COGR
Council On Governmental Relations
An Association of Research Institutions

FEBRURARY 2021 UPDATE

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Announcements

Council on Governmental Relations Meeting – February 24-26, 2021 Virtual Meeting (NEW)

Registration is now open for our upcoming COGR Meeting. COGR members can register online or through paper registration and pay via check. If using the latter to register, please be sure to notify Toni Russo and include a copy of the check and registration form. If your institution will be registering five or more individuals, there is a special pricing code available. The meeting agenda is also available on the COGR website here.

New for this meeting, we will also be hosting a breakout room session after Committee Reports on Friday, February 26. In this session, attendees will have the opportunity for face to face (virtual) interaction to discuss a variety of topics in one of four breakout rooms, each facilitated by a COGR Director and Committee Chair. In addition, David Norton, COGR Board Chair, and Wendy Streitz, COGR President, will host a fifth breakout room for new(ish) attendees that would like to learn more about COGR. If you have any questions about the upcoming meeting or would like to submit a question for one of the sessions in advance, please contact Toni Russo, Administrative Officer and Policy Analyst at trusso@cogr.edu.

Cross Cutting Issues: Science and the New Administration

Outreach to the New Administration (NEW)

COGR has submitted a letter to the Biden administration, OSTP, and other relevant agencies to highlight the continued need for regulatory reform and offer succinct recommendations for key topics of interest to COGR members. Included in the letter are opportunities for increasing the impact of federal research dollars, advocating for a fair and rational rulemaking process with stakeholder engagement, a continued request to stand up the Research Policy Board, advocating for an appropriate balance between advancing science and protecting U.S. research, requesting a harmonization of conflict of interest requirements, and more. COGR will continue to keep the membership apprised of any developments in communications with the new administration.

Rules and Proposed Rules Revoked or Paused with Transition from Trump to Biden Administration (NEW)

On the day that President Biden was inaugurated, his administration issued a regulatory freeze memorandum entitled "Regulatory Freeze Pending Review." Under this memorandum, certain rules and proposed rules were paused while the new agency heads reviewed them. Additionally, President Biden issued several executive orders that revoked executive orders issued by President

Trump. COGR has created a chart that summarizes the status of several rules affecting academic research institutions.

GAO Releases Report on the Research Policy Board (NEW)

On February 3, GAO released a report (GAO-21-232R) recommending that OMB establish the Research Policy Board as mandated by the 21st Century Cures Act (see COGR December 2016 Update). The report also recommended that Congress extend the period of authorization for the Board.

According to the report, OMB stated that it had not established the Board because of issues with HHS's (including NIH's) full participation in the Board's work related to developing or implementing a modified approach to certain policies involving the indirect costs related to research projects. OMB cited a statutory provision that supposedly prohibits HHS from using funds to develop or implement a modified approach to indirect cost policies. However, HHS informed OMB that the indirect cost provision would not prohibit NIH's participation on the Board and that the department was not aware of any other appropriations law provision that would prohibit such participation. GAO noted that by not having established the Board, OMB is missing opportunities for the Board to provide information on the effects of regulations related to requirements for federally funded research, and to make recommendations to harmonize and streamline such requirements. OMB also noted that the 21st Century Cures Act does not specifically require the Board to examine indirect cost policies, and there are several other issues that the Board could consider examining under its mandate.

OMB's failure to establish the Board has long been a concern of COGR and other higher ed. associations. We are pleased that GAO has essentially called out OMB for failure to establish the Board. The Act required that OMB establish the Board within 1 year of the Act's enactment and that the Board submit its first required report to Congress and other entities containing recommendations within 2 years of enactment and once thereafter. Hopefully, Congress will extend the statutory deadlines and we have urged the Biden administration to take the necessary action to establish the Board and implement the Act's mandate.

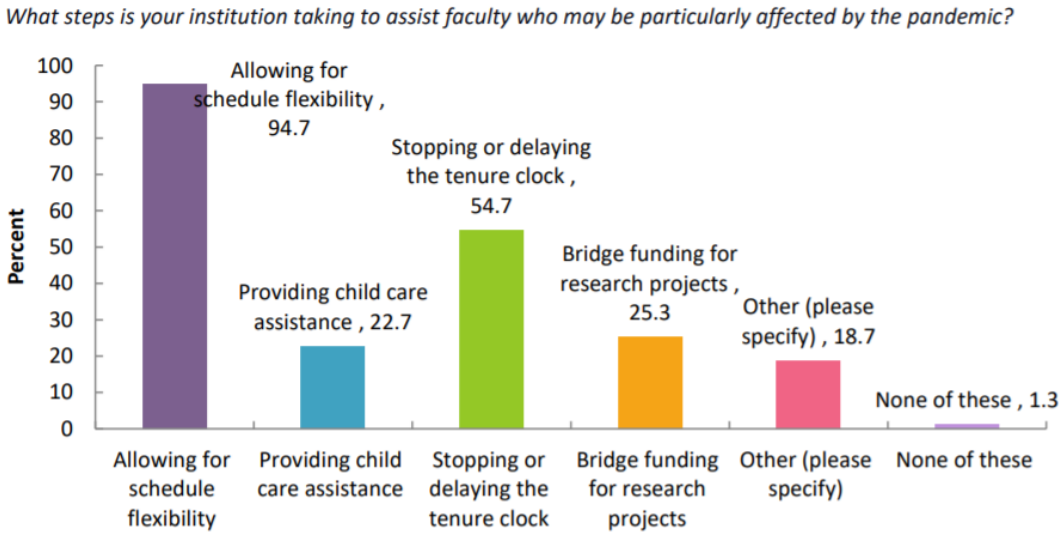
Cross Cutting Issues: COVID-19's Impact to Federal Research - General Updates

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.

