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#### **President's Message**

#### **Reflections, Updates, & Gratitude**

Dear Colleagues,

Thank you to everyone who was able to participate in COGR's October Meeting and 75<sup>th</sup> anniversary celebration. We had timely discussion of pressing and important issues. And we remembered our past and recognized that COGR's work today is as vital it has ever been to the partnership between the federal government and our institutions to perform research that bolsters our nation's health, security, and economic prosperity. A recording of the evening's presentation is <u>available here</u>.

For this month's President's Message, I want to share several important organizational developments.

- Earlier this fall, Bob Hardy, Director of Research Security & Intellectual Property, and Dave Kennedy, Director of Costing and Financial Compliance, announced to the COGR staff team and their committees that they will retire in 2024. Bob and Dave have each served COGR effectively and with distinction for decades, and their contributions to our community cannot be overstated. We will recognize their legacy of service at the June 2024 COGR Meeting. Early in the new year, we will start a search for Bob's successor, and in the spring we will initiate a search for Dave's successor. Among other places, the job announcements will be posted in the <u>COGR Job Bank</u> when the searches commence next year.
- In late October, Deborah Motton of the University of California succeeded Naomi Schrag of Columbia University as the chair of COGR's Research Ethics & Compliance (REC) Committee. We thank Naomi for her leadership of the committee for the past 3+ years, and we are grateful for Deborah taking on this important role with COGR.
- Last month, we welcomed the <u>Seattle Children's Research Institute</u> to the association. COGR now comprises 216 research institutions in 48 states and D.C. with over \$49 billion in combined annual federal research expenditures, as reported in the recently released 2022 NSF HERD Survey. COGR member institutions conduct the vast majority of federally sponsored research important to our country.
- Last week, COGR relocated to its new office. We downsized our office space to reflect COGR's primarily telework environment and to reduce costs. We are now located in the Homer Building at 601 13th St NW 12th Floor, Washington DC 20005. We remain in close proximity to key partner organizations, including AAU, APLU, AAMC, and others.

As the year winds down, I want to thank you for your participation in COGR. This past year brought significant proposals and changes to policies, regulations, and practices affecting federally sponsored research. Together, we engaged with purpose and integrity on a host of issues affecting research security, the Uniform Guidance, research misconduct, march-in rights, public access, the use of animals in research, and many more. We will continue to do so in the year ahead and we will advocate for sound, efficient, and effective regulation that safeguards research and minimizes administrative and cost burdens for the good of research and our nation.

The COGR team – Bob, Dave, Kris, Krystal, Mary, Toni, and I – wish you a wonderful holiday season. We look forward to engaging with you in the new year.

Matt Owens, President

#### Announcements

#### Save the Date: COGR's February 27-March 1, 2024 Virtual Meeting

Planning is underway for COGR's upcoming February 27-March 1, 2024 Virtual Meeting. Registration will open in early January via the COGR Listserv. Registration is open to all staff at COGR member institutions through the COGR Portal. Preliminary agenda topics will be released soon and the agenda will be available a few weeks prior to the meeting.

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 <u>memberservices@cogr.edu</u> with any questions, and we hope you'll 'save the date'!

#### October Meeting Session Recordings Available for Meeting Attendees (REMINDER)

Select sessions were recorded during the October 2023 meeting and <u>are available</u> for meeting attendees to view. If you attended the meeting and are having trouble accessing the recordings, please reach out to <u>memberservices@cogr.edu</u>. Slide presentations are posted on COGR's <u>website here</u>. The recordings will be released to all COGR members via the COGR Portal in January.

#### COGR Has Moved – Update Your Records by January 1, 2024! (NEW)

As announced at the October meeting in Washington D.C., COGR has moved into a new location. Effective now, COGR's new physical and mailing address will be:

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

If you are your institution's Primary Representative and/or Billing Contact, please ensure your institutional records are updated by January 1 to reflect our new address. Invoices for FY 25 (August 1, 2024-July 31, 2025) are expected to be ready by May 1, 2024 and will reflect the new address. 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 need institutional forms updated, and/or would like to set up EFT/ACH payments, please reach out to <u>memberservices@cogr.edu</u> now and allow for additional processing time.

Please reach out to <u>memberservices@cogr.edu</u> if you have any questions, and thank you for your institution's membership!

#### December 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>).

#### Follow COGR 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 an additional engagement platform for COGR members, we also use LinkedIn to help elevate COGR's effectiveness in affecting federal research policy and practices. 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

#### COGR Submits Comment Letter to OMB on NPRM on Uniform Guidance (NEW)

On December 4, COGR submitted a <u>comment letter</u> to OMB in response to <u>proposed revisions to 2 CFR</u> <u>Chapters 1 and 2</u> (also see <u>OMB's "red-line" version</u> to view the proposed revisions). The 51-page COGR letter includes over 100 COGR recommendations and 18 specific, priority requests encouraging OMB to take action on a wide-range of topics applicable (primarily) to 2 CFR Chapter 2, Part 200 (Uniform Guidance) and to 2 CFR Chapter 1, Parts 25, 175, 180, 182, and 183.

The 18 highlighted requests are the centerpiece of the COGR letter, though the 100+ recommendations are framed in a manner that urges OMB to consider every recommendation COGR has made. In addition to COGR, many other commenters responded to OMB's proposed revisions (including many COGR members!). There is a "strength-in-numbers" effect and your support of either specific COGR

<sup>&</sup>lt;sup>1</sup> COGR institutional annual dues invoices are available to generate now in the COGR Member Portal and were 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.

recommendations and/or recommendations important to your institution will impact how OMB responds. In total, over 1,000 comments were received under this docket. Comments can be reviewed on the regulations.gov "Guidance for Grants and Agreements" page.

