COGR
Council On Governmental Relations
An Association of Research Institutions

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JUNE 10-12, 2020 VIRTUAL MEETING REPORT

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

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

COGR's *Institutional and Agency Responses to COVID-19 and Additional Resources* page is publicly available and 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. On June 18, 2020, OMB released memorandum M-20-26 which rescinded M-20-17 and M-20-20. Accordingly, COGR retired from its website the matrix that addressed guidance issued by federal agencies with respect to flexibilities set forth in these rescinded memoranda, and will update our resources as agencies release any new guidance based on the OMB memo.

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.

At the June virtual meeting, two sessions focused exclusively on COVID-19:

- A REC panel presented on issues institutions should consider in ramping up on-campus research activities and provided an accompanying white paper: Research Ramp Up Road Map: A Guide to Considerations and Resources for Ramping Up On-Campus Laboratory, Animal and Human Subjects Research as COVID-19 Restrictions are Lifted.

- A CFC panel presented Telling the Research Impact Story of COVID-19. This session focused on estimating the economic impact at institutions via modeling and projections. COGR expects to further address this topic as the pandemic persists.

Additional activities of each COGR Committee pertaining to COVID-19 are described throughout this Meeting Report, and presentations from each session are available on COGR's website.. We encourage you to continue to reach out to COGR Staff.

OMB COVID-19 Guidance: Summary of OMB Memorandums, To-Date

To date, the OMB Memorandums shown below have been released. The M-20-17, now rescinded, was the primary OMB Memo implemented by most Federal agencies and used by COGR membership to support institutional policies during the COVID-19 pandemic.

Upon the release of M-20-26 on June 18, 2020, the flexibilities under M-20-17 and M-20-20 expired, effective on June 16th, and the flexibilities under M-20-11 will expire on July 26. A COGR analysis of M-20-26 is included in the following section of this Meeting Report.

- M-20-11 (WILL EXPIRE ON JULY 26TH): 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 (EXPIRED ON JUNE 16TH): 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 (EXPIRED ON JUNE 16TH): 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 carefully considered.

- M-20-26: Extension of Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus (COVID-19) due to Loss of Operations (6/18/20)
    - Rescinds M-20-17 and M-20-20; expires September 30, 2020.
    - Allows the continued charging of salary consistent with institutional policy across all funding sources but indicates recipients should retain documentation of their efforts to exhaust other funding sources and reduce overall operational costs.
    - Allows delay of completion and submission of the Single Audit in certain circumstances.

OMB Memorandum M-20-26: An Analysis

NOTE: *This analysis is dated July 1, 2020. As additional information is obtained, this analysis could be updated further. If/when it is updated, we will notify the COGR membership.*

On June 18th, OMB released OMB Memorandum M-20-26, Extension of Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus (COVID-19) due to Loss of Operations.

M-20-26 provides Heads of Executive Departments and Agencies authority to extend the salary charging flexibilities that were included in OMB Memorandum M-20-17. NIH and NSF have issued memoranda implementing M-20-26, but these documents repeat the language used in M-20-26, without providing further clarification as to the meaning of the language. Our understanding is that other agencies will follow a similar response—as such, the COGR analysis below is based on the language in M-20-26 and the assumption agencies will not provide additional clarification.

- M-20-26 is directed to Heads of Executive Departments and Agencies and subsequently will be directed by the agencies to their grantees that receive federal financial assistance. This includes programs well beyond research (e.g., Head Start, Community Health organizations, etc.). Therefore, when coming across language that suggests pursuing cost savings such as "*rent renegotiations*," this may be intended for other types of organizations.

- OMB may be reflecting the Administration's desire to have the country ramp up as soon as possible. Still, OMB recognizes there are challenges to ramping up (e.g., "*However, due to the uncertainty of the re-opening phase and the speed of the ramp-up effort, this memorandum provides an extension of [salary charging flexibilities]* …"). While there are more strict requirements for using the salary charging flexibilities (see below) as compared to M-20-17, OMB has allowed salary charging flexibilities to be used through September 30.

- The previous M-20-17 requirement that recipients have a "*policy of paying salaries (under unexpected or extraordinary circumstances) from all funding sources, Federal and non-Federal*" is still effective. Consequently, COGR Costing FAQs #22 and #23 (May 28 update) are still applicable under M-20-26, which address issues around consistency across funding sources, furlough programs, and related topics. We recommend consulting these COGR Costing FAQs.

- The two new and most strict requirements are captured in Appendix A, item 1, Allowability of Salaries and Other Project Activities, per M-20-26—"*Recipients should retain documentation of their efforts to exhaust other funding sources and reduce overall operational costs*."

- First, to use the salary charging flexibilities, institutions must document their efforts to "*reduce overall operational costs*." Institutions currently are implementing cost-cutting measures that include hiring and salary freezes, retirement incentives, furloughs and lay-offs, amongst other cost-cutting measures. While federal agencies are not asking for this documentation, institutions using this flexibility should have cost-cutting measures documented and available. As COGR has encouraged in its FAQs, ***the most important message as it relates to a documentation trail is to be intentional and focused on how you initiate and maintain the documentation. It will be critical for your institution to easily be able to refer back to this, possibly several years from now and show your justification and basis for institutional policies and practices that were implemented during the COVID-19 pandemic.***

- Second, to use the salary charging flexibilities, institutions must document their efforts to "*exhaust other funding sources*." COGR has published a new document, which is available on the COVID-19 FAQ and Resources Page titled: ***Funding Sources for Research Universities***. This document is an Addendum to the June 2014 COGR paper, *Finances of Research Universities*. The Addendum specifies the challenge being faced by research institutions is this: as funding sources have been exhausted or significantly diminished, institutional survival requires implementation of difficult cost-cutting measures in conjunction with maximizing the significantly diminished funding sources. This is an existential crisis, which requires leadership at universities and research institutions to prioritize the allocation of scarce funds and resources across multiple institutional functions. The COGR Addendum can be used as a resource for those institutions that choose to continue using the salary charging flexibilities and may help to document the dire status of institutional funding sources.

