COGR

Council On Governmental Relations

An Association of Research Institutions

JUNE 2021 UPDATE

Science and Security

NSF Legislation Includes Numerous Research Security Provisions (NEW)

On June 15 the House Science Committee, in a show of strong, bipartisan support, advanced the National Science Foundation for the Future Act (H.R. 2225) and the Department of Energy Science for the Future Act (H.R. 3593). The bills significantly boost authorized funding for the two agencies and make bold investments in scientific infrastructure and initiatives to broaden participation and diversity, equity, and inclusion. Several amendments were adopted during consideration of each bill.

One amendment directs NSF to prohibit participation by covered individuals (P.I.'s and other key personnel) in "malign" foreign talent recruitment programs from foreign countries of concern. It also requires certification by applicant institutions that covered individuals have been made aware of this requirement.

Other provisions in H.R. 2225 (Section 7) establish a research security and policy office at NSF; provide specific authorities to the new office of research security and policy; direct NSF to establish an online resource for stakeholders containing NSF's research security policies and guidance; create a new independent risk assessment center; require RCR training for researchers (in collaboration with NIH) and include information to raise awareness on potential security threats; require the National Academies to update their responsible conduct of research report "On Being a Scientist" to incorporate more on security threats relating to IP and research integrity; and require NSF to amend their award proposal instructions to include an ethics statement related to potential risks and social harm enabled by the research and a plan to implement mitigation measures. The House planned to consider the bill the week of June 28.

The legislation is the House counterpart to the vast Innovation and Competition Act (U.S. ICA; S. 1260, formerly known as the Endless Frontier Act) passed by the Senate on June 8, also with strong bipartisan support.

The ICA is a huge piece of legislation, some of it contradictory. It contains significant increases in funding authorizations for NSF and other agencies. A comprehensive summary can be found here.

Included in the ICA are over a dozen provisions dealing with research security. According to AAU, those of greatest concern are:

- Section 3138, requiring review by the Committee on Foreign Investment in the United States (CFIUS) of certain foreign gifts and contracts to higher education institutions that equal or exceed $1,000,000 in a single year or aggregate gifts or contracts from the same foreign source of a value over $1M during a two-year period. (Note: Section 5212 **prohibits CFIUS from reviewing or investigating gifts to an institution of higher education from a foreign person and prohibits use of funds to review or investigate gifts to an institution of higher education from a foreign person**).

- Section 2526, which mandates NSF to collect final copies of any contracts, agreements, or documentation of financial transactions between universities, their foundations, and related organizations and any educational, cultural, or language entity that is directly or indirectly funded by the Government of the People's Republic of China. Also requires NSF to collect a detailed description of any financial contributions from the Government of the People's Republic of China or its affiliates to the institution, a foundation of the institution, or related entities.
- Section 6244, which lowers the Section 117 reporting threshold of foreign gifts and contracts to $50,000; provides an annual disclosure date; outlines content of disclosure reporting; addresses sanctions for noncompliance; and establishes a single point of contact within the Department of Education. It also creates a new requirement in Sec. 124 of the Higher Education Act entitled "Institutional Policy Regarding Foreign Gifts and Contracts to Faculty and Staff" that would require universities to ensure that faculty and staff report any gifts from, or contracts entered into, with a foreign source, and then maintain this information in a searchable database and effectively manage potential espionage by foreign sources targeting faculty and staff. Also expands the definition of a contract for Sec. 124 reporting to include any "affiliation, agreement, or similar transaction" involving the use of the "name, likeness, time, services, or resources" of faculty and staff. Implementing regulations are to be issued following a negotiated rulemaking process starting within a year of enactment.

It is not clear how the House and Senate will reconcile the substantial differences between the House and Senate legislative versions. Hopefully, the provisions of greatest concern to our institutions will not be included in the final version.

State Legislation in Florida Addresses Research Security Concerns (NEW)

During the June COGR meeting, COGR Board Chair David Norton (VPR U. Fla.) discussed recent Florida legislation on research security. There are four principal features: restrictions or prohibitions on Florida universities from participating in agreements with certain countries; reporting requirements for contracts, gifts, grants, etc. from a foreign source with a value of $50,000 or more; detailed disclosure and screening requirements for applicants (including students) for research-related positions; and prior approval by the research integrity office for any foreign travel by university personnel.

Dr. Norton noted that this legislation could provide a template for consideration by other states or the Congress (similar legislation was proposed as an amendment to the US ICA but was defeated). Policymakers have an expectation that universities should know who is performing research at the university and their researchers' obligations and funding.

Dr. Norton's presentation is posted on the COGR website along with those of the other Science and Security panelists.

COGR White Paper on Foreign Influence (NEW)

COGR is developing a white paper on foreign influence issues and concerns. While still in early outline form, we expect it will address issues such as assessing and managing risks in international collaborations; managing conflicts of interest/commitments; managing foreign visitors; researcher participation in activities outside the institution; physical and cyber security; IP; reporting research outcomes; and agency disclosure requirements.

The paper might provide a basis for development of suggested practices to address these issues. We hope to have a draft available sometime this summer.

