

An Association of Research Institutions

SEPTEMBER 2020 UPDATE

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Council on Governmental Relations Meeting – October 2020 Meeting (UPDATE)

As communicated in our July 22 message on the COGR Listserv, our October meeting will be held virtually. We are targeting the week of October 19-23. Registration will open soon, and we will distribute a preliminary agenda shortly thereafter. Please send any questions to Toni Russo at trusso@cogr.edu.

Cross Cutting Issues: OMB Issues Uniform Guidance

OMB Issues Final Guidance to 2 CFR Parts 25, 170, 183, and 200 (NEW)

In COGR's <u>February Meeting Report</u>, we mentioned that a COGR workgroup was formed to develop a response to OMB's <u>Proposed Revisions to 2 CFR Part 200</u> of the Uniform Guidance with OMB's intent to align the revisions and clarifications with the <u>Results-Oriented Accountability for Grants</u>, per the President's Management Agenda (March 20, 2018). The deliverable from this workgroup resulted in a thirty-five-page <u>letter</u> submitted to OMB on March 23, 2020.

On August 13th, OMB issued the <u>final guidance</u> effective November 12, 2020, *except for the amendments* to §§ 200.216 (Prohibition on Certain Telecommunication and Video Surveillance Services and Equipment) and 200.340 (Termination), which are effective on August 13, 2020 (see "Prohibitions on Telecommunication Equipment and Services" on page 7 of this Update for additional information). In response, COGR has formed another workgroup to review the final guidance and will be providing a member update of the revisions/clarifications COGR requested in its March 20, 2018, letter compared to the revisions OMB implemented in its final Guidance. The workgroup will determine key issues that were not considered by OMB that may result in a follow-up letter to OMB. Although the guidance is final, going on record may prove useful for ongoing discussion with OMB. COGR staff noted many positive revisions and clarifications to the final guidance; this will be acknowledged in any subsequent correspondence to OMB. Other recommendations, including the codification of FAQs, termination, DS-2, and other prohibitions were not reflected in the OMB implementation of the final Guidance. Stay tuned for additional updates.

If you have any questions or concerns about the final OMB Guidance that could be helpful to our workgroup or any subsequent work product, please contact Jackie Bendall at jbendall@cogr.edu or Dave Kennedy at dkennedy@cogr.edu



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

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

COGR's <u>Institutional and Agency Responses to COVID-19 and Additional Resources</u> page is publicly available and regularly updated. In addition, COGR has presented <u>three webinars</u> on COVID-related topics, and we continue to regularly deliver the "COGR News Digest" (which includes COVID-19 developments) to the member listsery. COGR also has developed <u>FAQs</u> on various COVID related topics. On June 18, 2020, OMB released memorandum <u>M-20-26</u>, which rescinded <u>M-20-17</u> and <u>M-20-20</u>. 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. Additional activities of each COGR Committee pertaining to COVID-19 are described throughout this COGR Update. We encourage you to continue to reach out to <u>COGR Staff with questions</u>.

Summary of OMB Memorandums and an Analysis of M-20-26 (UPDATE)

In the <u>June Meeting Report</u> (July 7, 2020), we provided a summary of the OMB Memorandums released (and rescinded), to date. We memorialized all OMB Memorandums as part of the Costing FAQs—specifically, <u>Costing FAQ #27</u>.

Also in the June Meeting Report, we included an analysis of <u>OMB Memorandum M-20-26</u>: 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. Upon the release of M-20-26 on June 18, 2020, the flexibilities under M-20-11, M-20-17 and M-20-20 expired. We memorialized COGR's analysis of M-20-26 as part of the Costing FAQs—see Costing FAQ #28.

Our analysis of M-20-26 includes a link to the recently developed COGR paper titled <u>Funding Sources</u> for Research Universities. For those institutions that have continued to use the salary charging flexibilities under M-20-26, this paper could be a helpful resource to describe funding sources available in support of the M-20-26 requirement that institutions must document their efforts to "exhaust other funding sources." As funding sources have been exhausted or significantly diminished under the COVID-19 pandemic, institutional survival requires implementation of difficult cost-cutting measures in conjunction with maximizing the significantly diminished funding sources. COGR understands this to be an existential crisis, which requires leadership at universities and research institutions to prioritize the allocation of scarce funds and resources across multiple institutional functions.

Note, the flexibilities under M-20-26 expire on September 30, 2020, and we do not expect that they will be continued. However, we will provide updates to the membership as we get closer to the expiration date.



NIH COVID-19 FAQs (UPDATE)

<u>COGR's NIH COVID-19 FAQs</u> were updated to reflect changes stemming from NIH's nearly verbatim implementation of <u>OMB M-20-26</u>, which terminated the majority of flexibilities extended to grant recipients during the pandemic. See above for more on the OMB Memos. The NIH COVID-19 FAQs also were updated to reflect additional operational flexibilities for Institutional Animal Care and Use Committees (IACUCs) and research animal care and use programs.