The COGR letter would not have been possible without the amazing team of volunteers from COGR member institutions who worked tirelessly starting in late October and right up to the December 4 deadline to develop a comprehensive and compelling array of recommendations—and in many cases, detailed analyses in support of the recommendations. The 26 volunteers participated in nine thematic workgroups and diligently combed through every word of the OMB "red-line" version. The COGR letter paid great attention paid to the fine print of the proposal. This is an impressive testament to work of the 26 volunteers who are listed in <u>Appendix B.</u> We are grateful for their spot-on and expert contributions.

#### Uniform Guidance: What to Expect Next? (NEW)

At this stage, there is a "wait-and-see" element as to what to expect next. Based on past experience, we expect the following in terms of next steps:

- OMB will review all comments. Policy officials from the OMB Office of Federal Financial Management (OFFM). Deidre Harrison, Deputy Controller, and Steven Mackey, Policy Analyst have been good partners and we are confident they will consider all comments.
- OMB's timing to complete its review is "to-be-determined." While OMB has stated an aggressive timeline on numerous occasions, COGR's sense is that to thoroughly review all comments will take weeks, if not months, to complete.
- After reviewing all comments, OMB will develop final revisions to 2 CFR Chapters 1 and 2, which will then be published in the Federal Register. Again, the timing is uncertain. While there have been suggestions this would be published in the early Spring, that timing also is "to-be-determined."
- Public comments should/must be solicited. While this is the case, it is unlikely OMB will be open to significant comments. However, COGR's approach will be to closely review the final revisions, and if there are egregious oversights or concerns, COGR will respond and also encourage the community to direct comments to OMB.
- Included with OMB's publication of the final revisions will be the implementation schedule for 2 CFR Chapters 1 and 2. COGR's December 4 comment letter included several recommendations on how implementation should take place. We will pay close attention to this topic.

We will regularly update the COGR membership on the status as we move into the new year. If you have questions or comments, please contact Krystal Toups as <u>ktoups@cogr.edu</u> and David Kennedy at <u>dkennedy@cogr.edu</u>.

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

COGR's <u>Uniform Guidance Resource Page</u> will continue to be updated as OMB moves towards final revisions to 2 CFR Chapters 1 and 2. This page includes past COGR comment letters and other related resources. COGR's first engagement with this topic 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**

#### Department of Education Section 117 FAQs (NEW)

On November 29, 2023, The Department of Education announced the release of FAQs pertaining to Section 117 Foreign Gift and Contract Reporting. The FAQs provide general information on the requirements including examples of different reporting scenarios. The Department of Education states the FAQs "do not effect law or bind the public or create new legal standards, beyond what is required by Section 117." The FAQs will be updated periodically and are located <u>here</u>.

#### **DETERRENT Act Raises Concern (NEW)**

Among the more troubling pieces of pending legislation is <u>H.R. 5933</u>, the <u>DETERRENT Act</u> ("Defending Education Transparency and Ending Rogue Regimes Engaging in Nefarious Transactions Act"). It was reported favorably by the House Education and Workforce Committee in mid-November with some bipartisan support. On December 6, the House passed the bill. The Senate bill (<u>S. 3362</u>) was introduced on November 29 and has been referred to the Health, Education, Labor, and Pensions (HELP) Committee.

The Act would lower the Section 117 reporting threshold for foreign gifts and contracts to \$50,000, with a zero threshold for countries or entities of concern. Detailed reporting requirements are included, with batch reporting allowed. The Act would prohibit contracts with foreign countries or entities of concern unless a waiver is provided by the Department of Education. ED is directed to maintain a public searchable database of reports. Institutions also would be required to maintain a public database of any gifts or contracts from a foreign source to a faculty or other professional staff member with the information retained for 4 years. The requirements would apply to institutions receiving \$50 million or more in federal funds. The Act also includes disclosure requirements pertaining to investments. Fines for violations are set forth.

The Act would have onerous burden implications as well as privacy and security concerns related to faculty and staff disclosures. Moreover, it appears unlikely that many waivers would be provided for contracts with countries of concern. In effect contracts with such countries or entities might be prohibited. This would primarily involve China.

The other higher ed. associations have made their concerns about the Act known to Congress<sup>2</sup>. While COGR does not typically focus on pending legislation, this bill appears to be of particular concern.

<sup>&</sup>lt;sup>2</sup> See: <u>https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/Higher-Education-Legislation/Letter-House-DETERRENT-Act-120423.pdf</u>



#### Common Disclosure Forms Published by NSF (NEW)

NSF, on behalf of the National Science and Technology Council (NSTC) Research Security Subcommittee, <u>published</u> OMB approved forms for the <u>Biographical Sketch</u>, <u>Current and Pending</u> (<u>Other</u>) <u>Support Information</u>, and <u>Definitions</u>. The final forms conclude NSTC's work over the past several months to develop common disclosure forms for Federal research and development (R&D) grants and cooperative agreements as specified in the NSPM-33.

In response to a joint association <u>comment letter</u> submitted on September 11, 2023, the final forms included important changes, including the removal of inconsistencies in the Summary of In-Kind Contributions and alignment of the Malign Foreign Talent Recruitment Program definition with the CHIPS & Science Act.

NSF expects to implement the common forms in accordance with PAPPG 24-1 (anticipated effective March 2024). NIH has not specified when it will implement the forms. Any agency-specific changes to the forms must be approved by OIRA/OMB.

COGR will continue to monitor how agencies harmonize disclosure requirements through timely implementation of the OMB approved common forms.

#### **NSF Updates on SECURE Initiative (NEW)**

At COGR's October meeting, NSF presented the latest information on its plans to develop a research security information and analysis sharing organization known by the acronym "SECURE" (i.e., "Safeguarding the Entire Community in the U.S. Research Ecosystem"). At the end of September 2023, NSF issued a <u>program solicitation</u> for third party administrators to establish SECURE, with proposals accepted until October 30, and review of proposals scheduled to occur in early 2024. Institutes for higher education, non-profit research institutions, and small to medium-size business may be members of SECURE, but participation is not mandatory. SECURE will serve as a clearinghouse for research security risk information (although it will not handle classified information), and it will also develop risk assessment frameworks, best practices, and training support. Notably, SECURE will not offer institution-specific advice or make decisions on particular risk scenarios, nor will it establish policy.