NIH and NSF Guidance on the Reporting of Biosketch Information and Other Support/Current and Pending Support (UPDATE)

NIH's publication of NOT-OD-21-073, *Upcoming Changes to the Biographical Sketch and Other Support Format for Due Dates on or after May 25, 2021* ("Notice 073") prompted numerous questions from institutions implementing the new formats prescribed by the notice. COGR alerted the agency that institutions would need to implement significant system/process changes to comply with the Notice 073. In response to community concerns, NIH published NOT-OD-21-110, *Implementation of Changes to the Biographical Sketch and Other Support Format Page* extending the date on which the new formats become mandatory until January 25, 2022.

To address the many questions members raised regarding Notice 073, as well as NSF disclosure requirements set forth in NSF's FAQs on Current and Pending Support and the proposed FY 2022 *Proposal and Award Policies and Procedures Guide* (PAPPG) (now finalized as NSF 22-1), COGR engaged in communications with both NIH and NSF. Additionally, COGR hosted the following agency representatives at the June membership meeting: Jean Feldman, Head, NSF Policy Office, Division of Institution and Award Support; Rebecca Keiser, NSF Chief of Research Security Strategy Policy; and Mike Lauer, NIH Deputy Director for Extramural Research. A summary of the major points from this presentation and from additional follow-up communications are listed below:

- **Efforts at Harmonization** – Both NIH and NSF representatives emphasized that their agencies were actively working together, and with other federal agencies, to develop and implement consistent disclosure requirements when possible. The agencies also agreed that researchers should err on the side of over disclosure when questions arise as to a particular item or matter.

- **Interagency Working Group** – Michelle Bulls, Director of NIH Office of Policy for Extramural Research Administration (OPERA), and Jean Feldman are co-chairs of an interagency working group that is being formed under the auspices of the Office of Science and Technology Policy (OSTP) to coordinate research support disclosure requirements outlined in in the *Presidential Memorandum on United States Government-Supported Research and Development National*

Security Policy (NSPM-33). The group will work on standardizing definitions, policy scopes, and forms for the disclosure of researcher support and appointments/affiliations across agencies, as well as developing requirements for digital persistent identifiers (DPIs).

- **Development of NIH and NSF Training Materials** – Dr. Lauer and Dr. Keiser are co-chairing a working group organized through the National Counterintelligence Task Force to develop coordinated training modules on agency requirements to counter inappropriate foreign influence on research. NIH further elaborated that it may issue training materials in the form of a podcast followed by opportunity for questions on the podcast via a "townhall" type event.

- **In-Kind Contributions as Other Support** – Both NSF and NIH stated that they had considered and decided not to adopt any *de minimis* dollar or time commitment thresholds that would serve as a trigger for reporting in-kind contributions.

- **Consulting** – NIH requires researchers to report consulting as "Other Support" when the researcher "will be conducting research as part of the consulting activities." [NIH FAQS Other Support and Foreign Components, §I.15]. NIH indicated that it uses the Common Rule's definition of "research" [45 CFR 46.102(l)] as a benchmark for determining whether a researcher's activities constitute research and commented that co-authorship on a publication stemming from activities may be an indicator that the activities constituted research. [NSF's approach to consulting is discussed below.]

- **Updates to Disclosure Requirements** – NIH advised that it hopes to issue updates to its Biosketch FAQs and Other Support and Foreign Component FAQs in the next week or so. It anticipates including a preamble that provides context for implementation of the guidance.

- **Dedicated Mailbox** – Per NOT-OD-21-12, *Announcing New Inbox for Inquiries Related to Changes to Biographical Sketch and other Support Format Page*, NIH established a dedicated mailbox (**nihosbiosketch@nih.gov**) through which institutions may submit questions regarding the Other Support and Biosketch guidance. The expected turn-around time for addressing most questions is seven business days, and institutions should contact NIH if the response significantly exceeds this threshold. NIH prefers that institutions submit questions via a point person within the institution's sponsored programs unit.

Institutional Responses to Notice 073: At the June meeting, representatives from the CGA and REC Committees presented points institutions should consider in implementing the notice, as well as specific tools their institutions developed to assist researchers in making disclosures. The panel emphasized the need for institutions to develop and document appropriate policies and processes to address agency requirements, as well training research administrators and faculty on institutional obligations. The presentation discussed some of the more difficult aspects of implementation including pros and cons of reviewing consulting

agreements, valuation of materials, and tools for determining what scientific collaborations must be reported. The panel also discussed the "effort conundrum" that results from the need for institutions to consider the time researchers spend on external activities despite the Uniform Guidance's statement that effort is based on institutional based salary, and, by definition, does not include external activities.

NSF Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending Support Table (NEW)

Shortly after the June meeting NSF published a chart ("Table") that lists where pre- and post-award information regarding activities and support (e.g., appointments, contributions, consulting, travel) must be disclosed in sections of proposals, as well as in progress reports (e.g., Biosketch; Current & Pending Support; Facilities, Equipment and other Resources, etc.). The Table states that certain consulting activities, types of travel support, and graduate and postdoctoral students' effort on research projects need not be disclosed as Current and Pending Support. Although this guidance will lessen institution's administrative burden associated with reporting, it does introduce inconsistency with NIH reporting requirements under current NIH guidance and FAQs. Additionally, COGR has identified some areas of the Table that require clarification and has received questions from institutions in this regard. COGR plans on following up with NSF concerning these questions, which include the following topics:

- **Consulting**: Clarifying differences between NSF's FAQs on Current and Pending Support and the Table's guidance regarding the reporting of consulting. The FAQs call for reporting consulting as Current and Pending Support when "the individual will be conducting research as part of the consulting agreement," while the Table states that reporting of consulting is required only if it "falls outside of an individual's appointment."

