COGR
Council On Governmental Relations
An Association of Research Institutions

FEBRURARY 2021 MEETING REPORT & UPDATE

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Announcements

Council on Governmental Relations June Meeting Will Be Virtual

As communicated in COGR's March 5 listserv email to the membership, our June 2021 meeting will be held virtually. We are still targeting the week of June 7-11, 2021, for the meeting and anticipate opening registration in April. We will provide specific meeting details as they become available and look forward to when we can meet in person again.

Cross Cutting Issues: COVID-19's Impact to Federal Research - General Updates

COGR's Resources and Continued Activities on COVID-19's Impact on Research (ONGOING)

COGR's Institutional and Agency Responses to COVID-19 and Additional Resources page was initiated in March 2020 and continues to be publicly available and regularly updated. COGR remains focused on activities applicable to research operations under the pandemic. If you have questions or concerns, please reach out to the COGR Staff.

The American Rescue Plan and HEERF (NEW)

The American Rescue Plan was signed into law by President Biden on March 11, 2021. Of most significance for higher education is the inclusion of $40 billion designated for the Higher Education Emergency Relief Fund (HEERF), now referred to as HEERF III. This is in addition to HEERF I ($14 billion) directed to higher education under the Coronavirus Aid, Relief, and Economic Security (CARES) Act signed into law by President Trump on March 27, 2020, and HEERF II ($23 billion) directed to higher education under the Coronavirus Response and Relief Supplemental Appropriations (CRRSA) Act signed into law by President Trump on December 27, 2020. In each of the three relief bills, a small percentage of HEERF funds have been carved out as additional funding for minority-serving institutions—however, the large share of funding has been designated to higher education institutions using an allocation formula based on various student population metrics.

Two HEERF tranches (I and III) require higher education institutions to allot at least 50 percent of the HEERF funds to student grants. HEERF II requires spending on student grants that at least equals the amount required in HEERF I—the remainder can be used for allowable institutional uses. A Chart developed by the National Association of Student Financial Aid Administrators (NASFAA) is detailed and helpful, and explains key features and requirements of HEERF I, II, and III. In addition, the NASFAA website includes an article, American Council on Education Estimates New HEERF Allocations, which estimates the distribution of HEERF III funds across approximately 3,500 colleges and universities.

COGR's focus on HEERF is multi-tiered and includes:

- primary focus on the institutional portion of HEERF;
- determination of allowable charges, including allowable F&A rate application;
- the appropriate F&A rate to charge;
- compliance and reporting requirements, including 2 CFR Part 200 and Education Department Grant Administration Regulations (EDGAR);
- audit impact, both single audit (see pp. 66-69, 2020 Compliance Supplement Addendum) and OIG activity (see Education OIG HEERF report); and
- other items in need of attention and/or raised by the membership.

The Department of Education previously issued HEERF I guidance and HEERF II guidance. On March 19th, Education issued additional updates and guidance: 1) HEERF I, II, and III – Lost Revenue FAQs (e.g., see FAQs 3. and 5. and new flexibilities, including research), and 2) HEERF Update Letter (e.g., HEERF II funds can be retroactively charged back to March 13, 2020). As Department of Education HEERF guidance becomes more expansive and flexible, new issues are being raised.

Finally note, institutions should pay special attention to the January 15, 2021 Federal Register Notice regarding the 90-day requirement to begin drawing funds specific to HEERF II:

Recipient acknowledges that its failure to draw down any amount of its supplemental grant funds within 90 days of the date of this supplemental award will constitute nonacceptance of the terms, conditions, and requirements of this Supplemental Agreement and of these supplemental grant funds. In such event, the Department, in its sole discretion, may choose to deobligate these supplemental grant funds or take other appropriate administrative action, up to and including terminating the grant award pursuant to 2 CFR 200.340.

COGR will follow these HEERF developments closely. We are interested in how your institutions are approaching important issues specific to the use of institutional funds, reporting, audit, and other related issues. Please reach out to David Kennedy at dkennedy@cogr.edu to share questions, concerns, and perspectives.

Research Relief and the RISE Act (UPDATE)

Research relief was not included in the American Rescue Plan. However, six higher education associations, AAU, APLU, AAMC, ACE, AAAS, and COGR ("Research Relief Workgroup") will continue to advocate for important research relief that has been made necessary by the COVID-19 pandemic. The Research Investment to Spark the Economy (RISE) Act (see February 2021 Update, pp. 6-7) still is a viable vehicle to achieve research relief and has bipartisan and bicameral support.

