COGR
Council On Governmental Relations
An Association of Research Institutions

MAY 2021 UPDATE

Upcoming COGR Virtual Meeting June 8-11, 2021 and Looking Ahead to October 2021 (NEW)

Registration is still open for our June 8-11, 2021, Virtual Meeting, and the agenda is available online here. If your institution will be registering five or more individuals, please contact Toni Russo at trusso@cogr.edu for a special pricing code. New for this meeting, COGR is adding three discussion sessions to the agenda, in which attendees can engage directly with COGR staff, Committee members, and each other on a variety of meeting related topics. Attendees must register for these sessions and registration links will be sent to registered attendees the week before the meeting.

In planning for our October 2021 meeting, we anticipate sending a survey to the membership in later June to help gauge what budget and travel restrictions may look like in the fall for the membership, as well as how/when our membership expects to start traveling to conferences again. We will send the survey through our listserv once available and appreciate your valuable feedback. Please contact Toni Russo at trusso@cogr.edu if you have any meeting related questions.

Tidal Wave of Research Security Legislation Potentially Impacting COGR Institutions (NEW)

A great deal of legislation aimed at addressing research security concerns at universities is currently under consideration, particularly in the Senate. It reflects bipartisan concerns about foreign influence at our institutions. Much of this has been included in or proposed as amendments to the U.S. Innovation and Competition Act (**S. 1260**), formerly known as the Endless Frontier Act. This bill originally would have authorized greatly increased funding to NSF. It has undergone extensive revision since first introduced. A summary is available here.

The current measure packages a number of smaller security-related bills and amendments into the legislation. These include the following which may be of particular concern to COGR member institutions:

New database for gifts and contracts to individual faculty: The bill would create a new Section 124 for the Higher Education Act that would require institutions with more than $5 million in research expenditures to maintain a database to track contracts and gifts **of any amount** that a foreign source gave to their researchers and staff. Universities also would need to maintain and publish a policy requiring faculty and professional staff to report individual gifts and contracts.

Expanding CFIUS to including foreign gifts and contracts to colleges and universities: The bill would require the Committee on Foreign Investment in the United States (CFIUS) to review in advance many foreign gifts donated to and contracts entered into by colleges and universities. This would result in new compliance costs for institutions and delays in international research collaborations.

Increased foreign gift and contract reporting: The bill would lower the reporting threshold to $50,000 from the current level of $250,000 under an update to Section 117 of the Higher Education Act, among other changes. We have extensively reported on Section 117 issues over the past two years. This bill could be coupled with a

requirement for the Department of Education to engage in negotiated rulemaking with the community on Section 117. This would be an opportunity to engage ED on the many issues of concern with the implementation of Section 117.

The eventual outcome of the proposed legislation is unknown at this time. However, the lower Section 117 reporting threshold appears most likely to be enacted. AAU issued a statement outlining significant concerns with the provisions.

The state of Florida has enacted legislation along similar lines. In addition to lowering foreign gift and contract reporting thresholds to $50K, it restricts participation in Confucius Institute programs, requires formal screening of all faculty and staff foreign travel by the university research integrity office, and requires collection of data on and screening of all foreign national hires, including visiting researchers and students.

The current and pending state and federal legislation and the outlook will be discussed in a panel at the June COGR meeting.

COGR Holds "Listening Session" with DOD (NEW)

As discussed in the February Update, the Basic Research Office (BRO) in the Office of the Under Secretary of Defense for Research and Engineering (OUSD(R&E)) asked COGR to arrange a "listening session" with the academic community to discuss fundamental research policy and export control in DoD-funded research programs. DOD is hosting this event to help ensure that fundamental research and export control policies are implemented consistently across the DoD-funded academic research enterprise. It responds to a recommendation in a GAO report last year (see COGR May 2020 Update (*GAO Report on University Compliance Issues*; GAO-20-394)). It will provide input for development of new DOD guidance on fundamental research contracts.

COGR recently surveyed its membership to obtain data on university experiences with fundamental research determinations in DOD contracts. About half the COGR membership (96 institutions) responded to the survey. The February Update summarized the results. As we previously reported, the largest barrier to the negotiation of fundamental research was hesitancy or refusal of DOD 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.