- **Visiting Scholars**: Understanding the definition of a visiting scholar, as well as the possible discrepancy between the Table's direction that institutions need not disclose visiting scholars in labs versus the PAPPG's advice to disclose persons on a project that receive external funding as an in-kind resource.

- **Start-Up Companies**: Understanding the Table's new requirement regarding the reporting as Current and Pending Support of start-up companies based on "non-organization licensed IP."

COGR will update its Chart Comparing Disclosure and Other Requirements/Recommendations Among JCORE, NSPM-33, NDAA 2021, NSF and NIH (including NIH NOT-OD-21-073) after it receives this additional clarification.

U.S. I.C.A. Tech Transfer Provisions (NEW)

Section 2109 of the Senate ICA discussed above includes several provisions on tech transfer. It authorizes NSF, in coordination with NIST, to make awards to advance the development and commercialization of technologies, particularly those in the key technology focus areas. It also authorizes $4.06 billion from FY 2022 – FY 2026 for an NSF program to improve technology transfer in academia, to be carried out in coordination with NIST. It also authorizes the creation of regional collaborative tech transfer resource centers.

If enacted and funded, it would be the first time the federal government has provided direct support to tech transfer offices. Tech transfer always has been essentially an unfunded mandate under the Bayh-Dole Act. It is not clear what criteria and metrics would be developed to evaluate improvements. There is no House counterpart, so the prospects for this provision are uncertain.

Regulatory Update Includes NIST NPRM (UPDATE)

The June 11 Regulatory Agenda update included an item on the NIST NPRM on the Bayh-Dole implementing regulations (see COGR May Update). While some press coverage indicated that this implied the Administration was moving ahead with the proposed changes, it appears this was only a routine update on pending regulations. The statement basically reiterates our understanding of the current status. We will inform the membership if and when there are any real developments.

DOE Issues DEC to Promote Domestic Manufacture (NEW)

DOE recently issued a Determination of Exceptional Circumstances (DEC) purportedly increasing the domestic U.S. manufacturing requirement for DOE programs. It apparently was issued partly in response to E.O. 14005: *Ensure the Future Is Made in All of America by All of America's Workers* (1/21). The DEC adds a "U.S. Competitiveness Provision" to DOE funding agreements. The DEC indicates DOE may enforce the provision through forfeiture of rights to subject inventions. It cites the erosion of the U.S. manufacturing base and the need to secure U.S. supply chains for technologies funded by DOE.

The U.S. Competitiveness Provision requires that any products embodying any subject invention or produced through the use of any subject invention will be manufactured substantially in the United States unless the Contractor can show to the satisfaction of the DOE that it is not commercially feasible. A similar provision is already incorporated into large-business funding agreements through the DOE's patent waiver process, and the provision previously has been included in DECs for a number of specific DOE programs.

It is not clear that the U.S. Competitiveness Provision adds much substantively to existing laws and regulations. The Bayh-Dole Act always has included a requirement that exclusively licensed products subject to Bayh-Dole be manufactured substantially in the U.S. (35 USC 204; 37 CFR 401.14(i)). The requirement may be waived by the funding agency.

The DOE U.S. Competitiveness Provision theoretically is broader in that it applies to non-exclusive licenses as well as to product sales in foreign countries. However, these may not be major considerations for COGR

institutions (e.g., relatively few products are manufactured under non-exclusive licenses). While the DEC outlines a detailed waiver process involving many criteria that must be addressed, in recent years our member institutions have reported increased difficulties in obtaining waivers of the requirement from most agencies in any event.

The DEC indicates that DOE may require U.S. Manufacturing Plans from funding applicants, possibly in lieu of the U.S. Competitiveness Provision. Submission of such plans has been required in certain DOE programs previously. One possibly concerning feature of the DEC is a suggestion that existing funding agreements may be modified to include the competitiveness provision. If there are existing licensees this could raise complications, particularly with regard to foreign sales not subject to the current Bayh-Dole U.S. manufacturing requirement.

The actual provision contains some ambiguous language regarding DOE approval of any transfer of rights to subject inventions. DOE approval is required for changes in ownership or other transfers of rights in inventions. From the DEC discussion it appears DOE's concern is foreign entities acquiring rights to federally-funded technologies through stock/asset purchases and bankruptcy proceedings and then moving the manufacturing of such technologies offshore. While the DEC repeatedly claims the provision is narrowly tailored, the language is less clear on this point. We may need to seek further clarification.

The discussion in the DEC implies the competitiveness provision also was developed in response to Congressional requests. Much of the 15-page DEC reads like a political statement. It relegates the existing Bayh-Dole requirement to a footnote. While the practical effect may be limited, any provision that introduces additional uncertainty to the ability of institutions to license inventions is concerning and could be counterproductive.

