COGR

An Association of Research Institutions

JUNE 2022 UPDATE

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Announcements

Launching This Summer: COGR's Membership Portal

This summer, COGR will be launching a new COGR Membership Portal that will provide COGR members with the ability to update their contact and institutional information, access membership invoices, view members-only materials (including a video library with past meeting recordings!), register for meetings and webinars, sign up for our listserv, and much more. If you are your institution's primary representative, your account is already active in the system, and for everyone else, it's a very short sign-up process. More to come, but in the meantime, if you haven't seen it already, a short trailer is available on our website here (have your volume on and press play). Contact memberservices@cogr.edu with any questions and stay tuned!

Science & Security: Cross Cutting

Department of Education Holds Webinar on Section 117 (UPDATE)

On June 23, the Department of Education (ED) hosted an invitational webinar on Section 117 reporting. COGR and other higher ed. association staff and several institutional representatives participated.

At the outset, the ED representatives stressed the need for collaboration with higher ed. institutions in assuring 117 compliance. They recognized and acknowledged challenges related to the functionality of the reporting portal. Responsibility for 117 reporting is being transferred from ED/OGC to the Federal Student Aid (FSA) office. It is hoped that the reassignment of responsibility will lead eventually to the availability of more resources to address the portal issues. This will be a priority for FSA, but there is no firm timeline. ED believes the pending legislation which includes increased 117 reporting is likely to pass. This will add to the urgency. OGC currently is reviewing the status of each of the open investigations and will follow up with institutions, as necessary.

A PPT presentation by various ED representatives followed, addressed to many of the questions previously submitted (see COGR May 2022 Update). We will not attempt to summarize all of the questions addressed but will highlight a few of the responses. Many of the responses referred back to the February 2020 ED Information Collection Request (see COGR February 2020 Update). On questions that may be of particular interest to COGR members, ED expects institutions to exercise "reasonable due diligence" to determine foreign sources of gifts or contracts. This may involve going to the counterpart party directly or doing independent research, but the expectation is that institutions will make good faith efforts. On the question of U.S. subsidiaries, the exercise of control by the foreign parent is key. Reasonable valuation methodology should be used to determine the value of indeterminate gifts or contracts. Clinical trials are reportable, but reports submitted to other federal or state regulatory authorities may be used for 117 reporting if they contain substantially similar information. There is no distinction

between contracts and subcontracts; if the prime contractor is acting as an agent of the foreign source, the sub must report the contract. This may depend on the degree of control the foreign source exercises over the prime. With regard to intermediaries (e.g., university foundations), they are not required to report but the institution must report if the foreign gift or contract is received by the intermediary for the direct benefit of the institution.

Additional questions, or questions on the points covered in the presentation, should be sent to Bob Hardy of the COGR staff who will send on to ACE. Questions regarding the portal should be sent to foreigngiftaccess@ed.gov. ED promised to acknowledge all such requests within 5 days.

ED will send copies of the PPT to the associations. We also requested copies of the transcript. We will share these materials with COGR members once we receive them.

USICA/COMPETES Legislation May Be Narrowed (UPDATE)

Over the past year, COGR Updates and Meeting Reports have discussed the pending USICA/COMPETES legislation. The legislation includes a number of research security provisions of concern. It currently is under negotiation between the House and Senate (see May 2022 COGR Update).

Recent news reports have indicated that House and Senate leaders may try to narrow the scope of the USICA negotiations in an attempt to pass the package before the August Congressional recess. According to these reports, the negotiations seem to be increasingly focused on funding to boost chip manufacturing and NSF, as well as research security.

It is not clear which of the research security provisions might be included in the final package. However, on June 15, the President of AAU sent a letter to House and Senate leaders expressing concern about the Higher Education Act (HEA) Section 124 reporting requirement established by Section 6124(b) of S. 1260 (USICA). As we previously reported, this provision would create a new mandate requiring all university personnel to report to a publicly accessible data base any gifts from, or contracts with, any foreign source, with no dollar threshold. As discussed in the AAU letter, this requirement would result in greatly increased burden on institutions with little benefit to research security. It also increases the likelihood of inadvertent reporting errors and the potential for harassment of individual faculty and staff. The effect would be to discourage international collaborations and research relationships. The AAU letter also includes a series of questions about the scope and intent of the requirement.

July 4 remains the target date for agreement. If not passed before the August recess, chances of passage dwindle afterwards.

Recent Developments Regarding Implementation of the Presidential Memorandum on United States Government-Supported Research and Development National Security Policy (UPDATE)

Institutions continue to await the OSTP's publication of disclosure forms and instructions, as well as research security program standards. To facilitate alignment with the NSPM-33 Implementation Guidance's outline of disclosure requirements, agencies, including NIH, NSF, and DOE, have issued new and/or modified existing documents detailing biosketch and current and pending/other support disclosure requirements. Information regarding these documents can be found in the CGA section of this report.

Cost of Compliance, Research Security, NSPM-33: Friday Session – June COGR Meeting (NEW)

At the June 10 COGR Meeting, we presented a members-only session titled Research Security and the ROI. This session built upon the COGR "Research Security Costing Model Survey" study, with a focus on results from the survey and addressing these important questions:

- We support the federal efforts to promote research security, but costs are substantial, and the question of "how to pay?" should be contemplated with our federal partners.
- Further, should the "how to pay?" question be considered within the context that research security is a national security issue? If so, federal government participation in the cost burden is even more necessary.
- ROI—Agencies seem to be focused on enforcement numbers. Is "security" the "return," or is it "transparency"? Are case numbers the correct "return" metric?
- Will cost implications create barriers to entry for some, particularly smaller and mid-sized institutions?