Subsequently we coordinated the results with the responses to the recent FDP Troublesome Clauses survey data. The issues identified in the FDP survey included: publication prior approval; dissemination of data/data ownership; presence of the 7012 CDI/CUI clause; foreign national participation issues; not receiving the contract until after work had begun (interestingly that this was a stated issue for prime awards as well as subs); receiving the contract late in the federal year with high pressure to turn it around quickly; and lack of contractor

understanding of the issue and appropriate clauses for the activity. Most respondents reported getting to a conclusion or walking away within 60 days.

Stakeholders from across DOD have been invited by BRO to participate in the session, which has been **scheduled for June 10**. DOD suggested 12 university representatives. We identified the university representatives based on their survey responses. BRO now is in the process of inviting participants and developing the agenda. It is expected that each of the university representatives will briefly discuss their experiences and respond to questions from the DOD participants. COGR will provide an overview. We will report on the session in our next Update.

CMMC Academic Advisory Council Formed (NEW)

The COGR February meeting included a session on Institutional Experiences with the Cybersecurity Maturity Model Certification (CMMC). The slides are posted on the COGR website (see COGR October 2020 Meeting Report for discussion of the DFARS Interim Cybersecurity Rule).

Included in the CMMC framework is an advisory Accreditation Body (AB). COGR (Bob Hardy) has been participating in a small working group with EDUCAUSE and REN-ISSAC aimed at establishing an Academic Advisory Council (AAC) to the AB. A charter for this group has been approved. It will provide a venue for discussion of challenges and issues related to CMMC and higher education.

The group will include senior institution research administrators, security leaders, researchers, and university continuing and professional education representatives. Three non-voting representatives of higher ed. associations also will be invited to join. We currently are finalizing a list of suggested members.

The charter recognizes that CMMC poses unique challenges to institutions of higher education. The AAC will play a critical role in providing input to DOD from the community. Initial areas of focus may include higher education assessment methodology for CMMC, guidance for collaborative research activities, costing approaches, and strategic policy issues. A press release will be issued shortly.

DTAG Holds Plenary Meeting (NEW)

The Defense Trade Advisory Group (DTAG) held its semiannual plenary meeting on May 20. The group is advisory to the Directorate of Defense Trade Controls (DDTC) in the State Department. Most of the agenda consisted of working group presentations. These included working groups on ITAR 123.17 Personal Protective Equipment (PPE), Part 130 Reporting, ITAR Compliance, and ITAR 125.49 Exports of Technical Data.

The PPE group recommended simplifying PPE exemptions, including those which apply to researchers. Changes could include removal of pre-export inspection requirements and allowing institutions to ship the PPE in addition to individual hand carrying items abroad. The Part 130 group recommended adoption by DDTC of an annual report option. Of particular interest was the compliance group, which is co-chaired by Michelle Avalonne of Columbia and Jessa Albertson of Stanford. That group's recommendations included a draft Compliance Risk Matrix that includes university-specific concerns, that could be used both in internal compliance programs and as a quick reference guide. Compliance requirements are keyed to affirmative actions by exporters required by the

ITAR, with specific citations. Eight broad "tags" are included which correspond to broad areas of ITAR compliance requirements (e.g. Registration). The guide can be organized sequentially by the ITAR or by the eight broad tags. The DTAG voted to adopt the recommendations of all the working groups, meaning that the recommendations will be forwarded to DDTC for consideration. Slides will be posted to the DDTC website.

Other information provided at the meeting included that DDTC has received fewer license applications this fiscal year due to the pandemic. The temporary pandemic reduction in exporter registration fees will not be continued. A rule changing the definition of "regular employee" to accommodate teleworking will be published soon.

NIH Guide Notices on Other Support (UPDATE)

Background: On March 12, 2021, NIH published NOT-OD-21-073, *Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021* ("Notice 073"). Shortly after Notice 073 was published, COGR wrote to NIH to request that it consider delaying the notice's effective date to afford institutions time to develop system and process changes necessary to implement the notice's requirements. After gathering questions from members regarding Notice 073's requirements, in early April COGR staff met separately with Michelle Bulls, Director, NIH Office of Policy for Extramural Research Administration (OPERA) and Michael Lauer, Deputy Director, NIH Office of Extramural Research (OER) to discuss the notice and again ask NIH to consider an extension.