Higher Education Emergency Relief Fund COGR Session (UPDATE)

Rich Williams, Chief of Staff, Office of Postsecondary Education, U.S. Department of Education, presented at the June COGR Meeting—*Overview of the Higher Education Emergency Relief Fund under the American Rescue Plan of 2021*. The slide deck provides highlights of the Higher Education Emergency Relief Fund (HEERF) and links to resources and FAQs that have been developed by the Department of Education. The slide deck includes a disclaimer stating: "This document is being used in support of a live discussion. As such, it does not necessarily express the entirety of that discussion nor the relative emphasis of topics therein. Institutions are encouraged to carefully review the Department's full guidance at the end of this presentation and on the ARP HEERF III website." Despite the disclaimer, the slide deck provides a foundation for many of the issues of interest to the COGR membership and is a good starting point to assess important HEERF topics.

Mr. Williams fielded questions after his presentation. COGR documented his responses and is working with Mr. Williams and the Department of Education to make a written copy of those responses available to the COGR Membership (including topics that were not addressed during the session). COGR has developed HEERF FAQs (Version 2, updated April 30), and once we receive feedback from Mr. Williams and the Department of Education, our intent is to update the COGR version of HEERF FAQs.

After Mr. Williams' presentation, the session continued with *HEERF and University Perspectives*. The presenters were: Julie Schwindt, Associate VP, Finance & Administration, University of South Alabama; Jeffrey Silber, Senior Director, Sponsored Financial Services, Cornell University; and Lindsey Tepe, Director of Governmental Affairs, Association of Public and Land-Grant Universities (APLU). This portion of the session focused on case studies, decision-making, compliance, and the important message of transparency and communication, i.e., it behooves institutions of higher education to publicly demonstrate good stewardship and effective use of the HEERF.

A report by the U.S. Department of Education, Office of Inspector General (dated February 26, 2021) is a good document describing HEERF activity and compliance, as is the OMB Compliance Supplement (see section below, 2021 Compliance Supplement). We expect questions and issues around HEERF implementation, compliance, and audit will be hot topics of discussion for at least the next year, and COGR will continue to provide resources to the COGR membership and serve as a liaison (when needed) to the Department of Education. Contact David Kennedy at dkennedy@cogr.edu with questions, concerns, and/or other issues you would like to address.

Office of Management and Budget COGR Session (UPDATE)

Victoria Collin, Chief of the Management Controls and Assistance Branch, OMB-OFFM, and Gilbert Tran, Policy Analyst, OMB-OFFM, presented on Thursday morning (*Office of Management and Budget (OMB) Update)*. The slide deck provides highlights of OMB's oversight role in American Rescue Plan (also see PandemicOversight.gov) and recent Executive Orders issued by the Biden Administration. Other topics included: implementation of grant flexibilities under OMB Memorandum M-21-20; OMB initiatives around Grant Performance Management (see *Managing for Results: The Performance Management Playbook for Federal Awarding Agencies* available at the U.S. Chief Financial Officers Council website); and a recap of the revisions to 2 CFR Part 200 (implemented in August and November, 2020, plus FAQs issued on May 3, 2021).

The session included Q&A during which the following was covered:

- An update of the utility cost adjustment (UCA) was considered during the 2 CFR Part 200 revision process, but OMB decided this would wait until the next five-year update cycle.
- Proposal submission systems—a long term OMB goal is to establish a standard grantee interface that transcends all agency specific systems.
- 2 CFR Part 200.205 states "*agencies may impose legally binding requirements on recipients only through the notice and public comment process through an approved agency process.*" In other words, "policy by FAQ" is prohibited.

Active communication with OMB is essential to the COGR Membership and the broader research community. OMB staff can be contacted at GrantsTeam@omb.eop.gov. In addition, COGR looks forward to regular engagement with OMB on these and other important issues that arise.

Challenges with the Payment Management System (UPDATE)

As we reported in the May Update (see pp. 9-10), challenges with the Payment Management System (PMS) are an ongoing concern for the COGR Membership. Several of the items below were addressed in the Costing Hot Topics Discussion Hour during the June COGR Meeting. All of the items below will remain on our list to monitor and assist the membership, for as long as these challenges remain.

From an organizational standpoint, PMS is part of the HHS Program Support Center (PSC) (note, Indirect Cost Negotiations also are part of the PSC). The fact that PMS stands outside the traditional HHS Organizational Chart may explain some of the challenges to engage with and affect changes to PMS. Still, COGR will continue to work in a productive manner with leaders from HHS, NIH, and PMS. Currently, we are following:

- NIH Notice NOT-OD-21-102 (April 2, 2021) and NIH Notice NOT-OD-21-128 (June 1, 2021). The April 2 Notice was intended to be a reminder on the 120-day closeout requirement. However, the NIH Notice was not clear on the approval process if greater than 120 days was requested. COGR contacted NIH to express the concern and the June 1 Notice was released to serve as a clarification. In a recent conversation with NIH personnel, our understanding is additional clarity on how to request an extension will be provided via an NIH Notice (not available at the time of this COGR Update). COGR appreciates NIH's attention to this matter. The important take-away is that the community needs to be diligent on complying with the 120-day closeout requirement and to be discerning on requests for extensions. We expect NIH (and HHS) to be more attentive to (and strict on) enforcing the 120-day closeout deadline.

