COGR
Council On Governmental Relations
An Association of Research Institutions

MAY 2020 UPDATE

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Announcements

Council on Governmental Relations Meeting – June 10-12, 2020

Due to the ongoing public health crisis caused by COVID-19, COGR made the decision in early April to move our June meeting online. Registration is now open. Individuals from COGR member institutions can register online or via paper form. While the June agenda is being finalized, you can access a preliminary agenda here, along with relevant FAQs regarding the virtual meeting. All meeting registration cancellation requests must be received by Friday, June 5. For any questions or to submit questions in advance of the meeting, please contact Toni Russo at trusso@cogr.edu.

Cross Cutting Issues: COVID-19's Impact to Federal Research General Updates (ALL NEW)

COGR Support of the Membership During the COVID-19 Pandemic

COGR member institutions are on the front-line of service during the COVID-19 Pandemic. Your institutions are doing incredible work serving your communities—providing health-care to those at risk, donating PPE and professional services, maintaining education and research programs despite the near-impossible conditions of doing so, and figuring out how to continue to achieve your missions of education and research under the "new normal." We are thankful for everything you are doing!

COGR is committed to supporting you with the resources you need during the unprecedented COVID-19 pandemic. This COGR Update discusses how we will continue to support you, both on COVID-19 related topics and topics that have not disappeared since the pandemic hit home in March.

As we prepare for our first COGR virtual meeting, June 10-12, we encourage you to continue to send questions, comments, and concerns to COGR staff so that we can address those issues that are most pressing at your institutions. While we have a rich meeting and full schedule of sessions planned, we also will strive to have significant time for Q&A to address those specific issues you would like to raise.

We hope to see you "virtually" at the COGR meeting and please stay connected and let us know how we can be of service to you.

Sincerely,
The COGR Staff

Thank You to COGR's COVID-19 Workgroup

The resources and materials that have been developed in response to the COVID-19 crisis for our membership would not have been possible without the time, expertise, and support of the COVID-19 Workgroup. COGR staff would like to extend our appreciation to the following members for serving: Stephanie Endy (Case Western Reserve University), Joseph Gindhart (Washington University at St. Louis), Walter Goldschmidts (Cold Spring Harbor Laboratory), Dan Nordquist (Washington State University), Bruce Morgan (University of California, Irvine), James Luther (Duke University), David Mayo (California Institute of Technology), Jennifer Rodis (University of Wisconsin-Madison), David Richardson (University of Illinois), Craig Reynolds (University of Michigan), Naomi Schrag (Columbia University), Patrick Schlesinger (University of California, Berkeley), Jeffrey Silber (Cornell University), Ara Tahmassian (Harvard University), and Pamela Webb (University of Minnesota).

COGR's Resources on COVID-19's Impact on Research

COGR's *Institutional and Agency Responses to COVID-19 and Additional Resources* page is publicly available and is regularly updated. In addition, COGR has presented three webinars on COVID related topics, and we continue to regularly publish the "COGR News Digest" to the member listserv (with a necessarily heavy focus on COVID-19 developments). COGR has also developed FAQs on various COVID related topics and a matrix that details guidance issued by federal agencies to date. A newly developed resource from COGR is a web page on Institutional Resources on Ramping Up and Reopening. If your institution has a publicly available web page on this topic and you would like it to be included, please send an email to COVID19@cogr.edu. Each COGR Committee has been pulled into action around COVID-19 as appropriate and each section of this Update addresses those activities being addressed by the respective Committees. We encourage you to continue to reach out to COGR Staff and we will do our best to be responsive in as timely a manner as possible.

Survey of Institutions on COVID-19 Impact on Research Operations

In an effort to gauge some of the impacts of the pandemic on research institutions over time, COGR instituted a survey of its member organizations. The baseline survey includes questions regarding institutions' status (e.g., fully open, working remotely), compensation of personnel, and donation of personal protective equipment and/or reassignment of personnel to COVID-related patient care or research. The baseline survey closed on Tuesday, May 19, and a preliminary report is available on the COGR website. This baseline survey will be followed by a series of pulse survey questions that will help monitor COVID-19 impact over time. The initial results of the survey will be discussed at the June membership meeting.

COVID-19 Legislative Update

We recommend accessing the Association of Public and Land-grant University (APLU) webpage, under the section titled Federal Emergency Funding, as an excellent resource for tracking the status of COVID-19 related legislative updates. Below is COGR's summary, based on the APLU detailed analysis:

- March 6, Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. Provides $8.3 billion to boost the U.S. public health response to the virus.
- March 18, Families First Coronavirus Response Act (FFCRA). The multi-billion-dollar bill provides up to 12 weeks of paid leave for many workers, establishes free testing for the virus, and provides other support for those impacted by the spread of COVID-19.
- March 27, Coronavirus Aid, Relief, and Economic Security (CARES) Act. Provides over $2 trillion covering a wide range of initiatives, including support of small business (Paycheck Protection Program). Also provides research support specific to COVID-19 research, relief for students and institutions through the Department of Education, and other provisions that may be available to research institutions.
- April 24, Paycheck Protection Program and Health Care Enhancement Act. Provides an additional $484 billion to replenish funds for the Paycheck Protection Program, and also includes $75 billion for health systems and $25 billion to increase testing and contact tracing capabilities.
- May 15, House Democrats pass the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act, a $3+ trillion relief package, which includes some relief for research impacted by the COVID-19 pandemic.