Current Status: Taking into consideration the systemic changes that institutions must put in place to implement the notice, NIH published NOT-OD-21-110 ("Notice 110") which extended the date on which the new Biosketch and Other Support formats are mandated from May 25, 2021, to January 25, 2022. Shortly after issuing Notice 110, NIH updated its Other Support webpage and FAQs and posted a blog post regarding this extension. NIH made clear in Notice 110 that although the new formats were not mandated until January 25, 2022, applicants and recipients remain "responsible for disclosing *all* research endeavors regardless of the version of the forms used." After Notice 110 was published, COGR posed follow-up questions to Dr. Lauer.

A summary of the major points from COGR's communications with NIH regarding Notices 073 and 110 is set forth below:

Completed Support: Completed Support need only be reported in the Project/Proposal Section; it does not need to be reported for In-Kind Other Support. Copies of contracts with foreign entities (see "Supporting Documentation" below) do not need to be provided as supporting documentation for Completed Support.

- Supporting Documentation:
    - Supporting documentation does not need to be provided until January 25, 2022, except in cases in which NIH requests that an institution provide it.
    - Once the supporting documentation becomes mandatory, if Senior/Key Personnel list a "foreign appointment and/or employment with a foreign institution" as Other Support, then the relevant

contract, grant, or other agreement between the Senior/Key Personnel and the foreign entity (and translated copies, if necessary) must be provided to NIH. NIH indicated that the need for these contracts arose because many institutions were unaware that their researchers had such agreements in place and had never seen them.

  - For supporting documentation that is provided to NIH, applicants and recipients may redact confidential information from the documentation that they provide, but key provisions including award amounts and/or time and effort devoted to the activity must be provided. The information will be shared within NIH on a need-to-know basis during the pre-award process and access will be limited to appropriate staff in the eRA system.

- Definitions of Terms: NOT-OD-21-073 does not change any standard definitions from the NIH Grants Policy Statement.
- Biosketch**:** Researchers should go back three years in listing positions and scientific appointments. NIH has indicated that it will update the Biosketch FAQs in this regard, but to date, this has not happened.

COGR Activities Regarding the Notices: The REC and CGA Committees have formed a joint working group to carefully review the notice and associated FAQs, identify issues that require clarification, and discuss institutional approaches to addressing the notice's requirements. At the June membership meeting, members of the working group will present on approaches and considerations in implementing Notice 073's requirements, as well as tools that institutions have developed to assist researcher and sponsored programs' personnel in understanding the notice. COGR also updated its comparison chart to include the requirements from Notice 073. Finally, COGR will meet with Michelle Bulls in May, June, and July to discuss additional questions raised by members as they implement the notice. If you have questions regarding Notice 073, please contact Jackie Bendall at jbendall@cogr.edu or Kris West at kwest@cogr.edu.

NIH COGR Chart Comparing Disclosure and Other Requirements/Recommendations Among JCORE, NSPM-33, NDAA 2021, NSF & NIH (including NIH NOT-OD-21-073) (UPDATE)

COGR, AAU and APLU met with OSTP <title> Aaron Miles and received an update regarding OSTP's latest efforts regarding the implementation of the January 14, 2021, *Presidential Memorandum on United States Government-Supported Research and Development, National Security Policy* ("NSPM-33") and the Joint Committee on the Research Environment's *Recommended Practices for Strengthening the Security and Integrity of America's Science and Technology Research Enterprise* ("JCORE Recommendations"). After this discussion, Dr. Miles followed up by providing some comments to COGR regarding the above-captioned comparison chart. COGR reviewed these comments, as well as changes to NIH Notices 073 and 110, and made updates to the chart. COGR will continue to update the chart as additional information becomes available.