- Furthermore, as "*exhaust other funding sources*" is a subjective term, subject to broad interpretation across a diverse body of stakeholders, it will be imperative for institutions to again adhere to a disciplined approach to developing and maintaining documentation. While federal agencies are not asking for this documentation, it will be prudent to have clear definitions of institutional funding sources, restrictions on those funding sources, the extent to which those funding sources have been used (and exhausted) in support of other mission-critical institutional activities, and any and all additional documentation that will support that the institution's resources have been significantly depleted and exhausted. And as COGR has encouraged in its FAQs (and is worth mentioning for a second time), ***the most important message as it relates to a documentation trail is to be intentional and focused on how you initiate and maintain the documentation. It will be critical for your institution to easily be able to refer back to this, possibly several years from now, and show your justification and basis for institutional policies and practices that were implemented during the COVID-19 pandemic.***

As we are now months into the COVID-19 pandemic, institutions should begin to have a better sense of which projects are able to ramp up and those where challenges remain. For those where challenges remain and may require the salary charging "lifeline," we encourage your institution to: 1) review COGR Costing FAQs #22 and #23 (consistency across funding sources, furloughs, etc.), 2) take special care and have a good plan around

documentation as it relates to both "*reduce overall operational costs*" and "*exhaust other funding sources,*" and 3) premise the use of the salary charging flexibilities on sound risk-assessment practices and principles.

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. However, there has been no additional action to date.
- June 24, House representatives introduce the Research Investment to Secure the Economy (RISE) Act which would authorize $26 billion in emergency relief for federal science agencies to support the research that was impacted during the pandemic. This is a bipartisan initiative and is being closely tracked.

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.

COVID-19 Research Impact Survey Update

The COVID-19 Research Impact Survey project continues. To date the baseline survey and two of the 4-5 follow up pulse surveys have been administered. Results of the baseline[1] and first pulse survey were presented at the virtual June meeting. Major themes that emerged from the baseline and first pulse survey include the following:

- Reopening: Campuses are reopening, but as of the first week of June, most work was still being done remotely: 62% of research labs mostly or all working remotely; 61% of staff at academic medical centers working remotely; 87% of staff at academic research institutions working remotely.
- Payment for Persons Unable to Work because of the COVID Emergency: Two-thirds of responders tracked the payment of salaries to persons who were unable to work because of COVID-related circumstances. There was an interesting dichotomy between the institutions that tracked this data: approximately 19% of the institutions tracking this information were paying such salaries for 200 or more people and 22.8% were paying such salaries for fewer than 50 people.
- COVID's Economic Toll: Of 90 responders, 36 stated that they have not implemented or are not planning furloughs or lay-offs as of the first week of June, but 50 reported that salary freezes or cuts have already happened or been announced for the next fiscal year.
- Major Concerns: Institutions are very concerned about the availability of supplemental funding and what the new "normal" will look like.

As we conduct additional pulse surveys, we will update the membership on survey results.

Additional FDA Guidance Regarding Conduct of Clinical Trials During the COVID-19 Pandemic (NEW)

In early June, the FDA updated its *Guidance on the Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency* by adding an Appendix of 22 questions and answers. These questions and answers cover a wide spectrum of topics, including the following items:

- Factors sponsors and sponsor-investigators should consider in deciding whether to continue, suspend or initiate a study during the COVID-19 pandemic and/or whether to continue to administer an investigational product that appears to be providing benefit.
- How to manage protocol deviations and protocol amendments, including logistics of submitting protocol changes.
- Changes that may be made to protocols without the need to contact the FDA.
- FDA expectations regarding on-site monitoring and recommendations regarding the remote performance of site reviews.

[1] *The baseline survey preliminary results can be found here: https://www.cogr.edu/sites/default/files/u11/COGR%20topline%20survey%20results%20May%2021%202020.pdf*

- Informed consent considerations including logistics for obtaining informed consent from an isolated patient and patients who are unable to travel to a clinical site.
- Administration of investigational agents by local health care providers or securing FDA-approved investigational agents via commercial channels.
- Considerations regarding the conduct of trial participant visits via video conferencing.
- Reporting of adverse events.

With respect to informed consent, the FDA announced that it was making the COVID MyStudies app (formerly named "FDA MyStudies") available to investigators free of charge to use to obtain electronic informed consent from patients in clinical trials who are not able to participate in face-to-face consent processes because of COVID-19.

Finally, the FDA issued a guidance document entitled Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency. This guidance document lists statistical issues that sponsors and sponsor-investigators should consider when determining when to stop a trial early due to COVID exigencies and perform interim data analyses.