COGR is in regular contact with our association partners, APLU, AAU, AAMC, and ACE, all active in advancing the community's higher education and research interests. Our understanding is that there will be significant engagement and negotiation between the House, Senate, and White House as to the next round of relief legislation. COGR will provide updates, as we learn more.

OMB COVID-19 Guidance: Summary

To date, the OMB Memorandums shown below have been released. The M-20-17 has been the primary OMB Memo, implemented by most Federal agencies, and used by COGR membership to support institutional policies during the COVID-19 pandemic. COGR is paying close attention to the status of M-20-17, which includes the following statement: "*These exceptions are time limited and will be reassessed by OMB within 90 days of this Memo*."

This means well before June 17 we need to learn of the status of and/or updates to M-20-17. COGR is in contact with OMB and will share updates on the status of M-20-17 as we learn more.

- M-20-11: Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus (COVID-19) (3/9/20)
    - Initial flexibilities provided only to grant recipients performing essential research and services necessary to carry out COVID emergency response.

- M-20-17: Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus (COVID-19) due to Loss of Operations (3/19/20)
    - Overarching flexibilities provided to federal agencies for use with grantees whose operations were affected by COVID-19.

- M-20-18: Managing Federal Contract Performance Issues Associated with the Novel Coronavirus (COVID-19) (3/20/20)
    - Authorizes agencies to provide some flexibilities for contractors.

- M-20-20: Repurposing Existing Federal Financial Assistance Programs and Awards to Support the Emergency Response to the Novel Coronavirus (COVID-19) (4/9/20)
    - Authorizes agencies to allow donation of PPE and other supplies and re-assignment of personnel paid for with grant funding to emergency response efforts.

- M-20-21: Implementation Guidance for Supplemental Funding Provided in Response to the Coronavirus Disease 2019 (COVID-19) (4/10/20)
    - Emphasizes three core principles for agency operations during the COVID-19 crisis: Mission achievement, Expediency, and Transparency and accountability.
    - Note, While M-20-21 does not add specific reporting requirements to grantees, issues of documentation, reporting, and audit will need to be closely considered.

OMB has been a helpful partner throughout the COVID-19 pandemic. After we hear back from OMB concerning several issues we have raised, we will update the membership.

Cross Cutting Issues: Science and Security

Department of Education Issues Final Section 117 Reporting Requirements (UPDATE)

The February Update discussed the revised HEA Section 117 reporting requirements issued by the Department of Education (ED) on February 10, including the changes from the previous Information Collection Request (ICR). COGR had joined in a letter to ED in March from a large number of higher ed. associations again expressing concerns that the proposed revised requirements still exceeded the statutory requirements.

OMB completed its review of the revised ICR on April 13 with no changes. ED issued the requirements on April 16. The final requirements are identical to the requirements proposed in February.

The Summary of Public Comments with Responses included in the ED package contain some interesting discussion. With regard to gifts received through intermediaries, ED indicates that institutions have a duty "to conduct reasonable due diligence when they receive the benefit of a contract or gift from any entity to determine whether the gift or contract is from or with a foreign source." Later the (unnumbered) responses indicate that there is a rebuttable presumption that when legal entities that operate substantially for the benefit of or under the auspices of an institution receive money or enter into a contract with a foreign source, it is for the benefit of the institution and must be disclosed (if the $250k threshold is met). Institutions have a duty "to conduct reasonable due diligence on the source of funds" received from any entity. If the exercise of due diligence determines that certain gifts/contracts did not benefit the institution these items do not need to be reported. Another response reiterates that the institution has a duty "to exercise due diligence and to make a good faith effort to understand the source of the gift or the identity of the contracting party."

Other responses address contracts where the money goes to the foreign source (ED is working with institutions to clarify these types of contracts and will consider issuing formal guidance), conditional gifts or contracts (if they have the potential to meet the threshold they must be reported when entered into, and the required description of the conditions should be provided by an institution's employee who is familiar with the substance of the contract), and student tuition (must be reported if the $250k threshold is met).

The former e-App reporting questions have been expanded to specify each of the statutory disclosure requirements. The e-App reporting has been discontinued with the January 2020 report. The responses state that ED "is working very hard to implement an electronic system to streamline the reporting and public disclosure process and will work to improve that system moving forward." Allowing institutions to upload an Excel report will be considered for future iterations of the web portal but is not expected to be a feature of the initial version. User testing is being conducted.

The original requirement to submit "true copies" of covered gifts or contracts will be the subject of a separate rulemaking. We do not currently have a timetable for the proposed rule.

We are planning a session at the June meeting with ED to focus on the revised Section 117 reporting requirements. The session will not include CARES Act reporting. However, ED has expanded its investigation of the University of Texas's compliance with Sec. 117 reporting requirements to include gifts or contracts with a long list of Chinese entities, focusing particularly on the Wuhan Institute of Virology. We may include some discussion of this and other Sec. 117 investigations in the session.