Institutions have made significant investments in response to federal concerns regarding research security, including additional agency and NSPM-33 requirements designed to promote full disclosure of information that may bear on conflicts of commitment and/or interest. In light of these investments, the questions raised in the session are important and the survey results will help to provide answers. Twenty-six institutions have participated in Phase I of the survey, focusing on the cost impact of the new researcher disclosure requirements (Phase II will focus on implementation of the institution's research security program per OSTP's forthcoming guidance on NSPM-33). COGR is in the process of finalizing results from Phase I and plans to complete an analysis of the survey results this summer.

If you have questions on this topic, please contact Kris West at kwest@cogr.edu and/or David Kennedy at dkennedy@cogr.edu.

COGR Presentation to the National Science, Technology, and Security (NSTS) Roundtable (NEW)

COGR has been asked to appear at the June 29th meeting of the NSTS Roundtable on *Academic Perspectives on Promoting and Protecting Science and Technology Research and Advancing International Engagement.* COGR President Wendy Streitz, along with two other association representatives, will provide a brief presentation, and then engage in discussion, on the following topics:

- Promoting and protecting US-sponsored scientific research as a national security asset
- Foreign engagement and access to foreign STEM talent
- Accessing current and reliable foreign threat assessments and mitigation
- Establishing relationships between scientists and security professionals

HHS OIG Report "Opportunities Exist to Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support" (NEW)

In June 2020, HHS OIG published "Opportunities Exist to Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support", analyzing the results of the survey that it sent to NIH-funded research institutions in October 2020. The survey was received by a number of COGR member institutions, and COGR provided assistance with obtaining an extension of the deadline by which institutions were required to respond. The survey sought information about institutions' requirements for investigators to report sources of "other support" and "significant financial interests" (SFIs) per the PHS regulations for promoting objectivity in research at 42 C.F.R Part 50, Subpart F ("FCOI Regulations").

The survey was administered to 773 grantees and had a response rate of 80%. Only one-third of responders were comparable in funding size to COGR members, with 207 responses received from institutions with more than $10 million in annual NIH funding ("Larger Grantees") and 410 received from institutions with less than $10 million in annual NIH funding ("Smaller Grantees"). All grantees received the same survey questions, but 100 Larger Grantees received a "Detailed" version of the survey that also requested policy and procedure documentation.

The report pointed out several ways in which NIH recipients were out of compliance with NIH FCOI and Other Support disclosure requirements or best practices and stated that "[m]ore than two-thirds of grantees failed to meet one or more requirements for investigators' disclosure of all foreign financial interests and support." In some cases, the report seemed to take an unnecessarily negative view of the survey data, such as in the following statement:

> Nearly a quarter of grantees were not in compliance with Federal requirements to train investigators about their responsibility to disclose foreign financial interests. Specifically, 23 percent of grantees (140 out of 609) did not require investigators to complete all NIH-required training, and over half of these (81 out of 140) also did not require or offer any other training regarding disclosure of foreign financial interests.

Written differently, these numbers show that 87% of institutions **do** require or offer training regarding disclosure of foreign financial interests. Further, when viewed in light of the survey question's possible response categories (below), it is unclear what is meant by the phrase "all NIH required training":

a. Our institution requires investigators to complete financial conflict of interest training prior to engaging in research related to any NIH-funded grant
b. Our institution requires investigators to complete financial conflict of interest training at least every 4 years
c. Our institution requires any other trainings for investigators containing information about self-reporting all of their significant financial interests
d. Our institution offers voluntary trainings (e.g., presentations, online resources, or education materials) to investigators containing information about self-reporting their significant financial interests

Indeed, multiple institutions reported difficulty in interpreting survey questions, many of which focused on distinguishing between foreign and domestic sources of other support and SFIs, even though NIH does not require such distinctions.

It is also important to note that at the time the survey was administered, NIH guidance regarding the various components of other support (e.g., in-kind support, students, etc.) was still in development, as shown in Appendix I of this Update.

One note of concern was the OIG's finding that "almost half of grantees did not comply with disclosure requirements for non-publicly traded equity interests from foreign entities", meaning researchers are required to disclose any equity in a US non-publicly traded entity, but not interests in a non-US non publicly traded entity. Members should review their disclosure policies to ensure that disclosure of interests in non-US entities is required. We also urge members to review their training requirements to ensure that researchers receive FCOI training at least every four years in accordance with NIH policy.

Although the report noted that institutions are not addressing certain activities that are required by existing regulations, it also found fault with institutions not performing activities that NIH regulations and guidance do not currently require. For example, most institutions do not and are not required to ask investigators to distinguish in reports between foreign and domestic SFIs/other support. NIH does not

currently require that institutions have prescribed methods to verify information that investigators have reported.

Overall, HHS OIG provided the following recommendations to NIH, with which NIH has concurred:

- Ensure grantees comply with federal requirements to train investigators on the disclosure of SFIs and review SFIs that are disclosed for FCOIs.
- Require grantees to provide training and maintain a written policy regarding the disclosure of other support.
- Modify requirements to require grantees to indicate when SFIs and other support involve foreign entities.
- Conduct outreach to R13 conference grant recipients to ensure that they understand that they must comply with other support and SFI disclosure and review requirements.
- Clarify whether and how grantees should verify SFIs and other support before submitting information to NIH.
- Establish a method for grantees to share best practices for identifying/reviewing other support and SFIs.