COVID-19 Impact on the Conduct of Research Study (UPDATE)

The final phase of COGR's COVID-19 Research Impact Study was completed. The study consisted of a baseline study in May 2020 followed by four pulse surveys taken between June 2 and November 30, 2020 to assess the pandemic's impact on campus research activities. On December 21, 2020, COGR published its report analyzing the data from Pulse 3 and 4 and comparing the data gathered across all surveys. The data across all survey showed that on-campus research activity peaked during Pulse 3 in August but retrenched somewhat in November as infection rates surged. The data also showed the impact of the financial toll exacted by the pandemic with the number of institutions that reported furloughs or layoffs continually increasing from a low of 20.9% at Pulse 1 to 44.4% at Pulse 4, and 73.8% of responders reporting salary freezes/pay at Pulse 4. Despite difficulties, many responders reported taking actions to ameliorate negative effects on at-risk faculty (e.g., early stage, female and minority investigators) as shown in the chart below:



Additional pulse surveys may be considered depending on the pandemic's trajectory.

Research Output Loss and Financial Impact Under COVID-19: January 2021 Addendum (NEW)

COGR has published a *January 2021 Addendum* as an update to the August 2020 paper, *Research Impact Under COVID-19: Financial Crisis and the "Pandemic Normal."* The January 2021 Addendum includes new and expanded Case Studies and a concise summary of the urgent message at hand: ***As we approach one full year of life under COVID-19, it is more important than ever for federal leaders, research institutions, and all stakeholders to rally around the longstanding Federal Government - Research Institution Partnership.*** The January 2021 Addendum also was picked up in a recent article by the Research Professional News outlet (UK), further underscoring the gravity of this issue.

The original paper and addendum present a model—the Research Impact Metric (RIM) model—which estimates research output loss and financial impact, describes the challenges of doing research under the "Pandemic Normal," and advocates for renewed commitment and a substantial infusion of new research investment. The RIM model was conceived by Dr. Tanju Karanfil, Vice President for Research, Clemson University and Dr. Melur (Ram) Ramasubramanian, Vice President for Research, University of Virginia, soon after the start of the COVID-19 pandemic. Since their initial work, other institutions have used this model to estimate research output loss and financial impact due to the COVID-19 pandemic.

The Case Studies come from mission-diverse and geographically-widespread institutions, representing real-life research institutions. Using the RIM model, research output and financial loss are shown for the 12-month period of March 2020 through February 2021. These case studies demonstrate: 1) research output losses between 20 and 40 percent, 2) financial disinvestment impact in the hundreds of millions of dollars at individual institutions, and 3) potential impact approaching tens of billions of dollars across the entire U.S. research enterprise. An impact to this extent will threaten our global leadership in research, national security, and economic stability. ***The Federal Government-Research Institution Partnership has been the engine for fundamental research since the 1940s and now, more than ever, is the time to leverage the partnership.***

If your institution is interested in either sharing your experience or completing a case study using the RIM model, please contact David Kennedy at dkennedy@cogr.edu.

Research Relief and Legislative Developments (NEW)

As the Biden Administration works with Congress to advance the American Rescue Plan, six Higher Education Associations, AAU, APLU, AAMC, ACE, AAAS, and COGR ("Research Relief Workgroup"), continue to advocate for research relief to be included in a rescue package. Four of the associations from the Research Relief Workgroup, AAU, APLU, AAMC, and ACE, sent a Letter (which references the RIM model, see previous section) to Congressional leadership ***asking Congress to include $26 billion in supplemental funding for federal science agencies under the pandemic rescue package currently under consideration.*** This relief would provide critical support for the nation's scientists and engineers and the research operations that underpin the U.S. scientific enterprise, which are critical to beating the pandemic, supporting communities, and revitalizing the economy.

Concurrently, the bipartisan, bicameral Research Investment to Spark the Economy (RISE) Act (H.R. 7308 and S. 4286) from the last Congress remains a viable vehicle to achieve research relief, and was reintroduced in the new Congress on February 5. Under the creative and nuanced ways to pass legislation, there are multiple means to advance the $26 billion request included in the RISE Act (and emphasized in the associations' letter to Congressional leadership). While there is widespread support for the RISE Act, it is uncertain if research relief will be incorporated into the American Rescue Plan. To date, Congress remains focused on providing relief to higher education through the Higher

Education Emergency Relief Fund (HEERF), which does not include research relief. In fact, an important part of ongoing advocacy is to remind Congress that the HEERF excludes research relief and that research relief is equally important and necessary.