Research Impact Under COVID-19: Financial Crisis and the "Pandemic Normal" (NEW)

COGR has posted <u>Research Impact Under COVID-19</u>: <u>Financial Crisis and the "Pandemic Normal"</u> as a new COVID-19 resource. The paper presents a model for estimating research output loss and financial impact of COVID-19, describes the challenges of doing research under the new "Pandemic Normal," and advocates for renewed commitment and a substantial infusion of new research investment, calling on federal leaders, research institutions, and all stakeholders to rally around the longstanding Federal Government-Research Institution Partnership. The Research Impact Metric (RIM) Model, presented in the paper, is a tool institutions can use to estimate the research output loss and financial impact due to the COVID-19 pandemic. Case studies are shown, and other impact variables are described. COGR is interested in additional case studies, so please contact David Kennedy at <u>dkennedy@cogr.edu</u> if your institution has developed analyses using the RIM Model or similar tools.

COVID-19 Research Impact Survey (UPDATE)

The COVID-19 Research Impact Survey project continues with the issuance of the third pulse survey. Responses to this pulse survey were due on August 28, and an interim report will be provided after responses are reviewed. Depending on the pandemic's trajectory and continued impact, an additional pulse survey may be administered. Many thanks to all COGR members who have participated in this series of surveys examining COVID's effects on research institutions.

FDA Guidance Regarding Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Pandemic (NEW)

In August, the FDA <u>issued guidance</u> regarding gradual resumption of inspections that were temporarily suspended in March 2020 as a result of the COVID-19 pandemic. This Guidance covers inspections of clinical investigation sites under the Bioresearch Monitoring Program (BIMO). FDA will use a risk-based approach to determine what BIMO inspections it will undertake and will limit inspections to "mission critical" routine or for-cause inspections. Mission criticality will be determined based factors such as the need for the investigational product and stage of development, and site safety factors also will be considered.



COVID-19 Legislative Update (UPDATE)

In the <u>June Meeting Report</u>, we provided a summary of COVID-19 legislative initiatives, to date. *We recommend accessing the Association of Public and Land-grant University (APLU) webpage*, under the section titled <u>Federal Emergency Funding</u>, as an excellent resource for tracking the status of COVID-19 related legislative updates. As anticipated legislation has not moved throughout the summer, we will be paying close attention to developments when Congress reconvenes. 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. We will provide updates as we learn more.

Cross Cutting Issues: Science and Security

Section 117 Developments (UPDATE)

We have been updating the COGR membership over the past year on developments associated with <u>Higher Education Act Section 117</u> foreign gift and contract reporting required by the Department of Education (ED). Last June's virtual COGR meeting <u>included a session</u> with the ED Deputy General Counsel on this topic.

A large number of questions were raised in the Q & A at the COGR session, which we considered for possible follow up with ED (the June <u>Meeting Report</u> discussed the questions raised). The session also featured a screen shot "preview" of the new electronic portal which ED implemented for the recent July 31 reporting deadline.

On August 5, COGR held a virtual session as part of its Summer Series for members to discuss their experiences with the new reporting portal. Not surprisingly many issues and frustrations were raised. The main logistical issue raised was the lack of a batch functionality in the new portal and the inability to correct previous submissions. A number of policy issues also were raised. These included the reporting of gifts or contracts received from foreign subsidiaries, the type of contract restrictions that must be reported, and the reasonable due diligence required in transactions involving domestic entities.

On August 14, COGR sent a number of questions to ED. We raised the issues of foreign subsidiaries and contract restrictions. We also raised the issues of funding from US foundations where the original sources of funds are impossible to trace (a question that had come up in June), reporting of gifts of property with no fair market value (e.g. data or materials transfer agreements), and the preferred procedures for corrections to previous reports. The latter question has been asked by many of our member institutions. We included a separate list of questions and suggestions regarding the new reporting portal, including the need for upload functionality and a user's guide.



We did not include a question about due diligence in the submission to ED, although we previously had raised a related question with the ED Deputy General Counsel. It is a subjective standard and we are concerned about asking ED for additional specific guidance.

ED informed us that they plan to post responses on their Section 117 website, along with other questions from the general public.

In other developments, ED recently initiated Sec 117 investigatory requests to two <u>additional institutions</u>. The anticipated new ED rule requiring submission of "true copies" of foreign contracts or gift agreements still has not been issued. We expect that it may be issued shortly.

Prohibitions on Telecommunication Equipment and Services Raise Concerns (UPDATE)

On August 13, statutory prohibitions on the purchase and use of certain telecommunications equipment and services provided by Huawei and a number of other entities were implemented for both federal contracts and grants.

The statutory prohibitions were set forth in Sec. 889 of the <u>FY'19 National Defense Authorization Act</u>. COGR first alerted the membership about them in our September 2018 <u>Update</u>.

There are two contracting prohibitions and a separate prohibition on use of grant funds. The first contracting prohibition is on contracting to procure the covered equipment and services. It was effective last August 13. The second prohibition is on contracting with an entity that uses covered telecommunications equipment or services "as a substantial or essential component of any system." The grant prohibition is on use of grant funds for any contract to procure or obtain the covered equipment, services or systems. The latter two prohibitions were effective August 13 of this year.

An <u>implementing FAR rule</u> was issued on July 14. A previous <u>FAR rule</u> had been issued implementing the first prohibition. That rule required a representation by offerors regarding providing the covered equipment or services in contracts. The recent FAR rule requires a representation on use of the covered equipment or services by offerors. An <u>interim FAR rule</u> issued on August 27 provides for an annual "does not" representation in the System for Award Management (SAM) in lieu of a case-by-case representation. The FAR Council is considering expanding the rule to cover domestic affiliates of offerors. However only the procurement prohibition flows down; the "use" prohibition extends only to entities that agencies enter into contracts with (i.e. prime contractors). It does not extend to subcontractors.