REC and CGA are currently performing a detailed analysis of the survey report and intend to reach out to HHS OIG to see if would be willing to meet with COGR and provide additional information about the survey methodology and analysis, as well as any plans for follow-up surveys.

Meeting with National Security Council Representatives Regarding Malign Foreign Influence (NEW)

On June 14, COGR staff and representatives from other higher education associations met with representatives from the National Security Council (NSC) and OSTP to discuss the topic of malign foreign influence. The meeting was led by Amrit Bagia, Director of the NSC's Countering Foreign Malign Influence. Prior to the meeting, attendees were asked to review the Australian government's Guidelines to Counter Foreign Interference in the Australian University Sector, which covers a wide variety of topics including governance, risk assessment and mitigation, communications and cybersecurity.

The meeting, however, was narrowly focused on threats to free speech of students and faculty members from foreign governments (e.g., a foreign government seeking reprisal against a foreign student studying in the U.S. for making statements critical of the home country). The discussion did not encompass research security, which NSC and OSTP advised was being appropriately addressed via NSPM-33 and associated institutional efforts.

Associations advised that their members have not relayed much in the way of concerns or information on this topic but acknowledged that students and faculty may be reluctant to bring such situations to the institution's attention. Associations also noted that in many circumstances, institutions would not be able to provide appropriate protections to students/faculty given the involvement of foreign governments. Rather, institutions would look to the U.S. government in this regard. Associations agreed to discuss the issue further with their members and to determine how it might be possible to gather more data on the extent of this problem.

Updated NIH Disclosure Requirements (UPDATE)

On June 8, NIH posted an update to the Other Support and Biographical sketch disclosure chart. This update includes several new statements about what does not require disclosure. A comparison of the December 10th chart and this new chart can be found on the COGR website. NIH continues to move towards harmonization with the NSF disclosure requirements. Note that DOE and DOD are also moving towards harmonization with NSF, although there are still differences. Institutions await the OSTP's publication of disclosure forms, instructions, and research security program standards.

DOE Disclosure Requirements for Current & Pending Support (UPDATE)

On June 1, the Department of Energy issued PF 2022-32 Department of Energy Current and Pending Support Disclosure Requirements for Financial Assistance, directing program officers to implement new disclosure requirements for DOE and NNSA awards. Program officers will implement the provisions in new funding announcements effective immediately.

Several new provisions align the DOE requirements with the federal requirements expressed under NSPM-33, including:

- a reminder about the need to disclose participation in foreign talent recruitment programs
- requirement for senior/key personnel to certify the accuracy of the current and pending support, although no specific method for certification is mentioned, so institutions have flexibility
- a requirement to report past support on an as-needed basis as required in new award announcements, although DOE states that this requirement may not apply to fundamental research awards where the results have been published

However, the policy also requires recipients to report any changes in Current and Pending Support to the DOE within 30 days of a change, including situations when a previously reported pending proposal was funded or when senior/key personnel submit a new proposal. This requirement appears overly burdensome and is out of step with NSF and NIH requirements, which call for updating other support as part of the annual progress report. As discussed during Michael Zarkin's[1] presentation during the June

[1] *Director, Office of Grants and Contracts Support, Office of Science, DOE*

meeting, members should consider requesting that DOE revise this requirement in their awards to limit updates of Current and Pending Support to once a year, in the annual progress report, except in situations where an element of Current and Pending Support should have been reported but was not.

Research Security & Intellectual Property Management (RSIP)

Selected RSIP Committee activities related to Science & Security are reported above under the Cross Cutting Issues section of the COGR Update.

Export Control Developments

Russian Sanctions (UPDATE)

The March Update discussed the sanctions against Russia and Belarus in response to its invasion of Ukraine. This is a fluid situation with new sanctions announced frequently over the past several months[2]. The aviation and energy sections have been particularly targeted. In April, 120 entities were added to the BIS Denied Entity list and earlier this month an additional 71 entities were added, including Russian Academy of Science entities. OFAC also has issued sanctions against individuals and entities.

For COGR member institutions, any activities with a Russian "footprint" are currently problematic. Essentially, export of any item on the EAR control lists requires a license. In addition, any transfer of funds to Russian individuals or entities (e.g., payment of patent license costs) presents difficulties.

Penn Export Controls Conference (NEW)

On May 2-3, the University of Pennsylvania hosted a conference on Export Controls and Research Security at Higher Education and Scientific Institutions. The conference was widely attended both by security and funding agencies, including BIS, State, ODNI, OSTP, NSF and DOD. One interesting aspect was much discussion between the agencies on the implications of agency terms and conditions on export controls.

Another interesting aspect was the BIS presentation on Emerging and Foundational Technology Controls. Since enactment of the 2018 Export Control Reform Act (ECRA), BIS has issued 38 emerging technology controls, mostly on a multilateral basis. However, the point was made that BIS's implementation of controls on emerging technologies pre-dates ECRA in the sense that emerging technologies have always been dealt with through multilateral export control regimes. Technologies continue to evolve. Emerging technology controls are a work in progress.