Republican Congressmen Write to ED on 117, Citing Foreign Influence Concerns (NEW)

On May 4, seven Republican Congressmen under the auspices of the House Committee on Oversight and Reform wrote to ED Secretary DeVos, citing the new Sec. 117 reporting guidance and the ED investigations, specifically citing the UT investigation noted above. The letter asked for all documents pertaining to Sec. 117 investigations and preliminary findings on false or misleading reports as well as a staff briefing.

The letter cited a series of concerns about Chinse practices related to U.S. institutions of higher education, including Confucius Institutes, theft of IP, and recruitment of U.S. scientists. The letter questions whether U.S. institutions receiving federal funding should be allowed to accept funds from China. Legislation along these lines may be introduced in the House.

While the letter paints an alarming picture, many of the matters cited are not necessarily related and/or already have been significantly addressed by institutions. The letter acknowledges that institutions "are starting to acknowledge the threat of foreign academic espionage and have been working with the Administration and federal law enforcement…"[1]

ED responded to the letter on May 19. The ED response asserted that "massive investments of foreign money have bred dependency and distorted the decision making, mission, and values of too many institutions." There's a suggestion that higher ed. groups have opposed ED's revised reporting requirements and enforcement activities "to protect Institutions of higher education's access to foreign money." With regard to the document request, the letter claims institution counsels are blocking production of documents claiming various exemptions and privileges. ED will have to evaluate these claims. Finally, the letter indicates that the true copies rulemaking will be released shortly. We understand that a follow-up briefing to Congressional staff was held on May 21.

Other China-Related Congressional Activities (NEW)

House Republicans are moving ahead with establishing a "China Task Force." The intent is to look at a wide range of China-related issues, including influence operations targeting the U.S. including universities; economic threats; efforts to obtain technological advantage and China's role in the origin and spread of COVID-19. A report with legislative recommendations is due by October.

On May 12, Sen. Graham (R-SC), with 4 Republican co-sponsors, introduced the *COVID-19 Accountability Act*, which authorizes the President to impose sanctions on China if China fails to cooperate and provide a full accounting

[1] *(For more information about the letter to ED see also https://www.axios.com/lawmakers-betsy-devos-chinese-funding-us-universities-886ed4fd-d7d4-4f2e-aa3d-5d20ce620efd.html and https://www.foxnews.com/politics/chinese-efforts-to-infiltrate-us-colleges-gop-scrutiny).*

of the events leading up to the outbreak of COVID-19. Among the sanctions is a ban on the issuance of student visas to Chinese nationals.

Clearly, the issue of U.S. relationships with China has become highly politicized. We may expect to see more developments of this nature.

Senators to Introduce "Safeguarding American Innovation" Act (NEW)

It is our understanding that Senators Portman (R-OH) and Carper (D-DE) plan to introduce the "Safeguarding American Innovation Act" later this month. Sen. Portman described the planned legislation in a speech on the Senate floor on May 13. There is an ongoing effort by Portman and Carper staff to find co-sponsors.

There are a number of concerns with the latest bill draft. It would create a new "Federal Research Security Council" to coordinate research security across federal agencies under OMB auspices (Section 3). Our view is that coordinating functions rightly reside with the NSTC, especially given the work being done by the JCORE Research Security Subcommittee (of which OMB is a member). Sec. 8 would empower the Department of State to deny access to certain non-immigrants using a newly developed list of "goods, technologies and sensitive information" distinct from those already controlled (e.g. by export controls). We do not favor creation of a new separate list. Sec. 9 would use this listing to put limitations on cultural and exchange programs and broaden State Dept. authority to deny J-1 exchange visitors. Other provisions of the draft bill call for a uniform grant application process (including disclosure requirements), agency compliance and oversight programs that would assess grantees' foreign support and the impact on U.S. national and economic security, and an insider threat and research security warning program. Sec. 10 of the bill would reduce the Sec. 117 reporting requirement threshold to $50k.

Cross Cutting Issue: OSTP Joint Committee on the Research Environment (JCORE) Activities (UPDATE)

There is little new to report on the activities of the JCORE Subcommittees. We understand the ***Research Security*** Subcommittee's efforts have resulted in a set of federal-wide guidance on requirements for grantees to disclose other support and outside activities of project personnel. This guidance is expected to be issued as a directive to funding agencies. It has been working its way through a review process and OSTP has given no estimate on when it might issue. This subcommittee is also expected to release best practices for grantees at some point.

The subcommittee on ***Coordinating Administrative Requirements for Research (CARR)*** is focusing on two main areas. First is an attempt to drive a common approach to FCOI, and it sounds like they are making progress. They understand that the grantee community would NOT like the PHS policy to be used as a model. The last we heard (in April), they were hoping for a May release of common definitions and policy recommendations. The other area of focus is the grant application process, where they are looking at expanded use of preliminary proposals, Just-in-time processes, simplified initial budgets, and centralized researcher profiles. We understand that draft policy suggestions are in the process of agency review.

The subcommittee on ***Research Rigor and Integrity*** is in the process of drafting a report from a February AAAS meeting on the topic, and the ***Safe and Inclusive Research Environment (SIRE)*** subcommittee is considering whether a "pledge" of some sort among institutions might be effective and have also been working to drive common terms and conditions across agencies.