NIH Guidance on Clinical Trials (UPDATE)

On June 29, 2020, NIH updated the memorandum it issued in early June entitled *Considerations for New and Ongoing Human Subjects Research During the COVID-19 Public Health Emergency.* The memo discusses considerations in determining whether to pause or slow human subject research studies, particularly if there are competing clinical considerations; flexibilities available to investigators and IRBs with respect to changes that may be required in studies as a result of the pandemic; and flexibilities in monitoring activities. The memo also emphasizes the need to carefully follow OHRP guidance regarding engagement in research, as well as FDA requirements, including those regarding drug accountability.

Cross Cutting Issues: Science and Security

Foreign Influence on Research (NEW)

New COGR Science & Security Website: COGR has compiled COGR and non-COGR resources related to foreign influence on research in a new Science and Security website that is updated on a regular basis. The website contains recent news articles, COGR papers and comment letters, meeting presentations and reports, updates and other resources.

Multi-Committee Presentation at June Meeting (*Foreign Influence on Research: Handling Cross Cutting Issues*): During the June meeting, a panel with representatives from REC, RSIP, CGA and CFC presented a case study designed to highlight how various units within institutions (e.g., sponsored program, conflict of interest and

technology transfer offices) are working together to identify and address potential areas of concern including consistency across disclosures, accurate reporting of outside activities and support, and protection of intellectual property.

Secure Research Environments: At its most recent meeting, REC heard Lance Garrison from the Department of Energy (DOE) provide an overview of the DOE's cesium/cobalt irradiator removal program. Under this program, DOE absorbs the cost of irradiator removal (with some exceptions such as building alterations necessary to remove the unit) and pays 50% of the cost of replacing the irradiator up to $135,000. REC and the DOE agreed to discuss the possibility of a webinar on research security that includes information on this program.

Update on Section 117 Reporting Requirements (UPDATE)

The COGR virtual June meeting included a session with the Department of Education on the new Section 117 foreign gift and contract reporting requirements.

A number of helpful clarifications were provided. One was that institutions need not report a contract involving a transfer of funds to a foreign source (the example given was purchase of laptops). While this may have seemed clear from the intent of the statute, it had been left open in the ED responses to the comments submitted on the Information Collection Request (ICR). Another was a suggestion that contracts for an indefinite amount of money that present valuation challenges should be reported when entered to avoid potential later compliance issues. Examples were provided of the types of conditional gifts or contracts that must be reported. There was extended discussion of the ICR requirement for reporting contracts or gifts from "intermediaries." It was stressed that the penalties for inaccurate reporting involve knowing or willful falsifications, not simply mistakes.

ED also provided screen shots of the new reporting portal. While they were unable to confirm whether the portal would be operational in time for the July 31 reporting deadline, on June 22, ED announced the new reporting system. A notification was sent to the COGR membership. The electronic announcement of the new reporting portal is available here. The reporting portal can be accessed here. At the COGR session ED indicated that the "true copies" submission rule will not be published until later this summer, and will not be in place for the July 31 deadline.

A great many questions were raised in the subsequent Q & A. One was the effect on existing agreements of the pending true copies submission rule. Another had to do with gifts or contracts with multinationals and domestic entities with foreign parents or vice versa. Reporting requirements involving ownership changes also was raised, as were the complexities associated with valuation of in-kind exchanges. Many questions from COGR attendees involved "color of money" issues, especially involving funds from third parties. Clearly, ED had not considered many of these issues. It was agreed that COGR and ED might work together to address them, such as through FAQs or other guidance. While many might be fact specific, "one off" responses will impose a significant burden on ED as well as institutions.

We have been in touch with ED about the follow-up, and expect to work with them on the questions raised. One caution: while many questions from COGR members involved the "reasonable due diligence" requirement for contracts or gifts from intermediaries, hard and fast answers to what might constitute the necessary diligence in specific situations may not be possible or desirable.

The session slides are posted on the COGR website here.

China-Related Legislation (UPDATE)

Safeguarding American Innovation Act Introduced

The May Update included discussion of pending Congressional legislation related to concerns about Chinese academic espionage activities. It discussed specifically the "Safeguarding American Innovation Act' planned by Sens. Portman (R—OH) and Carper (D—DE).

The Senators finally introduced a somewhat narrower version of the Act on June 18, with eight Republican and five Democratic co-sponsors. Unfortunately, the bill retains most of the provisions of greatest concern. One is a provision (Section 5) that would allow the State Department to reject visa applications based on the applicant's cooperation with adversarial military organizations or foreign institutions involved in the theft of U.S. research or a government that seeks to undermine the integrity of the U.S. research community. This might exclude many Chinese graduate students or researchers. Another provision would permit rejection based on an applicant's access to export-controlled goods, technologies or sensitive information "notwithstanding any exclusions for items not normally subject to export controls." This could restrict access to fundamental research and open classroom instruction that currently are excluded from export controls.

There are two more provisions of particular concern. One (Section 4) would make failure to disclose any outside compensation in a grant application a federal crime. "Outside compensation" is defined very broadly as any compensation not received from the primary employer. This could include consulting or even income from a family business with no relationship to the grant application. The other (Section 7) would lower the Section 117 reporting threshold to $50,000 and include payment of any staff as reportable. It also would impose fines for violation. Lastly, the bill (Section 3) would establish a Research Security Council under OMB that among other things would be responsible for developing a uniform grant application process. OSTP would be "advisors."
While prospects for the bill being enacted separately may not be very good, it might be offered as an amendment to the FY'21NDAA.[2]

[2] *For more information see https://www.sciencemag.org/news/2020/06/us-science-groups-wary-new-senate-bills-curb-foreign-influences.*

Confucius Act Passes Senate

On June 10 the Senate passed the Confucius Act (S. 939). The bill establishes requirements for postsecondary educational institutions that receive federal funding and that have contracts or agreements with Confucius Institutes. The contracts or agreements must include clear provisions that (1) protect the academic freedom of the institutions; (2) prohibit the application of foreign law on the institutions' campuses; and (3) grant full managerial authority of the institutes to the institutions, including full control over teaching plans, activities, research grants, and employment decisions. While many institutions may agree with these provisions, there may be concerns about legislation specifying the terms for institution contracts or agreements.