The August 2020 COGR paper, *Research Impact Under COVID-19: Financial Crisis and the "Pandemic Normal,"* and the *January 2021 Addendum*, focus on the Research Impact Metric (RIM)—an estimator of research output loss and financial impact caused by the COVID-19 pandemic. The messaging of research output loss and financial impact over the past year remains important, and equally important is the role of research in restarting the economy. These will be themes the Research Relief Workgroup addresses as it continues to advocate for research relief, reinvestment, and the RISE Act.

Research Security and Intellectual Property

Discussions Continue with DOE on Foreign National Screening Requirement (UPDATE)

The COGR February Update discussed issues with the revised DOE Order 142.3B. The Order requires DOE approval for foreign national access to DOE sites, information or technologies. As we have reported, recently DOE program officers, particularly those reporting to the Office of Energy Efficiency and Renewable Energy (EERE) and the National Energy Technology Laboratory (NETL), have been aggressive in applying the order to DOE-funded projects. This includes suspending the participation of previously-approved PIs from T-4 countries pending DOE screening and approval.

COGR recently participated with a number of VPRs and other association staff in a call with the Director of NETL about the issue. We learned that in addition to the S&T Risk Matrix, DOE also is using lists of sensitive technologies and sensitive subjects for screening purposes. None of these lists are public. While the rejection rate is only ~1%, the screening may take 12-18 months. According to the NETL Director, all the cases involve cooperative agreements. By definition, there is more involvement by DOE program personnel in cooperative agreements and consequently more access to DOE information and technology. NETL recognizes there is a consistency issue with program managers applying different standards and is seeking to address it. The guidance is not expected to change with new leadership in DOE, but the approach may become more nuanced.

There was agreement in the call that development of exclusions would help streamline the process. We will continue to discuss this possibility with the other associations. However, it appears unlikely that the situation will change fundamentally without intervention by new DOD leadership. AAU/APLU will pursue arranging a meeting between new DOE leadership and senior institution representatives.

Additional Provisions in the FY'21 NDAA Worthy of Note (NEW)

The February Update noted a number of provisions in the FY'21 that may impact COGR members. The American Institute of Physics (AIP) recently published a comprehensive summary.

While the COGR Update mentioned many of these provisions, the AIP summary noted a number of others, such as Section 837, directing DOD to identify "policies and procedures protecting defense-sensitive United States intellectual property, technology, and other data and information … from acquisition by the government of China," and to establish additional protections if the existing ones are deemed insufficient." DOD also is to

consider how it might restrict current and former employees of DOD contractors that "contribute significantly or materially" to sensitive technologies from "working directly or indirectly" for companies that are wholly owned by the Chinese government or are deemed to be under its "control or influence."

Other provisions call for a variety of assessments by DOD and NIST of technologies of foreign adversaries, particularly China. DOD also is directed to initiate a National Academies study that compares efforts by the U.S. and China to "recruit and retain domestic and foreign researchers." Aside from examining the incentives the programs offer and their recruiting strategies, the study is to estimate the number of researchers participating in these programs and the subsets working in academia and U.S. defense and nuclear security labs. The study will also include a broad analysis of the risks and benefits of U.S.-China cooperation in scientific research (Sec. 283).

There also are a number of STEM-related provisions. Among others, Section 249 directs DOD to establish a program allowing university faculty members and students to work in the defense science and technology enterprise part-time or for a limited term. The program is required to create at least 10 such positions for faculty members in its first year, with at least five reserved for individuals working in the area of artificial intelligence and machine learning. Section 244 increases from three to four the number of multi-institutional consortia DOD is required to establish for expediting access to academic expertise. DOD also is directed to work to diversify participation in its SMART (Science, Mathematics, and Research for Transformation) scholarship-for-service program, including by partnering with educational institutions such as Historically Black Colleges and Universities and other minority-serving institutions.

Finally, Section 212 requires that, as of Oct. 1, 2021, any individual or entity receiving DOD R&D funding must "include, in any public document pertaining to such activities, a clear statement indicating the dollar amount of the funds received." The requirement does not apply to written statements "consisting of fewer than 280 characters."

Letter to OSTP Seeking Harmonization with FY 2021 NDAA (NEW)

The hoped-for cross-agency consistency in disclosure requirements has yet to materialize. Although the FY 2021 National Defense Authorization Act (NDAA), Presidential Memorandum on United States Government-Supported Research and Development National Security Policy (NSPM-33), and the Joint Committee on the Research Environment Recommended Practices for Strengthening the Security and Integrity of America's S&T Research Enterprise ("JCORE Recommendations") contain common elements, there are important differences in their details. Similarly, though NIH's publication of NOT-OD-21-073 (see CGA section of report for details) brings closer alignment with NSF in some areas, key differences in disclosure requirements remain between the two agencies.