Research Security and Intellectual Property

Removal of IHE Exemption to DOE Order 142.3A Raises Continuing Concerns (NEW)

The February Update discussed the recent Limited Change to DOE Order 142.3A that removed the exemption for grant-funded research at institutions of higher education from the requirement for DOE approval for foreign national access to DOE information, technologies or equipment, provided the research was to be published. A number of COGR member institutions have received amendments to contracts or agreements implementing the Limited Change.

COGR and AAU have had a number of discussions with senior DOE management about this issue. We've been told that there is no intent to apply the foreign national approval requirement to DOE-funded fundamental research at universities. A clarification has been repeatedly promised, but so far none has been forthcoming. The problem may be complicated by jurisdictional issues within DOE (the exemption always applied only to research funded by program offices that report to the DOE Undersecretary for Science and not to other DOE program offices that fund research at universities (e.g., Office of Energy Efficiency & Renewable Energy (EERE)). Many of the amendments received by universities involve EERE agreements or the National Energy Technology Laboratory).

COGR institutions originally negotiated the exemption with DOE. It is not clear who made the decision to remove the exemption or why. We will continue to pursue this matter with DOE management.

Export Control Developments (NEW)

GAO Report on University Compliance Issues

On May 12, the Government Accountability Office (GAO) released a report on Export Controls and University-Specific Compliance Issues. The GAO review was requested by Sen. Grassley (see COGR September 2019 Update). COGR and several other higher ed. association representatives were interviewed by GAO for the review as well as representatives from nine U.S. universities.

Overall, the report presents university compliance in a fairly positive light. It also lays out university concerns in (somewhat surprising) detail. It makes four specific recommendations, including two to State, one to Commerce, and one to DOD.

1. The Secretary of State should ensure that the Deputy Assistant Secretary for Defense Trade Controls, in consultation with university representatives, provides additional or revises existing guidance and outreach to address university-specific export control issues to further support universities' understanding and compliance with the International Traffic in Arms Regulations.
2. The Secretary of Commerce should ensure that the Under Secretary for Industry and Security, in consultation with university representatives, provides additional or revises existing guidance and outreach to address university-specific export control issues to further support universities' understanding and compliance with the Export Administration Regulations.
3. The Secretary of State should ensure that the Deputy Assistant Secretary for Defense Trade Controls revises existing export compliance guidelines to include information concerning periodic risk assessments to remind exporters that it is beneficial to periodically identify, analyze, and respond to new risks as part of an effective International Traffic in Arms Regulations compliance program.
4. The Secretary of Defense should ensure that the Under Secretary of Defense for Research and Engineering takes steps to ensure that its program officers and contracting officers are interpreting export controls consistent with regulations and guidance and consistently determining whether university research constitutes fundamental research.

Included in the report are a number of interesting details. Footnote 32 on page 18 indicates that in September 2019, State began a multi-rule initiative to improve the structure and organization of the ITAR. According to State DDTC officials, all ITAR definitions will first be consolidated into one part, followed by another rule that will clarify the licensing process and consolidate all ITAR exemptions into another part. There is a discussion on page 22 of JCORE activities, particularly development of conflict of interest guidance.

Finally, the discussion of agency comments on page 38 states that "DOD stated that it will develop new guidance for DOD personnel to clarify the process for identifying fundamental research, funding contracts containing fundamental research, and monitoring those contracts to ensure that they are performed in compliance with export control regulations and fundamental research policies. DOD also stated that it plans to work with State and Commerce to ensure that the new guidance is consistent with the ITAR and the EAR, respectively." This appears to be new information; we were not previously aware that DOD was developing new guidance on fundamental research contracts.

Commerce BIS Issues New Rules

Last month BIS issued a number of new export control rules. Perhaps the most significant is RIN 0694-AH53, *Expansion of Controls for Military End Use in China, Russia or Venezuela*. It expands licensing requirements for China to include military end users, in addition to military end use (which includes an expanded definition), broadens the list of items to which licensing requirements apply, creates new control reasons, and adds Electronic Export Information (EEI) Filing Requirements. Additionally, the rule limits the use of license exceptions for exports of these items to China, Russia and Venezuela.

The new rule applies to items that **support or contribute to** the operation, installation, maintenance, repair, overhaul, refurbishing, development, **or** production, of military items. The use of the term "or" rather than "and" means that an exported item used in connection with any one of these applications may now trigger this licensing requirement. The new rule also applies this restriction to a longer list of products (ECCNs). If the expanded licensing requirement applies, there is a presumption of denial. The new military end user definition includes any person or activity whose actions or functions are intended to support military end use. The new rule appears to respond to a requirement in the FY'19 NDAA for BIS to review existing controls on military end use and users in China.

The new EEI filing requirement will require EEI filing regardless of the value of the shipment and regardless of whether a license is required. In addition, the EEI filing must include the correct Export Classification Control Number (ECCN) regardless of reason for control. This is a fairly significant change because currently, EEI filing is usually only necessary for anything requiring an export license and international shipments over $2500 and an ECCN does not need to be listed. The rule includes consumer electronics such as laptops and cell phones.