Other Legislation Under Consideration

As noted in our previous Update, there is a great deal of related Congressional activity. Several that are worthy of attention are:

- Sen. Cotton Legislation: Looking for cosponsors on a bill that would require key officials at colleges seeking SEVP certification to attend FBI briefings regarding espionage threats from near-peer strategic competitors use of nontraditional collectors on campus.
- Sen. Grassley Legislation: Looking for cosponsors on a bill that would require federal security background checks for all PI's. The bill also includes restrictions on entry for certain aliens identified as intending to steal intellectual property relating to goods, technology or sensitive information developed with federal research funding.
- Holding China Accountable Act (H.R. 7181): Rep. Nunes (R-CA) has introduced legislation to (1) require Chinese firms to confirm to either U.S. or European accounting standards, (2) prohibit travel to the U.S. by Chinese nationals whose visit to the U.S. involves STEM or a related field, and (3) tighten requirements on university reporting of foreign funding, notably reducing the reporting threshold to $25,000.
- America: Foreign Influence Resistance Starts with Transparency (FIRST) Act (H.R. 7170): Rep. Hern (R-OK) has introduced legislation to require institutions of higher education to disclose gifts from foreign sources in the publications of certain professors and affiliates. Penalties for failure to disclose permit the Department of Education to (1) impose a probationary period or limit eligibility to receive federal funds and (2) loss of nonprofit status for an institution, department, or affiliate.

We will continue to monitor these and other developments.

NDAA Provisions on Science and Security

The Senate version (S. 4049) of the FY'21 National Defense Authorization Act (NDAA) contains a number of provisions related to science and security. These include:

- Section 1285 requires updated and periodic briefings for appropriate senior officials of institutions of higher education from appropriate Government agencies that describe the espionage risks posed by technical intelligence gathering activities of near-peer strategic competitors.

- Sec. 232 provides that the National Academies shall carry out a comparative analysis of efforts by China and the United States Government to recruit and retain domestic and foreign researchers and develop recommendations for the Department of Defense, including: (1) List of "talent programs" used by China and a list of incentive programs used by the United States (2) Types of researchers and fields that are targeted (3) Recommendations on policies the United States can take to improve recruitment and retention of researchers.
- Sec. 891 calls for the establishment, enforcement, and tracking of actions being taken to protect defense-sensitive United States intellectual property, technology, and other data and information, including hardware and software, from acquisition by China. Also requires a new list of critical national security technology. Restricts current and former Defense Department employees from working with/for companies owned/directed by China.
- Sec. 1632 requires an assessment of adequacy of the requirements at each level of the Cybersecurity Maturity Model Certification including requirements germane to continuous monitoring, discovery, and investigation of anomalous activity indicative of a cybersecurity incident.
- Modification to Initiative to Support Protection of National Security Academic Researchers from Undue Influence and Other Security Threats. Amends Section 1286 of the FY19 NDAA to designate an academic liaison with principal responsibility for working with the academic community to protect department-sponsored academic research from undue foreign influence.

Other provisions call for various assessments of the national security industrial/innovation base, disclosure of DOD grant funding in any communications describing a project, and prize-based technology challenges.

The House markup was held on July 1. and passed out of Committee by a vote of 65-0, including Amendment #370 offered by Rep. Waltz to the House version of the NDAA (H.R. 6395) requiring disclosure by principal investigators of all current and pending support with certification by the institution that the investigators have been made aware of the requirement. Rep. Banks amendment expanding the required information on participating researchers from applied to basic DOD-funded research projects was accepted.

Administration Proclamation on China's Military—Civil Fusion Strategy

On May 29, the President issued a Proclamation suspending entry of an F or J visa applicant "who receives funding from or who currently is employed by, studies at, or conducts research at or on behalf of, or has been employed by, studied at, or conducted research at or on behalf of, an entity in the PRC that implements or supports the PRC's "military-civil fusion strategy." An additional widely-noted provision directs the State Department "to consider whether nationals of the PRC currently in the United States pursuant to F or J visas and who otherwise meet the criteria described in section 1 of this proclamation should have their visas revoked."

Very little information has been provided to date about the implementation of the Proclamation. On June 16, the State Department hosted a Roundtable call with higher education representatives including COGR. In the call it was

stressed that the U.S. continues to welcome international students, including from China. However, China's "all of state" approach to take advantage of the open U.S. university system to obtain sensitive technologies through the military civil fusion national strategy was highlighted. China is exploiting the access that Chinese students and scholars have to advance that strategy. Consular officials will review each applicant through the regular vetting process to determine if they are covered by the Proclamation. If denied they will be notified of the reason. Denied applicants can reapply.

There were many questions from the higher education representatives, particularly as to the list of banned entities and fields of study. The lists are being finalized but will not be made public. Too much information cannot be provided because of national security concerns. State suggested that the Australian Strategic Policy Institute Defense Universities Tracker could provide insight as to high risk Chinese universities. DHS will be responsible for reviewing current visa holders so State could not comment on the timeline for review. There is an interagency coordination process.

