team and other research-connected offices to sign up and stay up to date with COGR.

## 2 CFR 200 "Uniform Guidance": Cross Cutting Issues

#### Revisions to the Uniform Guidance "Unofficially" Available (NEW)

On September 22, OMB posted the following notice to the community stating:

Earlier today OMB posted a <u>blog</u> highlighting proposed <u>updates to the Uniform Grants</u> <u>Guidance</u>. OMB concurrently submitted the proposed updates to the Federal Register, which will be posted for public comment soon for a period of 60 days. We will provide an update when the notice is published for public comment. In the meantime, we encourage you to share this information broadly. We look forward to continuing to work with you as this process moves forward and want to express once again our appreciation for all of the contributions thus far.

Sincerely,

Deidre A. Harrison Office of Management and Budget, Office of Federal Financial Management

The *updates to the Uniform Grants Guidance* link points to the Federal Register Notice with all revisions included. However, the revisions to the Uniform Guidance have <u>not</u> completed OMB clearance protocols, and therefore, the revisions should be considered "unofficially" available. OMB clearance protocols could be a two-day or two-week process. If not posted within the next several days, and with a federal government shutdown looming, it is likely we would not see an "official" Federal Register Notice until after a shutdown is resolved. While this creates some uncertainty, the good news is that the 60-day public

<sup>&</sup>lt;sup>1</sup> COGR institutional annual dues invoices are available to generate now in the COGR Member Portal and due on August 1, 2023. To generate, you must be a Primary Representative or financial billing contact. Click on the 'renewal badge' on the Dashboard, update your contact information, and generate the invoice. Contact <u>memberservices@cogr.edu</u> with any questions.



comment period would not be triggered until an "official" posting in the Federal Register. We are grateful to OMB for sharing this now and giving the community a head start in reviewing the revisions. We will keep the membership posted on all developments.

#### COGR Strategy to Address Revisions to the Uniform Guidance (NEW)

As noted in the previous item, OMB has shared the "unofficial" revisions to the Uniform Guidance and the "official" revisions will be shared through a proposed rule in the Federal Register. Once it is published in the Federal Register Notice it will trigger a 60-day public comment period. COGR will submit a robust response and encourage active participation from the COGR membership.

Leading up to the October COGR meeting, the Costing and Financial Compliance (CFC) and Contract and Grant Administration (CGA) Committees will begin a thorough review of the revisions and begin to draft responses. At the COGR meeting, the two committees will lead a panel session on Thursday October 26<sup>th</sup> to discuss the proposed rule and COGR's response. The panelists will provide a status report on COGR's response and seek questions and comments from the audience.

Using an approximate due date to OMB for public comments of November 28, we will share periodic drafts of the COGR response throughout the month of November. **COGR members will be encouraged to use the draft COGR response to shape their institutional letters, including expressing support for COGR's response.** With uncertainty surrounding the status of a federal government shutdown and the actual publication date of the proposed rule, COGR's response timeline is subject to change.

COGR has conducted this "drill" several times over the past decade and our approach to responding to OMB has proven effective! We welcome those of you who are interested in more formally participating in crafting the COGR response to reach out to COGR staff. CFC and CGA are in the process of creating a workgroup to complete this project.

If you are interested in volunteering for the Uniform Guidance workgroup, please contact David Kennedy at <u>dkennedy@cogr.edu</u> and Krystal Toups at <u>ktoups@cogr.edu</u>. We welcome your participation in this important project!

#### COGR Letter to OMB: DS-2, 21st Century Library, and Timely F&A Negotiations (NEW)

On July 21, <u>COGR wrote to OMB</u> to reemphasize our position on three topics that we have urged OMB to address as part of the revisions to the Uniform Guidance: 1) Eliminate the DS-2, 2) Recognize Fair Reimbursement for the 21<sup>st</sup> Century Library, and 3) Timing for Establishment of F&A Cost Rates. In support of COGR's position on the 21<sup>st</sup> Century Library, the Association of Research Libraries (ARL) wrote a <u>follow-up letter</u> addressing this issue in more detail. As we craft the COGR response to the Uniform Guidance revisions, we will carefully consider how to address these three issues effectively.



#### COGR's Uniform Guidance Resource Page (ONGOING)

COGR has developed a <u>Uniform Guidance Resource Page</u> to serve as an ongoing resource as the revisions to the Uniform Guidance unfold. This page includes past COGR comment letters and other related resources. COGR's first engagement with this issue was in 2011 when, under the auspices of an NIH RFI, we provided comments to the "A-21 Task Force" to address OMB Circular A-21.

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

#### <u>COGR Chart Documenting Current Status of Agency Implementation of NSPM-33 and 2022</u> <u>CHIPS and Science Act Research Security Provisions (NEW)</u>

The agencies involved in the NSTC-coordinated implementation efforts of NSPM-33 and research security related provisions in the 2022 CHIPS and Science Act ("CHIPS Act") continue to make steady progress. Simultaneously, agencies continue in their individual efforts to implement NSPM-33 requirements, and it remains to be seen how closely agencies will harmonize their approaches after the NSTC research security subcommittee publishes its common disclosure forms and common research security program standards.

COGR has <u>published a chart</u> providing an overview of where these efforts currently stand. It begins with a summary of NSPM-33 and the CHIPS Act's major requirements, and then provides a summary of individual agencies' implementation of those requirements. The chart is color-coded to indicate whether noted requirements are currently in place, in progress, or to be determined, along with any known timeframes for requirements that are in progress. COGR will continue to update this chart as additional information becomes available.

#### Associations Discuss CHIPS and Science Reporting Requirement with NSF (NEW)

On July 18, representatives of AAU, APLU, ACE and COGR met with NSF staff to discuss the CHIPS and Science Act Section 10339B<sup>2</sup> foreign gift and contract reporting requirement. That section requires annual reports from institutions of higher education (IHE) of gifts or contracts of \$50,000 or more from foreign countries of concern.