The Biden Administration's deadline for passage of the American Rescue Plan seems to be aligned with the expiration of the unemployment benefits that were authorized in the $900 billion pandemic relief bill signed into law in late December – March 14th. If research relief is not incorporated into the American Rescue Plan, our higher education association partners are cautiously optimistic that Congress will address research relief in a subsequent pandemic recovery bill, or through the FY2022 budget appropriations process, or via other creative mechanisms. ***COGR encourages COGR members to continue advocacy efforts for research relief, to communicate the message of research relief across your professional and personal networks, and to be on the look-out for stories and anecdotes that demonstrate the impact COVID-19 has had on the research enterprise.***

We will keep the Membership posted on all developments.

Cross Cutting Issues: Science and Security

HHS OIG Survey for Grantee Institutions on Actions Institutions are Taking to Address Foreign Influence (UPDATE)

In November and December, COGR engaged in multiple meetings with representatives from COGR institutions to discuss issues concerning this HHS OIG Survey. COGR engaged in discussions and correspondence with HHS OIG representatives regarding many of these issues, and HHS OIG were responsive to several of the major points that were raised, including making changes to the survey to permit information to be submitted anonymously. COGR appreciated HHS OIG's willingness to engage on these issues and looks forward to the resulting report after survey data is analyzed.

Results and Analysis from COGR Survey on Institutional Disclosure Practices (UPDATE)

COGR published the report "Survey on Institutional Disclosure Practices: Responding to Inappropriate Foreign Influence Amid Evolving Requirements" December 18, 2020 (available on request from COGR - please contact Toni Russo to request a copy). Numerous COGR member institutions completed this study for a response rate of 68%, and the data collected illustrate how institutions responded to concerns about inappropriate foreign influence in three major areas in which research information is collected: external activities, COI, and Current and Pending Support. Overall, institutions are collecting disclosure information from multiple paths and have or are working on processes to compare disclosures from different areas, as well as frequently triggering additional review (e.g., export control) if and when foreign activities are identified. An early comparison of the requirements set forth in NDAA 2021, the JCORE Recommended Practices for Strengthening the Security and Integrity of America's S&T Research

Enterprise ("Practices"), and Presidential Memorandum on United States Government-Supported Research and Development National Security Policy (NSPM-33) shows some inconsistency across the specific requirements of the documents. Nevertheless, federal agencies have all expressed a desire for achieving consistency to the greatest extent possible in this area, and COGR is hopeful that this consistency will be achieved in agencies' implementation of NDAA FY 2021 and similar initiatives.

JCORE Recommendations Released (NEW)

The long-awaited JCORE recommendations were released in January. The full package consists of a *Presidential Memorandum on U.S. Government-Supported R&D National Security Policy* (NSPM-33), issued on January 14, 2021, and the JCORE *Recommended Practices for Strengthening the Security and Integrity of America's Science and Technology Research Enterprise* ("Practices"), issued on January 19. There is also a fact sheet on the NSPM-33, and a "*Statement from the Press Secretary Regarding the National Security Presidential Memorandum on Research and Development Security* . The Memorandum NSPM-33 is addressed to agencies and the Practices are directed to research organizations.

COGR staff and Committees are analyzing the documents. Both the NSPM and the Practice document require detailed disclosure of information related to potential conflicts of interest and commitment. The NSPM requires the disclosures from PIs and senior research personnel, while the Practices expands the disclosure requirements to include postdocs, graduate students and visiting scholars. Both strongly encourage sharing of information about disclosure violations with federal funding agencies. Both provide a range of potential consequences and penalties for violations. NSPM-33 requires institutions with federal R&D funding in excess of $50M per year to establish a research security program. The Practices do not have a dollar limit and recommend designation of a chief research security officer by all research organizations. The Practices recommend that foreign travel both by researchers and administrators be reviewed.

Requirements for individual researchers to register for digital persistent identifiers (DPIs) also are set forth in both documents, although the Practices broaden that requirement to include research enterprise employees, contractors and affiliates. Both cite the importance of compliance with Section 117 reporting requirements, although NSPM-33 also discusses the importance of ED providing clear guidance.

The JCORE recommendations generally have been reviewed positively (see "*Parting Trump memo on U.S. research security seen as a road map for Biden,* Science (2021) see However, we have reservations about many of the aspects discussed above. In some cases, such as disclosures, foreign travel review and DPIs, the Practices appear to go well beyond the Memorandum. Information sharing could raise due process concerns. The relationship of Section 117 to research security is not clear. There is also a concern that the Practices might be used essentially as a checklist by security agencies.

It is not clear what the Biden Administration or the new leadership of OSTP will do about either of these documents. We note that Section 223 of the FY'21 NDAA calls on OSTP to assure consistency in agency disclosure requirements (it also sets forth sanctions against both individuals and entities for failure to disclose the required information, but the entity sanctions only apply essentially in the case of willful failures). However, the Memorandum and Practices go well beyond the NDAA.

Additionally, is not clear whether NSPM-33 is subject to the current regulatory freeze, or what its official status may be from a regulatory standpoint. JCORE will be the subject of ongoing discussions and reports by COGR, and we will keep the membership apprised of any developments. To aid in review, COGR has created a crosswalk comparison document "Institutional-Related Requirements Under Key Documents Pertaining to Federal Research Funding and Inappropriate Foreign Influence" available on the COGR website here, and there also will be a session at the February COGR meeting on disclosures.