Another final rule (RIN 0694-AH84) removes License Exception Civil End Users ("CIV"). BIS now will require a license for national security-controlled items to countries of U.S. national security concern, specifically, including China, Russia, Venezuela and others. Currently, License Exception CIV authorizes exports or reexports of certain items (as specifically designated on the CCL) destined to civil end-users or for civil end-uses that would otherwise require a license from BIS for NS reasons. Finally, a proposed rule (RIN 0694-AH65) would remove a provision which authorizes reexports of NS-controlled items from certain countries to the same countries as above, to align with the removal of License Exception CIV.

Institutions should ensure that offices engaged in international shipping are aware of the new requirements and are prepared to comply with the EEI filing requirements by the June 29, 2020, effective date.

Cybersecurity Developments (NEW)

FBI Issues Threat Warning to COVID-19-Related Research

On May 13, the Federal Bureau of Investigation (FBI) and the Cybersecurity and Infrastructure Security Agency (CISA) issued a public service announcement warning organizations researching COVID-19 of likely targeting and network compromise by the People's Republic of China (PRC). According to the announcement, health care, pharmaceutical, and research sectors working on COVID-19 response should all be aware they are the prime targets of this activity and take the necessary steps to protect their systems. The announcement is intended to raise awareness for research institutions and the American public and provide resources and guidance for those who may be targeted. The FBI requests organizations who suspect suspicious activity contact their local FBI field office. CISA is asking for all organizations supporting the COVID-19 response to partner with the agency in order to help protect these critical response efforts.

Additional technical details regarding the threat will be released in the coming days. CISA and the United Kingdom's National Cyber Security Agency released a similar alert earlier this month warning of malicious actors targeting COVID-19 response organizations using a tactic of password spraying.

COGR and EDUCAUSE Draft Letter to DOD on CMMC

The February Update described the DOD Cybersecurity Maturity Model Certification (CMMC) draft Framework. The intent is to develop uniform standards for future DOD acquisitions. The framework includes five levels of cyber "hygiene," each with several associated cybersecurity practices (described in more detail in the Update). DOD plans to phase in the model over the next 5 years starting later this year, eventually applying to all DOD contracts.

The COGR RSIP Committee met with EDUCAUSE representatives at the February meeting. Our principal concern is the application of the requirements to DOD contracted fundamental research at universities. As agreed, we now have drafted a letter to DOD expressing our concerns. The draft points out that prime contractors on defense projects often engage university researchers as subcontractors, to investigate related basic research questions. This raises issues about the application and management of CMMC certification levels between primary contractors and subcontractors. It is unclear how determinations regarding certification levels will be made. The draft expresses concerns about potential misapplication of certification requirements to fundamental research projects. This is particularly concerning because prime contractors often are unwilling to work with university subrecipients to resolve security issues, but instead simply flow down the prime contract requirements.

The letter requests establishment of a dialogue with DOD on these issues, facilitated by the DOD Basic Research Office. The aim would be to develop documentation to define how DOD, research institutions, and other stakeholders (e.g., prime contractors) can ensure that fundamental research does not become subject to inappropriate CMMC requirements.

We are discussing the draft with the DOD Basic Research Office in the hope they can facilitate the dialogue with appropriate DOD officials. AAU also may join in the letter. At this point our focus is on fundamental research. However, down the road there are potentially significant issues for those institutions that handle covered defense information (a category of Controlled Unclassified Information) in DOD-funded projects. Security requirements beyond the NIST SP-800-171 may apply to such projects, which may raise significant cost and compliance issues. Hopefully with the establishment of a dialogue with DOD we can address those issues down the road.

COGR Endorses AUTM COVID-19 Licensing Guidelines (NEW)

COGR, along with many other groups and institutions, has endorsed the AUTM COVID-19 Licensing Guidelines. These Guidelines support time limited. non-exclusive royalty-free licenses for most technologies related to COVID-19 in exchange for licensees' commitment to rapidly make and broadly distribute products and services to protect, diagnose, treat and contain COVID-19.

In a message to the COGR membership about the AUTM Guidelines and other pledges or statements related to COVID-19 IP rights and licensing of technologies, COGR suggested a number of considerations that should be kept in mind. One is the importance of considering the interests of all stakeholders in the institution, including faculty. Another is whether for a given technology, use of non-exclusive licenses is in fact the best and most effective strategy to facilitate rapid pandemic responses and broad distribution of technologies that address COVID-19. Finally, a commitment to such approaches should be viewed as applicable only in the extraordinary circumstances of the current pandemic, and not necessarily appropriate to achieving broad dissemination of and access to non-COVID -19-related technologies.

NIST To Hold Public Workshop on iEdison RFI Responses (UPDATE)

The February Update discussed the COGR comments submitted to NIST in response to the iEdison RFI. NIST received a number of responses as well as extensive feedback from other agency iEdison users. The COGR comments identified a number of challenges with the current system.

On June 22, NIST is planning to hold a virtual iEdison Feedback Session meeting. The workshop will be an opportunity for stakeholders to hear about the development plan for the system rebuild. There also will be a discussion of the feedback received and an opportunity to provide additional input, and to help NIST refine additional system requirements.