The NSF staff indicated they would work with the Department of Education (ED) to try to minimize the burden of the two separate reporting requirements (10339B of CHIPS and Higher Education Act Section 117). They intend to conduct stakeholder engagement and to beta test the reporting portal before full

<sup>2</sup> Additional resources on CHIPS: COGR's August 11, 2022 Webinar "A Look at the CHIPS on the Table:" <u>https://www.cogr.edu/looking-chips-table-webinar-august-11-2022</u> (Slides and recording available). A summary of research security provisions for the CHIPS and Science Act of 2022 (H.R. 4346), including Section 10339B, is available here: <u>https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/Science-</u>

<sup>&</sup>lt;u>Security/CHIPSandScienceFinalResearchSecurityProvisions.pdf</u> (Published August 8, 2022, Association of American Universities)



implementation. NSF chose to issue the requirement in the PAPPG because of information system priorities given to PAPPG requirements. The first reporting deadline will be July 31, 2024, covering the period July 1, 2023-June 30, 2024.

The association representatives raised several questions about NSF implementation of the requirement. One question involved the data elements required to be reported in the draft PAPPG. These go beyond Section 117 requirements (e.g., 5.f.). NSF asked for examples of the most burdensome requirements. A question also was asked about "countries of concern" that must be reported. NSF may clarify this in a FAQ. NSF likely will share the information with other agencies and conduct some kind of audit process.

Other questions were raised in a joint higher education association letter to NSF in June. One involved individual gift or contract disclosures vs. summary reporting. While the statute appears to require only summary reports, NSF indicated that disclosures of specific gifts and contracts will be required. NSF will prepare summary reports based on the disclosures received. In response to a question about reporting tuition, NSF indicated a literal reading of the statute requires that tuition be included. There were no clear answers to some of the other questions raised, such as the reporting of individual donor information.

It appears NSF is still considering all the issues associated with the new reporting requirement and the burden implications associated with the proposed implementation that COGR and our partner associations noted.

We will continue to engage with NSF and keep the membership apprised.

#### <u>COGR Submits Comments to NSF on Second Comment Period for the Common Disclosure</u> <u>Forms (NEW)</u>

NSF, on behalf of the National Science and Technology Council (NSTC) Research Security Subcommittee, <u>released</u> a second round comment period for the proposed Common Forms for the <u>Biographical Sketch</u> and <u>Current and Pending (Other) support (CPS)</u>. A summary of the responses to the comments received, including significant changes and clarifications, was provided in a <u>comment table</u>.

Notable revisions in the Common Forms include:

- New definitions added to the <u>NSPM-33 Implementation Guidance Appendix: Definitions</u> to define Academic Appointments and Positions, Foreign Country of Concern, Foreign Government-Sponsored Talent Recruitment Program, Institutional Appointments and Positions, Malign Foreign Talent Recruitment Program (MFTRP), Professional Appointments and Positions, and Scientific Integrity.
- Updated text simplifying the certification language, which includes the senior/key person to certify they are not a party to an MFTRP.
- Instructions for CPS revised to include new language to clarify types of consulting that must be



reported.

- Person-Months "Committed" changed to Person-Months "Devoted"
- CPS instructions for in-kind contributions updated to include reporting thresholds ("estimated dollar value of \$5,000 or more and that require a commitment of the individual's time"). Additionally, the requested categories were revised to better align with reporting in-kind information.
- Inconsistencies in data elements identified in the Common Forms in COGR's letter dated October 31, 2022 were addressed.

The August 7 notice sought comment on fatal flaws in the proposed Common Forms. COGR, joined by AAU and APLU, <u>submitted a response</u> on September 11. The letter commended revisions to the NSPM-33 Definitions Appendix that defined Institutional, Professional, and Academic Positions and Appointments; increased burden assessments; modified certification language; and modified in-kind contributions, including updating the required data elements and establishing a \$5,000 reporting threshold. Additionally, the COGR-AAU-APLU letter acknowledged the efforts of federal agencies to address community concerns/feedback. The letter identified four areas pertaining to fatal flaws: 1) in-kind contributions, 2) the definition of a malign foreign talent recruitment program, 3) consulting, and 4) person-month(s) per year devoted and provide comments on start-ups and appointments, requesting anything not deemed to be a fatal flaw by the agencies to be clarified in subsequent resources for the community, e.g., FAQs, guidance documents, or notices. Each of these are essential areas for the community to provide training and implement effectively. NSF recently clarified one such area, the definition of MFTRP, during the September FDP meeting. *NSF stated the interpretation of an MFTRP is, as it reads in CHIPS & Science, criteria listed in (A) AND (B).* 

While there is no specific date on when the final forms will be available, agencies have indicated they are working to finalize the forms and that institutions should socialize the proposed Common Forms for implementation.

#### Final NIH Written Subaward/Consortium Notice (UPDATE)

On June 5, NIH published an RFI seeking comments on NIH's <u>Notice to Announce NIH Updated Policy</u> <u>Guidance for Subaward/Consortium Written Agreements</u> ("Policy Update"). Although described by NIH as a reiteration of existing requirements, the Policy Update contained a new provision that required foreign subrecipients to provide prime recipients with all lab notebooks, data, and documentation that supports research outcomes described in progress reports. Institutions were concerned that this requirement was overly broad and would harm important international collaborations.

On June 30, COGR, submitted <u>comments</u> noting concerns with the Policy Update and suggesting an alternate approach. Many other associations and institutions also submitted comments as well. COGR supported NIH's longstanding requirement for a formal written agreement that details how grant



requirements will be fulfilled, but we objected to the tremendous burden associated with amassing and providing prime recipients with copies of all data that supports research outcomes at least once every six months. COGR also noted that the requirement is not risk-based and could potentially put subrecipients in violation of their countries' laws concerning privacy and confidentiality. Moreover, we suggested that access to supporting data could be more efficiently and effectively addressed by modifying NIH's existing Data Management and Sharing (DMS) Policy to give NIH authority to require that DMS plans include additional data and supporting documents when there is a specific need posed by the type of research (or proposed collaborators) and the research is located in a country of concern. After submitting comments, COGR engaged in follow-up with NIH and offered to arrange a meeting with researchers whose work would be negatively impacted by the Policy Update.