- NIH Notice NOT-OD-21-060 (February 4, 2021) and NIH Notice NOT-OD-21-138 (June 4, 2021). The February 4 Notice provided "leniency" on late Final Federal Financial Reports (FFRs), due to the problem created by new PMS edit checks. The edits checks were loosened allowing institutions to submit the Final FFR as an Interim FFR. The June 4 Notice reiterated the "leniency" described in the February 4 Notice, and further indicated that institutions should use the "Remarks" section to indicate if the submission is a Final FFR.

- The Final FFR PMS submission issue also is applicable to Training awards (T32s). Due to student timing issues, a T32 award may have an unliquidated obligation, which creates the same submission challenge. COGR's understanding is the solution is similar as described above—loosened edit checks will allow institutions to submit the Final FFR as an Interim FFR.

- Some COGR members have reported delays to carry-over request approvals. This challenge is related to changes in PMS processes and to recent personnel changes in the NIH Office of Financial Management.

NIH is aware of the issue and has indicated new staff is being on-boarded and soon will be up to speed. In the interim, contact your Grants Management Official (GMO) if approval is time sensitive.

- COGR continues to follow the promised elimination of the Federal Cash Transactions Report (FCTR), which will solve the reconciliation issue between the FCTR and the Final FFR. The most recent update we have received is that this will be addressed later in the 2021 calendar year.

- Finally, the longstanding G-account closeout issue also is a PMS issue. COGR's understanding is that HHS/PMS will continue a methodical approach to closing legacy G-accounts—and importantly, there should be no issues around inappropriate and/or unilateral closeouts, nor issues around debt collection actions. However, if your institution is struggling to resolve issues, please contact COGR.

COGR and the community appreciate the hard work being done by HHS, NIH, and PMS to resolve these challenges. We will keep the membership posted on all developments.

NSF Office of Inspector General (OIG) Audit Finding: Application of the F&A Cost Rate (UPDATE)

On May 14, COGR wrote a letter to the National Science Foundation (NSF) to address recent NSF OIG audit findings concerning the application of the F&A cost rate to a new award. Specifically, the NSF OIG cited the following as an audit finding: 1) an F&A cost rate was proposed at 52 percent, 2) at the time of award a new F&A cost rate of 54 percent had been negotiated, and 3) institutional policy allowed the proposed 52 percent F&A cost rate to be used on the award.

The NSF OIG position is that 2 CFR 200 (Uniform Guidance) requires the F&A cost rate of 54 percent to be used for the life of the award, rather than the proposed (and lower) 52 percent. (NOTE: A similar situation could exist in a PI transfer situation when the PI transfers their award(s) to a new institution with a higher negotiated F&A cost rate. Institutional policy may allow the original, lower F&A cost rate to be honored). COGR's position in both examples is that if institutional policy allows the lower 52 percent F&A cost rate to be used, proposed direct costs for the PI can be maintained and there is no harm to NSF. Our understanding is that NSF and OMB are reviewing the COGR letter. We will keep the membership posted on developments.

NSF OIG: NSF Award Recipient COVID-19 Audits (ONGOING)

We have been reporting on this NSF Office of Inspector General (OIG) initiative—*NSF Award Recipient COVID-19 Audits*—for the past six months. Audit reports are being regularly posted and can be found on NSF OIG Audit Reports (see External Report links). Management Responses to External Audits and Internal Reviews also can be found on the NSF OIG website. This particular initiative focuses on OMB COVID-19 flexibilities under M-20-17, M-20-20, and M-20-26 and how they were implemented. Many of the audit reports are stating: "*there were no exceptions identified with [the institution's] use of the administrative flexibilities granted through NSF's implementation of OMB Memoranda M-20-17, M-20-20, and M-20-26.*" While this is good news, cost

disallowances and compliance findings—unrelated to the COVID-19 flexibilities—are being identified (including the application of F&A cost rates, see previous section).

On a separate note, NIH-related audit reports can be found on the HHS OIG website (see Reports / Office of Audit Services). Recently, there has not been activity associated with NIH grantees. Also, DOJ settlements are available by accessing the DOJ News page at the DOJ website. We encourage you to contact COGR when relevant issues affect your institution.

2021 Compliance Supplement (ONGOING)

We continue to follow and report on single audit developments. The 2020 Compliance Supplement and the 2020 Addendum (released in September 2020 and December 2020, respectively) are the most current versions available. We expect the 2021 Compliance Supplement to be released soon, which would be followed by a 2021 Addendum. As we have previously reported, important issues for the FY2021 audits should include:

- HEERF, for almost all institutions, is a major program. Auditors are awaiting audit guidance, which will be available in the 2021 Compliance Supplement and Addendum. Both HEERF audit guidance (CFDA 84.425x, see pp. 66-76) and Provider Relief Fund audit guidance (CFDA 93.498, see pp. 86-92) were included in the 2020 Compliance Supplement Addendum and will be further updated in the 2021 Compliance Supplement and Addendum.

- Our understanding is that Research & Development (R&D) Cluster guidance will not have significant changes. In fact, the R&D Cluster might not be emphasized in FY2021 audits as HEERF (and other programs authorized under COVID-19 relief legislation) will be the audit priority.