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)

COGR has followed the American Rescue Plan (signed into law by President Biden on March 11, 2021) and in particular, the Higher Education Emergency Relief Fund (HEERF). The February Meeting Report (pp. 2-3) included a full update. Also note:

- COGR has developed HEERF FAQs (Version 2, updated April 30), which will be updated on a regular basis to serve as an easily accessible resource for the Membership. Note, the COGR focus is on the institutional portion of HEERF, though as needed, we will direct members to resources applicable to the student portion.

- The U.S. Department of Education released HEERF III FAQs on May 11th. We will follow all questions and developments that arise.

- Audit impact, both single audit (see pp. 66-76, 2020 Compliance Supplement Addendum) and federal activity (see Education OIG HEERF report) will continue to be a COGR priority. We are awaiting status of the 2021 Compliance Supplement (see subsequent section, below) and how it defines audit focus for HEERF and other programs authorized in COVID-19 legislation.

In addition, we have scheduled a session at the June COGR Meeting titled "Higher Education Emergency Relief Fund (HEERF): Department of Education Update and University Perspective." The session will be presented in two parts: Part I, an update from Rich Williams, Chief of Staff from the Office of Postsecondary Education, U.S. Department of Education, and Part II, a university perspective presented by leaders from the COGR Costing and Financial Compliance (CFC) Committee. We encourage you to send questions and/or observations to David Kennedy at dkennedy@cogr.edu in advance of the June COGR Meeting. We will incorporate your questions into the session.

Research Relief and the RISE Act (ONGOING)

COGR has been a regular participant on the "Research Relief Workgroup," working with the five other associations—AAU, APLU, AAMC, ACE, and AAAS—to advocate for important research relief that was made necessary by research output losses experienced during the height of 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. However, the prospects for obtaining research relief via the RISE Act remain uncertain. COGR will continue to participate on the "Research Relief Workgroup" and will share developments with the Membership

COGR Paper: Facilities and Administrative (F&A) Cost Rates Under COVID-19 (NEW)

In April, COGR released the paper, *F&A Cost Rates and Reimbursement Pressures Under COVID-19: Maintaining a Fair and Reliable System*, and a corresponding Executive Summary. Both are available on the COGR website. We also expect to make available a PPT slide deck. Issues addressed in the paper include: 1) deciding whether or not to submit an F&A cost rate proposal, 2) challenges of completing a proposal during these challenging times, and 3) prospective issues applicable to F&A costs that may arise beyond the COVID-19 pandemic. A special *Thank You* goes to the COGR Workgroup who researched and wrote this paper. The contributors are shown on page 4 of the paper. For additional information, please contact David Kennedy at dkennedy@cogr.edu and/or Toni Russo at trusso@cogr.edu.

Challenges with the Payment Management System (NEW)

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

- NIH Notice NOT-OD-21-102 (April 2, 2021) was intended to be a reminder on the 120-day closeout process. However, the NIH Notice was not clear on the exact process changes implemented in PMS. COGR has contacted NIH and our understanding is that a subsequent NIH Notice (not yet released at the time of this COGR Update) will be released to clarify the process. While NIH recognized better clarity is needed, NIH also indicated they will be more attentive to (and strict on) enforcing the 120-day closeout deadline.

- NIH Notice NOT-OD-21-060 (February 4, 2021) provided "leniency" on late Final Federal Financial Reports (FFRs), which was a problem created by new PMS edit checks. The edits checks were loosened and have allowed institutions to more easily submit final FFRs.

- However, there remains a potential PMS 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. COGR has shared this potential PMS issue with NIH and our understanding is that solutions are being developed.

- Some COGR members have reported delays in approvals of carry-over requests. This also is related to changes in PMS processes and may also be connected to personnel changes in the NIH Office of Financial Management. COGR has shared this issue with NIH and our understanding is that it is being reviewed.

- COGR continues to follow the promised "elimination of the Federal Cash Transactions Report (FCTR)," which will solve the reconciliation issue between the FCTR and the Final FFR. Our understanding is that HHS is advancing this solution and key internal steps are being taken.

- Finally, the longstanding G-account closeout issue also connects to PMS. See ***CFC Other Issues*** (below) for the status on this topic.