The grant prohibition was included in the <u>Uniform Guidance (UG)</u> issued on August 13 (200.216, pp. 49515-6; p. 49543; 200.471, p. 49570). It prohibits federal award recipients from using government funds to enter into contracts (or extend or renew contracts) to procure or obtain equipment, services or systems that use covered telecommunications equipment or services as a substantial or essential component of any system or as critical technology as part of any system. The UG further provides that costs incurred for any



such purposes are unallowable. The prohibition applies even if the purpose of the contract is not to procure or obtain any such equipment, system, or service.

While these prohibitions appear similar, the consequences differ. The grant prohibition appears to extend to subrecipients, which the contract prohibition does not. There is a <u>two-year waiver</u> provision in the contract rule. (DOD already has obtained a temporary waiver through September 30 for all of its contractors.) There is no comparable waiver authority for grants. However, unlike contractors, the statute does not prohibit grant recipients from using non-federal funds for the covered equipment or services.

When the UG was proposed earlier this year COGR objected to including this provision given the possibility of subsequent statutory changes. It is not clear whether the description of the prohibition in II.A. of the UG is fully consistent with the actual language of 200.216. This raises the potential for confusion (e.g. does incidental use of covered cell phones by foreign grant subrecipients fall under the prohibition)? Already COGR has been made aware that some agencies appear to have different interpretations. For example, USAID stated (July 27 General Notice): "The prohibition of "covered telecommunications equipment or services" will prevent the Federal Government from making or extending awards to implementing partners that use equipment, systems, or services from Huawei (et. al.)." NASA has stated (August 20 email to Grant and Cooperative Agreement Recipients) "Recipients shall ensure that none of the funding from their federal award is used for the purchase of covered telecommunications equipment or services, or expenses associated with the covered telecommunications equipment or services."

A further issue is that neither the FAR nor the UG define "substantial or essential component" or "critical technology." Some agencies (e.g. AHRQ) also are requiring case-by-case representations in contracts despite the provision allowing for an annual certification.

Comments on the FAR rule are due September 14. COGR is considering whether to submit comments. While the UG is final guidance, we may point out to OMB the differing interpretations and ask for clarification. Legislative clarifications are unlikely.

DOE to Clarify Scope of Order 142.3A (UPDATE)

Recent COGR Updates and Meeting Reports have discussed the December 2019 removal of the exemption for grant-funded research at institutions of higher education from the Department of Energy (DOE) Order 142.3A requirement for DOE approval for foreign national access to DOE information, technologies or equipment (see May 2020 <u>Update</u>). COGR has held a number of discussions with DOE senior leadership about the issue. We had been told that DOE would provide clarification that the approval requirement does not apply to DOE-funded fundamental research at universities, but no clarification has been issued to date.

Steve Binkley, Principal Deputy Director of the DOE Office of Science, spoke at the COGR August 18 webinar on Foreign Influence and Research Security. He stated that the purpose of the Order was to cover



only users of DOE facilities. The Order specifically applies to visits to DOE sites and labs and was not intended to apply to financial assistance agreements. The removal of the exemption of university fundamental research from the 142.3A requirement was unintentional. A revision process has been initiated. It is expected to be completed by the end of the year.

While this is welcome news, the details of any clarification will be important. The more applied research units at DOE (e.g. EERE, NETL) have been particularly active in claiming that the exemption does not apply. NSDD 189 defines fundamental research as both basic and applied. Any clarification that limits the exemption to basic research will not fully resolve the issues that institutions currently have with the foreign national approval requirement. This may be particularly problematic in applied projects where there is substantial collaboration between university researchers and DOE representatives and extensive exchange of data and information under cooperative agreements. In such cases DOE may continue to insist that the Order applies to any foreign participation. COGR will continue discussions with DOE on this issue.

Dr. Binkley also mentioned several other items of interest. DOE Order 486.1 prohibiting DOE federal and contractor employee participation in foreign talent recruitment programs is being updated to clarify that it applies only to the DOE labs and contracts issued by them (as opposed to DOE grants to institutions). It will include restrictions on certain affiliated activities, but will have an exemption process. It is now undergoing final review and release is imminent. Dr. Binkley also clarified that the S&T risk matrix that DOE had developed last year likewise applies only to the national labs and not financial assistance activities. Funding opportunity notices for FY21 will clarify that the disclosure requirement of current and pending support is to include ALL current and pending, including foreign support. There is a new requirement that the current and pending must be updated annually for multi-year awards.

Cybersecurity (CMMC) Developments (UPDATE)

The <u>February</u> and <u>May COGR Updates</u> discussed the DOD Cybersecurity Maturity Model Certification (CMMC) draft Framework. We are concerned about the application of the requirements to DOD contracted fundamental research at universities. COGR and EDUCAUSE have drafted a letter to DOD expressing our concerns.