With this background in mind, COGR sent a letter to the Office of Science Technology and Policy (OSTP), urging it to provide leadership in this area. The letter also recommended two specific actions in this regard: (a) harmonizing NSPM-33 with the NDAA, particularly the definitions, scope, and enforcement provisions; and (b) modifying NSPM-33 to include a carve-out from the requirement to report in-kind support for academic

collaborations that exist solely for the purpose of co-authorship of fundamental research where the results will be made publicly available, similar to an exclusion included in Department of Energy Order 486.1A.

CSIS Announces Renewing American Innovation Project (NEW)

On February 23, the Center for Strategic and International Studies (CSIS) announced a new "Renewing American Innovation" initiative (RAI). RAI recognizes the growing challenges the United States faces from robust competition in restoring the U.S. postwar status as the world's foremost center of innovation and advancement in science and technology. The goal is to identify effective approaches through written analysis, public events, and national leadership conversations that aim to bring together the best thinkers on innovation and intellectual property policy in government, academia, and industry for the benefit of the country.

The Project is led by Walter Copan, formerly Director of NIST, and Andre Iancu, former Director of USPTO. Dr. Copan led the NIST ROI Initiative (see COGR December 2018 Update) and was the guest speaker at the June 2018 COGR meeting. To some extent the RAI appears a successor to the ROI Initiative.

CSIS held a kickoff webinar for the Project on March 12. The discussion indicated the primary focus will be on assuring America's return on investment and improving/strengthening IP rights. There was little mention of concrete plans. We may seek to discuss the plans further with the Project leaders.

NASEM Security Roundtable Holds Second Meeting (NEW)

The National Academies of Science, Engineering, and Medicine (NASEM) have established a National Science, Technology, and Security Roundtable. The Roundtable was called for in the FY'20 NDAA and is jointly funded by DOD and NIH. The purpose is to identify and consider security risks involving federally-funded research and development, identify effective approaches for communicating risks to the academic and scientific community, and share best practices for mitigating these risks.

The second meeting of the Roundtable (RT) was held on March 11 (the first meeting on Nov. 30 was primarily organizational). The featured speaker was Aaron Miles, Assistant Director for National Security and International Affairs at OSTP. Dr. Miles' presentation was similar to his presentation at the February COGR meeting (slides available at COGR website). An extensive Q & A followed with RT members. There was polite but firm pushback about the costs, the lack of clarity about what is really permitted and not permitted, and the fact that the government is sometimes asking institutions for information they should be able to get internally from DHS. There was also acknowledgement from Dr. Miles that OSTP needs to do more stakeholder engagement.

A specific question was whether, with the change in Administration, NSPM-33 and the JCORE Recommended Practices would be subject to review by the Biden Administration. A similar question was raised at the COGR meeting. The response was that the Biden Administration has the prerogative to revisit the JCORE guidance, but there was broad-based agency support. Wide recognition of the challenges and need to address them make this unlikely. NSPM-33 is current policy and OSTP is moving forward with implementation.

The issue also was raised of lack of general awareness/understanding by the broad scientific community and concern about the role of the FBI. A specific question was how will ODNI support the research community (where is the support coming from, who is going to enforce the mandate, and will scientists/ institutions have the ability to get direct intel support if needed)? In response, Dr. Miles noted that the science and security agencies were both at the table in JCORE and there was greater common understanding. NSPM-33 may help in getting more intel out to the research community.

A final set of questions had to do with costs/burdens and harmonization. The response was that the approach taken by JCORE was to consider recommendations that did not involve huge burdens or costs. Institutions are best able to make determinations as to whether any given Recommended Practice works in their specific environments. On harmonization, the agencies will come together to monitor progress. A lot of the details have yet to emerge and the work is to be done in the implementation plan.

The status of the JCORE guidance and recommendations going forward is not fully clear. In a follow-up discussion with COGR staff following our meeting, Dr. Miles reiterated that the Recommended Practices should be considered by all institutions but were not viewed by OSTP to be binding guidance. From the RT discussion it seemed that some of the members share COGR's concerns. We will closely follow the implementation phase of the JCORE activity.

MITRE Study: Insider Risks in Higher Education (NEW)

The Department of Defense through the Office of the Undersecretary of Defense for Research and Engineering has engaged the MITRE Corporation to conduct a study seeking to understand the risk to the U.S. research enterprise through certain troubling behaviors at research institutions. MITRE is looking for universities who are willing to coordinate in-person one-hour interviews with individuals in specific roles (e.g., faculty in neuroscience and post-doctoral fellows in applied mathematics) to learn more about their roles, necessary qualification for their role, position stressors, and behaviors/practices that could lead to security concerns. MITRE will use the information they gather to develop insider threat awareness approaches to share with leaders in higher education. Interested research institutions should contact Dr. Deanna Caputo, MITRE Chief Behavioral Scientist for Cybersecurity, at dcaputo@mitre.org, or Dr. Brian Higgins, MITRE Lead Behavioral Scientist, at wbhiggins@mitre.org. This is only being reported here as information for our members; COGR has not directly discussed the study with MITRE.