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

COGR wrote a letter (May 14, 2021) to the National Science Foundation (NSF) to address recent NSF OIG audit findings concerning the application of the F&A cost rate to a new award. Specifically, the NSF OIG cited the following as an audit finding: 1) an F&A cost rate was proposed (for example) at 52 percent, 2) at the time of award a new F&A cost rate (for example) of 54 percent had been negotiated, and 3) institutional policy allowed the proposed 52 percent F&A cost rate to be used on the award. The NSF OIG position is that 2 CFR 200 (Uniform Guidance) requires the F&A cost rate of 54 percent to be used for the life of the award. COGR's position is that if institutional policy allows the 52 percent F&A cost rate to be used, proposed direct costs for the PI can be maintained—and at the same time, there is no harm to NSF. COGR hopes to engage NSF on this issue and will keep the Membership posted on developments.

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

The first completed audit report applicable to the NSF Office of Inspector General (OIG) initiative—*NSF Award Recipient COVID-19 Audits*—was posted (and additional ones are being posted as they are completed). For NSF OIG activity, you can review NSF OIG Audit Reports (see Internal and External Report links) and the Management Responses to External Audits and Internal Reviews. Ten institutions were selected to look at how OMB COVID-19 flexibilities under M-20-17, M-20-20, and M-20-26 were implemented. This first completed audit report stated: "*there were no exceptions identified with [the institution's] use of the administrative flexibilities granted through NSF's implementation of OMB Memoranda M-20-17, M-20-20, and M-20-26*." While this is good news, cost disallowances and a compliance finding—unrelated to the COVID-19 flexibilities—were identified.

For HHS OIG activity, the HHS-OIG Work Plan and NIH-related audit reports can be accessed. Recently, there has not been activity associated with NIH grantees posted on the HHS-OIG website. DOJ settlements are available by accessing the DOJ News page at the DOJ website. We encourage you to contact COGR when relevant issues affect your institution.

OMB M-21-20 and Grant Flexibilities (NEW)

On March 19, 2021, OMB issued M-21-20, *Promoting Public Trust in the Federal Government through Effective Implementation of the American Rescue Plan Act and Stewardship of the Taxpayer Resources.* Included in M-21-20 is Appendix 3, *Disaster Relief Flexibilities to Reduce Burden for Financial Assistance* (pp. 10-11), which specifies:

> *OMB is allowing Federal awarding agencies the authority to grant the following exceptions to recipients affected by the pandemic as they deem appropriate and to the extent permitted by law. These exceptions apply not only to recipients with COVID-19 related Federal financial assistance awards,* ***but also to recipients with assistance awards not related to COVID-19 {emphasis added}.*** *Federal awarding agencies must specifically consider exceptions that can advance racial equity and support for underserved communities.*

Of significant note, the flexibilities mirror many of the flexibilities that were included in M-20-17, issued by OMB last year. To some extent, many agencies continued to make available the flexibilities available on a case-by-case basis. However, with OMB M-21-20 now in effect, this formalizes their availability to agencies. To-date, NSF has implemented the flexibilities and we expect other agencies to do so, as well.

GAO Study on Grants Management and the OMB COVID-19 Flexibilities (NEW)

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

2021 Compliance Supplement (NEW)

We regularly have reported on single audit developments associated with the 2020 Compliance Supplement (released in September 2020) and the 2020 Compliance Supplement

Addendum (released in December 2020). We now are turning our attention to the 2021 Compliance Supplement and what we believe could be important issues for FY2021 audits. These include:

- HEERF, for almost all institutions, will be considered a major program. Furthermore, audit guidance to the auditors will need to be clarified in the 2021 Compliance Supplement (and in an expected 2021 Compliance Supplement Addendum).

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

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

The release date for the 2021 Compliance Supplement is unknown, though we believe it may be available in June. Also, we should expect a 2021 Compliance Supplement Addendum to follow. We will keep the Membership updated.

Costing & Financial Compliance (CFC): Other Issues

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

HHS/PMS Closeout of G-Accounts (ONGOING). 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 (ONGOING). 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 whether 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*).

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

COGR Comments on NIST NPRM (UPDATE)

The February Update and Meeting Report 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.