On September 16, NIH released its <u>Final Updated Policy Guidance for Subaward/Consortium Written</u> <u>Agreements</u> ("Final Updated Policy") after considering all submitted comments. The Final Updated Policy provided some reduction in the burden placed upon foreign subrecipients by stating they need only "provide access to" (as opposed to copies of) "copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report, to the primary recipient." The Final Updated Policy also reduced the frequency for the provision of access from every six months to once per year, and it noted that access may be entirely electronic.

COGR will work with its member institutions to monitor the impact of the Final Updated Policy on international research. We stand prepared to alert NIH to negative impacts that may emerge, such as the withdrawal of foreign subrecipients from international collaborative research projects<sup>3</sup>.

#### **Department of Energy (DOE) Interim Financial Conflict of Interest (FCOI) Policy (UPDATE)**

In response to concerns raised by COGR members, COGR contacted the Department of Energy (DOE) with respect to certain COI provisions in DOE's "Federal Assistance Reporting Checklist." Specifically, the terms called for institutions to make DOE aware of a covered individual's newly acquired "significant financial interests." In response to COGR's inquiry, the DOE Office of Sponsored Activities advised that DOE would correct these provisions to make clear that "there is no requirement to notify DOE" of newly acquired significant financial interests. Rather, researchers are required to report newly acquired significant financial interest to the institution for determination under the institution's processes as to whether they constitute a FCOI, and whether the FCOI can be managed or mitigated.

<sup>&</sup>lt;sup>3</sup> On 10/17, NIH will host a webinar: "Join NIH Policy Experts for a Guided Tour of Subaward Agreements — Sections, Requirements, & Key Policies" <u>https://nexus.od.nih.gov/all/2023/09/07/nih-webinar-join-nih-policy-experts-for-a-guided-tour-of-subaward-agreements-sections-requirements-key-policies/</u>



## **DOE EERE FOA Application Section "Transparency of Foreign Connections" Raises Questions (UPDATE)**

COGR reported in the <u>June 2023 Update</u> that we received questions from several member institutions regarding the "Transparency of Foreign Connections" in the DOE Office of Energy Efficiency & Renewable Energy (EERE) Funding Opportunity Announcements (FOA) and DOE's Risk Assessment for foreign influence.

In August, COGR, AAU, and APLU met with Dr. <u>Harriet Kung</u>, the Deputy Director for Science Programs in the Office of Science; Julie Anderson, the Acting Director of the Office of Research, Technology, and Economic Security; and Jeremy Ison, Program Analyst for Research Security. They were receptive to engaging on the subject and to receiving feedback. They shared DOE is in the early phase of building the <u>Office of Research, Technology & Economic Security</u>, which is expected to be the designated office to handle these matters. Their goal is to build more transparency around DOE's risk assessment and research security efforts. For the Transparency of Foreign Connections in the FOA, they clarified that it is expected that IHEs will complete a subset of applicable questions. We shared that members report two versions of this requirement, a subset of questions for IHEs and a version without the carveout for others. DOE advised it may be due to version control of the FOA and that institutions should utilize the FOA FAQ mechanism to request clarification.

DOE will join a research security panel for the October COGR meeting on the afternoon of Thursday October 26 to discuss their efforts. COGR will continue to monitor and will follow up with the community on any new developments.

#### Department of Defense (DOD) Holds Research Security Sessions (NEW)

The DOD Basic Research Office is holding two sessions on research security, focused on DOD implementation of risk-based security reviews for fundamental research proposals. The first session hosted by APLU was on September 12. DOD Basic Research Director Dr. Bindu Nair was the presenter. Slides from the presentation are available <u>here.</u>

The focus was on the DOD June 30 Policy on Countering Unwanted Foreign Influence in Fundamental Research at Institutions of Higher Education (see COGR June 2023 Update). The Decision Matrix for Risk Mitigation<sup>4</sup> and the 1286 entity and foreign talent program lists are included in the Policy<sup>5</sup>. According to Dr. Nair, key takeaways from the session include DOD's commitment to preserving the funding of open science, the need to mitigate risks posed by conflicts of interest, the need for transparent

<sup>&</sup>lt;sup>5</sup> See COGR's July 2023 analysis "Overview of Department of Defense Statement on Countering Unwanted Foreign Influence in Department-Funded Research institutions of Higher Education": <u>https://www.cogr.edu/sites/default/files/Overview%200f%20Department%20of%20Defense%20Statement%20on%20Counter</u> ing%20Unwanted%20Foreign%20Influence%20in%20Department%20July%208%2020223.pdf



and consistent implementation of the policy across DOD, no discrimination in implementing the policy, no penalty for activities prior to the October 19, 2019 letter from DOD Undersecretary Griffin (see COGR October 2019 Meeting Report), and the need for feedback from institutions as implementation proceeds.

Dr. Nair clarified that once the OSTP disclosure forms are finalized, DOD will use them (although it was unclear whether they will replace the current SF 424). She also clarified that any required insider risk awareness training will primarily use the training modules currently under development by NSF. Additionally, two unmitigable risks after August 9, 2024 are 1) indicators of participation in a malign foreign talent recruitment program (MFTRP) or 2) the policy of the Proposing Institution employing the covered individual does not prohibit participation in a MFTRP.

In response to a question, Dr. Nair indicated her expectation that it will take time for all DOD components to fully implement a consistent approach (6 months was suggested). DOD plans to update the 1286 lists annually. AAU will host a similar session in October identical to the webinar hosted by APLU. Dr. Nair will also be speaking at the October COGR meeting.

#### Administration Issues Executive Order on Investments in Certain Technologies (NEW)

On August 9 the Administration issued an *Executive Order on Addressing United States Investments in Certain National Security Technologies and Products in Countries of Concern*. The EO requires Treasury to issue regulations that require United States persons to provide notification of information relative to certain transactions involving covered foreign persons and that prohibit United States persons from engaging in certain other transactions involving covered foreign persons. Notifiable transactions involve covered national security technologies and products that the government determines may contribute to the threat to the national security of the United States. The regulations will require United States persons to notify the Department of the Treasury of each such transaction and include relevant information on the transaction in each such notification.