COGR Survey on Fundamental Research Determinations (NEW)

For some time COGR has been discussing with the DOD Basic Research Office (BRO) difficulties our members have experienced in obtaining fundamental research determinations for DOD-funded projects. BRO expressed interest in receiving data on the experiences of institutions on the issues, as input for a "listening session" with a number of DOD components.

COGR recently surveyed its membership to obtain the data. About half the COGR membership (96 institutions) responded to the survey, which we highly appreciate. Of these, 69% were public and 31% were private. 49% of the respondents reported DoD spending of less than $25M per year, with another 20% with spending of between $25 and 50M. 75% of the respondents reported experiencing delays in DoD contracting due to time spent negotiating. 61% of the institutions have policies generally requiring the ability to publish the results of research, and 81% of the respondents reported encountering issues in contracting for fundamental research. Issues causing institutions to decline specific DoD contracts include project scope incompatible with institutional mission as well as restrictions on participation.

The largest barrier to the negotiation of fundamental research was hesitancy or refusal of Prime contractors to work with institutions to seek determinations of fundamental research on behalf of the institutions. Other issues included lack of clarity on the presence or absence of CUI and difficulty in communicating about fundamental research with the contracting offices. There also were many individual comments, which taken together provide a rich source of information on institutions' experiences.

We conveyed the survey results and comments to BRO. We indicated we felt there were enough responses and enough institutions (with sufficient institutional diversity) willing to participate in a listening session with DOD to schedule the event. In the meantime, FDP has launched a transaction-focused survey aimed at updating its Troublesome Clause database. Some FDP data may be available in the next few weeks.

We are now discussing scheduling with BRO. The plan is to schedule the session for early April. We will keep the membership informed of developments.

COGR Comments on NIST Notice of Proposed Rulemaking (UPDATE)

The February Update discussed the proposed rule (NPRM) issued by NIST revising the regulations on rights to federally-funded inventions and the licensing of government-owned inventions (86 FR 35). The NPRM implements some of the findings of the NIST Return on Investment (ROI) Initiative. NIST held a public listening session on February 25 on the NPRM, at which almost all participants spoke in favor of the proposed rule.

As discussed in the Update, the NPRM responds to the NIST ROI, which COGR and other higher ed. associations strongly supported. COGR will be submitting comments on the NPRM jointly with other associations. We plan to express agreement with the clarification that march-in rights should not be exercised on pricing grounds. We also will reiterate our support for clarifying the scope of the government use license. Most of the NPRM changes amount to removal of obsolete material and updating references. NIST also has proposed changes to Part 404 of the regulations, which deal with the licensing of government owned inventions. While not directly affecting our member institutions, the changes seem appropriate from a public policy standpoint.

Comments are due April 5. We plan to post the draft joint association comments a couple of weeks earlier. We encourage COGR member institutions to consider submitting their own comments. A large volume of supportive

comments particularly with regard to march-in and the government use license will be helpful to NIST. AUTM also will be submitting comments, which should be available soon.

Costing and Financial Compliance (CFC)

*Selected Committee activities related to COVID are reported above under the **Cross Cutting Issue: COVID-19's Impact on Research - General Updates** section of the COGR Update. Other items being followed by CFC are covered below.*

Facilities and Administrative (F&A) Cost Pressures Under COVID-19 (UPDATE)

The Costing Committee led a session at the February COGR Meeting covering the pressures—current and prospective—related to F&A issues. Some institutions will need to complete a FY21 or FY22 base year proposal and establish F&A rates for FY23 and beyond. The February session included discussions on: 1) deciding whether or not to submit a proposal, 2) challenges of completing a proposal during these unprecedented times, and 3) prospective issues applicable to F&A costs beyond the COVID-19 pandemic. In fact, certain prospective issues may need to be considered as institutions establish (and negotiate) F&A rates well beyond FY23. COGR is finalizing a whitepaper on this topic and expects to make it available to the membership in April.