Other NDAA Provisions That Impact COGR Members (NEW)

We mentioned Section 223 of the FY'21 NDAA above in connection with JCORE. There are additional provisions that also are worthy of note.

Section 1299 (*MODIFICATION TO INITIATIVE TO SUPPORT PROTECTION OF NATIONAL SECURITY ACADEMIC RESEARCHERS FROM UNDUE INFLUENCE AND OTHER SECURITY THREATS*) includes a substantial overhaul of Section 1286 of the FY'19 NDAA (see COGR September 2018 Update).

One new addition is a requirement for senior officials at institutions of higher education to receive periodic threat briefings (1286(c)(2)(C)). Another calls for the National Academies of Science, Engineering, and Medicine to develop an additional list of foreign talent programs that pose a threat (1286(9)(A)). That list and the previously required DOD list of "bad actor" foreign academic institutions is to be submitted to Congress annually and published on a public DOD website (1286(f)). DOD is required to designate an academic liaison from DOD R&E to work with the academic and research communities to protect DOD-sponsored research from foreign threats. This includes responsibilities for outreach and education to the communities and policy coordination (1286(g)). The former basic research exemption language was struck from the provision requiring DOD to collect information on individuals who participate in DOD-funded R&D (1286(d)(1)(A)).

Section 1062 provides that no DOD funds can be provided to an institution of higher education that hosts a Confucius Institute, beginning in FY'23. Waiver requests must be submitted to the DOD academic liaison.

Conflict of Commitment Principles Project (UPDATE)

COGR's Research Ethics & Compliance Committee (REC) formed a working group that met regularly during the fall and winter months to develop a framework document discussing principles that institutions should consider in examining conflict of commitment (COC) policies and processes. With the release of the JCORE Practices and NSPM-33, COC policies/practices have taken center stage as an area that must be considered with respect to inappropriate foreign influence concerns, and many institutions are currently reviewing their processes in this area. The COC framework takes a broader perspective by examining underlying principles in this area and the benefits of faculty participation in external activities, while recognizing the need for appropriate "guardrails" and highlighting points that must be considered in policy drafting. The framework document will be released during the February COGR membership meeting and will include case studies and a chart the compares requirements of the Practices, NSPM-33, NDAA FY 2021, and current NIH and NSF requirements in the COC area.

GAO Releases Report on Foreign Influence (NEW)

On December 17, GAO released a report *FEDERAL RESEARCH: Agencies Need to Enhance Policies to Address Foreign Influence* (GAO -21-130).

The report reviewed the conflict of interest and conflict of commitment policies of 11 institutions and five federal agencies. It found that the policies of all the institutions addressed both, but only three of the five agencies had policies on conflicts of interest and none had conflict of commitment policies. It also found that clear enforcement procedures were lacking for most agencies. The report recommended that all agencies develop policies addressing both financial and non-financial conflicts.

All the agencies but NSF agreed with the recommendations. NSF pushed back on the notion that the policies should be combined, arguing that they serve different purposes. We tend to agree with NSF. Conflicts of interest typically are defined in terms of financial interests. The notion of "non-financial" conflicts of interest appears contradictory. We agree that conflicts of commitment should be addressed in both institution and agency policies, but they are not necessarily the same as conflicts of interest.

The GAO report was sent to the Senate Committee on Finance. Given the subsequent mandates in the NDAA and JCORE recommendations, it is not clear what impact the report will have at this point.

MITRE Releases Report on Improper Influence (NEW)

On December 31, the MITRE Corporation released a report: *Improper Influence in Federally Funded Fundamental Research* (#20-3551).

Based on interviews with 19 university and 8 federal agency representatives, the report calls for a risk-reduction-based approach applied through the entire grant cycle, alignment of disclosure requirements and guidance across federal agencies, an information sharing center and development of metrics for the effectiveness of research reduction efforts. Perhaps the most surprising finding is that some universities did not view foreign government influence as a significant problem.

The report contains many other findings and recommendations, including the need for more consistent guidance across federal agencies, a common theme in reports on these issues. Many of the conclusions and recommendations also echo those in other reports on these issues. We do not know if MITRE plans any follow-up.

DOE Revises Foreign National Screening Order (UDPATE)

On January 15, the Department of Energy (DOE) issued a revised order on its Unclassified Foreign National Access Program (DOE O 142.3B). The Order requires DOE approval for foreign national access to DOE sites, information or technologies. Requests are screened against DOE's (non-public) S&T Risk Matrix.

The previous version of the Order (142.3A) had included an exemption for institutions of higher education. This exemption, which COGR and others negotiated with DOE, was removed in late 2019 (see COGR February 2020 Update). DOE previously assured COGR that the exemption would continue to apply (except for access to DOE sites), and that this would be clarified in the revised order (see COGR September 2020 Update and October 2020 Meeting Report). However, the previous exemption was limited to research funded by program offices that report to the DOE Office of Science. In any event the revised Order does not contain the clarification.

Recently DOE program officers, particularly those reporting to the Office of Energy Efficiency and Renewable Energy (EERE), have been aggressive in applying the order to DOE-funded projects. These include long-running grant-funded projects that involve foreign national PIs. In some cases, the PIs' participation has been suspended pending DOE screening and approval. This has resulted in confusion and hardship in the research community.