The regulations also identify categories of prohibited transactions that involve covered national security technologies and products that are determined to pose a particularly acute national security threat because of their potential to significantly advance the military, intelligence, surveillance, or cyber-enabled capabilities of countries of concern. The regulations will prohibit United States persons from engaging, directly or indirectly, in such transactions. Countries of concern are identified in an annex, and essentially include only China. "Covered foreign person" means a person of a country of concern who is engaged in activities involving one or more covered national security technologies and products. "Covered national security technologies and products in semiconductors and microelectronics, quantum information technologies, and artificial intelligence sectors that are critical for the military, intelligence, surveillance, or cyber-enabled capabilities of a country of concern.

An implementing ANPRM was issued on August 14 (88 FR 54961). According to the ANPRM, Treasury



will establish an implementing program. Transactions covered by the program would include certain acquisitions of equity interests (*e.g.*, mergers and acquisitions, private equity, and venture capital), greenfield, joint ventures, and certain debt financing transactions by United States persons. Treasury will not review transactions case-by-case. The parties are to determine if the transaction requires notification. Civil penalties will be assessed for violations. The ANPRM sets forth a series of issues for public comment, mostly involving definitions of terms or directed to specific covered technologies.

Importantly, the ANPRM indicates that the requirements are not intended to cover university-to-university research collaborations or IP licensing. We are continuing to assess the EO and ANPRM. While there may not be much direct impact on COGR member institutions, there could be indirect effects (e.g., institution investments in equity funds).

Comments on the ANPRM are due September 28.

#### Association Leaders Meet with New FBI Assistant Director for Counterintelligence (NEW)

On August 22, COGR President Matt Owens, along with the Presidents of AAU, ACE, APLU, and staff met with new FBI Assistant Director of the Counterintelligence Division Susanne Turner, Deputy Assistant Director Scott Grady, and other FBI representatives.

The associations' Presidents described the steps that institutions have taken to address research security concerns in the past several years. Tensions between the need for security and openness in research were discussed. A specific concern raised was the lack of information about risks that government agencies may possess but often do not share. Ms. Turner expressed understanding of the community's concerns. The group discussed possible options for addressing the concern, including security clearances for designated individuals on campus or "one-off" meetings between FBI and other agency officials and university representatives, with non-disclosure agreements required of university participants. This option may be less burdensome than requiring security clearances for university officials.

The FBI raised concerns about transnational repression on university campuses, mostly involving students. The associations' participants noted they shared the concern, but there is a lack of systematic reporting on such incidents and consequently the nature and scope of the problem is unclear. The FBI also raised issues about "shadow" 501(c)(3) organizations funded by foreign entities. The associations' representatives agreed that it is important to know one's partners, but this information often is not readily available. We have not been made aware by our institutions of concerns about such 501(c)(3) organizations.

The associations' representatives noted that the dialogue between our institutions and local FBI field offices is much improved. Ms. Turner indicated that any problems with communication should be brought to her attention. It was agreed that discussions on information sharing about risks should continue.



The associations' representatives agreed that the discussion was productive. Ms. Turner's predecessor Alan Kohler spoke at the June 2022 COGR meeting. We hope Ms. Turner will participate in a future COGR meeting.

#### **COGR's Cost of Research Security Compliance Workshop (NEW)**

On September 27, COGR <u>will host a workshop</u> for institutions to discuss plans for compliance with the forthcoming research security program standards, along with associated administrative burdens and costs. The workshop will begin with an overview of the standards' requirements. Next, panelists will review the methodology COGR plans to use for Phase II of its survey on research security compliance costs<sup>6</sup>. This will be followed by a discussion of one institution's approach to considering and budgeting for research security costs. Workshop attendees will then participate in virtual breakout rooms for discussion, followed by a general question and answer session. Information gained from this workshop will be presented at COGR's October membership meeting. The discussion in the main sessions of the workshop will be recorded and available in the COGR Portal after the session.

#### **Research Security & Intellectual Property (RSIP)**

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

#### Administration Issues Executive Order on Domestic Manufacturing (UPDATE)

On July 28, the Administration released an Executive Order (EO 14104) on *Federal Research and Development in Support of Domestic Manufacturing and U.S. Jobs.* The COGR March 2023 Update mentioned that such an EO was under consideration. The EO seeks to ensure the commercialization of federally funded inventions by U.S. manufacturers. It has substantial implications for research institutions' technology transfer operations.

An analysis of the EO is included on the <u>COGR website</u>. The EO directs DOD, Ag, Commerce, HHS, DOE, DOT, DHS, NSF, and NASA to encourage domestic manufacturing in their R&D solicitations and funding agreements, including OTA's and SBIR/STTR programs. The agencies also are encouraged to enhance their technology transfer and commercialization capabilities. The EO sets forth several new reporting requirements. It assigns significant implementation responsibilities to NIST, including development of award terms and conditions, an action plan to transition agencies to the iEdison invention reporting system along with common invention utilization questions, and guidance for considering waivers of the Bayh-Dole domestic manufacturing requirement.

<sup>6</sup> COGR's Research Security Cost of Compliance Phase I Report available here:

https://www.cogr.edu/sites/default/files/Version%20Dec%205%202022%20research%20security%20costs%20survey%20FI NAL.pdf



The EO directs agencies to consider whether "exceptional circumstances" exist to warrant restricting title to federally funded inventions in certain critical and emerging technologies, or to extend the Bayh-Dole Act domestic manufacturing requirement to non-exclusive licenses and sales of inventions outside the U.S. along the lines of recent Department of Energy requirements (see COGR <u>March 2022 Update</u>). However, it suggests that such terms should not be applied to small businesses and nonprofit organizations.

As discussed in COGR's analysis, the EO presents a mixed bag of outcomes. On the positive side, we long have advocated standardization of invention reporting and use of iEdison by all agencies. However, reporting challenges and burdens will increase, particularly with the new requirement to report manufacturing locations. The tech transfer community mostly has responded to the EO with a sense of relief (see White House manufacturing order has tech transfer experts sighing in relief | Science | AAAS).