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[2] *See https://www.bis.doc.gov/index.php/policy-guidance/country-guidance/russia-belarus for a list of the announced sanctions, including FAQs and other resources.*

In November 2020, COGR joined other associations in a letter to BIS expressing concerns about the potential adverse effects of controls on foundational technologies. In the letter, we reiterated that foundational technologies are essential to innovation. We stated that particular care needs to be taken to assure that any controls imposed on such technologies are not unnecessarily broad and do not result in unintended consequences with regard to the further development and use of such technologies and U.S. economic competitiveness. BIS did not specifically respond to our letter. However in a recent proposed rule BIS referred to new technology controls as "ECRA Section 1758 controls", rather than distinguishing "emerging" and "foundational" technologies, and discussed the difficulties with the distinction.

GAO Report on University Research Security and Export Control Enforcement (NEW)

On June 14, GAO published a follow-up report to their 2020 report on Export Control Outreach by State and Commerce (see COGR May 2020 Update). The new report (GAO-22-105727; *Export Controls: Enforcement Agencies Should Better Leverage Information to Target Efforts Involving U.S. Universities*) found that agencies do not base outreach on analysis of universities' risk level or risk factors for sensitive technology transfers. The report is a public version of a previous (March 2022) sensitive report that looked at enforcement challenges particularly related to deemed exports at U.S. universities and enforcement agency coordination and information sharing. The current public report's objective was to examine the extent to which U.S. agencies are assessing universities' risk of unauthorized deemed exports in order to prioritize outreach to universities.

The current report found that agencies base outreach efforts on only one (unspecified) risk factor. Identifying and analyzing any additional relevant risk factors could provide a more complete understanding of universities' risk levels and could further inform Commerce's, DHS's, and FBI's efforts to target limited resources for outreach to at-risk universities. The report contains a series of recommendations to export enforcement agencies (Commerce, ICE, and the FBI) to "strengthen… (their) ability to prioritize outreach to at-risk universities." All three agencies concurred with the recommendations.

According to the report, DHS/ICE has developed a list of approximately 150 U.S. universities ranked according to their risk of sensitive technology transfers. The report identifies a list of 10 factors that may indicate universities increased risk of sensitive technology transfers. Half of these involve risk factors pertaining to foreign students or scholars; the other half pertain to U.S. universities.

We had not previously been aware that the government had developed a ranked list of U.S. universities based on their risk level. Many of the additional risk factors advocated by GAO apply to most foreign students or universities (e.g., students who study or conduct research at a graduate level; universities that have doctoral programs with high research activities or receive large amount of federal funding). Appendix II of the report discusses non-export-controlled technologies at universities that are targeted by foreign adversaries and the challenges posed by emerging technologies.

The previous GAO report presented university export control compliance in a fairly positive manner. The recommendations to agencies were not of particular concern. The current report is more concerning in its discussion of risks posed by universities and recommendations that enforcement agencies determine which universities are at greater risk for purposes of targeted outreach and education.

New White House Guidance on Scientific Cooperation with Russia (NEW)

On June 11, the White House issued new guidance on scientific and technological cooperation with Russia. The guidance states that the USG will wind down institutional, administrative, funding, and personnel relationships and research collaborations in the fields of science and technology with Russian government-affiliated research institutions and individuals who continue to be employed by or work under the direction of those institutions. Such projects and programs that commenced and/or were funded prior to Russia's invasion of Ukraine in February 2022 may be concluded, but new projects in affected subject areas will not be initiated. Interaction with the leadership of Russian government-affiliated universities and research institutions should be curtailed. The guidance states that "non-government institutions should make their own determinations regarding how to proceed with contact and collaboration between the United States and Russian scientific communities, in furtherance of an open exchange of ideas within the international science and technology community."

NIST To Roll Out New IEdison System (NEW)

We previously have reported on the transfer of responsibility for the iEdison invention reporting system from NIH to NIST and NIST's plan to rebuild the system (see COGR December 2019 Update and June 2020 Meeting Report).

NIST plans to initially roll out the new system in early August. Demonstration videos and user guides will be posted on the iEdison website. More enhancements will follow. The rebuilt system will provide for more notifications, including disclosure acceptances and weekly updates. Late submissions will be flagged. Utilization reporting will be a standard feature for all agencies. The status of domestic manufacturing waiver requests will be included in the system. Ultimately the plan is to integrate and automate the system with PTO filings.

According to NIST, 37 agencies now have joined the system including some that have not previously participated (e.g., FAA). NIST is in discussions with others. NIST has a dedicated budget for iEdison going forward as part of the Lab to Market initiative.

Unquestionably the rebuilt iEdison will be more robust. However, it also may lend itself to greater burden potential for users. Agencies are increasingly interested in technology commercialization and may request much greater reporting on invention status than currently. We will continue to monitor activities as the rollout of the new enhanced system proceeds.

New BIO/AUTM Report Shows Increased Economic Impact of Academic Licensing (NEW)

An updated study[3] released on June 14 by the Biotechnology Innovation Organization (BIO) and AUTM shows that academic patent licensing contributed up to **$1.9 trillion** to the U.S. economy while supporting **6.5 million jobs** between 1996 – 2020. This impact increased substantially since the last survey was released three years ago which showed an economic impact of $1.7 trillion with 5.9 million jobs supported. This is especially striking since the study includes the year 2020 when COVID-19 largely shut down the U.S. economy.