#### **NSF Updates on Research Security Training Modules (UPDATE)**

NSF's update at the October meeting also included an update on the research security training modules that it funded for development. The modules are expected to be issued at different times in 2024 and will cover the following topics: what is research security, disclosures, managing and mitigating risk, and international collaborations.

#### Associations Preview NSF Disclosure Reporting Portal (NEW)

COGR and other higher education associations were asked by NSF to review and provide feedback on the draft NSF CHIPS and Science Act Foreign Financial Disclosure reporting portal. The portal is modeled on the ED Section 117 portal. It has multiple screens that seek detailed information on donors and includes a certification requirement. In COGR's feedback to NSF, we raised the issue of why a file upload approach (e.g., csv) was not chosen, and encouraged NSF to consider such an approach in the future to reduce burden.

Other issues we raised in our feedback included:

- the use of many undefined terms;
- the extraordinary degree of due diligence required in the intermediary certification requirement;
- the designation of institution Authorized Organization Representatives (AORs) as responsible officials for disclosures;
- the reporting of multiyear gifts and contracts;
- the lack of explicit exemption of tuition from the requirements although NSF had indicated this intent;
- the applicability of the requirement to individual researchers;
- the requirements for institutions to complete a report even if no reportable gift or contract was received;
- the handling of anonymous gifts; and
- the clarification of due dates.

After COGR provided this feedback, NSF contacted COGR regarding a possible opportunity for review of the portal by persons at institutions who are responsible for Section 117 reporting, as many institutions have indicated that NSF reporting responsibilities also may be assigned to these individuals. COGR contacted its committee members to determine interest and provided NSF with a list of institutions who were interested in participating, along with relevant points of contact.

We understand the Federal Demonstration Partnership (FDP) provided feedback along similar lines. We hope responses to the feedback will be reflected in the next version of the portal.

#### **Research Security Program Standards (UPDATE)**

Earlier in 2023, OSTP expressed optimism that the research security program standards would be issued by the end of the year. In March, NSTC published a <u>request for information</u> seeking public input on draft standards. Although the comment period ended on June 5, 2023, NSTC has indicated that comments are still under review, and it has not provided any timeline for publication of the final standards.

Institutions have begun some preparations for the program standards, including taking stock of current policies and processes that can be leveraged to meet the standards' requirements, but understandably, many institutions are waiting for the final standards before fully implementing their security programs. At the end of September 2023, COGR hosted a workshop on institutional compliance efforts and associated costs. The workshop included benchmarking polls, an overview of the University of Pittsburgh's experience in

planning for the research security program standards, and discussion of COGR's plans for conducting Phase II of its cost of compliance survey, which will be issued after the program standards are published. The workshop also provided an opportunity for institutions to candidly discuss their approaches to various research security issues.

Polls of workshop attendees demonstrated that nearly 40% of attendees believed their institutions would be able to meet the research security program requirements by leveraging current policies/processes, while 44% stated that their institutions could not fully assess compliance readiness until the final program standards are issued. Nearly 50% of the attendees advised that they would allocate the research security officer role to an existing employee. Further, attendees reported that the areas that will require the most resources to ensure compliance are information technology, research compliance, and processes for managing international travel.

# Department of Defense (DOD) Policy for Risk-Based Security Reviews of Fundamental Research (UPDATE)

At COGR's October membership meeting, DOD's Dr. Bindu Nair presented on the agency's "Policy for Risk-Based Security Reviews of Fundamental Research Policy." [Attendees can access slides at <u>Multi-Agency Panel on Research Security Risk Assessment & Analysis October 26, 2023 (cogr.edu)</u>]. This policy includes a <u>risk assessment matrix</u>, which lists four broad areas of risk factors (foreign talent recruitment programs, funding sources, foreign patent filings, and entity lists) that DOD will consider in evaluating funding proposals. DOD's risk assessment will also consider the timing of affiliations or activities in determining risk mitigation levels or prohibited activities. For example, after August 9, 2024, DOD will no longer fund proposals in which a covered individual has indicators of current participation in a Malign Foreign Talents Recruitment Program (MFTRP) and/or for which the applicant institution does not prohibit participation in MFTRPs.

The DOD risk assessment matrix is expected to drive consistency across DOD units. However, to date, neither DARPA, nor the Army Research Lab (ARL) have removed their unit-specific risk assessment matrices from their websites, and ARL confirmed to COGR that their ARL-specific matrix remains in effect at this time. (*See,* <u>ARL Devcom Army Research Risk Assessment Protection Program (AARP) Risk</u> <u>Matrix/Rubric</u> and DARPA <u>Senior/Key Personnel Foreign Influence Risk Rubric</u> and <u>Countering Foreign Influence Program</u>).

#### Other Agencies Efforts to Develop Risk Assessment Processes/Matrices (UPDATE)

Similar to DOD's approach, other agencies are working to develop risk assessment matrices and/or processes to promote transparency on how research security related information disclosed by covered individuals will be considered in making funding decisions. The Department of Energy (DOE) Office of Research, Technology, and Economic Security (RTES) discussed its approach to due diligence reviews (see, <u>Multi-Agency Panel on Research Security Risk Assessment & Analysis October 26, 2023 (cogr.edu</u>)), and NSF mentioned that it is also working on a risk assessment matrix.

#### <u>Department of Energy (DOE) Funding Opportunity Announcement Provisions Regarding Current</u> <u>and Pending Support (NEW)</u>

DOE included provisions in several FOAs requiring reporting of "[i]nternally-provided research support, whether designated as 'seed' funding, startup funds, laboratory directed research and development (LDRD) funding, or any other name" as current and pending support. This approach contradicts OSTP's <u>NSPM-33 Implementation Guidance Table</u>, which does not require reporting of "organizational startup packages provided to the individual from the proposing organizations." A few institutions have contacted DOE with respect to this inconsistency, and COGR has noted that in recent weeks DOE has removed this provision from all open FOAs, except <u>DE-FOA-0003177</u>.