We have been discussing the issue with senior DOE management in the Office of Science. AAU is convening a group of senior research officers to meet with the Director of NETL/EERE to discuss the concerns. Previous DOE leadership was not responsive to our concerns. We are hopeful that with new leadership in the Department we may make better progress, particularly if oversight of Energy and Science are combined into one Undersecretary position.

Section 117

Notice of Interpretation (NEW)

On November 13, ED published a Notice of Interpretation (NOI) in the Federal Register. It addresses ED's enforcement authority for failure to adequately report under Section 117. The NOI claims that ED has authority to implement a range of corrective measures for an institution that fails to adequately report under the HEA Title IV Student Financial Aid Program, including termination of the institution's Title IV participation. The NOI claims similar enforcement authority under Title VI. The NOI was effective immediately.

COGR joined ACE and 25 other higher education associations in comments submitted on December 14. The comments questioned ED's legal authority to take enforcement actions under Titles 4 or 6. An accompanying memorandum of law pointed to serious legal flaws in ED's justification. Section 117 expressly assigns enforcement authority to DOJ. Also, the Notice appears to require rulemaking under the Administrative Procedures Act as a "legislative rule," given its claimed legal effect. Finally, Section 117 is promulgated under Title I of the HEA. It has no relationship to Title IV. In effect, ED's interpretation could convert all federal reporting requirements for institutions of higher education into Title IV requirements. We have asked the new Administration to rescind the NOI.

Investigations (UPDATE)

In the final days of the Trump Administration, investigation letters were sent to six universities regarding their section 117 disclosure of foreign gifts/contracts. Additionally, investigations were closed at three universities. In total, the department has 15 active investigations and 4 closed investigations. For a list of institutions and copies of the letters see ED's Section 117 website.

"True Copies" NPRM

On January 13, the Department of Education (ED) published a proposed rule on its website that would require submission of "true copies" of gift and contract agreements subject to Section 117 reporting requirements.

The true copies submission requirement originally had been included in ED's proposed Information Collection Request (ICR). Following strong objections from COGR and other higher education groups, OMB directed ED to remove the requirement from the ICR and make it subject to a separate rulemaking (see COGR February 2020 Update). However, it was never officially published in the Federal Register. The NPRM is characterized by accusatory statements alleging deliberate university non-compliance with the Section 117 requirements. It asserts that true copies are necessary for the Department to assure compliance. ED estimates that on average 3500 copies would be submitted annually.

Submission of true copies would be extremely burdensome to institutions, with substantial cost and resource implications. It also raises serious confidentiality concerns as we noted in previous COGR comments (see above Update). Other means of assuring compliance such as including Section 117 reporting in annual institutional audits would be more effective and less burdensome than requiring true copies submissions.

The NPRM has no official status and has recently been removed from the ED Section 117 website. It appears unlikely that the Biden Administration will move forward with it, though this could change. For now, however, we do not plan to submit comments and are not encouraging COGR members to do so. Should the situation change we will inform the membership.

UC—FBI Host Symposium on Research Security (NEW)

On January 26, the University of California System and FBI hosted a virtual symposium on *"Protecting the Research Enterprise: Transparency, Integrity & Reciprocity."*

UC President Drake and FBI Director Wray kicked off the meeting. Dr. Drake mentioned the "dynamic challenge" of protection vs. openness. Director Wray noted that universities have become a "prime target" for foreign adversaries, and the need for partnerships between the higher education community and the FBI to deal with the threats.

A panel of research agency representatives provided their perspectives. There were concurrent sessions on cybersecurity and new Congressional views and activities regarding foreign influence. A case study was presented (which included statements by the FBI representative on the need to revisit and potentially update NSDD-189 and that all fundamental research might be considered "sensitive"). A closing panel of university representatives (moderated by COGR President Wendy Streitz and including COGR Board member Missy Peloso) discussed university practices and perspectives. The need for greater uniformity by federal agencies again was highlighted.

The FBI is interested in hosting similar sessions with other universities. We are discussing plans for a possible symposium this spring in the Northeast. COGR and other higher ed. associations worked closely with the FBI in planning for the UC symposium. We expect to continue the close working relationship.

Research Security and Intellectual Property

Committee activities related to inappropriate foreign influence are reported under the ***Cross Cutting Issue: Science and Security*** *section of this report.*

NIST NPRM (NEW)

On January 4, NIST issued a proposed rule (NPRM) 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.

COGR and other higher education groups strongly supported the ROI Initiative, which was aimed at fostering and encouraging the transfer of federally-funded innovations to the marketplace (see COGR February 2019 Update). The NPRM makes a number of changes and updates to the implementing regulations (37 CFR 401) for the Bayh-Dole Act (35 USC 200 *et seq*), which governs rights in federally funded inventions. Comments are due April 5.

While the proposed revisions in the NPRM do not fully address the ROI findings, they are responsive to the ROI goals and objectives. These include a clarification that "march-in rights" should not be exercised by agencies exclusively on the basis of business decisions by contractors regarding the pricing of commercial goods and services arising from the subject inventions. This essentially restates the understanding most stakeholders have had of the proper application of march-in rights since the implementation of the Bayh-Dole Act. For the government to intervene in these decisions could have a considerably adverse effect on the ability to commercialize the inventions. Unfortunately, this clarification may prove controversial. The NPRM also poses a number of questions, including revisions that would help clarify the scope of the Government Use license provided by Bayh-Dole. The ROI had recommended a clarification that COGR supported. It would be helpful for the community to reiterate support for that clarification, which was not included in the NPRM changes.