WTO Waiver of IP Rights to Covid Vaccines Raises Concerns (NEW)

On June 17, the World Trade Organization announced a decision to adopt a temporary TRIPS waiver on intellectual property rights to COVID-19 vaccines. The agreement provides for compulsory licensing of such vaccines by developing countries without the agreement of patent holders. However, the waiver includes a number of clarifications and conditions that limit its scope, and language that appears to exclude China from taking advantage of the waiver. It also does not cover trade secrets.

Many patent stakeholder groups including the Bayh-Dole Coalition, BIO, PhARMA, and the U.S. Chamber of commerce immediately criticized the decision as discouraging innovation and setting a harmful precedent[4].

Cybersecurity Developments

EDUCAUSE Engagement Session with OSTP on NSPM-33 (NEW)

COGR was invited to participate as an observer in an EDUCAUSE engagement session with OSTP on June 6. Much of what was presented reflected other presentations, including at COGR. There was an emphasis on the need to tailor cybersecurity requirements to the risk level of particular research activities. Harmonization in terms of the need for a standardized risk management framework is needed, but this should not result in standardized controls applying to all research (as in a FAR-like checklist of compliance requirements). Another big emphasis was on non-discrimination, with references both to persecution of Chinese faculty and the need not to create heightened barriers to participation by minority-serving and emerging research institutions. This may be a particular challenge with cybersecurity.

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[3] *An accompanying press release is at https://www.bio.org/press-release/licensing-academic-patents-contributed-19-trillion-us-economy-supported-6.5-million*

[4] *See e.g. https://www.bio.org/press-release/wto-decision-waiving-intellectual-property-rights-distraction-real-work-needs-be-done and https://bayhdolecoalition.org/bayh-dole-coalition-statement-on-wto-decision-to-suspend-global-ip-rights/*

CMMC (UPDATE)

The CMMC Accreditation Body has been rebranded as "The Cyber AB." Its responsibilities have not changed. The rebrand in part reflects a desire to grow beyond DOD. The plan also is to spin out the AB's training and professional certification activities into a separate business unit. The CMMC Academic Advisory Council has become active after a slow start. DOD has moved up the timetable to roll out CMMC 2.0. The new interim DFARS rule now is expected in March.

Revised FTC Safeguards Rule (UPDATE)

Last fall, the Federal Trade Commission published a revised Safeguards Rule (*86 FR 70308*[5]). The Safeguards Rule requires covered financial institutions to develop, implement, and maintain an information security program with administrative, technical, and physical safeguards designed to protect customer information. The Rule's major new provisions will take effect on December 9, 2022.

The institutional role in relation to federal student aid programs under Title IV of the Higher Education Act makes colleges and universities subject to FTC jurisdiction in this area. Meanwhile, the Office of Federal Student Aid (FSA) incorporated Safeguards Rule compliance into the Title IV Program Participation Agreements several years ago. As a result, institutions will have to accommodate FSA's compliance guidance regarding the Rule as well once FSA makes it available (the timeline for which is still unknown). Finally, "student records" constitute CUI under the National Archives and Records Administration CUI regulations, meaning that the NIST SP 800-171 security requirements will eventually apply to student financial aid data, too.

Research Ethics & Compliance (REC)

Selected REC Committee activities related to Science & Security are reported above under the Cross Cutting Issues section of the COGR Update.

Human Subjects Research

Continuing Meetings with OSTP re. Emergency Clinical Trial Agreement (UPDATE)

COGR staff continue to regularly meet with OSTP representatives to discuss the possibility of developing an agreement to help speed the implementation of clinical research in a public health emergency. We will keep the membership posted as this effort progresses.

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[5] *For a review of the changes from a higher education perspective, see the EDUCAUSE analysis from last December, which was updated in March: https://er.educause.edu/articles/2021/12/policy-analysis-revised-highly-prescriptive-ftc-safeguards-rule.*

Secretary's Advisory Committee on Human Subject Research (SACHRP) Regarding "Engagement in Research" (UPDATE)

The REC Committee hosted Mark Barnes, Co-Chair of SACHRP's Subcommittee on Harmonization, at its first in-person meeting in over two years. Mr. Barnes discussed his presentation at the March 11-12, 2022, SACHRP meeting on reinterpreting the term "engaged" in research, as it appears in 45 C.F.R. Section 46.101(a). He noted that "engaged in research" is not a defined term in the Common Rule, but rather has been defined through examples in a series of Office of Human Research Protection guidance documents. [*See*, OHRP, "Engagement of Institutions in Human Subjects Research" (2008); "Determining When Institutions are Engaged in Research" (Jan. 13, 2009); "Correspondence on 'Non-Engaged' Scenarios" (Sept. 22, 2011)]. SACHRP is considering recommending to OHRP the harmonization of the current guidance and the development of an additional exception for entities/individuals who are not key participants in the conduct of the research and whose activities are limited to normal business activities and do not substantively increase risk to participants.

REC believes that a clear definition of the term "engaged in research" would benefit the research enterprise, and it supports SACHRP's discussion of ways in which to limit the definition so that it does not apply to persons only tangentially involved in research. REC members noted that at the height of the COVID-19 pandemic, many studies wanted to involve home health care agencies or pharmacies to reach diverse patient populations. These entities, however, were frequently unwilling to participate if they were considered to be "engaged" in research and thus required to file a Federal Wide Assurance (FWA). Importantly, these entities are generally under the jurisdiction of a single IRB, and thus the requirement of an FWA would not significantly add to the human subject protections that are already in place. REC is drafting a letter to SACHRP and OHRP to support their continuing efforts to develop a clearer and more targeted definition of the term "engaged."