We will closely follow implementation of the EO and provide feedback as appropriate. The COGR <u>RSIP</u> <u>Committee</u> is planning to meet with NIST representatives at the October meeting for further discussion.

#### GAO Review of DOE Tech Transfer and IP Protection Activities (UPDATE)

The COGR <u>February 2023 Update</u> mentioned that the General Accountability Office (GAO) had been asked to review DOE's new domestic manufacturing award terms, focusing on the <u>June 2021</u> <u>Determination of Exceptional Circumstances</u> (DEC). Last year's <u>March Update</u> discussed the DEC and its subsequent modifications.

Several COGR member institutions with DOE funding have received a detailed and comprehensive questionnaire from GAO. It asks about patent licensing practices broadly and those related to DOE-funded technologies as well as specific questions about the DEC. One set of questions involves DOE patent licensing compliance reviews. Twenty-one (21) questions pertaining specifically to the DEC are included. Another set of questions involves experiences with waiver requests to DOE. A final set of mostly non-DOE specific questions involve consideration of risks in licensing critical and emerging technologies.

A total of 55 questions, some with subparts, are included in the questionnaire. Some involve specific data and documentation requests. Responses were due August 14, but we understand that date may have been extended. Responses will not be attributed in GAO's final report to Congress. Completion of the questionnaire required considerable time and effort on the part of the respondent institutions.

We have no indication of when the final report will be released. However, the length and scope of the survey questions suggests that analysis and development of the report may take some time.

#### NIH Holds Technology Transfer Workshop (NEW)

On July 31 NIH held a workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer. The workshop attracted a great deal of attention and concern in the tech transfer community. A large number of comments were submitted, and many people registered to speak. COGR <u>submitted joint comments</u> with AAU. However, the focus was on NIH intramural patenting and licensing practices. While several critics of these practices spoke, most of the discussion was positive. Bayh-Dole issues, such as march-in rights, were barely mentioned.

NIH's purpose and motivation in holding the workshop remain unclear. The webcast and comments may be viewed <u>here.</u>

## **Contracts & Grants Administration (CGA)**

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

#### <u>NIH Publishes Notice (NOT-OD-23-161)</u> Eliminating Single Data Management & Sharing (DMS) Cost Line Item (NEW)

We were pleased to see NIH publish <u>NOT-OD-23-161</u>, which goes into effect for applications submitted for due dates on or after October 5, no longer requires the use of the single DMS cost line item. The change recognizes these costs may impact many cost categories, e.g., personnel, equipment, supplies, and other expenses. Instructions for submitting requests for DMS costs are updated accordingly with the R&R Budget Form or PHS 398 Modular Budget Form as applicable. NIH will require applicants to specify estimated DMS cost details within the budget justification. NIH updated the corresponding <u>Budget/Costs FAQs</u>.

This is a welcome change, and we commend the many efforts of NIH partners and the community to address this issue.

#### System for Award Management (SAM) Registrations (NEW)

Several member institutions contacted COGR with challenges regarding SAM renewals and registration. Reports include challenges with the lack of timely and effective communication from the Federal Service Desk (FSD), issues with verification documents to validate entity information, and ineffective remedies for entities with multiple UEIs, which require extensive time and effort to resolve and risk a lapse in their status.

COGR will meet with Government Service Agency (GSA) officials to discuss these concerns. We will



follow up with the community on developments as we continue to monitor and track issues. Contact Krystal Toups at <u>ktoups@cogr.edu</u> if you have any concerns to report or comments related to SAM registration.

#### **Prohibition on a ByteDance Covered Application, TikTok (UPDATE)**

In the June 2023 COGR Update, COGR reported on the new interim rule <u>FAR 52.204-27</u>, Prohibition on a ByteDance Covered Application, on any information technology owned or managed by the Government or on any information technology used or provided by the contractor under a contract. On August 1, COGR joined EDUCAUSE in responding to requests for comment. The letter sought clarification in the scope of the rule of ByteDance applications and requests explicit guidance around "incidental" use and "performance of a Federal contract." The letter states that the rule should explicitly specify the scope of the research activities that may be excluded from the ban in accordance with <u>M-23-13</u>. It also highlights that the true impact will be significant, considering the complexity of the research university network and device support operations.

On September 6, COGR hosted a webinar outlining essential information about the implications of the various federal and state requirements banning TikTok for institutions. The panel included representatives from EDUCAUSE, the Hogan Lovells law firm, and institutional representatives. The slides and recording are available <u>here</u>.

#### **Costing & Financial Compliance (CFC)**

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

#### 2023 F&A Cost Rate Survey: Update (Part II) at the October Meeting (NEW)

The Part I Update took place at the June COGR Meeting. CFC Committee members led a panel discussion covering the preliminary results from the 2023 F&A Cost Rate Survey. A summary of that presentation is available in the <u>June Meeting Report</u>, the <u>slide presentation</u> is available on the COGR website, and the session recording is available in the <u>COGR Portal video library</u>. (Log in required).

#### The Part II Update at the October Meeting will cover additional analysis of the F&A Survey results.

To date, COGR has released the first report from the 2023 Survey of F&A Cost Rates—<u>F&A Cost Rates</u> <u>by Institution</u>—and it is available in the COGR Portal (log in required). This report should be used for institutional purposes only and should not be shared beyond the institution. We will release additional reports over the next few months and provide updates on new developments. Thank you to all the institutions that participated in the 2023 Survey of F&A Cost Rates<sup>7</sup>!