NIST is holding a public listening session on February 25 on the NPRM (advance registration required). COGR will be represented at the session. We expect to submit comments on the NPRM, in conjunction with AUTM and other higher ed. associations. It is unclear what effect the current regulatory freeze may have on the NPRM since the April 5 date is beyond the 60-day freeze period. We will share draft comments with the COGR membership.

Costing and Financial Compliance (CFC)

Selected Committee activities related to COVID are reported previously 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.*

Submission of Final Federal Financial Reports into the Payment Management System (NEW)

> ***Note: This is a time-sensitive issue that has not been resolved as of the writing of the COGR Update. An NIH Grants Notice, NOT-OD-21-060, published on February 4, addresses the issue and provides leniency appliable to submission of "late reports." When new updates are available, we will immediately update the COGR Membership.***

COGR is actively engaged 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) to help identify solutions to recent concerns related to the submission of Final Federal Financial Reports (FFRs) into the Payment Management System. COGR has highlighted the following:

- Timing issues for submitting a Final Federal Financial Report (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 has been exposed via the edit checks in PMS. Under the current configuration of PMS, Final FFRs cannot be accepted due to the reconciliation challenge.

- This is an HHS-wide issue, not just NIH. The high volume of NIH awards has uncovered the administrative burden associated with this process.

- ***Initial workarounds suggested by PMS have proven not to be viable and have raised significant concerns around compliance, financial integrity, and audit risk.***

- Allowing selected fields for Final FFR submissions to be editable (similar to the Annual, non-final FFRs) could provide an effective solution. *COGR members stand ready to assist with beta testing or any other assistance that will be helpful.*

- Elimination of the FCTR is the ultimate solution, for which COGR has advocated the past five years.

- While all solutions should be considered, COGR advocates for solutions that will not create administrative burden. For example, if PMS edit checks are eliminated for the short-term, but institutions are required to resubmit at a later date, this would be a burdensome outcome.

- Depending on the resolution, ***institutions should not be put at risk for being cited by auditors for submitting "Late" reports.*** HHS and NIH recognize this (see beginning of this section).

- Finally, in the course of working through the new process of using the PMS portal for FFR submission, another concern applicable to FFR reporting at the end of a competitive segment on T32 training awards should be noted. According to PMS, a Final FFR is not allowed to have an unliquidated obligation. However, T32 awards often will have an unliquidated obligation for trainees that are appointed during the final budget period of a competitive segment when a competing renewal has been awarded. *With the PMS edit checks in place, submission of Final FFRs for T32 awards under this scenario will be problematic.*

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.

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

Nothing has been "typical" during the COVID-19 pandemic, including creating and negotiating an F&A cost rate proposal. Some institutions, however, will need to complete an FY21 or FY22 base year proposal and establish F&A rates for FY23 and beyond. The February COGR Meeting will include a session that will address: 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, some of the prospective issues may need to be considered as institutions establish (and negotiate) F&A rates well beyond FY23. COGR is working on a paper to formalize some of these topics, and this session will preview the paper.

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

At the October 2020 COGR Meeting, Mark Bell, Assistant Inspector General, Office of Audits, and Ken Lish, Director, Contract Grant Audits, presented an *Update from the National Science Foundation, Office of the Inspector General (NSF OIG)*. A wide range of topics were covered; most notable were comments specific to a current audit initiative—*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. ***Note, 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. The final output of these ten audits will be a "Capstone Report," which can then be used as a resource for the entire community.

COGR is following the progress on these audits and 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). Feedback from institutions is that the process is not going as quickly as originally indicated (the NSF OIG indicated the audits would be completed within six months) and the process is absorbing significant staff time.

Feel free to contact David Kennedy at dkennedy@cogr.edu if your institution is engaged in this NSF OIG audit initiative and/or if you have additional insights to share.

2020 Compliance Supplement and Addendum (NEW)

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 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 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.

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 (NEW and ONGOING)

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

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*).

Update to NIH FAQs on Charging PPE to NIH Grants and Cooperative Agreements. 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* [in line with standard conditions of allowability].

Office of Management and Budget, New Data Collection Requirements, Single Audit. 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. COGR has been involved in two calls (June 16 and October 19) with the U.S. Government Accountability Office (GAO) related to this study by the GAO. 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 in the Spring of 2021.

HHS/PMS Closeout of G-Accounts. We continue to follow this item and are working under the assumption that G-account closeouts still have not been prioritized. However, if your institution has provided HHS/PMS with data and has not heard back, you should reach out to Dan Long at PMS and/or policy staff at HHS to remind them that you are waiting for HHS/PMS to respond. If needed, we can provide direct email contacts to Mr. Long or policy staff at HHS.