Additional Research Ethics & Compliance Committee Issues (NEW & ONGOING):

At the June 8 meeting, REC members discussed plans for the following new projects:

- **Updating Conflict of Interest (COI) Publication**: The current COGR publication on COI has not been updated in several years, and REC will assemble a working group to review the document and revise it to reflect changes in regulations and the new focus on COI as a part of research security concerns.
- **Research Environment Safety**: There research workspace is undergoing tremendous changes as the relationship between PIs and graduate students/post-docs continues to evolve, and institutions focus on providing an environment free from bullying and harassment. Agencies continue to issue reporting and other requirements designed to promote a safe workspace, both on and off campus

(e.g., conferences). REC, in conjunction with CGA, will be developing a session on this topic for the October meeting, along with a possible paper.

- **Faculty Entrepreneurial Activities**: REC is also considering a session for the October meeting that focuses on changes in the employment model for faculty members from one in which faculty work exclusively for the university to one in which faculty may have multiple appointments associated with entrepreneurial activities with industry and translational research. These changes have the potential to bring about great benefits for institutions, faculty, and students, but they have associated risks, particularly in the area of conflict of commitment and interest.
- **Underrepresented Populations in Clinical Trials**: REC previously heard from FDA representatives regarding the promotion diversity in clinical trial participation, and noted that the National Academies recently published a report entitled *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups.* REC plans to invite a report author to meet with REC members to discuss the report's findings and recommendations.

Costing & Financial Compliance (CFC)

Selected CFC Committee activities related to Science & Security are reported above under the Cross Cutting Issues section of the COGR Update.

Federal Panel and Agency Updates: Thursday Session – June COGR Meeting (NEW)

At the June 9, 2022, COGR Meeting, COGR hosted a session titled Federal Panel and Agency Updates. The panel included ***Jean Feldman*** – Head, Policy Office, National Science Foundation (NSF); ***Michelle Bulls*** – Director, Office of Policy for Extramural Research Administration, National Institutes of Health (NIH); ***Debbie Rafi*** – Director, Contracts, Grants, and Acquisitions, Office of Naval Research (ONR); and ***Gilbert Tran*** – Office of Federal Financial Management, Office of Management and Budget (OMB).

A wide variety of topics was covered, including: 1) status of the NSF Proposal & Award Policies & Procedures Guide (comments have been received and the release date should be October 2022); 2) status of the NIH Grants Policy Statement (going forward, this document—like the NSF PAPPG—will provide the community with public comment opportunities); 3) updates applicable to disclosure requirements, research security, and NSPM-33 status; 4) increased use of non-traditional authorities at ONR and DOD; 5) and a reminder to pay attention to OMB Memorandums M-22-11 (Buy American Preference, per the Infrastructure bill) and M-22-12 (Effective Stewardship, per the Infrastructure bill).

Also of interest was a discussion on the status of 2 CFR 200 (the Uniform Guidance). Legislative actions that impact 2 CFR 200—such as the Buy American Preference, per the Infrastructure bill—require 2 CFR 200 to be updated to incorporate new statutory provisions. While the intent of updating 2 CFR 200 is meant to be narrowly focused on the statutory provisions at-hand, it may be appropriate to comment on other topics. In fact, Debbie Rafi suggested that topics such as the DS-2, the 1.3 percent utility cost

allowance (UCA), and restrictions on F&A reimbursement are appropriate to be raised, especially in light of new cost and administration burden created by recent new compliance requirements (e.g., research security, data management and sharing).

At the conclusion of the session, COGR extended congratulations and warm wishes to Debbie on her upcoming retirement, effective July 31st. Debbie has been a trusted partner and a wonderful friend since she joined ONR in the early 1990s. COGR wishes Debbie all the best!

2022 Compliance Supplement and COGR Response (NEW & ONGOING)

The 1,968 page 2022 Compliance Supplement was posted on May 11th (at least three months early compared to previous years) on the OMB, Office of Federal Financial Management (OFFM) website. Comments on the 2022 Compliance Supplement, as specified in the Federal Register Notice, are due to OMB by July 11, 2022 (late comments will be considered to the extent practicable).

COGR will submit comments to OMB regarding the 2022 Compliance Supplement. In particular, we will again address the longstanding topic applicable to Part 3 – Compliance Requirements, C. Cash Management. At issue is the common practice when institutions request federal reimbursement upon initiation of a payment to a vendor. One version of audit expectation is that the reimbursement request should be made after the vendor processes the payment. This is a problematic expectation and not consistent with standard business practices. Note, this has not been identified as a universal audit concern, but it has been raised by selected auditors. Addressing this in the Compliance Supplement could alleviate this ongoing issue.

The COGR comment letter will be made available on the COGR website in early July. If this issue is of concern to your institution, we encourage you to reference the COGR response and/or provide comments via any one of the following: https://www.regulations.gov/; GrantsTeam@omb.eop.gov; and/or Hai_M._Tran@omb.eop.gov. Comments will be addressed in the development of the 2023 Compliance Supplement.

Some items of note in the 2022 Compliance Supplement are:

- ***Applicability of 2 CFR Part 200 FAQs (p. 28 and p. 1778)***. As COGR requested upon the original release of 2 CFR 200, the FAQs applicable to 2 CFR Part 200 (Uniform Guidance) are recognized in the Compliance Supplement.