The COGR August 18 webinar included a presentation on the CMMC by Michael Corn, Chief Information Security Officer at UCSD and Co-Chair of the EDUCAUSE Higher Education Information Security Council. In his presentation Mr. Corn discussed issues related to the institutional certifications that will be required and contract flow downs. Institutions that handle Controlled Unclassified Information will be required to implement the CMMC at some level. Other research agencies are discussing use of the model with DOD, so this may affect most COGR member institutions at some point. Mr. Corn pointed to the need to begin to shift institution culture to proactive cybersecurity management. His <u>slides</u> are posted on the COGR website.



We have held the COGR/EDUCAUSE letter to DOD based on advice from the DOD Basic Research Office. However, we now plan to send the letter to DOD management. Hopefully, this will create an opportunity for further discussions. AAU and APLU have indicated that they plan to join or endorse the letter.

State Dept. Sends Letter to University Governing Boards (NEW)

State Department Under Secretary for Economic Growth, Energy, and the Environment Keith Krach sent a letter on August 18 to the governing boards of American colleges and universities and their affiliates seeking their assistance to safeguard American technology and asking institutions to ensure national and economic security remain safe and free from foreign interference. In the letter, Mr. Krach describes the "growing threat of authoritarian influence," and outlines the administration's efforts to guard against the threat the Chinese Communist Party poses to academic freedom, human rights in the People's Republic of China, investments and endowment funds, and intellectual property. The letter asks colleges and universities to critically examine the activities of Confucius Institutes on their campus, protect their intellectual property, and divest from Chinese holdings in their endowments. The letter also notes that "it is imperative that we distinguish between the CCP's totalitarian regime and the Chinese people, whom we must steadfastly defend from abhorrent acts of xenophobia, racism, and hatred, including those from the PRC government."

The letter does not necessarily call for a response. Most COGR member institutions already have taken steps to respond to the concerns expressed in the letter.

Commerce/BIS Issues ANPRM on Foundational Technologies (NEW)

On August 27 the Commerce Bureau of Industry and Security (BIS) issued an <u>ANPRM</u> on *Identification* and Review of Controls for Certain Foundational Technologies.

Identification of critical emerging and foundational technologies was called for in the Export Reform Act of 2018. BIS issued an ANPRM on emerging technologies in November 2018 (see COGR December 2018 Update). COGR submitted comments in January 2019 jointly with other higher education associations.

BIS is seeking public comments to inform an interagency process to identify and describe foundational technologies. Feedback also is sought on the impact of controls on such technologies. The ANPRM gives examples of possible foundational technologies (semiconductor manufacturing equipment and associated software tools). It also indicates that some "EAR 99" items may be reviewed to determine if they warrant controls as foundational technologies.

We will discuss submission of comments on the ANPRM with the other associations. Comments are due October 26.



NIH Webpage Protecting U.S. Biomedical Intellectual Innovation (NEW)

In July, NIH posted a <u>new webpage</u> that included a chart labeled *Examples of What to Disclose to NIH about Senior/Key Personnel on Applications and Awards*. This chart lists various types of external activities and compensation and when/how they should be reported to NIH (e.g., reported in Biosketch, reported as a foreign component, reported at other support, etc.). The last column in this chart is labeled "Review for Potential FCOI," and COGR members raised several questions regarding the items listed in this column in the context of FCOI regulation. COGR brought these concerns to NIH's attention, and NIH advised that it would take COGR's concerns and recommendations into consideration in revising/issuing clarifications regarding the chart. NIH stated that is it actively reviewing the chart, but it did not specify a timetable for when additional changes can be expected.

Interview with HHS OIG (NEW)

COGR staff were interviewed by the Department of Health and Human Services Office of Inspector General (DHHS OIG) regarding a survey that the DHHS OIG plans to conduct of U.S. academic institutions this autumn. The survey will focus on (a) how institutions are ensuring that researchers are disclosing significant financial interests and other support, including support received from foreign institutions; and (b) how institutions are reviewing and acting on reported disclosures and reporting issues to NIH. OIG was aware of the survey that COGR was conducting regarding institutions' disclosure practices, and COGR reported that other entities had conducted similar surveys as well. COGR emphasized that not all items that NIH has requested be disclosed fit within the regulations governing conflict of interest, and institutions frequently have multiple disclosure and review channels depending the type of information involved (e.g., conflict of interest, external activities, technology transfer, research support). COGR also emphasized that institutions were very attuned to issues concerning inappropriate foreign influence on research and were working earnestly to improve disclosure and review processes.

COGR Survey on Institutional Disclosure Practices (UPDATE)

At the beginning of August, COGR completed data collection for its survey on Institutional Disclosure Practices, and data analysis is underway. The survey had an excellent response rate with 127 of the 190 institutions surveyed submitting complete responses. The largest group of responders was colleges and universities (n =116), and 54 of these institutions had an associated academic medical center. Themes that have emerged thus far from data analysis include the following:

• Institutions are beginning to compare faculty disclosures made via different paths (e.g., disclosures made to conflict of interest offices and sponsored programs offices) to ensure consistency, particularly with respect to processes for reporting conflict of interest and external activities.



- Institutions have, or are developing, processes for monitoring disclosures made by faculty members. Seventy-five institutions reported that they either have or are developing processes to monitor external activity disclosures, and 85 institutions reported that they have a process for monitoring conflict of interest disclosures. Development of monitoring processes for disclosures of current and pending support is a bit slower with only 52 institutions reporting that they either have or are developing a process.
- A majority of responding institutions have training programs for faculty in the areas of conflict of interest and reporting of external activities, and they are beginning to develop current and pending support training programs as well.