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

COGR recently updated the <u>Comparison Chart</u> documenting the current status of agency implementation of NSPM-33 and the 2022 CHIPS and Science Act. The chart summarizes the requirements of various research security laws, policies, and guidance. The chart now encompasses the OMB approved common disclosure forms the Biographical Sketch and Current and Pending (Other) Support developed by the National Science and Technology Council (NSTC) Research Security Subcommittee. See the section below for additional information on the Common Forms.

COGR also published a revised version of the <u>Quick Reference Table of Current & Upcoming Federal</u> <u>Research Security Requirements</u> to incorporate these changes. The Quick Reference Table summarizes individual agencies' implementation of research security provisions. 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.

#### **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.

#### NIST RFI on Draft Guidance Framework for Considering the Use of March-In Rights (NEW)

On December 7, the Biden Administration <u>announced</u> a new proposed framework "for agencies on the exercise of march-in rights on taxpayer-funded drugs and other inventions, which specifies that price can be a factor in considering whether a drug or other products are accessible to the public." On December 8, NIST issued a "<u>Request for Information</u> Regarding the Draft Guidance Framework for Considering the Use of March In Rights," indicating the information received would help inform NIST and its Interagency Working Group<sup>3</sup> for Bayh-Dole (IAWGBD)<sup>4</sup> (a working group chaired by NIST to reviews issues relating to extramural research activities within the field of tech transfer and works to create consensus and policy

<sup>&</sup>lt;sup>3</sup> See <u>https://www.hhs.gov/about/news/2023/03/21/hhs-doc-announce-plan-review-march-in-authority.html</u>

<sup>&</sup>lt;sup>4</sup> See COGR's June 2023 Update for additional background: <u>https://www.cogr.edu/sites/default/files/June%202023%20Update%20Final\_0.pdf#page-17</u>

across all federal agencies) for Bayh-Dole in "developing a final framework document that may be used by an agency when making a march-in decision." Among other concerns, the proposed guidance would provide agencies with justification to use pricing as a consideration to exercise march-in rights if inventions (and resulting patents) were developed with taxpayer funding:

"If the contractor or licensee has commercialized the product, but the price or other terms at which the product is currently offered to the public are not reasonable, agencies may need to further assess whether march-in is warranted. Whether action may be needed to meet the needs of the Government or protect the public against nonuse or unreasonable use of the subject invention may include consideration of factors that unreasonably limit availability of the invention to the public, including the reasonableness of the price and other terms at which the product is made available to end-users<sup>5</sup>."

As noted in <u>COGR's June 2023</u> update on this issue, COGR has long been concerned that any government exercise of march-in rights on pricing grounds could have a potentially substantial effect on COGR member institutions' ability to transfer technology to the private sector for commercialization. As the Bayh-Dole Coalition stated in a <u>March 17, 2022</u> letter to DHHS Secretary Becerra (COGR was a signatory), "the Bayh-Dole Act does not sanction marching in because critics don't like the price of a successfully commercialized product that partially arose from a federally funded invention." Similarly, in July 2022, COGR joined a <u>multi-association letter</u> to Secretary Becerra noting: "If the government can order compulsory relicensing of patents, private investment will go elsewhere, and promising innovations will once again waste away as was the case prior to the passage of the Bayh-Dole Act."

No agencies to date have exercised march-in, and in fact, earlier this year NIH denied a petition for march in-rights for Xtandi (see COGR <u>March 2023 Update</u>). The proposed guidance framework could certainly make it easier for agencies to do so, and subsequently this would have potential detrimental implications for technology development and transfer in the United States that could have global repercussions.

NIST held a <u>public informational webinar</u> on December 13 on the draft guidance, and indicated the recording will be made available on its website. Comments to the RFI are due on February 6, 2024. RSIP is assessing the proposed framework and conferring with members of The Bayh-Dole Coalition and others. We will keep the membership apprised of new developments on this issue and COGR's plan to comment.

#### Discussion with NIST on Domestic Manufacturing and iEdison Reporting (NEW)

The RSIP Committee met with NIST representatives to discuss the new Domestic Manufacturing reporting requirements of <u>EO 14104</u> (see COGR <u>September Update</u>) and the implementation through the iEdison invention reporting system. Other issues pertaining to iEdison also were subjects of discussion. NIST representatives were <u>Henry Wixon</u>, Chief Counsel; <u>Mojdeh Behar</u>, Associate Director for Innovation and Industry Services; and <u>Bethany Loftin</u>, Interagency and iEdison specialist.

We provided NIST in advance with a list of questions for discussion. These included NIST's plans for the

<sup>&</sup>lt;sup>5</sup> See <u>https://www.govinfo.gov/content/pkg/FR-2023-12-08/pdf/2023-26930.pdf#page=6</u>, mid-page.

transition of all agencies to iEdison as mandated by the EO, guidance for agencies on requests for domestic manufacturing waivers, and some specific questions regarding iEdison reporting.

NIST's goal is to encourage currently non-participating agencies to use iEdison in order to develop better and more consistent data on federally funded inventions and related items such as domestic manufacturing waivers. NIST cannot compel participation, but the EO mandate and interagency tech transfer working group discussions hopefully will serve as a strong incentive. While there is anecdotal information about waiver requests, hard data is lacking. NIST plans to issue an RFI regarding guidance on waivers, including criteria and processes.

There was extended discussion of the new (October 1) iEdison <u>invention utilization questions</u>. These include a requirement to report the manufacturing location for all products embodying subject inventions. Tech transfer offices have not routinely collected this information from licensees. One issue is the lack of definition of *substantially* manufactured in the U.S. for purposes of the requirement. There was agreement that flexibility was needed in interpretation of the requirement, but recognition that there could be ambiguities in determining the actual manufacturing location.