- ***Part V: R&D and SFA Clusters (p. 1776 and p. 1781).*** COGR reviews the Compliance Supplement for updates to the R&D Cluster and found there are no significant changes to the R&D Cluster.

- ***Appendix IV: "Higher Risk" programs (p. 1931).*** This section updates the list of COVID-19 programs that have been determined as "higher risk."

- ***Appendix VII: Federal Audit Clearinghouse transition (p. 1959).*** This section provides the timing for the Federal Audit Clearinghouse transition from Census to GSA, effective October 1, 2022.

If you have any other issues or concerns, please contact David Kennedy at dkennedy@cogr.edu. You may also reach out to the OMB Grants Team at GrantsTeam@omb.eop.gov with questions.

Audit Update: Single Audit and Federal Developments (REMINDER)

COGR follows audit developments both on the single audit and the federal Office of Inspectors General (OIG) fronts. Below is a summary of audit developments we are following (each of these also was addressed in the May 2022 COGR Update):

- ***Cost Allocation Services (CAS) and F&A Cost Rates.*** The HHS OIG has listed a new audit initiative: Audit of Cost Allocation Services' Negotiation and Approval of Indirect Cost Rates for Nonprofit Organizations. In its summary of this initiative, the HHS OIG writes: "*Previous OIG audits of nonprofit organizations have raised concerns about the indirect cost rate negotiations and subsequent agreements*." We recommend that institutions that are engaged in F&A cost rate negotiations take note of this backdrop and how it may impact the negotiation process.

- ***Department of Health and Human Services, Office of Inspector General (HHS OIG) Workplan.*** In addition to the CAS initiative above, the HHS OIG Workplan can be followed at the HHS OIG website. Also of interest to some COGR members is a new initiative to look at compliance associated with the Provider Relief Funds and billing requirements for out-of-network patients.

- ***The National Science Foundation, Office of Inspector General (NSF OIG)*** released a report in January titled Promising Practices for NSF Award Management. The report was prepared by NSF OIG contractor Cotton & Company LLP and designed as a resource for the research community to identify "promising practices" gleaned from eighteen separate NSF OIG audits. COGR has raised two concerns: 1) the report does not include management responses, audit resolution, or any other counter to the auditor perspective, and 2) "promising practices" could unintentionally transform into new audit standards. COGR met with NSF OIG officials to share our concerns, and while we were assured the intent was not to create new audit standards, COGR members still should take note of this NSF OIG report.

- ***Resolution to NSF OIG Audit Finding and Following Other NSF OIG Developments.*** We have reported in recent COGR Updates on the favorable resolution as to how F&A rates can be applied to new awards in select situations. An NSF Management Response to an External Audit (see Resolution 19-1-013) affirmed the common institutional policy of using the proposed lower F&A cost rate despite the subsequent negotiation of a new higher F&A cost rate now in effect. This allows proposed direct costs for the PI to be maintained, and there is no harm to NSF. Also

emphasized was the importance of internal controls to ensure that the F&A cost rate applied to a new award does not exceed the F&A cost rate in effect at the time of the award. Other NSF OIG developments and recent audit reports can be found on the NSF OIG Reports & Publications page.

We encourage COGR members to contact COGR when audit issues arise. When appropriate, we can connect institutions and/or provide feedback that may be relevant to the issue at hand.

Retirement of the FCTR by the U.S. Department of Health and Human Services (REMINDER)

Effective April 1st, the U.S. Department of Health and Human Services (HHS) has retired the Federal Cash Transactions Report (FCTR), i.e., OMB Standard Form 272. This was announced in NIH Notice NOT-OD-22-099: *Upcoming Changes to the Federal Financial Report (FFR) Beginning April 1, 2022* (applicable to both NIH and AHRQ). This also was announced HHS-department wide: "*Effective 4/1/2022, HHS grant recipients are no longer required to submit quarterly cash transaction reports (aka Federal Cash Transaction Report (FCTR)*."

This initiative culminates a 5-year+ process of engagement between COGR, NIH, and HHS, and solves the longstanding and problematic reconciliation issue between the FCTR and the Final FFR. It further reduces administrative burden – by cancelling the FCTR, it eliminates the redundant and unnecessary step of completing the FCTR, which became obsolete since HHS/NIH introduced "subaccounts" more than five years ago. COGR appreciates the patient and dedicated work by individuals from NIH and HHS to make this happen.

Costing & Financial Compliance: Other Issues (NEW & ONGOING)

The items below are issues that the CFC Committee has recently reported and/or issues that we continue to follow:

Data Management and Sharing: Cost & Administrative Burden Survey. The Costing Committee, in partnership with the Contracts & Grants Administration (CGA) Committee, is crafting several surveys around the *Final NIH Policy for Data Management and Sharing,* NOT-OD-21-013—effective January 25, 2023. The first survey is anticipated to be a "Rapid Survey" and will be available to the entire COGR membership in July. We will notify the membership via email when it is ready to be accessed.

Proposed NASA Term and Condition Regarding Procurement. COGR sent a Comment Letter to NASA on April 21st raising a concern about a proposed NASA term and condition. ***NASA currently is reviewing all comments and will keep the community posted on developments.*** While COGR fully supports robust and proactive initiatives to expand procurement opportunities for small minority businesses, women's business enterprises, and labor surplus area firms, the proposed term would be problematic on several fronts and be inconsistent with 2 CFR 200.321,

Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms.