- We should pay attention to how agencies have implemented the November 2020 revisions to 2 CFR 200 (Uniform Guidance). Many agencies have adopted the revised 2 CFR 200. However, to date, HHS (and by association, NIH) have not adopted the revised 2 CFR 200. This could have audit implications.

We will keep the membership posted on the status of both the 2021 Compliance Supplement and the Addendum.

Costing & Financial Compliance (CFC): Other Issues (ONGOING)

The items below are ongoing issues that the CFC Committee is following:

Facilities and Administrative (F&A) Cost Rates Under COVID-19. In April, COGR released the paper, *F&A Cost Rates and Reimbursement Pressures Under COVID-19: Maintaining a Fair and Reliable System* and a corresponding Executive Summary. Both are available on the COGR website. We also expect to make available a PPT slide deck. Issues addressed in the paper include: 1) deciding whether or not to submit an F&A cost rate proposal, 2) challenges of completing a proposal during these

challenging times, and 3) prospective issues applicable to F&A costs that may arise beyond the COVID-19 pandemic. A special thank you goes to the COGR workgroup who researched and wrote this paper. The contributors are shown on page four of the paper. For additional information, please contact David Kennedy at dkennedy@cogr.edu and/or Toni Russo at trusso@cogr.edu.

GAO Study on OMB COVID-19 Flexibilities. The U.S. Government Accountability Office (GAO) released the report, *OMB Should Collect and Share Lessons Learned from Use of COVID-19-Related Grant Flexibilities* (March 2021, GAO-21-318). Note, as specified at the end of the report: as the "*audit, evaluation, and investigative arm of Congress, [the GAO] exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people*." The focus of this GAO report is how OMB and the agencies implemented the flexibilities and how institutions reported using them. The sole recommendation from the report is: *OMB [should] collect and share lessons learned from the use of grant flexibilities. OMB generally agreed with the recommendation*.

OMB M-21-20 and Grant Flexibilities. On March 19, 2021, OMB issued M-21-20, *Promoting Public Trust in the Federal Government through Effective Implementation of the American Rescue Plan Act and Stewardship of the Taxpayer Resources.* Included in M-21-20 is Appendix 3, *Disaster Relief Flexibilities to Reduce Burden for Financial Assistance* (pp. 10-11), which permits agencies to implement several of the COVID-19 grant flexibilities that were offered last year under OMB Memorandum M-20-17. While M-21-20 is not as robust as M-20-17, agency implementation of M-21-20 could be helpful in certain situations.

2019 NSF Higher Education Research & Development (HERD) Survey is Available. The release includes the annual summary InfoBrief and the complete suite of 2019 Data Tables (which includes the popular *Table 21 – Higher education R&D expenditures, ranked by all R&D expenditures, by source of funds: FY 2019*).

Please contact David Kennedy at dkennedy@cogr.edu to further discuss any of these issues above, or other items that have not been covered.

NSF Proposal and Award Policies and Procedure Guide (PAPPG) (NEW)

On June 22nd, NSF released the newly updated version of the NSF 22-1 PAPPG for proposals submitted or due on or after October 4, 2021. COGR's comment letter to the draft version of the PAPPG suggested NSF consider clarifications and revisions to sections including Current and Pending Support, In-kind support, Appointments, and Travel Proposal. NSF's final Travel Proposal section is consistent with COGR's request to require AOR certification that the meeting organizer has a written policy or code-of-conduct addressing harassment be done prior to the proposer's participation in the meeting rather than at the time of the proposal. However, there are other sections that could benefit from additional clarification such as how NSF defines visiting scholar, the

treatment of consulting permitted by an individual's appointment versus consulting that falls outside of an individual's appointment, and questions related to start-up companies. COGR intends to address these questions and others with NSF. If you have questions regarding the PAPPG, please send them to Jackie Bendall at jbendall@cogr.edu. In the meantime, NSF plans to conduct a webinar covering the PAPPG changes. Visit the NSF policy outreach website to register.

Data Management and Sharing (UPDATE)

In COGR's May 2021 Meeting Update we mentioned that COGR would be hosting representatives from NIH and Purdue University during the June meeting to hear the latest updates from NIH regarding implementation of the final policy and learn about Purdue University's Research Repository (PURR), a web-based platform that Purdue researchers can use to share data and collaborate on research. Presenters on the panel representing NIH included Drs. Lyric Jorgenson, Acting Assoc. Director for Science Policy and Acting Director of the Office of Science Policy and Gregory Farber, Director, Office of Technology, Development and Coordination, National Institute of Mental Health. Since release of the Final NIH Policy on Data Management and Sharing and Supplemental Guidance published on October 30, 2020 (effective January 2023), NIH has been working on a variety of projects including the creation of a website that will host up-to-date information from Institutes and Centers (ICs) on Data Management and Sharing, a suggestion included in COGR's January 10, 2020 letter to NIH.