Submission of Final FFRs into the PMS (UPDATE)

COGR continues to engage with leaders from the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), and the Payment Management System (PMS) as it relates to the submission of Final Federal Financial Reports (FFRs) into the Payment Management System. Timing issues for submitting a Final FFR and the Quarterly Federal Cash Transactions Report (FCTR) have been a long-term concern, making reconciliation between a Final FFR and the Quarterly FCTR problematic. This long-term issue was exposed via the edit checks in PMS. However, progress has been made:

- PMS edit checks have been loosened, allowing schools to submit final FFRs.
- NIH Grants Notice, NOT-OD-21-060 (published February 4th) is helpful by providing "leniency" on late reports. Still, institutions should remain diligent in documentation in case of auditor questions.
- There remains a potential issue with Training awards (T32s) and Final FFR submission. Due to student timing issues, a T32 award may have an unliquidated obligation, which makes submission—despite the new PMS edit checks—a challenge.
- Elimination of the FCTR is the ultimate solution, for which COGR has advocated the past five years. Our understanding is that HHS is advancing this solution and key internal steps are being taken.

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

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

COGR continues to follow the current audit initiative by the NSF Office of Inspector General (OIG)—*NSF Award Recipient COVID-19 Audits.* Ten institutions have been selected (and these audits are underway), with the focus on how the OMB COVID-19 flexibilities under M-20-11, M-20-17, M-20-20, and M-20-26 were implemented. As we have reported, ***the NSF OIG position is that the emphasis will not be on cost disallowances,*** but rather on fact-finding to determine how the flexibilities were implemented and related compliance analysis. Our understanding is that auditors are reviewing a limited number (i.e., less than seventy-five) of transactions (e.g., payroll, general ledger, cost transfers, etc.). If the transactions are associated with the OMB COVID-19 flexibilities, the auditors are requesting additional information and justifications. The audits are being conducted by Cotton & Company LLP (an NSF OIG contract firm). Based on COGR's recent contact with the NSF OIG, they expect to issue the majority of the ten reports by the end of April with the remainder being issued by the end of May. The NSF OIG also expects to release a "Capstone report" in mid- to late-summer.

Tracking NSF and HHS OIG Activity and DOJ Settlements (ONGOING)

For recent NSF OIG activity, we recommend reviewing both the Audit Reports (see Internal and External Report links) released by the NSF OIG and the Management Responses to External Audits and Internal Reviews. For recent HHS OIG activity (specific to NIH and NIH grantees), we recommend reviewing reports released by the HHS OIG Office of Audit Services. Also note, you can access DOJ settlements by accessing the DOJ News page at the DOJ website. We encourage you to contact COGR when relevant issues affect your institution.

2020 Compliance Supplement and Addendum (UPDATE)

As we reported in the February 2021 Update, the 2020 Compliance Supplement Addendum was released in December (note, the initial 2020 Compliance Supplement was released in September). Both can be accessed from the OFFM website. As specified in the Addendum: *This addendum supplements the 2020 OMB 2 CFR 200 Part 200, Appendix XI Compliance Supplement (Supplement) to provide additional guidance for programs with expenditures of COVID-19 awards that the auditor determines are major programs in audits performed under 2 CFR 200 Subpart F.*

The Addendum continues: *The COVID-19 awards are funded under the following Acts:*

- Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 16-123)
- Families First Coronavirus Response Act (Pub. L. 116-127)
- ***Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136)***
- Paycheck Protection Program and Health Care Enhancement Act (Pub. L. 116-139)

Programs/awards funded under these Acts that may be of interest to COGR institutions include:

- COVID-19 Telehealth Program (32.006)
- ***Higher Education Emergency Relief Fund (84.425)***
- Provider Relief Fund (93.498)
- COVID-19 Testing for the Uninsured (93.461)
- Awards designated as COVID-19 related, such as awards from NSF or NIH

Other observations made by leadership on the COGR CFC Committee include:

- There is an increased emphasis on transparency-related requirements, including review of Federal Funding Accountability and Transparency Act (FFATA) subaward reporting (COVID-19 funding only).
- ***A 3-month audit submission extension*** for single audits with 2020 year-ends through September 30, 2020, year-ends (only for recipients that received COVID-19 funding) is included in the Addendum.
- General guidance on the Student Financial Assistance (SFA) cluster is included in the Addendum.
- Discussion on the auditor's use of Agency Guidance, recognizing that it was a rapidly changing environment, is included in the Addendum.
- If donated, federally-paid PPE was received, a FMV estimate of the value should be included as a SEFA footnote, which can be indicated as UNAUDITED. This value does not affect the type A/B threshold and does not require any auditing.

Some audits are being completed under the normal schedule, while others are utilizing the 3-month extension. The Higher Education Emergency Relief Fund ***(see Cross-Cutting Issues at the beginning of this report)***, as well as other programs authorized under the March 27, 2020, Coronavirus Aid, Relief, and Economic Security (CARES) Act, may be considered "major programs" and need to be audited. Also note, it is at this time of year COGR would expect to be engaging with OMB on a Draft Version of the 2021 Compliance Supplement. As of this writing, the Draft Version has not been shared with the community. We encourage you to contact David Kennedy at dkennedy@cogr.edu if you have questions, comments, or observations that you would like to share.