We also raised concerns about the effect of the <u>2018 Bayh-Dole II regulations</u> on contractors' patenting strategy. Now that provisional patent applications are considered "initial patent applications," contractors have much less flexibility in the timing of conversion to non-provisional applications or refiling provisionals. The NIST representatives indicated that the 2018 change was intended to benefit contractors and grantees, but if it was not achieving the purpose perhaps it should be reconsidered.

We asked about the status of the interagency report on the use of march-in rights. The NIST representatives stated that once it is released NIST is committed to a public comment process. Subsequently, on December 8, NIST released for public comment its "*Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights*" via the Federal Register. (See previous section for additional details). RSIP will continue to collect suggestions and potential solutions to iEdison reporting issues. We also will continue the dialogue with NIST on these issues as well as on manufacturing waivers, and march-in.

#### Senator Baldwin Introduces "Invent Here, Make Here" Act (NEW)

In June, Senator Baldwin (D-WI) introduced the "Made Here, Invent Here" Act (<u>S. 1956</u>). The bill strengthens the existing Bayh-Dole Act domestic manufacturing preference (35 USC 204) to make domestic manufacturing a requirement. Waivers would be allowed but only if it is shown that U.S. domestic manufacturing is not commercially feasible or that unsuccessful efforts have been made to find domestic manufacturers. No waiver may be granted for manufacturing in countries of concern. The bill also includes a definition of "manufactured substantially in the U.S. ("manufactured substantially from all articles, materials, or supplies mined, produced, or manufactured in the United States"). The bill also directs NIST to conduct a study and review of the commercialization of federal research by domestic manufacturers, including barriers and the role of investors.

While COGR typically does not report on most pending legislation, Senator Baldwin clearly has a keen

interest in advancing this bill. It reflects concerns similar to those leading to the domestic manufacturing EO discussed in the <u>September Update</u>. We understand some members of the Senate Commerce, Science, & Transportation Committee have expressed concerns about the bill as written. The bill to date has not been reported out of committee. COGR will monitor and report on further activity related to the legislation.

#### COGR Signs onto Letter to President Opposing Waiver of Covid IP Rights (NEW)

On December 4, COGR joined a large number of other associations and groups <u>in a letter</u> to the Biden Administration opposing the World Trade Organization's (WTO) proposed waiver of intellectual property rights for Covid-19 therapeutics and diagnostics.

The letter was originated by the Council for Innovation Promotion (C4IP), a bipartisan advocacy group chaired by two former directors of the U.S. Patent and Trademark Office. It cites an <u>October 2023 report</u> from the International Trade Commission (ITC). The ITC report found disparities between countries in access to Covid-19 treatments and diagnostics, but these disparities stem from non-IP barriers. Instead, the root causes are logistical challenges related to storage and distribution.

The letter expresses concern that a waiver could undermine public health and urges the President to oppose the waiver in the absence of a sound public health justification. It cites the investments in the development of Covid-19 vaccines and treatments which would not have occurred without the protection of IP rights. A waiver will have chilling effects on future investments and endanger IP-intensive industries such as biotech. It also cites the fact that U.S. companies have entered into over 400 licensing agreements around the world for Covid-19 diagnostics and treatments.

#### New FAR Cybersecurity Rules (NEW)

On October 3, two new FAR cybersecurity rules were published: FAR Case 2021-019 <u>Standardizing</u> <u>Cybersecurity Requirements for Unclassified Federal Information Systems</u> (88 FR 68402) and FAR Case 2021-017 <u>Cyber Threat and Incident Reporting and Information Sharing</u> (88 FR 68055).

The first rule (2021-019), FAR Case 2021-219, focuses on contractors who develop, implement, operate, and/or maintain Federal Information Systems (FISs) on behalf of federal agencies. The scope seems fairly limited and unlikely to affect many COGR member institutions. Comments were due December 4, and COGR did not comment.

The second rule (2021-017) is a different matter. It implements <u>E.O. 14028</u>, *Improving the Nation's Cybersecurity*. It includes a new FAR clause (52.239-ZZ). The clause is required for all FAR contracts. The requirements apply where information and communications technology (ICT) is used or provided in the performance of the contract. ICT is defined broadly.

The rule includes detailed incident reporting requirements (e.g., 8 hours reporting timeline to the CISA incident reporting portal after discovery of an incident) as well as requirements for contractors to develop and maintain software bills of materials for any software used in the performance of the contract,

engagement with CISA and other agencies (e.g., FBI), etc. The clause flows down.

The scope of the proposed requirement is unclear. It could be read to apply whenever a computer or smart phone is used in the performance of the contract ("products or services containing ICT"). The applicability of the requirements to research contracts where ICT may be used in the performance of the research is uncertain. While the rule revises Part 39 of the FAR pertaining to Acquisition of Information Technology by or for the use of federal agencies, the new FAR clause will be included in **all** federal contracts.

The comment deadline has been extended to February 2, 2024<sup>6</sup>. The proposed rule includes a list of questions for comment, including the compatibility between the FAR requirements and other cyber incident reporting requirements (e.g. DOD DFARs 252.204-7012). Given the potentially very broad implications, COGR has joined an EDUCAUSE working group to develop comments. We encourage COGR members to analyze the potential impact of the requirements and also consider commenting.

#### Cyber-Related False Claims Act Suits on the Rise (NEW)

There have been a number of recent developments with regard to cyber-related lawsuits and other legal actions, some involving universities. In September, a whistleblower lawsuit against Penn State University was made public, alleging non-compliance with DFARs 252.204-7012 information security requirements. Among the allegations were false self-attestations by the university of compliance with the 110 NIST 800-171 security controls as required by the DFARs 7012 clause (The DFARs 7012 requirements were extensively discussed in the COGR February 2016 Meeting Report).