We also learned that NIH ICs in their funding opportunities may designate specific data repositories for researchers to store data. A central website for institutions to access, including information from the ICs on where to deposit data, will reduce burden and save time for faculty and administrators. Additional undertakings at the NIH include community outreach, possible development or expansion of existing tools and/or new tools for estimating data management and sharing costs (informed by the 2020 NASEM report on forecasting costs & April 2021 NASEM workshop on the culture of data management & sharing), templates to assist researchers when writing data management and sharing plans, and FAQs. Dr. Farber's presentation focused on efforts underway by the National Institute of Mental Health (NIMH) including consultation with the Wellcome Trust and other funders of mental health research to develop a minimal list of data collection instruments for the purpose of harmonizing mental health data collection across various laboratories. The collective efforts of NIH and others such as COGR's Data Management and Sharing Workgroup will help to ensure a smoother transition in January 2023. COGR's Workgroup will convene in July to discuss next steps on how best to serve its members and will continue to address concerns and make recommendations on NIH's implementation of the Final Policy. Please send your comments or questions to Jackie Bendall at jbendall@cogr.edu. Click here to review the power point presentation.

NASA Requests Information on Advancing Racial Equity and Support for Underserved Communities in NASA Programs, Contracts, and Grants Process (NEW)

On June 15th, NASA released a Request for Information (RFI) seeking comments to remove systemic inequitable barriers and challenges facing underserved communities. COGR will be responding to the notice and invites input from its members regarding the questions contained in the RFI. NASA will assess community feedback to evaluate, implement, modify, expand, and streamline its programs, procurements, grants, regulations and policies. Comments are due no later than July 12, 2021. Please send your comments to Jackie Bendall at jbendall@cogr.edu.

Diversity Toolbox "Fill the Box" Challenge (UPDATE)

At the June meeting, COGR announced the "Fill the Box Challenge" for the Diversity Toolbox webpage. As reported in the May update, the toolbox page will have drawers with (a) tools for starting DEI conversations among researchers and research administrators; (b) laws, regulations, policies, and guidance in this area; and (c) tools that institutions have developed to promote DEI in specific sectors of human subject research environment (e.g., IRB, study recruitment, etc.). Each COGR member institution is asked to provide a tool for the toolbox by July 31, 2021. Tools (e.g., PDF documents, forms, or links to websites) should be emailed to REC Director Kris West at kwest@cogr.edu. Kris will provide institutions that submit tools with an intake form that collects information on how the tool may be shared and whether it may be modified, and will label the tools and sort them into the appropriate drawer. The webpage is not yet live but will be developed as a part of COGR's larger website improvement project that will take place this summer.

REC Meeting with Candice Wright, Acting Director of the General Accounting Office's (GAO) Science, Technology Assessment and Analytics Office (UPDATE)

On June 8, 2021, Acting Director Wright, Assistant Director Farahnaaz Khakoo-Mausel, and Senior Analyst Caitlin Dardeene met with REC. Ms. Wright discussed GAO's December 2020 report GAO-21-130, *Agencies Need to Enhance Policies to Address Foreign Influence*, as well as a recent survey concerning research reliability. Ms. Wright explained why the report used the term non-financial conflict of interest (COI) to refer to circumstances that many institutions would label "conflicts of commitment" (COC). GAO writes its reports for the public at large and believed the term non-financial COI would be more broadly recognized. She also advised that although "non-financial COI" is similar in meaning to COC, GAO's focus encompassed more than time commitment. Specifically, GAO considered how non-financial COIs can affect the objectivity of the research, as opposed to solely considering whether a researcher has enough time committed to complete the work. Ms. Wright stated that many institutions have COC policies, but these policies focus on time commitment issues, as opposed to foreign influence and objectivity issues.

GAO personnel noted that in most cases lack of disclosure at institutions did not stem from failure to have institutional policies. Rather, policies were in place, but neither agencies nor institutions monitored

compliance with and/or enforce those policies. GAO went on to state that agencies were clear that they expect institutions to be responsible for such monitoring and enforcement.

GAO personnel also provided information on the following additional projects on the which they are working:

- A research reliability project initiated at the request of the Senate Commerce, Science and Transportation Committee in response to reproducibility issues that were identified in cancer research. The project will build on the National Academies on Science, Engineering and Medicine's 2020 report on Reproducibility and Replicability in Science and identify actionable steps that institutions may take to promote reproducibility. GAO is reaching out to subject matter experts in this area, and REC volunteered to assist.

- A project regarding U.S. and China research collaborations that will look at the extent and type of funding that U.S. researchers are receiving from China, types of research collaborations, and appropriate balancing of risk and reward.

- A project on export controls conducted by GAO's International Affairs and Trade unit. The report from this project will be a sequel to the GAO report on export controls that was issued in 2020 (GAO 20-394).

Office of Research Integrity Scope of Research Misconduct Announcement (NEW)

On May 27, 2021, the Office of Research Integrity published a guidance document entitled "Scope of Research Misconduct." The research misconduct regulations require institutions conducting investigations to "pursue diligently all significant issues and leads discovered that are determined relevant to the investigation." [42 CFR §93.310(h)]. These leads include any "evidence of additional instances of possible research misconduct." In framing a proceeding, institutions must determine when it is appropriate to examine additional publications, grant applications and research data for evidence of possible research misconduct.