Costing & Financial Compliance (CFC): Other Issues

The items below include both new and ongoing issues that the CFC Committee is following:

HHS/PMS Closeout of G-Accounts (NEW). We continue to follow this item. One COGR member shared that an open G-account, with a surplus, was unilaterally closed by PMS. Also, there still are a number of situations where G-account deficits have not been resolved, despite documentation being sent to PMS. COGR's understanding is that HHS/PMS will continue a methodical approach to closing legacy G-accounts, ***and there should not be 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.

Cloud Computing and F&A (UPDATE). Last year at this time, COGR was looking closely at cloud computing and the application of F&A to cloud computing expenditures. We did significant research on this topic and had planned to release a short "Considerations" paper. As related issues around NIH data sharing and date storage have emerged, COGR is revisiting our previous work on cloud computing and positioning ourselves to share more with the COGR membership.

Department of Treasury Offsets (ONGOING). COGR members regularly have voiced their frustration regarding "Treasury Offsets." Treasury can reduce an institution's cash draw by an amount related to a non-research reimbursement, and often it is the case that Treasury does not provide a reference for the offset. The offsets seem to regularly relate to tuition issues associated with students receiving VA tuition benefits. However, better transparency still is necessary. As the new Administration settles in, COGR will revisit this issue and explore if more transparency and better processes can be made available.

2019 NSF Higher Education Research & Development (HERD) Survey is Available (ONGOING). 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*).

Update to NIH FAQs on Charging PPE to NIH Grants and Cooperative Agreements (ONGOING). NOT-OD-20-164, released on September 11, 2020, provided policy guidance for charging PPE to NIH grants and cooperative agreements, and FAQs followed. The initial version of FAQ #3 caused concern as at least one IC did not accept a budget line request for PPE on a basic research award. To clarify allowability, NIH revised FAQ #3 to state: "… *in line with NIHs longstanding cost policy, recipients conducting research that is not a clinical trial or clinical research may charge PPE as a direct cost* [consistent with standard conditions of allowability]. COGR's understanding is that the revised FAQ # 3 has been helpful and that the ICs have responded favorably.

Office of Management and Budget, New Data Collection Requirements, Single Audit (ONGOING). In December, under the auspices of the Grant Reporting Efficiency and Agreements Transparency (GREAT) Act of 2019 (P.L. 116-103) and the former President's Management Agenda (PMA), OMB requested grantee feedback on data collection activities associated with the Single Audit. Based on robust feedback from COGR members (thanks to all who responded!), we provided a detailed response into an OMB-designed Workbook. We included 109 responses to the Data Intake tab and 91 responses to the Data Consumer tab. We expect these new data collection activities and data elements will be formally introduced through a Federal Register Notice.

GAO Study on Grants Management under the OMB COVID-19 Flexibilities (ONGOING). COGR was involved in two calls (June 16 and October 19) with the U.S. Government Accountability Office (GAO) on this topic. The GAO is looking at how both federal agencies and research institutions responded

to OMB COVID-19 flexibilities provided under M-20-11, M-20-17, M-20-20, and M-20-26. The report is expected to be completed this Spring.

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

Research Ethics and Compliance

Publication of Conflict of Commitment Principles Framework Document (UPDATE)

REC spent a great deal of time and effort this past autumn and winter developing and drafting the Principles for Evaluating Conflict of Commitment Concerns in Academic Research. This document provides a framework that institutions can use in assessing their policies and processes for identifying and analyzing conflicts of commitment (COC). The framework highlights the need for institutions to strike the appropriate balance between permitting faculty members to engage in external activities that benefit the institution and ensuring that there are sufficient guardrails in place to clearly establish that the faculty member's primary obligation is to the home institution, protect institutional resources and intellectual property from being improperly used or diverted, ensure transparency and proper identification/management of conflicts of interest (COI) and COCs, and protect against inappropriate foreign influence. The framework discusses common conundrums in this area such as nine-month faculty appointments, review of consulting agreements, effort reporting, and due diligence to detect unreported activities. Many of the issues addressed in the framework take on new significance with the publication of the JCORE Recommendations and NIH's issuance of NOT-OD-21-073. The framework includes several case studies that can be used to foster discussion and for training purposes.

The COC framework document also includes a chart that compares the requirements/recommendations detailed in the NSPM-33, JCORE Recommendations, FY 2021 NDAA, and current NIH and NSF policies and guidance. This chart is currently being updated to reflect the new requirements set forth in NIH Notice NOT-OD-21-073.