<sup>&</sup>lt;sup>7</sup> *Reports from COGR's 2017 F&A Survey can be viewed in the COGR Portal here (log in required):* <u>https://cogr.member365.org/sharingnetwork/workspace/view/6</u>



#### Financial Reporting Developments at NASA (NEW)

In a September 18 email to the COGR membership, we reported that NASA delayed its most recent new financial reporting requirement—*Transition from FCTR to FFR*. COGR shared its concerns with NASA that a transition to a quarterly Federal Financial Report (FFR) for each individual NASA award would be excessively burdensome, especially for institutions that have numerous NASA awards. After our conversation with NASA, they agreed to change the original transition date effective for the reporting period ending September 30, to the reporting period ending December 31. The official notice is available on the <u>NASA Procurement webpage</u> via a <u>Grant Information Circular (GIC) notice</u>.

Prior to the transition, NASA relied on the Federal Cash Transaction Report (FCTR). However, the Payment Management System (PMS) no longer will support the FCTR, so NASA's solution is to address financial reporting expectation through a quarterly FFR for each individual NASA award. In response to COGR's concerns with this approach, NASA agreed to delay implementation and to work with COGR to explore other solutions. Leaders from COGR's CFC Committee are scheduled to meet with NASA in October to discuss alternatives.

Also at play is oversight of NASA management and operations by the <u>NASA Office of Inspector General</u> (<u>OIG</u>). This type of OIG oversight is applicable across all federal agencies, and in the case of NASA, a 2019 NASA OIG audit report (Report No. IG-19-020) addressed selected concerns associated with NASA management of federal awards.<sup>8</sup> Consequently, it is not surprising that NASA management has been active in reviewing all of its grantee oversight policies. In the Spring NASA implemented its *Routine Monitoring–Financial Transaction Testing Review program* (see <u>COGR May 2023 Update</u>). The program requires institutions to provide a quarterly expenditure list for selected NASA awards. In a May 2 meeting with NASA, we raised concerns around the burden and intent of this program. While NASA indicated their commitment to maintain the program, they agreed to be more transparent and flexible in their outreach to grantees.

COGR will continue to engage with NASA on these matters related to financial reporting and compliance and will keep the membership updated. Please contact David Kennedy at <u>dkennedy@cogr.edu</u> with questions or feedback.

<sup>&</sup>lt;sup>8</sup> NASA'S COMPLIANCE WITH THE IMPROPER PAYMENTS INFORMATION ACT FOR FISCAL YEAR 2018 (Report No. IG-19-020, June 3, 2019, p. 3): Based on our review, we concluded the Agency complied with IPIA. However, as we reported last year, NASA did not use all available data to determine the risk rating in two categories: Internal Monitoring and Assessments and External Monitoring and Assessments. In addition, NASA failed to provide documentation of the analysis supporting its rationale for using the existing scoring criteria for the Materiality of Disbursements risk condition—a methodology we believe is not representative of NASA's disbursement activity. These two issues impact the basis for assigning ratings within the Agency's risk assessment and the determination of whether programs are susceptible to significant improper payments.



#### New NSF Project Reporting Compliance Program (NEW)

COGR members have reported receiving email messages from NSF introducing a new *Project Reporting Compliance* program. The email message references NSF award terms and conditions and the responsibility of PIs to submit annual project reports 90 days prior to the end of the annual budget period of the project. If reports are not approved by the cognizant NSF program officer by this date, the report is considered overdue. According to NSF, they have identified a significant number of overdue annual reports, which puts them at risk to effectively implement the agency's programs.

The email goes on to state that in order to encourage more timely submission of annual project reports, NSF plans to exercise their existing authority to *temporarily withhold cash payments {emphasis added}* pending the submission and approval of annual project reports. This includes awards that have overdue project reports of 60 days or more from three participating NSF Divisions: the Divisions of Computing and Communication Foundations (CCF); Civil, Mechanical and Manufacturing Innovation (CMMI); and Information and Intelligent Systems (IIS).

COGR has reached out to key contacts at NSF to seek additional background on this initiative, including the NSF plan to *temporarily withhold cash payments*. We will keep the COGR membership updated on new developments. Contact Krystal Toups at <u>ktoups@cogr.edu</u> and David Kennedy at <u>dkennedy@cogr.edu</u> with questions and other comments.

#### ASAP, IPP, and ID.me: Personal Information and Log-on Concerns (NEW)

The <u>Automated Standard Application for Payments (ASAP)</u> is an electronic payment system maintained by the Department of the Treasury that is used by many federal agencies (e.g., DOE, USDA, DOJ, etc.) to securely transfer money to recipient organizations. The <u>Invoice Processing Platform (IPP)</u> is a related electronic system, also managed by Treasury, which requires regular access by grantees. COGR members have shared significant concerns with new ASAP and IPP log-on procedures requiring personal information such as one's social security number, copies one's driver's license and/or passport, and other sensitive personal information. Intersecting with these log-on procedures are the log-on procedures associated with <u>ID.me</u>, which allows one to access their personal information at the Social Security Administration, the IRS, and other government entities.

Individuals at your institutions who are responsible for accessing ASAP and IPP are being placed in the awkward position of having to enter their personal information to access these systems. Understandably, this is creating significant concerns among employees required to follow these log-on procedures. Leaders at the Federal Demonstration Project (FDP) have engaged federal officials to share this concern and COGR is in communication with FDP leaders to strategize on how best to address this issue. We will keep the COGR membership updated on developments. Contact Krystal Toups at <a href="https://ktousgl.k



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

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

#### Federal Audit Clearinghouse to be moved to GSA in October 2023

We have followed the <u>FAC Transition website</u> over the past six months and it appears the FAC site is operational. COGR submitted a <u>letter to GSA</u> on February 21 and emphasized the importance for GSA to actively communicate with all stakeholders during the transition. We encourage COGR members to reach out to COGR if there are complications or other issues of concern.

#### Single Audit Developments

The <u>2023 Compliance Supplement</u> was released by OMB in May. Active engagement by COGR members to raise concerns about auditor actions on the timing for requesting cash reimbursements from federal agencies proved crucial to affecting the changes made to the <u>Cash Management section (see page 3-C-3)</u>. COGR members are welcome to contact COGR when audit issues arise. When appropriate, COGR can reach out to its contacts at the audit firms and/or engage in other ways that may be helpful to address issues at hand.