Costing and Financial Compliance (CFC)

CFC's focus since March has been on the COVID-19 pandemic—this is the primary topic covered in the CFC section of the Update. At the end of this section, updates on several additional issues are provided.

COGR FAQ Addendum #2: CFC FAQs (last updated on May 1st), includes detailed material on "costing" and related topics. ***COGR FAQ Addendum #4: CGA FAQs*** (last updated on May 8th), also includes topics that crosscut from a costing perspective. ***COGR FAQ Addendum #1: NIH Specific FAQs*** (last updated on April 13th) also is a helpful resource and includes NIH-specific topics, some from a costing perspective. All FAQ documents are available on the FAQ Page, found on the COGR website.

OMB COVID-19 Outreach: Single Audit, F&A Proposals, Equipment/Property Inventories (NEW)

Issues being raised with OMB include: ***Single Audit***—starting in March, everything changed, and we are asking OMB to consider refining policies and practices to ensure the FY2020 audit is manageable, fair, and representative of the "new normal"; ***F&A Cost Rate Proposals***—M-20-17 provides relief for submitting an FY2020 F&A proposal, and the same relief will almost certainly be necessary for FY2021; ***Equipment/Property Inventories***—complying with the biennial property/equipment inventory requirement per 2 CFR 200.313(d)(2) may be unsafe and unrealistic and administrative flexibilities are necessary. We will keep the membership posted as we learn more on each of

these issues. We also encourage you to contact David Kennedy at dkennedy@cogr.edu if you have any experiences with these topics.

COVID-19: Costing and Compliance (NEW)

The ***FAQ Addendum #2: CFC FAQs***, found on the FAQ Page, includes FAQs (last updated on May 1st) on a wide-range of Costing-related topics. Issues around the COVID-19 pandemic are an ever-evolving list of issues ***and we expect to publish FAQ Addendum #3 at the end of May***. Topics we are paying attention to are:

- ***Compensation and Institutional Policies.*** FAQ Addendum #2 addresses these (see Costing FAQ 4), but institutional policies continue to be updated for both summer and fall operations. Additionally, OMB guidance on administrative flexibilities, after June 17, will have an impact on these policies.

- ***Financial Challenges and Furloughs.*** As institutions address the new reality of severe financial pressures, many cost-cutting strategies are being considered. Accordingly, COGR has updated a paper first written in 2009 during the Great Recession—***Furlough Programs and Implications for Financial Research Compliance***. The 2020 updated version covers issues around consistency and compliance, which should be considered in the context of employees paid on federal awards.

- ***Treatment of New and Unique Cost Items.*** Costs incurred during the "ramp-down" and costs now being incurred during the "ramp-up" comprise a whole range of new and unique cost items (e.g., monitoring personnel, contact tracers, sanitization and safety, PPE and related supplies, etc.). Allowability, allocability, and consistency principles should be considered; at the same time, recognition that these may be new and unique cost items influences Direct or F&A treatment.

- ***Research Financial Losses.*** Internal modeling for estimated losses over the spring academic term, and projections for the summer and beyond, are already being done at institutions. At the same time, grant-by-grant analysis for federal agency purposes will be necessary in RPPRs and other reporting mechanisms. COGR plans to address this issue in a session at the June 10-12 COGR Meeting.

- ***Documentation and Audit.*** FAQ Addendum #2 addresses these issues (see Costing FAQ 6), but this is an ongoing and open topic that COGR will continue to address (also see previous section on Single Audit). OMB guidance on administrative flexibilities after June 17, could have an impact, as will agency requirements and possible new reporting requirements under federal legislation (see below).

- ***Relief Opportunities and Federal Legislation (also see previous section in this COGR Update).*** COGR's focus will continue to be on costing-related topics around federally-funded research, though we have stayed (and will continue to stay) connected to all relief opportunities and the related federal legislation. Department of Education relief funds, deferred payment of employer payroll taxes, and employee retention tax credits

each have been addressed in federal legislation passed over the last two months. We expect additional legislation to be passed, which could include specific relief applicable to research.

Please continue to share your insights, questions, and concerns. If we have missed a question you have raised previously, please understand that we are doing our best to keep up. *And do not hesitate to resend costing-related questions, which have not been addressed, to David Kennedy at dkennedy@cogr.edu—reminders are encouraged!*

Other CFC Business (UPDATE)

Proposed Revisions to the Uniform Guidance – 2 CFR Part 200

COGR submitted a Comment Letter to OMB on March 23rd. Our understanding is that OMB hopes to finalize revisions later this summer. In the context of the COVID-19 pandemic, we are not sure of the status. We will keep the membership posted as we learn more.

HHS/NIH G-Accounts and Reconciliation

We provided an update in the February Meeting Report (pp. 6-7). COGR's core priorities have been to protect institutions at risk of having non-reconciled G-accounts unilaterally closed and, in the case where there are alleged deficits, ensure these deficit amounts are not sent to collections. In the fall of 2019, COGR conferenced with representatives from the HHS Grants Policy Office, and in that call *HHS representatives assured COGR that G-account deficit balances at the pooled account level would not move to collections.* In a follow-up call in January 2020, Alice Bettencourt (the new Deputy Assistant Secretary, HHS Office of Grants) and Richard Brundage (Acting Director, Division of Grants Policy, Oversight, and Evaluation) indicated HHS/PMS was undertaking an initiative to close all pooled G-accounts. However, in the context of the COVID-19 pandemic, any new actions by HHS/PMS would seem to be unreasonable. Please contact David Kennedy at COGR at dkennedy@cogr.edu if your institution has updates to share.