At the inquiry stage, the document advises institutions to perform a "cursory review" of other papers and grant applications with the six-year statute of limitation set for at 42 CFR §93.105(a) to determine whether the research misconduct may be more widespread than presented by the initial allegations. At the investigation stage, the document recommends reviewing all underlying raw data/documents that support the research findings, as well as the respondent's papers and grant applications that contain data elements similar to those mentioned in the allegations. The guidance suggests that patterns of behavior, lack of research records, and testimony that experiments were not performed may constitute "leads" that warrant expanding an investigation's scope. Significantly, the guidance includes several case studies of inquiries

and investigations. The case studies detail ways in which ORI directed the institution to expand the scope of review beyond the original allegations, as well as identifying elements of the investigation that were not appropriately conducted.

U.S. Dept. of Agriculture Animal & Plant Health Inspection Service (USDA APHIS) Publication of Proposed Rule on Contingency Planning for Research Facilities and Others (UPDATE)

USDA APHIS published a proposed rule to amend the Animal Welfare Act regulations (9 CFR Parts 1-3) to require contingency plans for disasters and emergencies that disrupt the ability to carry out normal care and may adversely affect animal health and welfare. This rule was originally published on December 31, 2012 (77 F.R. 76815), but it was stayed on July 31, 2013, to permit further study. The rule has now been re-published as a proposed rule (86 FR 33567) with some minor modifications. Contingency plans must identify situations in which the plan would be triggered, establish a chain of command and roles and responsibilities, and address necessary materials, resources, and training. In addition to establishing the plan, the facility must review the plan annually and train staff on the plan. For current registrants, staff must be trained on the plan within 60 days after the plan is implemented, and re-training on changes in the plan must take within 30 days after the changes are made. REC is reviewing the rule to develop comments, which are due August 24, 2021.

Office of Laboratory Animal Welfare (OLAW) Guidance on Using Portions of the AAALAC Program Description to Prepare the OLAW Assurance Document (NEW)

As part of its efforts under the 21st Century Cures Act mandate to reduce administrative burden associated with laboratory animal research while protecting animal health, safety, and welfare, NIH issued NOT-OD-21-130. This Notice permits AAALAC accredited institutions to use certain sections of the AAALAC International program description for their OLAW Animal Welfare Assurance. OLAW has published a webpage that provides detailed implementation instructions for the notice. Additionally, OLAW's progress toward compliance with the 21st Century Cures Act mandate can be tracked on another newly published OLAW webpage.

NIH Advisory Committee to the Director (ACD) Working Group Report on Animal Research (NEW)

At the June 11th meeting of the NIH ACD, the above-referenced working group released its report *Enhancing Rigor, Transparency and Translatability in Animal Research* ("Report"). COGR submitted comments in response to NIH's June 16, 2020, Request for Information (RFI): Enhancing Rigor, Transparency, and Translatability to Improve Biomedical Research Involving Animal Models, Notice Number: NOT-OD-20-130, and there was some notable alignment between those comments ("RFI Comments") and the Working Group's recommendations in its Report. The Report's major themes and some of its more notable recommendations are listed below.

Recommendations similar in nature to items included in COGR's RFI Comments are noted with an asterisk. NIH will review the recommendations and make implementation decisions.

Theme 1: Improve Study Design and Data Analysis. Recommendations:

(a) Expand and improve statistical training for animal researchers and improve collaborations between animal researchers and statisticians.*
(b) Add an additional page to the NIH grant application research strategy section that is dedicated to the description of critical elements of study design (e.g., inclusion/exclusion criteria, sample size, data analysis plan, etc.)

Theme 2: Address Incomplete Reporting and Questionable Research Practices. Recommendations:

(a) Establish a program to raise understanding of prospective study registration.
(b) Develop a pilot program to generate data on and evaluate solutions that include prospective study registration.*

Theme 3: Improve Selection, Design, and Relevance of Animal Models. Recommendations:

(a) Establish a framework for rationalizing the scientific and translational relevance of animal models as a part of the justification for a grant application.
(b) Provide adequate research support for larger and long-lived, non-rodent species when justified.*
(c) Educate the public on the value of animal research, including research involving long-lived, non-rodent mammals.*
(d) Charge a working group to examine non-animal modeling systems in biomedical research.

Theme 4: Improve Methodological Documentation and Results Reporting. Recommendations:

(a) Require that supporting data for animal research submitted in support of a grant application include information on quality/uncertainty of the statistical information being provided.
(b) For all vertebrate and cephalopod animal research, require include the ARRIVE Essential 10 information in the manuscript submitted for publishing.* (The ARRIVE Essential 10 includes items such as sample size, inclusion/exclusion criteria, randomization, blinding, outcome measures and statistical methods used.)

Theme 5: Measure Costs and effectiveness of Efforts to Improve Rigor, Transparency, Reproducibility, and Translatability. Recommendations:

(a) Evaluate progress in implementing the Report's recommendations, as well as their impact, implementation challenges, costs, and impact on NIH-funded research portfolio.

New FDA Guidance Document on Sponsor Safety Reporting Requirements under INDs (NEW)

The FDA has published a new guidance document *Sponsor Responsibilities – Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies*. The Guidance combines sponsor/sponsor-investigator safety reporting requirements for clinical investigations from two previous guidance documents issued in 2012 and 2015 and adds recommendations regarding planned unblinding and review of aggregate data. Notably, the guidance separates out investigator safety reporting requirements that were included in prior iterations. FDA will publish investigator safety reporting responsibilities in a separate guidance.

COGR would like to thank COGR Board Chair David Norton (University of Florida) 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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