#### Federal Office of Inspectors General (OIG) Developments

COGR members are encouraged to follow NIH-related audit activity posted in the <u>HHS OIG Workplan</u>, as well as completed reports posted by the <u>Office of Audit Services</u> and the <u>Office of Evaluation of</u> <u>Inspections</u>. For activity from the NSF OIG, the <u>NSF OIG Reports & Publications page</u> lists recently completed reports. Further, the <u>NSF Management Responses to an External Audits</u> is a helpful resource for reviewing NSF OIG audit resolutions. COGR members are welcome to contact COGR when audit issues arise. When appropriate, COGR can connect institutions and/or provide feedback on the issues in question.

#### 2021 NSF Higher Education Research & Development (HERD) Survey

The 2021 HERD was released on December 15, 2022, and includes the <u>InfoBrief</u> summary and the complete suite of <u>2021 data tables</u> (which includes the popular *Table 22 – Higher education R&D* expenditures, ranked by all R&D expenditures, by source of funds: FY 2021). Also of interest is *Table 17 – Higher education R&D expenditures, by type of cost, highest degree granted, and institutional control:* FYs 2010-21. Table 17 includes data on recovered and unrecovered indirect costs, in aggregate, for all institutions. For FY2021, the total recovered indirect costs were \$14.7 billion and the total unrecovered indirect costs were \$5.9 billion.

Please contact David Kennedy at <u>dkennedy@cogr.edu</u> 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.

#### Response to NASA's RFI on Freedom of Information Act (FOIA) Disclosures (NEW)

On June 27, NASA <u>published an RFI</u> seeking comments on a proposal to require institutions to indicate in grant applications which information qualifies for the Confidential Business Information (CBI) exemption under the FOIA regulations (5 USC §552(b)(1)-(9)). On July 19, COGR <u>submitted a letter</u> to NASA noting that the status of information as CBI requires legal analysis, which investigators who submit applications are not equipped to perform. Further, given that CBI status can change over time, this analysis must always be performed at the time of the FOIA request. Accordingly, COGR urged NASA to maintain its current FOIA processes that permit – but do not require – researchers to designate confidential commercial at the time of application and that provide institutions with notice and an opportunity to object if an FOIA request is received.

#### Human Subjects Research

#### FDA Guidance Documents (NEW)

The FDA issued final versions of the following guidance documents of importance to human subject research protection programs:

#### Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)

This <u>final guidance</u> provides a long-awaited update to the FDA's previous 1998 guidance on informed consent. It addresses the informed consent process and provides a detailed summary of requirements and recommendations for each of the basic and additional elements of informed consent set forth in the FDA's regulations (21 CFR Part 50). For many of the elements, the guidance provides possible sample text, including samples of exculpatory/non-exculpatory language and provisions to address compensation and medical treatment in the event of subject injury. The guidance goes on to address documentation of the informed consent process and methods for consent beyond traditional face-to-face discussions, as well as roles and responsibilities of IRBs, sponsors, and investigators in the informed consent process.

#### Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products (September 2023)

This guidance describes the FDA's requirements for IRB review of individual patient expanded access



submissions (21 CFR §312.310) and sets forth recommendations for procedures that IRBs should consider implementing to carry out their duties with respect to these submissions. These recommendations include procedures for single member review of expanded access requests for individual patients, including information that should be provided and components of the IRB's review.

#### Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies (September 2023)

This <u>final guidance</u> provides detailed FAQs that cover many of the issues that arise with respect to the initiation or continuation of clinical trials during a pandemic or other public health emergency. The FAQs provide details on factors to consider in determining whether to suspend an on-going trial, managing protocol deviations arising from the public health emergency, and making protocol changes that utilize virtual and other remote modalities to carry out trial visits and procedures. The guidance also encourages sponsors, investigators, and IRBs to consider developing/modifying policies and procedures to address the potential disruptions to clinical trials arising from public health emergencies.

#### Response to Congressional RFI on Federal Regulation of Cannabidiol (NEW)

On August 17, COGR <u>submitted comments</u> in response to a <u>Congressional RFI</u> requesting stakeholder input on the current federal regulation of cannabidiol (CBD). These comments were designed to raise awareness of the hurdles that investigators face in conducting research on products that are classified as Schedule I Controlled Substances under federal law, but that are widely available to the public in states that have legalized CBD and/or cannabis. COGR urged Congress to establish a process that permits researchers studying CBD to obtain, synthesize, and conduct research on CBD products without the need for a DEA Schedule I registration regardless of whether the CBD is derived from a hemp plant, a marijuana plant, or chemically synthesized. Such research is essential to understanding both beneficial and detrimental effects of products that are in widespread use in many parts of the U.S.

#### Biosafety (NEW)

## <u>Proposed Changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid</u> <u>Molecules (August 2023)</u>

These <u>proposed changes</u> harmonize the NIH's Guidelines with those of the <u>Centers for Disease Control</u> and <u>Prevention's Biosafety in Microbiological and Biomedical Laboratories</u> (BMBL) and provide additional oversight of "gene drive technology." REC is developing comments that support this alignment, and that will urge NIH to better define the term "gene drive." Comments are due October 10.



<u>Request for Information; Potential Changes to the Policies for Oversight of Dual Use Research of</u> <u>Concern (DURC) and the Potential Pandemic Pathogen Care and Oversight (P3CO) Policy Framework</u> <u>(September 2023)</u>

The <u>Request for Information</u> proposes combining the following three policies into one:

- <u>Recommended Policy Guidance for Departmental Development of Review Mechanisms for</u> <u>Potential Pandemic Pathogen Care and Oversight (P3CO)</u>
- U.S. Gov. Policy for Oversight of Life Sciences Dual Use Research of Concern
- <u>U.S. Gov. Policy for Institutional Oversight of Life Sciences Dual Use Research</u>

The new merged policy would apply to: (a) all institutions in the U.S. that receive U.S. government funding for life sciences research and conduct research that falls within the scope of the merged policy, whether or not the project being reviewed was funded by the U.S. government; and (b) institutions outside the U.S. that receive U.S. government funds to conduct or sponsor research that falls within the scope of the new policy.