On April 5 COGR, along with AAU, APLU, AAMC, and ACE submitted joint comments to NIST on the NPRM. The most contentious issue is a proposed provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention (401.6 (e)). While sharing the widespread public concerns about the high cost of prescription drugs, our associations supported the clarification. We do not believe march-in is an appropriate remedy for this problem. Focusing on one subset of patents—those that have received federal government funding—and failing to address the larger issue of drug pricing is not good public policy.

Two other concerns identified in our comments was the failure to include in the NPRM a limitation on the scope of the government use license, as recommended in the ROI, and the need to facilitate more timely responses to requests for U.S. manufacturing waivers. Our other comments mostly supported changes to other provisions suggested by AUTM as well as changes in licensing requirements.

NIST received 81,000 public comments on the NPRM. Most of these were in the nature of form letters generated by public interest groups opposed to the proposed change in the march-in provision. NIST had hoped to issue a final rule by July. We understand there may be some public action in the near future, but we have no further information. Many observers think it unlikely that the march-in clarification will be included in the final rule, especially given the Administration's well-publicized recent waiver of IP rights related to Covid vaccines. We will continue to report on developments.

Diversity Toolbox (UPDATE)

The REC subgroup working on this project have mapped out a webpage that will appear on COGR's website. The page will serve as a space in which institutions can share information and "tools" they have developed to address diversity, equity, and inclusion in the conduct of research involving human subjects. Tools will be separated into three "drawers": (a) tools for starting DEI conversations among researchers and research administrators; (b) laws, regulations, policies, and guidance in this area; and (c) tools that institutions have developed to promote DEI in specific sectors of human subject research environment (e.g., IRB, study recruitment, etc.).

Acting Director of the General Accounting Office's (GAO) Science, Technology Assessment and Analytics to Meet with REC

Acting Director Candice Wright will meet with REC at its regularly scheduled meeting on June 8. Ms. Wright headed-up the GAO's study of federal agency and university of conflict of interest (COI) policies and disclosure requirements, which covered "non-financial COIs" and included conflicts of commitment (COC) in this category. The study results were published in the December 2020 report to the Chairman of the Senate Finance Committee entitled *Agencies Need to Enhance Policies to Address Foreign Influence*. This report concluded that "grantmaking agencies [should] address non-financial conflicts of interest in their COI policies and develop written procedures for addressing cases of failure to disclose required information." On April 22, 2021, Ms. Wright testified regarding this report before the Senate Health, Education, Labor & Pensions (HELP) Committee at a full committee hearing on "Protecting U.S. Biomedical Research: Efforts to Prevent Undue Foreign Influence."

REC provided Ms. Wright with a copy of its recent paper *Principles for Evaluating Conflict of Commitment Concerns in Academic Research*, which also addressed the issue of conflicts of commitment. REC asked Ms. Wright if she could meet to discuss this topic and GAO's recommendations in this regard.

Additionally, Ms. Wright heads GAO's current project regarding research reliability. Some member institutions reported receiving a GAO survey to identify subject matter experts for this project, and Ms. Wright advised that she would be willing to discuss this project with REC as well.

Revised FDA Guidance Document on Form FDA 1572

On May 19, the FDA published a revised *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions Statement of Investigator (Form FDA 1572) (Revision 1)*. The revisions to the guidance are helpful to sponsors, sponsor-investigators, and IRBs conducting or overseeing clinical using investigations using FDA-regulated investigational drugs at non-U.S. sites. The guidance sets forth requirements that sponsors/sponsor-investigators must meet if an investigator at a non-

U.S. site cannot or will not sign a Form FDA 1572. Specifically, the sponsor/sponsor-investigator must (a) obtain a waiver from the FDA of the 1572 signature requirement; or (b) the trial cannot be conducted under an IND, and if the data is to be used in a marketing application, the trial must be conducted in accordance with 21 CFR 312.20, *Foreign Clinical Studies Not Conducted Under an IND*. The guidance goes on to specify how to submit a waiver request and the information that the request must obtain, including a description of the alternate approach that a sponsor will use to satisfy the purpose of the Form 1572. Finally, the guidance outlines some specific differences between the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Efficacy Guideline 6, Good Clinical Practice (GCP) ("ICH E6") and 21 CFR 312 that must be addressed if a foreign site is conducting a trial under ICH E6 requirements.