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

*Committee activities related to COVID are reported under the **Cross Cutting Issue: COVID-19's Impact on Research General Updates** section of this report, and activities related to inappropriate foreign influence are reported under the **Cross Cutting Issue: Science and Security** section of this report. Issues concerning the new administration are reported under **Cross Cutting Issue: Science and the New Administration** section of this report.*

Research Integrity and the Responsible Conduct of Research

ORI RFI on Fostering Research Integrity and RCR (NEW)

In December, COGR submitted comments in response to the federal Office of Research Integrity's Request for Information (RFI) on fostering research integrity and the responsible conduct of research. This RFI sought information "best practices, challenges, and needs related to teaching the responsible conduct of research, promoting research integrity, and preventing research misconduct." In its response, COGR noted that in developing and implementing RCR educational programs, institutions have encountered challenges tailoring programs to multiple specific audiences, encouraging promotion of RCR goals by senior investigator, and ensuring that the subject matter focus is appropriate and is conveyed via efficient and effective training modalities.

NIH Notice of Clarification: Policy for Managing COI in NIH Peer Review (NEW)

NIH issued NOT-OD-21-019 in late October 2020, clarifying that any involvement in an application by an investigator may be considered a COI if that investigator serves on a scientific review panel that considers the application. Further, if a member of a scientific review panel fails to disclose a conflict of interest, NIH will consider this a breach of the integrity of the peer review process. As investigators may be involved in various aspect of multiple funding applications, they will need to carefully track their involvement to ensure accurate reporting if they are also serving on NIH peer review panels.

Clinical Investigations and Human Subjects Research

FDA Guidance Document: Enhancing the Diversity of Clinical Trial Populations: Eligibility Criteria, Enrollment Practices & Trial Designs (NEW)

FDA issued a new guidance document setting forth steps that sponsors and sites can take to increase the diversity of participants in clinical trials. Measures include designing studies to make participation less burdensome, such as by having fewer site visits and using easier communication channels (e.g., apps, telemedicine), as well as using electronic informed consent, when possible. NIH also has issued guidance in this regard, and at the February COGR membership meeting, REC will present a panel at which institutions will discuss approaches that they have taken to improve the diversity of participants recruited for clinical trials.

Contracts and Grants Administration

NSF Releases Draft Proposal and Award Policies and Procedures Guide (PAPPG) (NEW)

On December 14, 2020, NSF released for comment an updated draft of the NSF PAPPG (22-1). Comments are due February 12, 2021. COGR is in the process of finalizing its comments and will be submitting a letter suggesting clarifications and revisions to several sections, including Chapter I. Pre-Submission Information, Section E.6. Foreign Organizations. In this section NSF refers to "other direct funding." COGR seeks clarification on the meaning of this term and whether NSF anticipates updating the NSF proposal cover sheet to reflect the new requirement. COGR also believes the use of "organization," "individual," and "counterpart" in the provision as written invite confusion rather than clarity if those are truly three different entities. We will recommend that NSF make it clear in this section that counterpart refers to the ***foreign*** counterparts' individual (which we interpret to be the same as the foreign organization's individual).

In addition, COGR will recommend that NSF add helpful language from the NSF FAQs to the Current and Pending Support section in the PAPPG. It is important to include this language in the provision itself

in order to make the disclosure requirements clearer for researchers to understand. We will also seek inclusion of additional language to clarify what NSF is *not* interested in having institutions report, such as FAQ #15 instructing institutions not to include consulting unless the faculty member is doing research as part of that consulting agreement.

Other comments pertain to Chapter II, Travel Proposal. We believe this section is intended for the situation where the meeting organizer is someone *other* than the prime recipient institution. In lieu of requiring an AOR to certify on the Cover Sheet ***at proposal submission time*** that the meeting organizer has a relevant written policy or code-of-conduct**,** COGR will propose that the AOR will assure that such a policy is in place *before the participant attends the meeting*. Alternatively, NSF could include this as a term and condition of the award rather than a certification. As long as the meeting organizer's policy is provided to the institution *prior to travel*, this should be sufficient to meet the original intent of the compliance requirement.

For additional questions or comments. Please contact Jackie Bendall at jbendall@cogr.edu.

NIH Guide Notices Released (NEW)

NIH released a host of guide notices in January including the salary cap guide notice for grants and cooperative agreements on January 29, 2021. The salary limitation for Executive Level II is $199,300. On January 27, NIH released a guide notice increasing the stipend levels for FY 2021 Kirschstein-NRSA awards for undergraduate, predoctoral, and postdoctoral trainees and fellows.

DEA Issues Final Rule to License More Growers for Marijuana Research (UPDATE)

DEA has released the long-awaited final rule to increase the number of licensed growers of cannabis for research purposes on December 18, 2020, with an effective date of January 19, 2021. COGR's comment letter to DEA's March Notice of Proposed Rulemaking noted four areas of concern: 1) DEA's resistance to act on the backlog of pending applications, 2) lack of researcher access to a diversity of strains currently available on the open market, 3) the need for more clarity in explaining DEA's role for taking "physical possession" of marijuana and the absence of responsibility for DEA to assure quality of product in DEA's possession, and 4) DEA's variable administrative fee for recovering costs to administer the marijuana growers program.