NSF and HHS OIG Activity and DOJ Settlements

The NSF OIG Workplan is available on the NSF OIG website, and we recommend members review both the Audit Reports (see External Reports link) released by the NSF OIG and the Management Responses to External Audits and Internal Reviews. The HHS OIG approach has moved to a more real time, dynamic version of their workplan where the plan is updated regularly. Also, if you access the HHS OIG Workplan website and click on the "Active Work Plan Items" link (and then search on NIH), you can see the status of workplan items. Finally, you can access DOJ settlements by accessing the DOJ News page at the DOJ website. We encourage you to contact COGR when relevant issues affect your institution.

2020 Compliance Supplement

We previously reported that the draft version of the 2020 Compliance Supplement (CS) was available, with the expectation that the final version would be released this spring. However, under the context of the COVID-19 pandemic, we are not sure of the status of the 2020 CS. We hope to address this with OMB (see earlier section), with the understanding that in the context of the COVID-19 pandemic, policies and practices to ensure the FY2020 audit is manageable, fair, and representative of the "new normal" need to be established.

Research Ethics and Compliance

COVID-19 Impacts on Clinical and Animal Research (ALL NEW)

The COVID-19 pandemic has tremendously impacted all facets of the university and research institution operations. Federal regulatory and funding agencies have issued a number of guidance documents addressing the impact of COVID-19 on the conduct of clinical and animal research. Federal guidance is added to the COGR COVID website as it becomes available. The key notifications include:

Guidance Regarding COVID-19 Impact on Clinical Research

- FDA *Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic*, updated May 14, 2020
- Office for Human Research Protections (OHRP) *Guidance on COVID-19*, April 8, 2020.
- NIH Notice NOT-OD-20-087, *Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19*, March 16, 2020
- NIH *Considerations for New and On-going Human Subjects Research During the COVID-19 Public Health Emergency*, May 4, 2020 (under "Human Subjects & Clinical Trials" tab)

The implications of the foregoing guidance documents are discussed in the **COGR FAQs on Human Subjects Research** (updated May 15, 2020). These FAQs also provide examples of pertinent guidance, policies, and processes that institutions have adopted to address the impact of the COVID public health emergency on clinical research.

Guidance Regarding COVID-19 Impact on Animal Research

- Office of Laboratory Animal Welfare COVID-19 Pandemic Contingency Planning for Animal Care and Use Programs
- NIH Notice NOT-OD-20-088, *Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees (IACUCS) Due to COVID-19*

In addition to the foregoing specific documents, NIH has developed the *Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding* website that lists all manner of COVID-related FAQs, including FAQs on animal and clinical research. Many of these FAQs were developed based on questions presented to NIH by COGR and other associations at weekly teleconferences with NIH to discuss COVID-related issues.

Office of Research Integrity (ORI) Request for Information (NEW)

On April 29, 2020, ORI published a request for information (RFI) in the Federal Register (85 FR 23834) on the sequestration of electronic data. The RFI seeks information from institutions subject to the Public Health Services Policies on Research Misconduct (42 CFR Part 93) regarding challenges in sequestering data kept in digital format, including approaches used to identify and secure such data. Comments are due on or before June 15, 2020, and COGR will be submitting comments. Please contract Kris West at kwest@cogr.edu with your comments.

Interviews with the General Accounting Office (GAO) (NEW)

COGR, along with a number of universities and higher education associations, participated in interviews with GAO personnel on the following two topics:

• **Conflict of Interest and Effective Practices to Mitigate Threats from Foreign Entities**: COGR was interviewed by GAO regarding policies and processes in place to identify, manage and monitor potential conflicts of interest, particularly as they pertain to faculty's receipt of funding from foreign entities. During the interview, COGR emphasized the differences between conflict of interest and conflict of commitment concerns, as well as the various improvements institutions have made to disclosure processes and training to improve compliance in this area. GAO also plans to interview a number of universities, all of which should have already been contacted.

• **Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act**: COGR was interviewed by GAO in connection with Public Law 116-114, which requires GAO to conduct a study of the effects of scheduling all fentanyl analogues as Schedule I substances under the Controlled Substances Act. COGR emphasized that research institutions share the goal of preventing diversion of harmful drugs, but that security measures must permit the conduct of important research regarding potential medicinal uses, as well as the causes and treatment of drug addiction.

Notices of Proposed Rulemaking (NEW)

REC Committee members reviewed the following notices of proposed rulemaking or guidance documents:

- *FDA Inclusion of Older Adults in Cancer Clinical Trials Draft Guidance*, 85 FR 13167 (comments due May 5, 2020): The goal of this guidance is to increase the enrollment of older adults in FDA-

regulated oncology clinical trials. REC noted nothing objectionable in the guidance, which will have its main impact on sponsors establishing eligibility criteria.