Office of Laboratory Animal Welfare RFI on Zebrafish

The Office of Laboratory Animal Welfare (OLAW) recently published a *Request for Information (RFI) on Flexibilities to Reduce Administrative Burden While Continuing to Apply the PHS Policy to Zebrafish Immediately After Hatching*. OLAW states in the RFI that the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) will apply to zebrafish larvae that have just hatched because there currently is insufficient evidence to "indicate beyond a reasonable doubt that zebrafish larvae are incapable of pain and suffering at hatching." OLAW goes on to request information on the following flexibilities that it believes will "reduce the administrative burden in research involving zebrafish while [ensuring institutions maintain] oversight immediately after hatching": (a) require institutions to "only general approximate number of animals be used; (b) use designated member review for research project with zebrafish unless full committee review is requested; and (c) includes persons knowledgeable about zebrafish as ad hoc consultants to assist in developing tracking, care, and euthanasia methods. REC will review the RFI and consider commenting. Comments are due August 9, 2021.

OMB Releases 2 CFR 200 FAQs

On May 3, 2021, OMB released 146 FAQs to address questions most commonly asked related to the latest revisions of 2 CFR 200 (Uniform Guidance). These FAQs follow OMB's most recent federal register notice in February that amended citations, references, and clarified language in the August 12, 2020, Final Guidance. If you have any concerns with the FAQs where COGR can be of assistance, please contact Jackie Bendall at jbendall@cogr.edu or David Kennedy at dkennedy@cogr.edu.

Data Management and Sharing

COGR's NIH Data Management and Sharing workgroup has been reviewing the NIH Final Data Management and Sharing Policy and discussing implementation strategies over the past several months. The work group has engaged with NIH Institute and Center representatives to hear about I/C priorities and address workgroup questions. At the June virtual meeting, COGR will host representatives from NIH and Purdue University. During

this session we will hear the latest updates from NIH representatives regarding implementation of the final policy and learn about Purdue University's Research Repository (PURR), a web-based platform that Purdue researchers can use to share data and collaborate on research.

DEA Issues Press Release Regarding Expanded Access to Marijuana for Research

On May 14, DEA issued a press release giving hope to those who have been waiting years for licenses to cultivate marijuana for medical and scientific research purposes. Until now, the University of Mississippi has been the only approved grower. COGR's cannabis and hemp workgroup was formed to address concerns regarding the ability to conduct research on marijuana and had previously written letters to Congress, FDA, and the DEA regarding DEA's lack of movement to expand the number of approved growers since DEA's policy notice in 2016. Following DEA's issuance of a final rule in December 2020 (effective January 19, 2021) laying out controls to enhance the cultivation of marijuana research, this press release, together with helpful bills in both the House and Senate, offers some promise for the ability to conduct scientific research on cannabis. Click here to read the press release. For more information, please contact Jackie Bendall at jbendall@cogr.edu.

NIFA Updates

- In April, NIFA updated its Federal Assistance Policy Guide to align with the changes in 2 CFR 200. To review the guide by section, click here. NIFA has also posted a recorded tutorial of the changes to the guide.
- COGR's February meeting report described concerns expressed by members regarding NIFA's December 12, 2020, memo to Title IX coordinators regarding sexual harassment. The memo requires campus Title IX coordinators to notify NIFA Equal Opportunity Staff within three business days of any administrative or disciplinary action taken that are 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. Subsequently, COGR and other associations met with NIFA to discuss institutional concerns including absence of a formal rule-making process, privacy concerns associated with reporting such actions to NIFA (e.g., via the template through non-secure email), and the inconsistency of the approach taken by NIFA as compared to other federal agencies such as NASA, NSF, and NIH.

As a result, USDA's Assistant Secretary for Civil Rights and NIFA have postponed the requirements in the December 12 memo until further notice. Both agencies are collaborating to consider an online method of reporting similar to NSF and NASA and to include a similar timeframe for submissions. We are told that once a decision is determined, additional guidance will be issued. Please contact Jackie Bendall at jbendall@cogr.edu with questions.

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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