Given these developments and the pending FAR rule, cybersecurity compliance has become an increasing challenge for COGR member institutions. For more discussion see <u>Government Contractors Beware: New</u> Cybersecurity Rules and False Claims Act Enforcement Actions on the Rise | Akin Gump Strauss Hauer & Feld LLP and <u>https://www.jdsupra.com/legalnews/recent-cyber-related-false-claims-act-5531892/</u>.

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

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

#### Department of Energy Acquisition Regulation (DEAR) (NEW)

On October 26, the Department of Energy published <u>a notice of proposed rulemaking</u> proposing a comprehensive revision of its Acquisition Regulation (<u>48 CFR chapter 9</u>). The rulemaking proposes to update and streamline the policies, procedures, provisions and clauses that are applicable to DOE contracts. The rule proposes the addition of several new clauses as well as amendments to several existing clauses, to promote more uniform application of the DOE's contract award and administration policies.

<sup>&</sup>lt;sup>6</sup> See Extension of Comment Period in the Federal Register: <u>https://www.federalregister.gov/documents/2023/11/01/2023-</u> 24025/federal-acquisition-regulation-cyber-threat-and-incident-reporting-and-information-sharing-extension

CGA is evaluating the proposed rule for comment and welcome any comments the community may have on the topic.

Comments to the proposed rule are due on December 26 and submitted electronically using the Federal eRulemaking Portal at <u>www.regulations.gov</u>.

#### <u>NSF Seeks Comments on NSF Public Access Plan 2.0: Ensuring Open, Immediate, and</u> <u>Equitable Access to National Science Foundation Funded Research (NEW)</u>

NSF released an <u>Request for Information (RFI)</u> seeking public input on implementing NSF Public Access Plan 2.0: Ensuring Open, Immediate, and Equitable Access to National Science Foundation Funded Research. The plan re represents an update to NSF current public access requirements in response to recent White House Office of Science and Technology Policy guidance comments on a proposed revised framework for evaluating and scoring peer review criteria for National Institutes of Health (NIH) research project grant (RPG) applications. This is an opportunity for the community to provide input before implementation. Contact Krystal Toups at <u>ktoups@cogr.edu</u> for any comments you would like to share with COGR as we work to fully understand the impact on the community. Comments are due on or before 11:59 p.m. (EST) on Friday, January 19, 2024.

#### **Costing & 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.

#### New CAS Requirement to Adjust Indirect Cost Pools (NEW)

In October, COGR members reported a new development regarding negotiations of their F&A cost rates with Cost Allocation Services (CAS). At the direction of the Department of Health and Human Services, Office of Inspector General (HHS OIG), CAS began requiring institutions to remove salary costs from their indirect cost pools for the portion of the salary cost (of an individual) exceeding the Executive Level II (NIH, HHS) salary cap. This new requirement was based on a finding in an OIG report, <u>Cost Allocation Services Needs to Update its Indirect Cost Rate Setting Guidance</u>. (see p. 23, *Indirect Cost Rate Proposals Included Potentially Unallowable Compensations Costs*).

Effectively, the HHS OIG finding revised longstanding and established 30-year policy as to how the Executive Level II salary cap applies to F&A cost recovery. As COGR understands the issue, the HHS OIG is requiring CAS to direct grantees to apply the salary cap to direct salaries <u>and indirect salaries</u>. The impact on COGR members is significant on two fronts: 1) new administrative burden, and 2) fair F&A cost recovery. In particular, non-profit research institutions are disproportionately impacted and implementation of this requirement will have a huge impact on their F&A cost rates. Interestingly, in the CAS response to the audit report, CAS did not agree with the HHS OIG finding (see p.26). However, to-date, the HHS OIG position has held.

COGR has elevated concerns to the <u>HHS Office of Grants</u>, and in turn, the HHS Office of Grants has been in communication with the <u>Program Support Center</u> (who oversees CAS). COGR's position is three-fold:

1) this new requirement, emanating from the HHS OIG, violates the proper protocol for policy setting; 2) it further violates the statutory intent of the salary cap, which was first implemented in 1990; and 3) it violates a ruling by the HHS General Counsel, also from 1990, that the salary cap is not applicable to indirect salaries.

COGR has requested that this new requirement be put on hold and that *all* stakeholders should be engaged to determine appropriate next steps. The HHS Office of Grants has been in regular communication with COGR. We will update the membership on new developments.

#### 2022 NSF Higher Education Research & Development (HERD) Survey (NEW)

The 2022 HERD results were released on November 30, 2023. Included are the <u>InfoBrief</u> and the complete suite of <u>2022 data tables</u> (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 <u>InfoBrief</u>, 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).

#### 2023 F&A Cost Rate Survey Reports Available (ONGOING)

To date, COGR has posted two reports (cost rates by institution and definitions) on its <u>2023 F&A Survey</u> <u>Report page</u> (password protected, log in required). These reports are meant to be used for institutional purposes only and should not be shared beyond the institution. In addition, both the June and October COGR Meetings featured updates on the results of the F&A survey, and both the <u>June presentation</u> and the <u>October presentation</u> include analyses that may of interest to the COGR membership. We will continue to release new reports and analyses, with an expectation of producing an F&A Survey Capstone report in the first quarter of 2024.

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

Leaders from COGR's CFC Committee met with leaders from <u>NASA's Grants Policy and Compliance</u> <u>Team (GPC)</u> on October 25 to discuss financial reporting developments with NASA over the past eight months. The GPC is led by Ms. Antanese Crank, and she and her team are committed to working with COGR and the research community on issues and concerns.

As previously reported, 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 a 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 via a <u>Grant Information Circular (GIC) notice</u>.

Also, as COGR also has reported, in the Spring NASA implemented its *Routine Monitoring–Financial Transaction Testing Review program* (see COGR May 2023 Update, p. 24). The program requires



institutions to provide a quarterly expenditure list for selected NASA awards. In a May 2<sup>nd</sup> meeting with NASA, we raised concerns around the burden and intent of this program. While NASA officials indicated their commitment to maintain the program, they agreed to be more transparent and flexible in their outreach to grantees.