A particular concern was expressed by the higher education representatives about universities extending admission offers to students who are ultimately denied. This is particularly challenging given the lag time between recruitment and visa application. If there were some way to provide additional insight to institutions prior to visa application, it would be extremely helpful. State indicated understanding of the need to partner with universities in this process, and plans to remain in close contact.

H-1B Visas Suspended

On another immigration-related matter, on June 22, the White House issued a proclamation, Suspending Entry of Aliens Who Present a Risk to the U.S. Labor Market Following the Coronavirus Outbreak, suspending the issuance of new visas for certain categories of nonimmigrant programs, including H-1B visas, through December 31, 2020. Effective June 24, the proclamation argues restrictions on nonimmigrant visas will help restore the American economy. The proclamation also extends the suspension on immigrant visas published on April 22, which focused primarily on green card applicants. The new policy is applicable to certain nonimmigrant visa applicants outside of the U.S. at the time the order was issued and does not apply to those already in the country seeking to change their immigration status.[3]

[3] *For a detailed summary see https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/Immigration/Compete-NIV-EO-proclamation-final%206-24-2020.pdf*

Research Security and Intellectual Property

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

NIST Holds iEdison Workshop

On June 22 NIST held an all-day virtual iEdison Feedback Session workshop. The workshop discussed the responses to the NIST RFI (see COGR December 2019 and February 2020 Updates). COGR submitted comments, which are posted on the COGR website.

NIST staff reviewed the comments submitted at the workshop. The morning session dealt with user comments on the system; the afternoon with policy comments which we had focused on in the COGR comments. The new iEdison dashboard was previewed and demonstrated. It will not be fully operational until 2022. The leading policy comment was the failure of all agencies to use iEdison. This also was highlighted in our comments. NIST indicated they could not mandate other agencies to use the system. However, they currently are talking with non-users, particularly NASA and the Air Force. Other concerns were unclear reasons for rejections of submissions, lack of updated agency points of contact, lack of consistency both within and among agencies in reporting rules and standards, the lack of resources such as FAQs, and lack of training. NIST is factoring all these issues into the system rebuild. The inability to identify whether or not the grant(s) reported for the technology fall under the Bay-Dole 1980 regulations or the revised Bayh-Dole 2018 regulations is another persistent problem. There are now two distinct sets of compliance rules depending on the date the grant was issued or renewed. NIST also is working on this although the problem should diminish over time.

The reaction of the participants to the workshop was positive. NIST will post the workshop slides and FAQs on the website . They also plan to record a longer demonstration and to hold another meeting before the end of the year. In our comments we had recommended NIST establish a stakeholder group. That still appears to a recommendation NIST should consider. There remain some policy questions such as the adequacy of invention disclosures that the new system will accept, particularly for early stage inventions, and the duration of the required utilization reporting, particularly when there has been no recent activity. We will reiterate this suggestion to NIST.

The status of the ROI Green Paper NPRM (see COGR February 2020 Meeting Report) also was briefly addressed. A package with regulatory changes responding to 6 of the Green Paper findings currently is at OMB for review, following an 8-month interagency review process. It is expected to be issued later this summer. NIST also is planning to issue a prize challenge later this year on mechanisms to incentivize enhanced Bayh-Dole compliance reporting.

Costing and Financial Compliance

Committee activities related to COVID are reported under the ***Cross Cutting Issue: COVID-19's Impact on Research General Updates*** *section of this report.*

The CFC focus since March has been on the COVID-19 pandemic. Most of this material is covered in the opening section of this Meeting Report (see Cross Cutting Issues).

As a reminder, *COGR FAQ Addendum #2: CFC FAQs, VERSION 3.0* (last updated on May 28th), 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 June 12th) is also a helpful resource and includes NIH-specific topics, some from a costing perspective. All FAQ documents are available on the FAQ and Resources Page, found on the COGR website. (***NOTE: The most current version of the CFC FAQs was published before the release of M-20-26. We expect to update the FAQs. However, until updated, the COGR analysis of M-20-26 included above can be referenced).***

In addition, other COVID-19 issues that COGR has raised with federal officials 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.

These issues were not addressed in M-20-26. However, COGR will continue to raise these issues (and other issues that develop) with federal officials. We will keep the membership posted as we learn more, and we encourage you to contact David Kennedy at dkennedy@cogr.edu if you have any experiences with these topics.

Proposed Revisions to the Uniform Guidance – 2 CFR Part 200 (UPDATE)

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.

Submission of HHS/NIH Federal Financial Report (FFR) and Federal Cash Transactions Report(NEW)

Submission of the FFR for HHS Operating Divisions (which includes NIH) will change for the 10/1-12/31 quarter (i.e., reports due Jan. 31, 2021). This is considered Phase I, of two phases, specific to changes in HHS/NIH financial reporting. The FFR will be submitted via a newly designed portal in the HHS Payment Management System (PMS). We expect details to be released soon, including training and other operational instructions. Later, in 2021 or 2022,

Phase II, will be implemented. This will entail the quarterly SF-272 (FCTR) to be eliminated and replaced with a new "Certification of Cash Drawn" process. By eliminating the FCTR, this also will eliminate the difficult and confusing reconciliation process between the FFR and the FCTR. COGR will continue to engage with HHS/NIH to learn more about training and other end-user issues, and we also understand that the FDP-ERA subcommittee will be actively involved in this process.