DEA's final rule and actions to date have been disappointing for institutions interested in cultivating or obtaining a wider variety of cannabis for research purposes. Since 2016 when DEA first notified the public that additional growers would be considered, 2-3 dozen applications have been submitted and remain pending despite congressional pressure. DEA indicates because of the need to balance limited resources to vet applicants including the 60-day public comment period, DEA cannot act on applications in shorter timeframes. As a result, DEA declines to adopt a specific approval date applicable to all applications for registration to bulk manufacture marihuana. Current applications in the pipeline, however,

will receive priority. Applications filed after January 19, 2021, will not be considered until all applications accepted filed on or before that date have been granted or denied by the Administrator.

COGR also asked for additional clarity regarding DEA's administrative fee. DEA stated that the administrative fee added to the sales price of marihuana on a per transaction basis is necessary for recovering its costs of administering the marihuana growers program. DEA claims that because the vast majority of marihuana will be sold to researchers, a waiver of the administrative fee involving researchers would not allow DEA to properly recover its costs of administering the program. Finally, DEA claims that in order to avoid disputes between buyers and sellers, DEA accepts no liability with regard to the performance of any of the terms agreed to by a grower and buyer of marihuana, including but not limited to the quality of the marihuana, despite DEA's "physical possession." COGR will be following congressional and federal updates closely. For more information, please contact Jackie Bendall at jbendall@cogr.edu.

USDA Issues Final Rule for the Domestic Production of Hemp (UPDATE)

On January 15, 2021, USDA issued a final rule for the production of domestic hemp with an effective date of March 22, 2021. The final rule addresses comments to the interim final rule (IFR) published in October 2019. USDA addressed the following key provisions raised in COGR's January 29, 2020 letter.

The IFR indicated that a testing measurement of 0.5% THC or more would be considered "negligence" – triggering potentially severe penalties. *The margin of error in the final rule has been increased from a total of 0.5% to 1% before THC levels are considered negligent. The final rule also limits producers to one (1) negligent violation in a growing season within a calendar year.*

- DEA regulations provide that a DEA-registered lab can only accept materials for testing from a schedule 1 license holder if the testing is not for law enforcement testing purposes. *Under the final rule, USDA maintains the requirement that hemp be tested at DEA certified labs but has delayed enforcement of the rule until December 31, 2022.*

- The IFR required enforcement agency or approved DEA laboratories to collect samples from growers/manufacturers for delta-9 tetrahydrocannabinol concentration (THC) level testing no more than 15 calendar days prior to the anticipated harvest of hemp plants. *The final rule has increased the harvest time window from 15 calendar days to 30 calendar days.*

Other notable key provisions are as follows:

- USDA has modified pre-harvest sampling to require that samples be taken from approximately 5 to 8 inches from the "main stem," "terminal bud," or "central cola," including the leaves and the flowers, of the flowering top of the plants as opposed to whole-plant samples. This was recommended by many stakeholders during the comment period.

- USDA's temporary revision to allow farmers to destroy "hot hemp" on site has been made permanent. The IFR previously required DEA or those authorized to handle schedule 1 substances to destroy the plants in an off-site location.

Please contact Jackie Bendall at jbendall@cogr.edu for additional information or questions.

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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.

Research Security and Intellectual Property (RSIP)

Elizabeth Peloso (Chair)	University of Pennsylvania
Alexandra Albinak	Johns Hopkins University
Allen DiPalma	University of Pittsburgh
Cindy Kiel	Stanford University
Michael Moore	Northwestern University
Dan Nordquist	Washington State University
Jennifer Ponting	University of Chicago
Kenneth Porter	University of Maryland
Fred Reinhart	University of Massachusetts
John Ritter	Princeton University
Janna Tom	University of California
Kevin Wozniak	Georgia Institute of Technology

Costing & Financial Compliance (CFC)

Joseph Gindhart (Chair)	Washington University St. Louis
Sarah Axelrod	Harvard University
Vivian Holmes	Boston University
Cynthia Hope	Georgia Institute of Technology

Michael Legrand	University of California, Davis
Nate Martinez-Wayman	Duke University
Gerald Mauck	University of Denver
Lynn McGinley	University of Texas Medical Branch, Galveston
Jeffrey Silber	Cornell University
Marcia Smith	University of California, Los Angeles
Cathy Snyder	Vanderbilt University
Renotta Young	Columbia University

Contracts & Grants Administration (CGA)

Walter Goldschmidts (Chair)	Cold Spring Harbor Laboratory
Stephanie Endy	Brown University
Jeffrey Friedland	University of Delaware
Jeremy Forsberg	University of Texas, Arlington
Charles Greer	University of California Riverside
Jennifer Lassner	University of Iowa
Steven Martin	Indiana University
Lisa Mosley	Yale University
Twila Reighley	Michigan State University
Craig Reynolds	University of Michigan
Jennifer Rodis	University of Wisconsin-Madison
Pamela Webb	University of Minnesota

Research Ethics & Compliance (REC)

Naomi Schrag (Chair)	Columbia University
Lynette Arias	University of Washington
Lois Brako	University of Michigan
Theresa Colecchia	Johns Hopkins University
Grace Fisher-Adams	California Institute of Technology
Keri Godin	Brown University
Karen Hartman	Mayo Clinic
J.R. Haywood	Michigan State University
Mary Mitchell	Mass General Brigham
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Debra Thurley	Pennsylvania State University