COGR continues to actively engage with NASA and the GPC Team, and we expect to have additional updates in the near future. Please contact David Kennedy at <u>dkennedy@cogr.edu</u> with questions or feedback.

#### 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:

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

We first reported on this topic in the <u>COGR September Update</u> (p. 20). NSF has 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.

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

We first reported on this topic in the <u>COGR September Update</u> (p. 20). The <u>Automated Standard</u> <u>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 of 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 ID.me, which allows one to access their personal information at the Social Security Administration, the IRS, and other government entities. While the focus has been on ASAP, issues around "Personally Identifiable Information" (PII) and "Protected Personally Identifiable Information" (PPII) transcend ASAP and may be larger issues that need additional attention. COGR is closely following developments and will advocate, accordingly.

#### Federal Audit Clearinghouse Moved to GSA in October 2023 (ONGOING)

We have followed the <u>FAC Transition website</u> over the past eight months and 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 the GSA (and to COGR) if there are complications or other issues of concern.



#### Single Audit Developments (ONGOING)

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 us when audit issues arise. When appropriate, we can reach out to our 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 (ONGOING)

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 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 us when audit issues arise. When appropriate, we can connect institutions and/or provide feedback on the issues in question.

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.

#### Office of Research Integrity's (ORI) NPRM on Research Misconduct Regulations (NEW)

At the beginning of October 2023, ORI issued a NPRM proposing substantial revisions to the research misconduct regulations at 42 CFR Part 93, which were last revised in 2005. COGR, along with AAMC, AAU, APLU, and ARIO submitted a joint letter requesting an extension of the comment period, and although, ORI initially denied the extension request, it recently changed its position and <u>extended the comment period until January 4, 2023</u>.

Significant changes proposed in the NPRM include:

- Major changes to existing defined terms and the addition of numerous additional defined terms;
- Formalizing the initial assessment of allegations and requiring automatic advancement to inquiry for assessments that take longer than 30 days;
- Requiring institutions to keep a very detailed and formalized institutional record during all phases of the review process;
- Requiring institutions to transcribe all interview that take place at any point during the review process;

- Prohibiting institutions from considering the defenses of honest error or difference of opinion at the inquiry stage;
- Requiring ORI to approve any institutional decision that the subsequent use exception is inapplicable; and
- Allowing ORI to publish institutional findings from research misconduct review processes even when ORI has not settled the case or made its own findings.

The proposed regulations will substantially reduce institutional autonomy in handling the review of research misconduct regulations, particularly at the pre-investigation stage, eliminate mechanisms for resolving matters at assessment or inquiry despite solid supporting information and documents, and harm institutional effort to encourage reporting of research integrity questions and concerns. COGR is also concerned that the proposed regulations do not appropriately protect respondents' reputations and due process rights.

COGR submitted a <u>very detailed comment letter</u> ahead of the comment period deadline. ORI has indicated that it will consider the number of comments received in determining whether to make changes to the proposed regulations, and COGR strongly encourages institutions to submit their own comment letters and include support for COGR's letter in their comments. To assist institutions in submitting comments, COGR also posted a <u>template letter in the COGR member portal</u> that institutions can use in developing their own comments.

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

On August 10, NIH's Office of Science Policy (OSP) <u>issued a notice</u> in the Federal Register "Proposed Changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)<sup>7</sup>. These proposed changes harmonize the NIH's Guidelines with those of the <u>Centers for</u> <u>Disease Control and Prevention's Biosafety in Microbiological and Biomedical Laboratories</u> (BMBL) and provide additional oversight of "gene drive technology." On October 6, COGR <u>submitted comments</u> supporting the proposed amendments alignment with the BMBL and providing suggestions for clarifying the definition "gene drive." COGR also sought clarification with respect to whether the NIH Guidelines' current exemption under Appendix C-VII for the purchase or transfer of transgenic rodents that require BL1 containment remains in place.

#### OSTP RFI on Potential Changes to the Policies for Oversight of Dual Use Research of Concern (DURC) and the Potential Pandemic Pathogen Care and Oversight (P3CO) Policy Framework (UPDATE)

As noted in COGR's <u>September 2023 Update</u>, OSTP <u>issued an RFI</u> on "Potential Changes to the Policies for Oversight of Dual Use Research of Concern (DURC) and the Potential Pathogen Care and Oversight (P3PO) Policy Framework. On October 13, COGR submitted <u>comments</u> in response to this RFI which

<sup>&</sup>lt;sup>7</sup> See September 2023 Update: <u>https://www.cogr.edu/sites/default/files/September%202023%20Update.pdf#page=23</u>

proposes moving from a "list-based" to "risk-based" DURC review process and 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.S. Gov. Policy for Institutional Oversight of Life Sciences Dual Use Research

COGR's response expressed institutions' concerns that defining DURC as research that 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" would place an untenable burden on PIs and IREs to conduct risk assessments of an unlimited number of pathogens and toxins. Our comments focused on the need for more, not less, clarity as to the research that requires DURC review, as well as the need for agencies to provide institutions with more support for DURC review efforts including detailed guidance and training. Additionally, COGR urged OSTP to retain exceptions in the P3CO Policy for certain types of research involving surveillance activities and vaccine development/production to permit institutions to quickly stand-up research in these areas during public health emergencies.

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

In response to a charge to examine the disclaimer set forth in the NIH/USDA/FDA report entitled <u>Reducing</u> <u>Administrative Burden for Researchers: Animal Care and Use in Research</u> ("Report"), OLAW issued an RFI on an "Update to the Current OLAW Guidance Disclaimer (<u>NOT-OD-23-157</u>) which proposed changing their disclaimer language as follows:

Current Text: "[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."

Proposed Text: "OLAW's guidance expands upon statutory and regulatory requirements of Public Law 99-158 [Health Research Extension Act of 1985], Sec. 495, and the PHS Policy on the Human Care and Use of Laboratory Animals."