The RFI also proposes moving away from the current "list-based" approach that requires DURC review for research that uses one of more of the listed select agents/toxins, to a "risk-based" approach that would require DURC review for research that "directly involves any human, animal, or plant pathogen, toxin, or agent that is reasonably anticipated to result in one or more of the seven experimental effects outlined in the DURC Policy."

REC has formed a working group to develop comments, which are due October 16.

#### Animal Research (NEW)

## Multi-Organization Statement on Addressing the Shortage of Long-Tailed Macaques for Research

COGR joined with 40 organizations and professional associations representing scientific research, conservation, and veterinary constituencies in signing onto a public statement supporting recommendations to address critical shortages of long-tailed macaques that are essential to the conduct of vital biomedical studies. These recommendations will help to ensure that health research can continue to be conducted in the United States, while preserving wild macaque populations.

#### <u>Response to RFI on Clarification of Animal Activities Exempt from PHS Policy Requirements for</u> <u>IACUC Review</u>

OLAW issued this RFI (<u>NOT-OD-23-119</u>) in response to the CURES Act's mandate to review "applicable regulations and policies for the care and use of laboratory animals and to make revisions, as



appropriate, to reduce administrative burden on investigators<sup>9</sup>" while maintaining research integrity and protecting the health, safety, and welfare of research animals. In July 28 letter, COGR noted that this RFI followed OLAW's pattern of reiterating long-standing guidance and interpretations of the PHS Policy, as opposed to taking a fresh look at the PHS Policy to identify interpretations that would achieve the CURES Act's goal. COGR recommended that instead of using this RFI to reissue its FAQs on the PHS Policy on Humane Care and Use of Laboratory Animals in a different format, OLAW instead clarify the existing FAQs. The remainder of COGR's letter offered suggestions as to how provisions of those FAQs could be clarified.

#### Upcoming Office of Laboratory Welfare (OLAW) RFI's (NEW)

COGR's Research Ethics & Compliance Committee (REC) has formed working groups to draft comments on the following new RFIs issued by OLAW:

## <u>Request for Information (RFI) on Flexibilities for Streamlining IACUC Review of Protocols and</u> <u>Significant Changes – NOT-OD-23-152 (Comments Due October 11)</u>

<u>This RFI</u> is yet another issued in response to the aforementioned CURES Act's mandate. As it has with similar RFIs, COGR will identify areas in which previous OLAW guidance has been reiterated, as well as identifying opportunities to clarify that guidance and new approaches to reduce burden, while ensuring the health and welfare of animals used in research.

# <u>Request for Information (RFI) on an Update to the Current OLAW Guidance Disclaimer– NOT-OD-23-157 (Comments Due October 22)</u>

In <u>this RFI</u>, OLAW seeks comments on proposed changes that would substantially alter the nature of the disclaimer that it attaches to its guidance documents. The current disclaimer states that "[u]nless specific statutory or regulatory requirements are cited, the Notices should be viewed as recommendations in that an institution may use an alternative approach if the approach satisfies the requirements of the PHS Policy." This text appropriately acknowledges the statutes and regulations that set forth the outer boundaries of OLAW's regulatory authority. However, the proposed disclaimer muddies these clear legal boundaries when it states that "OLAW's guidance expands upon statutory and regulatory requirements of Public Law 99-158, Sec. 495, and the PHS Policy, including incorporated references." COGR's comments will note this approach inappropriately expands OLAW's jurisdiction.

<sup>&</sup>lt;sup>9</sup> See: <u>https://olaw.nih.gov/policies-laws/21st-century-cures-</u> <u>act#:~:text=The%2021st%20Century%20Cures,on%20investigators%20while%20maintaining%20the</u>



<u>Request for Information (RFI) on Proposed Guidance to Assured Institutions on Cephalopod Care and</u> <u>Use – NOT-OD-23-176 (Comments Due December 22)</u>

Currently cephalopods lie outside the jurisdiction of both the Animal Welfare Act and its implementing regulations and the PHS Policy. <u>This RFI</u>, however, seeks comments on proposed new requirements for institutions with PHS Animal Welfare Assurances that:

"[E]nsure that cephalopod activities are subject to review and approval by IACUCs or other oversight bodies, and subsequent post-approval oversight, in accordance with U.S. Government Principles[, including semiannual evaluations of cephalopod programs]"

[Encourage] IACUCs and oversight bodies . . . to develop institutional policies and Standard Operating Procedures (SOPs) that summarize expectations and promote consistency and quality of cephalopod care and use.

COGR appreciates the need to consider and evaluate the need regulation for different types of animal species, but it has deep concerns about the development of such regulations outside the scope of current legal authorities. Accordingly, COGR will consider the issue of underlying authority for OLAW's proposed requirements in its comments, as well as providing comments on the substance of those recommendations.

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## 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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## **Appendix A – Upcoming Comment Due Dates**

Agency	Description	Due Date	Notes
EO "Addressing US Investments of Certain National Security Technologies and Products in Countries of	Implementing Advanced Notice of Proposed Rulemaking (ANPRM)	September 28	COGR is assessing the EO and ANPRM.
Concern" National Institutes of Health (NIH)	Proposed changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules	October 10	COGR will comment.
Office of Laboratory Animal Welfare (OLAW)	RFI on Flexibilities forStreamlining IACUC Reviewof Protocols and SignificantChanges NOT-OD-23-152	October 11	COGR will comment.
Office of Science & Technology Policy (OSTP)	RFI on Potential Changes to the Policies for the Oversight of Dual Use Research Concern (DURC) and the P3CO) Policy Framework	October 16	COGR will comment.
OLAW	RFI: Update to Current OLAW Guidance Disclaimer NOT- OD-23-157	October 22	COGR will comment
Office of Management and Budget (OMB)	<u>Proposed Updates to the</u> <u>Uniform Guidance</u>	Late November (Est.)	Due date will be 60 days from the date published in the Federal Register.
OLAW	RFI on Proposed Guidance toAssured Institutions onCephalopod Care and UseNOT-OD-23-176	December 22	COGR will comment.