HHS/NIH G-Accounts and Reconciliation (UPDATE)

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 a recent follow-up with Alice Bettencourt, she indicated that due to the COVID-19 pandemic, immediate actions would not be imminent.*** 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 (NEW)

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. COGR is following a recent May 2020 item, Review of Institutions of Higher Education Grantees Receiving National Institutes of Health Award—please contact COGR if your institution is notified of a pending audit.

Also note, you can access DOJ settlements by accessing the DOJ News page at the DOJ website. We encourage you to contact COGR when relevant issues affect your institution.

2020 Compliance Supplement (UPDATE)

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 believe there will be some form of an "Addendum" specific to new programs (new CFDAs) authorized during the COVID-19 pandemic; but again, this is all very

unclear. COGR will continue to engage in advocacy around FY2020 audits that are manageable, fair, and representative of the "new normal."

Research Ethics and Compliance

Committee activities related to COVID are reported under the ***Cross Cutting Issue: COVID-19's Impact on Research General Updates*** *section of this report.*

Responsible Conduct of Research/Research Misconduct/Safe Research Environment (UPDATE)

Comment Letter to Office of Research Integrity: COGR submitted comments in response to the Office of Research Integrity's Request for Information on the sequestration of electronic evidence. The comments emphasized the need for flexibility in sequestration requirements because of the extensive variety of cases, as well as the differences among institutions in size, resources and caseload. The comments also pointed to problems unique to sequestering electronic evidence such as its unique portability characteristics and the fact that it can be contained on both institutional and personal devices.

NIH Guidance Regarding Change in Status, Including Absence of PD/PI and Other Key Personnel Named in the Notice of Award (NEW)

On June 11, NIH published a NOT-OD-20-124, clarifying what information it expects to receive from institutions in connection with requests submitted for a change in PD/PI or key personnel or a change in an institution receiving an award, each of which require prior approval from NIH. Of note, is the requirement set forth in the Guidance that *"the request for approval should include mention as to whether change(s) in PD/PI or Senior Key Personnel is related to concerns about safety and/or work environments (e.g., due to concerns about harassment, bullying, retaliation or hostile working conditions)."* The Notice also states that the foregoing information should be included in a request to change recipient institution. Further, both relinquishing and applicant organizations must disclose the following information:

> [W]hether a Change of Recipient Organization is occurring within the context of an ongoing or recent investigation of misconduct of any kind, including but not limited to professional misconduct or research misconduct.

COGR plans to follow up with NIH to seek more information on the scope of activity covered by this notice, as well as how this requirement should be implemented with respect to confidentiality requirements concerning personnel and research misconduct reviews.

Interview with the General Accounting Office (NEW)

GAO is looking at how agencies have used the various flexibilities offered in OMB Memoranda M-20-11, 20-17 and 20-20. As part of this process, GAO personnel interviewed COGR staff regarding federal guidance on grant flexibilities in response to COVID-19. During this interview GAO asked a series of questions about how institutions availed themselves of the various flexibilities, including which flexibilities were most useful to grantees. GAO also asked several questions on how federal agencies and grantees worked together to understand and implement the flexibilities, as well as what additional flexibilities might prove useful to grantees.

Animal Research (NEW)

U.S. Department of Agriculture (USDA) Amendments to Animal Welfare Act Regulations Concerning Licensees and Veterinary Care and Watering Standards for Regulated Dogs: The USDA issued a final rule that made several changes to the licensing requirements for breeders, exhibitors and operators of auction sales, including licensing specific numbers (in 50 animal increments) and specific types of animals, as well as requiring a new license before any change in name, address, control/ownership of the business enterprise, or activities. The final rule also addresses the following issues that are of significance to research institutions that are registered with USDA ("registrants"):

- **Change in the Definition of Business Hours**: "Business Hours" are no longer limited to weekdays and are now defined as "a reasonable number of hours between 7 a.m. and 7 p.m. each week of the year, during which inspection by APHIS may be made." [9 CFR Section 1.1]
- **Appeal of Inspection Report**: The regulations now specifically state the manner per which a registrant or licensee may appeal the findings of an inspection report. Appeals must be submitted in writing to the USDA Deputy Administrator within 21 days of the date on which the inspection report is received. [9 CFR Section 2.13]
- **Publication of Lists of Research Facilities**: The regulations now state that lists of research facilities will be published solely on the Animal & Plant Health Inspection Service (APHIS) website (as they have been); publication in the Federal Register will no longer occur. [9 CFR Section 2.38].
- **Watering Standards for Dogs**: The regulations have been amended to require that potable water be made continuously available to dogs, unless restricted by the attending veterinarian (AV) or during transit. [9 CFR Section 3.10]
- **Veterinary Care for Dogs**: Research facilities must have a written program of veterinary care for dogs that is developed and signed by the AV. The program must include visits by the AV to all premises where dogs are kept at least once every 12 months and a complete head to tail exam by the AV within the same time frame. The program also must meet standards for preventative care, vaccinations and medical records. [9 CFR Section 3.13].

NIH Request for Information (RFI): Enhancing Rigor, Transparency, and Translatability to Improve Biomedical Research Involving Animal Models (NOT-OD-20-130): The NIH has requested comments from the public on actions hat NIH can take to improve the quality, transparency and translatability of animal research. Questions posed include the following:

- How a requirement to submit research plans to a registry in advance of a study would impact animal research;
- How to address complexity and expense related to the use of large animals;
- Actions that NIH can take to facilitate translatability of animal research to human biology/disease;
- How NIH can partner with the academic community, professional societies and the private sector to enhance animal research translatability; and
- The effect of research culture on the choice of animal models and how researchers are educated in research design, statistical considerations and research transparency.