A presentation on the data from the survey will be provided at the October COGR membership meeting.

Science and Security Legislative Update (UPDATE)

The June <u>Meeting Report</u> discussed pending legislative actions relating to security issues, particularly with regard to China. Many of these were included in the House and Senate versions of the FY'21 NDAA.

Both Houses now have passed their versions of the NDAA. A conference is pending. The NDAA provisions were discussed by Hanan Saab of AAU at COGR's <u>August 18 Foreign Influence</u> webinar.

One provision of particular concern in the House NDAA package is an amendment offered by Rep. Gallagher (R-WI) which would prevent foreign components from being utilized in drones used or supported by federal agencies. The language also applies the used of drones supported with "federal funds awarded through a contract, grant, or cooperative agreement." The concern is that this new requirement could have significant implications for the use of drones being utilized to by universities to conduct federally sponsored research. AAU has expressed concerns about it to DOD officials and plans to discuss further with and Congressional staff.

The June Meeting Report discussed in detail the Safeguarding American Innovation Act introduced by Sens. Portman and Carper. The bill (S. 3997) was approved by the Senate Homeland Security and Governmental Affairs Committee along with several other bills approved in an en bloc voice vote in July. Prior to the markup, AAU, APLU, AAMC, and ACE sent a letter to committee leaders expressing concerns about the bill. During the markup, Senators Portman and Carper said they will continue to take input and comments on the legislation, though Senator Portman expressed concerns that research universities continue to be "naïve" to the threat to the research enterprise and appear unwilling to take these threats seriously. The associations have since met with Portman's and Carper's staff to suggest specific changes to the bill There was agreement with staff that the associations would continue to engage to discuss specific language that might help to address the concerns and improve the bill. Meanwhile, the Senate Republicans' COVID-19 relief package includes S. 3997. AAU has expressed its opposition to the House and Senate leaders to the inclusion of S. 3997 in a final COVID-19 relief package on the grounds



that that bill should continue through regular order so that congressional committees with jurisdiction of key sections of the legislation have the opportunity to weigh in. Throughout this process AAU has consulted with COGR on the bill's implications and impacts.

Research Security and Intellectual Property

Intellectual Property Developments

State Attorneys General Letter on Remdesivir (NEW)

On August 4 a bipartisan group of state attorney generals sent a letter to HHS and FDA <u>urging the government</u> to exercise march-in rights under the Bayh-Dole Act to require Gilead Sciences to license its COVID drug Remdesivir to lower the price and increase the supply.

The letter has been <u>widely criticized</u>. A major issue is that it misstates the underlying patents as subject to the Bayh-Dole Act. The underlying inventions were privately funded by Gilead with no federal support, which HHS has confirmed. They are not inventions subject to Bayh-Dole march-in rights. The letter also states that march-in is appropriate on pricing grounds, which has been consistently refuted including by the authors of the Act.

AUTM has <u>posted a response</u> that discusses the concerns. AUTM also is planning a virtual discussion on September 9. Despite the pushback, we are concerned that the letter is out there with so many signatories, given its mischaracterizations. (Informally we understand some state AGs have indicated they may not have fully understood the implications of the letter).

ROI Green Paper Implementation Finally Moves Forward (UPDATE)

For some time, we have reported on the status of NIST's implementation of the Return on Investment (ROI) Green Paper findings (see COGR February 2020 Meeting Report). Review by the Interagency Committee on Tech Transfer evidently has taken much longer than expected (NIST had expected to issue a NPRM last April). However, COGR has been informed that a package of regulatory changes has been forwarded to OMB and sent out for formal interagency review. We had understood that most of the changes to the Bayh-Dole regulations involve removing obsolete or explanatory language dating back to their original issuance. We do not know if there will be changes to the march-in provisions, or whether the findings in the ROI Green Paper with regard to the government use license or U.S. manufacturing waivers will be addressed. Hopefully, given that a protracted interagency review process already has occurred, the formal interagency review process will not take long.

There also is a companion package of legislative changes. Most of these involve changes to the Stevenson-Wydler Act which applies to federal employee inventions. It is not clear whether these changes will move forward. They may be deferred to the next administration.



Bayh-Dole Act 40th Anniversary Plans (UPDATE)

This year marks the 40th anniversary of the Bayh-Dole Act. A coalition in which COGR is participating is planning appropriate commemorations. A virtual event is planned for mid-October. The program will be primarily a celebration of the public benefits the law has brought through the commercialization of federally funded R&D. Other themes will include the substantial effort needed to develop a Bayh-Dole subject invention and that the risks fall on the private sector; misusing march-in rights for price control will threaten the system; and Bayh-Dole requires a strong, dependable US patent system to succeed. COGR will provide more information on the event when it is available.

Costing and Financial Compliance (CFC)

Committee activities related to COVID are reported under the Cross Cutting Issue: COVID-19's Impact on Research General Updates section of this report. Several other items related to COVID are covered below, in addition to non-COVID related items.