In addition to working on the framework, REC and RISP worked cooperatively on a discussion panel at the February membership meeting. The panel members discussed both the new disclosure and the COC principles document, including some of the hurdles institutions face in drafting or improving COC policies and processes.

Promotion of Intra-Agency Consistency Regarding the National Human Genome Research Institute Guide Notice (NEW)

COGR continues to promote consistency requirements among units within agencies. During the March multi-association meeting with Dr. Lauer, Deputy Director for Extramural Research at NIH, COGR pointed to the National Human Genome Research Institute's notice NOT-HG-21-023, Guidance for Third-Party Involvement in Extramural Research as an example of institute/center actions that harm uniformity efforts within NIH. Dr. Lauer appreciated COGR bringing this notice to his attention and advised that he would look into the matter.

Enhancing Diversity in Clinical Trials Presentation (NEW)

At the end of 2020, FDA issued new guidance for industry entitled "Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs ("FDA Diversity Guidance"). The FDA Diversity Guidance discusses several avenues for increasing the diversity of clinical trial populations by age, gender, and race and ethnicity including the use of broader eligibility criteria, making trial participation less burdensome, and adopting enrollment and retention practices that increase population diversity. The NIH also has significant guidance and policy documents regarding the inclusion of women and minorities in research involving human subjects, as well as its Inclusion Across the Lifespan policy to increase enrollment of participants of all ages.

At the February members' meeting, REC presented a panel that discussed efforts to improve diverse participation in clinical research. The panel began with a presentation by Dr. Milena Lolic of FDA discussing FDA's analysis of diversity data for trial of FDA regulated products. Next, Dr. Robert Fullilove of Columbia University and Dr. Efren Flores of Harvard University and Mass General Hospital presented on the history of efforts in this area and current researcher-directed activities to improve diversity. The panel concluded with presentations by Ms. Martha Jones of Mass General Brigham and Ms. Megan Singleton of Johns Hopkins University presenting on IRB and institutional efforts to improve diversity. After receiving requests from several members to share the recorded presentation within their institutions, COGR opted to provide a public link to a recording of this presentation on its website.

Development of Toolkit for Promotion of Diversity, Equity, and Inclusion (DEI) in Human Subjects Research (NEW)

To assist institutions, REC is forming a working group to develop a "toolkit" that institutions can use in their efforts to improve DEI in human subjects research. The toolkit will recap guidance in the area and point to tools that institutions have developed to improve DEI in clinical research. The toolkit also will include ideas for jumpstarting discussions in this area and identifying barriers to DEI, including regulatory barriers.

Extension of Comment Period Regarding Proposed Changes to HIPAA Privacy Rule (UPDATE)

The comment period for the notice of proposed rulemaking regarding the HIPAA Privacy Rule has been extended from March 22 to May 6, 2021. [86 FR 13683]. The proposed rule included additional definitions and changes to the definition of "health care operations." It also strengthened an individual's right to inspect and copy protected health information (PHI) through provisions such as shortening the time within which to reply to a request for access, reducing verification of identification requirements for access to PHI, clarifying provisions regarding disclosure of PHI for care coordination, and eliminating the requirement to obtain written acknowledgement of the receipt of a notice of privacy practices.

21st Century Cures Act Progress (NEW)

The Office of Laboratory Animal Welfare (OLAW), U.S. Department of Agriculture (USDA) and the FDA produced a webinar that summarizes the actions these agencies have taken to implement 21st Century Cures Act requirements regarding harmonization and reduction of administrative burden.

OLAW will be issuing new guidance on topics on which REC submitted comments, including clarification of institutional responsibilities regarding grant to protocol congruency comparison. OLAW also will be developing new guidance for comment on the following topics:

- Use of designated member review for low-risk activities
- Activities that are exempt from IACUC review
- Options for IACUC review of the use of non-pharmaceutical grade substances in protocols
- Reporting noncompliance
- Departures from the Guide.
- Applicability of the PHS Policy to zebrafish immediately after they hatch

OLAW and USDA are working on several harmonization efforts, including participation in a Federal Demonstration Project (FDP) effort to create a universal protocol template and develop a single on-line portal for submitting annual reports.

The USDA is currently processing changes to the Animal Welfare Act regulations on which REC submitted comments. These changes include (a) replacement of annual protocol review with a three-year review; (b) eliminating the requirement for an institution's CEO and Institutional Official to sign the annual report; and (c) eliminating the three-year registration renewal requirement. The Biden administration is currently reviewing the proposed final rule. Finally, the USDA reported that new guidance regarding field studies is in the clearance process, and the FDA is finalizing its guidance on enforcement discretion for compounding animal drugs from bulk substances.