- *Registration and Reregistration Fees for Controlled Substance and List I Chemical Registrants,* 85 FR 14810 (comments due May 15, 2020): This proposed rule increases DEA registration fees, including researcher registration fees by 21%. The proposed fee increase appeared reasonable and the last fee increase took place in 2012, therefore comments were considered unnecessary.
- *National List of Reportable Animal Diseases,* 85 FR 18472 (comments due June 1, 2020): The proposed regulation would require biomedical researchers to report to state officials' certain diseases affecting livestock. Veterinary/animal research personnel at two member institutions reviewed the proposed regulations and found the requirements to be reasonable.
- *Possession, Use and Transfer of Select Agents and Toxins; Biennial Review and Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of Select Agent and Toxin List,* 85 FR 15087 (comments due May 18, 2020): The Department of Health and Human Services and the Department of Agriculture are seeking input on the Select Agents and Toxins that should be removed or retained on the current lists. REC members did not see a need to comment.

Contracts and Grants Administration

COGR Responds to OSTP Federal Register Notice on Desirable Characteristics of Repositories (UPDATE)

The February COGR update mentioned a January 17 OSTP call for comments to the Federal Register Notice, "Request for Public Comment on Draft Desirable Characteristics of Repositories for Managing and Sharing Data Resulting From Federally Funded Research." On March 17, 2020, COGR submitted a response, which can be found here. Among other things, we discuss administrative challenges and cost considerations that need to be considered.

COGR and Other Associations Respond to OSTP Federal Register Notice on Public Access (NEW)

On February 19, OSTP issued an RFI regarding "Public Access to Peer-Reviewed Scholarly Publications, Data and Code Resulting From Federally Funded Research." After successfully receiving an extension of the deadline, COGR, AAU, and APLU submitted a joint response on May 6, noting barriers to and opportunities for change as OSTP continues to seek input from stakeholders prior to implementation of a government-wide public access policy. As noted in the letter, the COVID-19 pandemic further highlights the significance of sharing results and data produced by the scientific community. We support the efforts made to date toward more open science but cautioned OSTP that additional time will be necessary to develop and implement new models and costing mechanisms to ensure broad based and more immediate public access to research results.

COGR and Other Associations Respond to EPA Rule on "Strengthening Transparency in Regulatory Science" (NEW)

On May 18th, COGR, AAU, APLU and AAMC submitted a joint response to EPA's Supplemental Notice of Proposed Rulemaking on "Strengthening Transparency in Regulatory Science." COGR and the other associations urged EPA to withdraw the proposed rule and supplemental guidance, reiterating a request made in a joint response to the initial EPA NPRM.

The joint letter emphasizes that science does not depend on the public availability of underlying data to indicate quality and reliability of evidence and public availability of research data is not a proxy for the reproducibility of science. Furthermore, EPA already has the authority to determine what studies it will consider in rulemaking. If this rule is made final, the EPA will fail to meet a key component of its enabling legislation that requires the agency use the "best available science" in its regulatory decisions. Stay tuned for additional updates.

COGR Responds to Drug Enforcement Agency (DEA) NPRM Regarding Cannabis Cultivation (NEW)

On March 23, 2020, the DEA released a Notice of Proposed Rulemaking (NPRM), entitled "Controls To Enhance the Cultivation of Marihuana for Research in the United States." Pursuant to the Controlled Substances Act (CSA) and provisions of the Single Convention of Narcotic Drugs, 1961 (Single Convention), DEA proposes to register additional marijuana producers with the following conditions: 1) DEA will purchase and take physical custody of the marijuana crops produced by DEA-registered manufacturers and 2) DEA will have the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of marijuana other than those held by DEA-registered manufacturers and distributors of medicinal cannabis or cannabis preparations. DEA notes in the NPRM that it has a backlog of approximately 35 applications and will consider pending applications on the effective date of the final rule before considering any new applications.

COGR agrees that the expansion of manufacturers that can grow cannabis is critical to support expanded research on impacts to public health. We urged DEA to act expeditiously to approve the current backlog of 35 applications submitted since DEA's 2016 invitation for applicants. In addition, COGR notes confusion and potential problematic implications of DEA taking physical on-site "possession" of cannabis materials. COGR also stresses that if the proposed fees to manufacturers are passed down to researchers, it may serve as an impediment to the conduct of research. Stay tuned for additional updates.

NSF 2020 PAPPG Revisions: Current and Pending Support Forms (UPDATE)

The new version of NSF's Proposal and Award Policies & Procedures Guide (PAPPG) becomes effective on June 1. For the most part, this does not seem to be creating challenges for grantees. The exception that we are hearing concerns the NSF approved Current and Pending Support forms. To implement the new forms, some institutions are having to make changes to their IT systems, and most will need to introduce training on filling out the form

appropriately. In addition, there is confusion over how to meet the new expectations, such as reporting of in-kind support and associated estimated time commitment and dollar value. Perhaps the biggest challenge is that the effective date is happening while campuses are spending a tremendous amount of effort figuring out how to start ramping up on-campus research in a manner that is safe and thoughtful. COGR has raised this concern with NSF and is engaged in ongoing discussion. We will keep the membership posted of developments, if any.

COGR would like to thank COGR Board Chair Pamela Webb (University of Minnesota) 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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