Comments are due by July 31, 2020. REC is currently reviewing to provide recommendations regarding possible comments.

Contracts and Grants Administration

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

We mentioned in our May Update that we're hearing from COGR members that NSF's Proposal and Award Policies & Procedures Guide (PAPPG), effective June 1, revision of Current and Pending Support (C&P) disclosures is confusing and will create additional burden on institutions (e.g., IT system changes, training, confusion with respect to reporting, etc.). This is particularly challenging as campuses are focusing on safely ramping up on-campus research. In early May, COGR staff met with NSF's Jean Feldman, Head of Policy, and Dr. Fleming Crim, Chief Operating Officer (COO) to discuss these concerns. NSF subsequently moved the mandatory requirement to submit C&P on the two NSF-approved formats to October 5, 2020, but did not delay the requirement to comply with the new reporting elements. While this does allow for more time to make necessary IT changes, it does not address the lack of clarity on what to report and how to report it. Nor does it address the challenge created by having to train campus personnel on the new requirements while ramping up on-campus research.

In a follow-up meeting, we were joined by two institutional reps. After this conversation, it was clear that our concerns were understood, but NSF was unable to delay compliance requirements of the existing requirements to October 5. The reporting requirements that recipients include all resources made available to an individual in support of and/or related to all of his/her research efforts, regardless of whether or not they have monetary value remain intact and must be reported for each individual designated as senior personnel.
NSF has made clear as noted in the NSF FAQs that in-kind contributions not intended for use on the project/proposal being proposed and with no associated time commitment do not need to be reported. However, in-kind contributions used on the project must be included as part of the Facilities, Equipment, and Other Resources section. We will

continue to take your questions and work with Jean to obtain answers. Please send your questions to Jackie Bendall at jbendall@cogr.edu.

NSF Session at Virtual June COGR Meeting (NEW)

COGR was pleased to have Jean and Dr. Rebecca Keiser, in her new role as NSF's Chief of Research Security Strategy and Policy (CRSSP), join our virtual June meeting. Dr. Keiser presented first on "Strengthening Integrity and Security of the U.S. Research Enterprise", discussing actions NSF has taken to improve transparency and clarification for disclosure. She also discussed changes to NSF employment requirements, mandatory science and security training for NSF employees, the development of a risk assessment and analysis recommended by the JASON independent advisory group, communication and awareness with the scientific community, and coordination with USG interagency partners. When asked about Chinese collaborations, Dr. Keiser noted that China is one of the top countries in terms of international collaboration with NSF-funded U.S. researchers. For example, in FY 2019 China was #5 on NSF's list of top partner countries, collaborating on 196 NSF-funded awards and 3 active programs with NSF-China, as well as China's Ministry of Science and Technology. COGR will continue to engage with Dr. Keiser on integrity and security issues.

In Jean's presentation, she discussed several new changes in the coming weeks and changes to the NSF-approved formats for biosketches. For a list of these changes, please click here.

NSF and NIH Release Guidance on Implementation of OMB's Memorandum M-20-26 (NEW)

As mentioned in the CFC report above, on June 25th, NSF issued guidance on NSF's implementation to OMB's Memorandum M-20-26, entitled, *Extension of Administrative Relief for Recipients and Applicants of Federal Financial Assistance Directly Impacted by the Novel Coronavirus (COVID-19) due to Loss of Operations* for recipients affected by COVID-19. NSF notes that the guidance extends two of the short-term administrative relief provisions, allowability of salaries and other project activities and single audit submission beyond what OMB previously outlined in Memorandums M-20-17 and M-20-20 (now rescinded). NSF reminds recipients to continue to maintain appropriate records and documentation to support the charges in accordance with institutional policies and procedures. NIH released nearly identical guidance[4] later the same day. We continue to hear your concerns about what this means, however it is unlikely that federal agencies will provide additional guidance to this language. Please contact Jackie Bendall at jbendall@cogr.edu for questions.

NIH Summary Statement Available in eRA Commons with Signing Official (SO) Roles (NEW)

On June 18th, NIH announced via Guide Notice NOT-OD-20-126 that impact scores and previously issued summary statements will be made available through eRA Commons for users with Signing Official (SO) roles, effective on June 24, 2020. Previously only principal investigators have had access to review statements and impact

[4] *Under "Proposal and Award Management," dated 6/25/20.*

scores. This change follows a Federal Register notice published in September 2019 that authorizes NIH to disclose information to applicants related to NIH award programs. According to NIH, this is slated to be an improvement and does not require any action from an AOR or SO to take action other than being informed of knowing what happens after peer review.

NIH Announces Process Change to Federal Financial Reports (FFRs) (NEW)

On June 24, NIH posted a process change for submission of FFR reports. Beginning January 1, 2021, for awards requiring FFR submissions, the eRA Commons/FFR Module will no longer be available. Grant recipients will now be required to submit SF-425 Federal Financial Reports (FFR) in the Payment Management System (PMS). For additional information, see the full Guide Notice .