F&A Cost Rate Proposals and FY 2021 Base Years (NEW)

COGR met with Alice Bettencourt, Deputy Assistant Secretary for Grants, and Jimmie Curtis, Director, Division of Grants Policy to discuss this topic, and several others. *For those institutions that are HHS-CAS Cognizant*, Ms. Bettencourt reiterated that Mak Karim, Director of Cost Allocation Services (HHS-CAS) is the primary point-of-contact. However, during the call, we were able to raise the situation where the COVID-19 pandemic would make submitting an FY 2021 base year rate proposal a challenge. If this is the case for your institution, according to Ms. Bettencourt, you should have requested a waiver by 8/31/2020. However, you still can make the request after 8/31/2020. Requests should be made to CAS. If your request is due to the COVID-19 pandemic, be clear in expressing the impact of the COVID-19 pandemic (e.g., it creates as challenge to complete a representative space survey). You also should be clear that your request is for a one-year waiver and how this request might intersect with a future request for a 4-year rate extension (as permitted under the Uniform Guidance). *For those institutions that are ONR Cognizant*, Wade Wargo shared that ONR will treat this issue on a case-by-case basis and that Brian Bradley, ONR Director of IDC, is the point-of-contact.

Property/Equipment Biennial Inventory (NEW)

In the same call, COGR addressed concerns related to completing the biennial property/equipment inventory requirement as specified in <u>2 CFR 200.313(d)(2)</u>. For those institutions that are HHS-CAS Cognizant, HHS Grants Policy (Jimmie Curtis) is the point of contact to receive relief on completing the inventory. If you have had any pushback on this in the course of your single audit, we encourage you to reach out to HHS Grants Policy immediately to request a waiver. According to Mr. Curtis, address your request to Jimmie Curtis, Director, Division of Grants Policy and use "Urgent Inventory Exception" as



your subject header. Send the request to: <u>GrantPolicyREQ@hhs.gov</u>. Note, HHS cognizance means that approval by HHS Grants Policy is the equivalent to approval by all federal agencies. *For those institutions that are ONR Cognizant*, Wade Wargo shared that ONR will treat this issue on a case-by-case basis and that Brian Bradley, ONR Director of IDC, is the point-of-contact. If your institution has been challenged by your single auditors on this issue, please feel free to share with COGR by contacting Dave Kennedy at dkennedy@cogr.edu.

HHS/PMS Closeout of G-Accounts (NEW)

Also on the same call, COGR addressed the status of the HHS/PMS (Payment Management System) issue related to closing out the legacy G-accounts (pooled cash draw accounts). Pre-COVID-19, the message from Alice Bettencourt was that HHS/PMS would soon initiate the closeout of G-accounts. In the spring, after the beginning of the COVID-19 pandemic, Ms. Bettencourt indicated that G-account closeouts would not be prioritized. Per our discussion with Ms. Bettencourt, she reiterated that there would not be an active push to close G-accounts in the immediate term. However, if your institution has provided HHS/PMS with data and has not heard back, you should reach out to Dan Long at PMS and/or Jimmie Curtis at HHS to remind them that you are waiting for HHS/PMS to respond. If needed, we can provide direct email contacts to Mr. Long and Mr. Curtis.

A Note on HHS Grants Policy and HHS/CAS Cognizance (NEW)

For institutions that are HHS/CAS Cognizant, there often is confusion on how to obtain approvals on costing related issues. Normally, CAS is responsible for F&A cost rates and the DS-2 approval. The HHS Grants Policy Office is responsible for most other (including direct cost) issues. Consequently, requests such as changes to effort reporting / payroll confirmation systems and increasing the micropurchase threshold to a level greater than \$10,000 should be made to the HHS Grants Policy Office.

ONR and the DS-2 (NEW)

Several COGR members have shared a letter to their institution from Brian Bradley, ONR Director of IDC, requesting that the "University submit a current, accurate and complete copy of its Disclosure Statement no later than January 4, 2021." Included in the letter are several onerous expectations (e.g., "Any changes made or anticipated to be made to the disclosed practices within the past six years from certification date up to the beginning of your next accounting period should be identified using red font and include an effective date."). COGR reached out to Mr. Bradley and learned that DCAA and ONR are trying to address the issue of DS-2s and proposed revisions (going back to the mid-1990s) that never were reviewed or approved. COGR expressed concern that the requests in the letter are unreasonable and that all stakeholders need to be engaged before any new reporting requirement is finalized. ONR expressed



the willingness to be flexible and indicated that they will revisit the letter over the next several weeks. We will keep you posted on all developments.

HHS/NIH Federal Financial Report (FFR) and Federal Cash Transactions Report (UPDATE)

As reported in the <u>June Meeting Report</u>, 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 one 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 two will be implemented (please note, per HHS/NIH, all dates are subject to change). This will entail the quarterly SF-272 (FCTR) being eliminated and replaced with a new "Certification of Cash Drawn" process. By eliminating the FCTR, this will also 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.

2020 Compliance Supplement (NEW)

OMB and Gilbert Tran from the OMB Office of Federal Financial Management (OFFM) announced the availability of the <u>2020 Compliance Supplement</u>. The 2020 Compliance Supplement replaces the 2019 Compliance Supplement and applies to fiscal year audits beginning after June 30, 2019. The 1,559 page document also can be accessed from the OFFM website.