Contracts and Grants Administration

NIH Guide Notice on Other Support (NEW)

During NIH's virtual fall seminar in October 2020, and again at the Federal Demonstration Partnership meeting in January 2021, NIH informed participants that changes to NIH's Other Support Guidance would be forthcoming. The anxiously-awaited changes arrived on March 12, via NIH Guide Notice NOT-OD-21-073, "Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021" and associated Biosketch and Other Support FAQs. Notable new items in the notice include:

- Requirement to provide copies of translated contracts/other agreements specific to

- senior/key personnel foreign appointments and/or employment with a foreign institution.
- Process for immediately notifying NIH of undisclosed Other Support.
- Requirement for listing all positions/scientific appointments (foreign and domestic) in Biosketches.

Members have raised several significant concerns regarding the notice's requirements such as (a) the time and burden associated with collecting and uploading contracts/agreements and privacy concerns related to non-disclosure or confidentiality requirements in those agreements; (b) inconsistencies among the guidance notice, FAQs, and associated forms; (c) lack of clarity regarding what type of consulting activities must be disclosed; (d) difficulty in determining when certain students who work in labs should be considered as "in-kind" support.

Although the notice does better align some of NIH's requirements with those of NSF, key differences remain in other areas. COGR will continue to engage with NIH in this area and will apprise the membership as additional information becomes available.

As mentioned above, COGR recently sent a letter to OSTP urging OSTP leadership to drive consistency across agencies. In that letter, we cite this NIH Guide Notice as an example of requirements that continue to diverge.

Please send your questions and concerns regarding the Guide Notice to Jackie Bendall at jbendall@cogr.edu.

NIH Data Management and Sharing (UPDATE)

In the October Meeting Report, we mentioned that COGR formed a Data Management and Sharing (DMS) Work Group to review key issues related to NIH's Final Policy for Data Management and Sharing. At the February COGR meeting, DMS work group members led a round table discussion with Dr. Carrie Wolinetz, Associate Director of Science Policy, and Jerry Sheehan, Deputy Director of the National Library of Medicine (NLM), to discuss key concerns around implementation of the policy. Additional panelists included Drs. Suzie Allard, Professor of Information Sciences and Assoc. Dean for Research, College of Communication and Information, University of Tennessee Knoxville, and Shawn Murphy, Professor of Neurology, Mass General Brigham and Professor of Biomedical Informatics, Harvard Medical. The panel was moderated by James Luther, Associate Vice President of Finance and Compliance Officer at Duke University. Dr. Wolinetz and Jerry Sheehan provided an update on where NIH currently stands regarding implementation of the policy and addressed questions submitted in advance by the work group. Drs. Murphy and Allard each discussed the policy from their perspectives as researchers. Key points made during the roundtable are as follows:

- The data eco-repository system will continue to evolve over time.
- This will be a marathon, not a sprint. NIH is currently meeting with the Institutes and Centers to determine resources needed and to provide training.
- NIH is paying attention to data standards so that data are more consistent across research studies.
- As data standards are developed, tooling will need to evolve to expedite the sharing of data.

- NLM was engaged with OSTP in the review of OSTP's January 2020 Request for Information (RFI) on Desirable Characteristics for Repositories. The comments received by OSTP will be used to further discussions at NIH.
- NIH expects to issue additional costing guidance and other resources at a future date.
- Funding is needed to share and manage data correctly (e.g., through local data enclaves).
- Changing the culture will require incentives and education to train the next generation of researchers.

If you have any additional questions, contact Jackie Bendall at jbendall@cogr.edu. Slides for the presentation can be found on the COGR website at this link.

National Institute of Food and Agriculture (NIFA-USDA) Memo to Title IX Coordinators Regarding Sexual Harassment (NEW)

In February, NIFA directed Title IX campus coordinators to notify NIFA Equal Opportunity Staff within ***three (3) business days*** of ***any*** administrative or disciplinary action taken as related to sexual harassment concerns and/or complaints in a NIFA-funded program or activity. The NIFA notification also included an excel template that could be used to submit such actions. COGR is concerned on a number of fronts, including the absence of a formal rule making process, privacy concerns regarding how to report such actions to NIFA (e.g., template through non-secured email providers), and the inconsistency of the approach taken by NIFA as compared to other federal agencies (i.e., NASA, NSF and NIH). COGR is working with other associations and is in communication with NIFA to resolve these issues. Please contact Jackie Bendall at jbendall@cogr.edu for additional concerns or questions and stay tuned for additional updates.

GSA Webinar on Transition from beta.SAM.gov to SAM.gov (NEW)

On March 16, GSA conducted a webinar for COGR members to describe the new merger from beta.SAM.gov to SAM.gov. The merger is expected to occur on May 24th. The presentation slides are available here. In addition, once the recording becomes available a link will be posted in the same location.

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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