COGR submitted <u>comments</u> objecting to the proposed disclaimer because it incorrectly suggests that OLAW, through guidance, can add to or increase the requirements of its underlying statutory/policy authority (i.e., the Health Research Extension Act of 1985 and the PHS Policy on the Humane Care and Use of Laboratory Animals). Further, the proposed disclaimer contravenes the Report's directive that "unless specific statutory or regulatory requirements are cited, [OLAW] guidance should be viewed as recommendations in that an institution may use an alternative approach if the approach satisfies the requirements of the PHS Policy." COGR urged OLAW to abandon the proposed disclaimer text and instead adopt the Report's directive, or alternatively pattern its disclaimer after those used by FDA and OHRP, which are similar to the directive.

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

On July 11, OLAW issued an RFI on Flexibilities for Streamlining IACUC Review of Protocols and Significant Changes (NOT-OD-23-152)<sup>8</sup> outlining proposed guidance for "streamlining" IACUC review process in response to the 21<sup>st</sup> Century Cures Act mandate to reduce administrative burden in animal research. COGR submitted <u>comments</u> expressing its disappointment that the RFI failed to include new revisions to existing guidance that actually reduce burden, but rather re-stated long-standing flexibilities that have been in effect since well before the 21<sup>st</sup> Century Cures Act was enacted in December 2016. COGR also strenuously objected to the RFI's statement that an IACUC member may "at any time" request full committee review (FCR) and noted that this approach "completely undercuts the concept of IACUCs establishing effective pre-determined periods during which FCR may be requested." COGR urged OLAW to permit IACUCs instead to establish a reasonable and enforceable period for receipt of FCR requests.

#### **OLAW Updates to FAQS (NEW)**

OLAW issued updates to its FAQS regarding the counting and tracking of animals used in research. Updated FAQ A.9. addresses the question of whether the PHS Policy "applies to animal that are not directly involved in research, research training, experimentation, or biological testing or for related purposes." The updated FAQ makes clear that "intended for use" includes "breeders, animals that do not meet specific study criteria, and animals that are being held but not currently assigned to a research activity, and that such animals must be included in the animal care and use program (e.g., IACUC review, inspections, etc.). Updated FAQ F.2 addresses how animals should be tracked on approved protocols. It contains the following provisions about when animals should be counted:

Therefore, all live vertebrate animals, including their offspring, should be accounted for in a timely manner that ensures the animal numbers approved by the IACUC are not exceeded. Animals born or hatched should be accounted for at the first opportunity without compromising the health and welfare of the animals. Preweaned animals from litters are to be tracked at the time of first manipulation, e.g., first cage change. The PHS Policy applies to amphibians and fish upon hatching (see FAQ <u>A4</u>, <u>A5</u>). For example, zebrafish typically hatch 3 days post-fertilization, subject to environmental conditions. Per the <u>Guide</u> (page 87), because it can be difficult to individually identify some small aquatic species throughout their lives, group identification may be more appropriate in some situations or an approximate number of animals may be used.

The provisions with respect to pre-weaned mouse and rat pups may be exceedingly difficult to implement, particularly for large animal care and use programs. COGR plans to follow up with OLAW to obtain further information regarding application of the suggested group identification method.

<sup>&</sup>lt;sup>8</sup> See September 2023 Update for more background: <u>https://www.cogr.edu/sites/default/files/September%202023%20Update.pdf#page=25</u>

#### <u>OLAW Request for Information (RFI) on Proposed Guidance to Assured Institutions on</u> <u>Cephalopod Care and Use – NOT-OD-23-176 (UPDATE)</u>

On September 7, OLAW published a RFI on Proposed Guidance to Assured Institutions on Cephalopod Care and Use (NOT-OD-23-176). Comments are due December 22, and REC is working on drafting a response. Currently cephalopods lie outside the jurisdiction of both the Animal Welfare Act and its implementing regulations and the PHS Policy. This RFI, 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 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	Note
OLAW	RFI on ProposedGuidance to AssuredInstitutions onCephalopod Care andUse NOT-OD-23-176	December 22, 2023	s COGR is drafting comments.
DOE	NPRM on Department of Energy Acquisition Regulation (DEAR)	December 26, 2023	COGR evaluating rule.
ORI	<u>NPRM on Research</u> <u>Misconduct Regulations</u>	January 4, 2024	COGR has submitted <u>comments</u> .
NSF	RFI: Public Access Plan2.0: Ensuring Open,Immediate, andEquitable Access toNational ScienceFoundation FundedResearch	January 19, 2024	COGR is reviewing.
DOD/GSA/NASA	FAR: Cyber Threat and Incident Reporting and Information Sharing; Extension of Comment Period	February 2, 2024	COGR/Educause working group developing comments.
NIST	Draft Guidance Framework for Considering the Use of March-In Rights	February 6, 2024	COGR is reviewing and will comment.

#### Appendix B - Recognition of COGR's Working Group on Uniform Guidance

To our 26 working group members who spent countless hours providing expertise and helping write and/or review COGR's 50+ page response to the proposed revisions to the Uniform Guidance – <u>THANK YOU!</u>

- Sarah Axelrod, Harvard University\*
- Urmila Bajaj, University of Virginia
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- Thomas Burns, Johns Hopkins University
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- Stephanie Endy, Brown University\*
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- Jeremy Forsberg, University of Texas at Arlington
- MC Gaisbauer, University of California San Francisco\*
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- Charles Greer, University of California Riverside
- Cynthia Hope, Georgia Institute of Technology
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- Mike Kusiak, University of California San Diego
- Nate Martinez-Wayman, Duke University\*
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- **Twila Reighley**, *Michigan State University*
- Craig Reynolds, Van Andel Institute\*
- Aimee Roundtree, Texas State University
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- Jeffrey Silber, Cornell University
- Maria Soliman, University of Iowa
- Pamela Webb, University of Minnesota\*
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