Public comments, as specified in the Federal Register Notice, are due by October 10, 2020. Key highlights, identified by OMB, include the reduction of the number of compliance areas for auditor review (see Part 2) from twelve to six (first implemented in the 2019 version) and guidance related to coronavirus administrative relief (included in Part 8, Appendix VII, page 1542) of the Supplement. OMB plans to work with federal awarding agencies to identify the new COVID-19 programs with special compliance and reporting requirements that could be included as an addendum to the Compliance Supplement, as appropriate. Also note the R&D Cluster (Part 5, page 1384-1388)—we encourage a close review of these five pages.

COGR regularly comments—in July 2019, COGR submitted a <u>Comment Letter</u> addressing several topics—and we will consider submitting a comment letter on the 2020 Compliance Supplement. If you have concerns, OMB encourages outreach to the OMB Grants Team at <u>GrantsTeam@omb.eop.gov</u> or Gilbert Tran at <u>hai m. tran@omb.eop.gov</u>. Also, feel free to contact David Kennedy at <u>dkennedy@cogr.edu</u> if you have observations or comments that you would like to share.



NSF and HHS OIG Activity and DOJ Settlements (NEW)

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

Research Ethics and Compliance

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

<u>Drug Enforcement Agency (DEA) Notice of Proposed Rulemaking (NPRM) Reporting of Theft or Significant Loss of Controlled Substances (NEW)</u>

This <u>NPRM</u> proposes the following two changes to existing controlled substance regulations that apply to practitioner and non-practitioner registrants, including investigators using controlled substances for research:

- (a) Current regulations do not prescribe a period within which a completed DEA Form 106, *Report of Theft or Loss of Controlled Substances* must be submitted to the DEA. The proposed rule would require that Form 106 be submitted within 15 calendar days of the discovery of the theft or loss.
- (b) The current regulations do not state how Form 106 must be transmitted to the DEA. Most registrants submit the form online, but some still mail it in. The proposed regulation would require that Form 106 be submitted online.

REC reviewed these proposed changes and did not believe that comments were warranted, as the changes were reasonable.

Animal Research

COGR Response to NIH Request for Information (RFI): Enhancing Rigor, Transparency, and Translatability to Improve Biomedical Research Involving Animal Models (NOT-OD-20-130) (UPDATE)

COGR submitted a <u>response</u> to this RFI on August 19, 2020. COGR's response was supportive of NIH's efforts to improve the quality, transparency and translatability of animal research but urged NIH to pilot any research pre-registration process with the research community prior to implementation. COGR also encouraged NIH to explore opportunities to strengthen current review processes, while ensuring that any additional processes that may be implemented truly add value. COGR urged NIH to work with institutions



and associations in demonstrating to the public the necessity of and support for animal research. COGR also advocated that NIH support journals in their efforts to enforce the use of existing standards for the proper planning and preparation of studies such as the <u>PREPARE guidelines</u>, as well as standards for animal research reporting (e.g., the <u>ARRIVE guidelines</u>).

<u>Virtual Public Meetings on the Issue of Establishing Animal Welfare Act (AWA) Standards for Birds</u> (NEW)

The AWA permits the U.S. Department of Agriculture (USDA) to regulate birds that are not bred for use in research, and the USDA will hold <u>virtual public meetings</u> this autumn to collect information that will be used to develop AWA standards for birds. It is not clear from the notice's description how these proposed standards will affect research on wild-caught birds, and COGR will attend one of the meetings to collect additional information. REC also will collect information from institutions that conduct this type of research to ensure that concerns around potential standards are understood.

Office of Laboratory Animal Welfare (OLAW) RFI Seeking Comments on *Flexibilities for Conducting Semiannual Animal Facility Inspections* (NOT-OD-20-145) (NEW)

OLAW has identified the issue of semi-annual animal facility inspections as an area in which administrative burden for animal care and use programs may be decreased. In this RFI, OLAW has highlighted flexibilities available to IACUCs in conducting semi-annual inspections, including rolling inspections processes, use of consultants and/or subcommittees to conduct inspections, and use of photos, videos and written descriptions in carrying out inspections in some circumstances such as field studies. OLAW is seeking comments on these flexibilities, and REC has convened a subgroup that will draft and submit comments. Comments are due October 22, 2020.

OLAW RFI on *Clarification of Institutional Responsibilities Regarding Grant to Protocol Congruency* (NOT-OD-20-153) (NEW)

Institutions are required by the <u>PHS Policy on the Humane Care and Use of Laboratory Animals</u> and the <u>NIH Grants Policy Statement</u> to conduct a congruency review between grants/contracts and animal research protocols to ensure consistency. Generally, this congruency review is conducted by an institution's IACUC, although it could be conducted by another institutional unit. OLAW has identified this area as one in which there may be opportunities for reduction of administrative burden and has requested comments on institutional responsibilities for conducting grant to protocol congruence review. REC has established a subgroup that will draft and submit comments. Comments are due October 29, 2020.



OLAW Updated FAQ on Research Animal Adoption (NEW)

In July, OLAW updated its <u>FAQ</u> on research animal adoption to make clear that research animals no longer required for a study are considered supplies, and applicable institutional policies should include adoption of former research animals as pets as an acceptable means of property disposition after research has ended.

Human Subjects Research

OHRP Guidance on Elimination of IRB Review of Research Applications & Proposals (NEW)

On July 20, 2020, OHRP <u>issued guidance</u> which states that Institutional Review Boards (IRBs) are no longer required to review research grant applications or proposals for non-exempt human subjects research that is subject to the July 19, 2018, version of the Common Rule. IRBs must continue to review the research protocol itself, and the institution must certify to HHS that this review has occurred.