NSF Higher Education Research and Development (HERD) Survey

During the Committee Report session of the June virtual meeting, we reported that CGA and CFC Committee members met with Michael Gibbons, Project Manager of the HERD Survey to continue an ongoing dialogue on how best to address combined responses on the survey from multiple campuses. Michael continues to work with us on how best to make refinements to the survey and appreciates COGRs support and recommendations. CGA and CFC have upcoming discussions with Mike on estimating costs and burden hours for completing the survey including how COGR can be helpful in assisting NSF with questions pertaining to COVID-19 in the next survey (e.g., level of interrupted research, unspent funds, R&D reassigned). Stay tuned for additional updates.

NRSA Training, Fellowship, and Career Development Award Update

On May 8, the CGA Committee hosted Dr. Kay Lund, Director of the Division of Biomedical Research Workforce within the Office of Extramural Research at the NIH. In advance of the meeting, the CGA Committee submitted a list of questions regarding NRSA awards. The following points were made during the discussion.

- Payback service obligations for NRSA postdocs may be extended to 3 years after the end of their first year of NRSA support due to the pandemic, though this is not yet finalized.
- Individuals receiving NRSA stipends can continue to use stipends during the COVID-19 pandemic. A brief check-in with the GMS should be considered, particularly for T32 programs regarding the status of the institution and what training and research can continue to be performed.
- If institutions have Graduate Research Assistants (GRAs) who will be starting coursework in the upcoming new academic year, or even this summer, and if classes are remote, tuition can be charged to appropriate NIH awards and grants.
- If T32 programs are unable to identify and appoint trainees because of COVID-19, they can consider utilizing the slots the following year.
- If a trainee's progress is delayed, planned renewal applications for a T32 or applications for a fellowship should explain the delay from both the trainee/fellow and mentor perspective.

- NIH is considering extending ESI status by an entire year for those negatively impacted by COVID-19, however, this has not yet been accepted or finalized.

COGR will continue to monitor subsequent changes or additions to these requirements. For additional questions, please contact Jackie Bendall at jbendall@cogr.edu.

Dr. Peter Preusch – NIGMS Program Official Discussion

On May 15th, CGA was joined by Dr. Peter Preusch, Biophysics Branch Chief at the National Institute for General Medical Sciences (NIGMS), for a discussion of expectations of NIGMS program staff regarding COVID-19 impacts to proposals and awards. During the discussion, Dr. Preusch made the following observations:

- Return to lab cautions taken should be governed by institutional policies
- Communications with NIH Program Staff via email should be well thought out and succinct
- No minimum effort requirements are being considered at this time for NIGMS-supported R01s and R21s
- NIGMS continues to encourage the use of their R35 mechanism, requiring that recipients devote at a minimum 51% research effort
- NIGMS continues to fund COVID-19 related research through supplements from their *Models of Infectious Disease Agent Study* (MIDAS) program
- Funding for new awards and continuations will be made on the same time schedules currently in place noting that additional time is always a possibility, but additional funding may be challenging
- Statements noting anticipated delays due to visa and travel restrictions, delays in hiring, etc., can and should be noted in competing renewal submissions

As agency implementation continues to evolve, we recommend that principal investigators and research administrators communicate regularly with program and grants management officials for questions related to COVID-19 impacts on proposals and awards. Please contact jbendall@cogr.edu for additional information.

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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.

Research Security and Intellectual Property (RSIP)

Patrick Schlesinger (Chair)	University of California, Berkeley
Alexandra Albinak	Johns Hopkins University
Cindy Kiel	University of California, Davis
Michael Moore	Northwestern University
Dan Nordquist	Washington State University
Elizabeth Peloso	University of Pennsylvania
Jennifer Ponting	University of Chicago
John Ritter	Princeton University
Janna Tom	University of California
David Winwood	Louisiana State University
Kevin Wozniak	Georgia Institute of Technology

Costing & Financial Compliance (CFC)

Joseph Gindhart (Chair)	Washington University St. Louis
Robert Andresen	University of Wisconsin-Madison
Sarah Axelrod	Harvard University
Michael Daniels	Northwestern University
Vivian Holmes	Boston University
Cynthia Hope	Georgia Institute of Technology
Michael Legrand	University of California, Davis
Nate Martinez-Wayman	Duke University
Lynn McGinley	University of Texas Medical Branch
Michael Moody	Massachusetts Institute of Technology
Jeffrey Silber	Cornell University
Marcia Smith	University of California, Los Angeles
Cathy Snyder	Vanderbilt University

Contracts & Grants Administration (CGA)

Walter Goldschmidts (Chair)	Cold Spring Harbor Laboratory
Allen DiPalma	University of Pittsburgh
Stephanie Endy	Case Western Reserve University
Jeffrey Friedland	University of Delaware
Jeremy Forsberg	University of Texas, Arlington
Jennifer Lassner	University of Iowa
Steven Martin	Indiana University
Lisa Mosley	Yale University
David Norton	University of Florida
Twila Reighley	Michigan State University
Craig Reynolds	University of Michigan
Jennifer Rodis	University of Wisconsin-Madison

Research Ethics & Compliance (REC)

Naomi Schrag (Chair)	Columbia University
Lynette Arias	University of Washington
Sara Bible	Stanford University
Lois Brako	University of Michigan
Karen Hartman	Mayo Clinic
J.R. Haywood	Michigan State University
Mary Mitchell	Partners Healthcare
Kerry Peluso	Florida State University
Brian Smith	University of California - San Francisco
Ara Tahmassian	Harvard University
Debra Thurley	Pennsylvania State University