FDA Final Guidance Documents (UPDATE)

The FDA issued several final guidance documents in July and August that impact clinical trials including the following:

- Final Guidance Regulatory Considerations for Human Cells, Tissues & Cellular & Tissue Based Products: Minimal Manipulation & Homologous Use: This guidance sets forth the standards that FDA will apply in determining when Human Cells, Tissues and Cellular & Tissue Based Products (HCTPs) should be treated as unapproved new drugs and require a IND in order to conduct research using them. The guidance also extends FDA's period of enforcement discretion for requiring an IND or a marketing application until May 31, 2021.
- FDA Guidance Documents Concerning Eligibility Criteria for Cancer Clinical Trials: The FDA issued the following final guidance documents that make recommendations to sponsors and sponsor-investigators about including in cancer clinical trials participants with certain conditions, as well as pediatric participants, who are typically excluded by eligibility criteria from participating:
 - o <u>Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or</u> Prior or Concurrent Malignancies



- <u>Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections</u>
- <u>Cancer Clinical Trial Eligibility Criteria</u>: <u>Minimum Age Considerations for</u> Inclusion of Pediatric Patients

Contracts and Grants Administration

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

On June 11, 2020, NIH published Notice 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. COGR has had discussions with NIH concerning problems that institutions are encountering in implementing the following Guidance requirement: "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)." Although initial discussions with NIH have not resulted in clarifications of this notice's language, REC is planning to invite NIH personnel to attend a joint CGA-REC meeting to discuss implementation concerns and potential solutions.

FDA Draft Guidance Regarding Cannabis and Cannabis-Derived Compounds: Quality Consideration for Clinical Research Guidance for Industry (NEW)

The FDA issued draft guidance on July 22, 2020, for parties interested in pursuing scientific research and development of drugs containing compounds derived from cannabis, indicating that the drug development and review process for drugs using cannabis and cannabis-derived compounds is no different than the process for drugs containing any other substance. The FDA recommends that persons interested in conducting research and development using hemp consult with the DEA as THC levels may rise above the 0.3% limit of hemp, making the substance illegal and subject to schedule I of the Controlled Substances Act (CSA). DEA's draft guidance primarily seeks comments on the calculation of THC and manufacturing processes that fall under the 0.3% threshold set by the 2018 Farm Bill (the Agriculture Improvement Act of 2018, Public Law 115-334). COGR will be discussing this with its cannabis and hemp working group to determine if comments should be submitted. Comments are due September 21, 2020.

DEA Issues Interim Final Rule Implementing the 2018 Agricultural Improvement Act (NEW)

Effective August 21, 2020, the DEA issued its <u>Interim Final Rule</u> (IFR) to implement changes made under the 2018 Farm Bill (the Agriculture Improvement Act of 2018) regarding controls over marihuana and marihuana-related compounds. DEA indicates that the IFR merely conforms DEA's



regulations to the statutory amendments to the CSA that have already taken effect and does not add additional requirements to the regulations. The four conforming changes are as follows.

- Revises the definition of "Tetrahydrocannabinols" in Schedule I of the CSA by qualifying that the term, as used in Schedule I, does not include any material, compound, mixture or preparation that falls within the definition of hemp established by the 2018 Farm Bill.
- Removes FDA-approved products containing CGD from control under Schedule V (e.g. Epidiolex).
- Removes FDA-approved products containing CBD from the list of substances requiring import and export permits from the DEA.
- Modifies the definition of "Marihuana Extract", limiting it to extracts "containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis."

One significant concern is whether and how the DEA will enforce materials in excess of the 0.3% THC threshold during the processing stage when content can easily exceed 0.3% THC prior to dilution or when the cannabis materials for research purposes are not further distributed. COGR's cannabis/hemp workgroup will discuss how best to respond. Comments are due October 20, 2020.

Department of Defense (DoD) Terms and Conditions (NEW)

On August 19th, DoD released the fifth and sixth final rules out of a sequence of six published in the Federal Register for purposes of updating the DoD Grant and Agreement Regulations (DoDGARs). The fifth rule, <u>Definitions for DoD Grant and Agreement Regulations</u>, provides definitions common to DODGARs along with a central location for the definitions. The sixth rule, <u>Award Format for DoD Grants and Cooperative Agreements</u> establishes a standard format for organizing the content of DoD Components' awards of grants and cooperative agreements and modifications to them. Both rules are effective October 19, 2020.

National Science Foundation (NSF) Proposal & Award Policies & Procedures Guide (PAPPG) Frequently Asked Questions (FAQs) (UPDATE)

On August 28, 2020, NSF released <u>NSF's FAQs</u> on proposal preparation and award administration related to the <u>PAPPG (NSF-20-1)</u>. The FAQs are in addition to the <u>Current and Pending Support FAQs</u> NSF released, most recently updated on July 30, 2020. If you have questions or concerns regarding the FAQs, please contact Jackie Bendall at <u>jbendall@cogr.edu</u>.



COGR would like to thank COGR Board Chair David Norton (University of Florida) and the COGR Committee members for their time, dedication, and expertise, without which the efforts and activities conveyed in these updates would not be possible.

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