Treatment of Procurement and Related Rebates. As we have regularly reported, we believe this issue is resolved, but we will continue to monitor as needed. The issue arose last fall in response to comments made by representatives from Cost Allocation Services (CAS, HHS) at several conferences. At issue was the treatment of rebates associated with institutional p-cards and similar lump-sum procurements, i.e., situations where rebates cannot be identified to individual federal awards with a high degree of accuracy. When a rebate can be identified to an award with a high degree of accuracy, the rebate must be applied to the award. However, when a rebate cannot be identified to individual federal awards with a high degree of accuracy, there should not be an expectation to develop a complex methodology to do so. We summarized many of the nuances related to this issue in the February 2022 Update, and while there are still situations where institutions may have questions on how to address this issue with CAS, the COGR summary from the February 2022 Update should be a helpful resource.

2020 NSF Higher Education Research & Development (HERD) Survey. The 2020 HERD was released on December 27, 2021, and includes the InfoBrief summary and the complete suite of 2020 data tables (which includes the popular *Table 21 – Higher education R&D expenditures, ranked by all R&D expenditures, by source of funds: FY 2020*). Also of interest is *Table 16 – Higher education R&D expenditures, by highest degree granted, institutional control, and type of cost: FYs 2010-20.* Table 16 includes data on recovered and unrecovered indirect costs, in aggregate, for all institutions. For FY2020, the total recovered indirect costs were almost $14 billion and the total unrecovered indirect costs were $5.7 billion.

Please contact David Kennedy at dkennedy@cogr.edu to further discuss any of these issues above, or other items that you would like to address.

Contracts & Grants Administration (CGA)

Selected CGA Committee activities related to Science & Security are reported above under the Cross Cutting Issues section of the COGR Update.

NIH Data Management and Sharing June Meeting Panel Session (UPDATE)

COGR hosted a panel discussion led by experts currently assisting PIs with the implementation of data management and sharing plans. The panelists were Twila Reighley, Associate Vice President for Research and Innovation at Michigan State University; Cynthia Hudson Vitale, Director, Scholars, and Scholarship at the Association of Research Libraries (ARL); and Yvette Seger, Director of Science Policy at the Federation of American Societies for Experimental Biology (FASEB).

Panelists described resources and approaches for complying with the new NIH requirements. The ARL and FASEB sites have numerous resources to help institutions, particularly principal investigators, with the requirements. The panel also discussed how the implementation is progressing from the standpoint of the sponsored research office. Finally, the panel included an update on the work of the COGR NIH DMS Working group, including a new Readiness Guide, which has been released on COGR's NIH DMS webpage. Chapters on "Getting Started" and a summary of the NIH policies are already released. Additional chapters will be released over the summer. As part of this initiative, COGR seeks volunteers to participate in the data management and sharing costing survey (discussed further in the Costing and Financial section of this Update).

National Science Foundation Proposal and Award Policies and Procedures Guide (PAPPG) (NSF 23-1) (UPDATE)

As previously reported, the NSF issued its annual PAPPG for review and comment, with a planned implementation date of January 2023. COGR responded to the NSF based on feedback from the members. NSF proposes several changes to fully implement Research.gov and retire Fastlane.gov for proposal submission effective January 2023. The revised PAPPG also includes changes to implementations for NSPM-33, and several additional changes, including:

- the required use of SciENcv for all biosketches and current & pending support for all senior/key personnel, and their certifications to the accuracy and completeness of the information
- submission of updated current and pending support information before award
- multiple references to NSPM-33 requirements (e.g., research security and penalties for non-compliance) that align with the White House memo
- introduction of two new tools for submissions to NSF - ProSPCT for submission of concept outlines for several programs (e.g., RAPID and EAGER); and the new BAAM tool for responding to Broad Area Announcements issued by NSF, which are being implemented due to the expansion of the types of collaborations expected under the new NSF TIP Directorate.
- required inclusion of a new plan to protect against harassment for off-campus projects: Plan for Safe and Inclusive Field/Vessel/Aircraft Research
- several clarifications to current policies to align the PAPPG with current practices

NSF included a high-level summary of the proposed changes as part of its NSF virtual conference. NSF plans to issue final guidance in October 2022 for a January 2023 implementation.

Other Transactions Authority (UPDATE)

CGA continues to monitor the increased use of Other Transactions (OTs) as an award mechanism for federal awards. CGA hosted a meeting with Dr. Traci Heath Mondoro, Chief, Translational Blood Science and Resource Branch of NHLBI, during the June Committee meeting, where we discussed NHLBI's use

of OTs for the sickle cell anemia project. The initiative involved four teams, each involving several traditional and non-traditional recipients, including industry, community partners, universities, and hospitals. The OTs facilitate these unique collaborations and include funded and non-funded collaborations. Dr. Mondoro discussed the need for institutions to consider what terms they would tolerate in order to engage in an OT and ways of emphasizing what they bring to the table to help the rest of the collaboration. In addition, institutions should discuss with NIH the risks the institution identifies and consider opportunities not currently available under the grant and contract model.

CGA is the process of forming a workgroup to develop guidance for member institutions to consider when negotiating OT terms and conditions. CGA will launch this workgroup over the summer.

Grant & Contract Administration: Other Issues (NEW & ONGOING)

The items below are issues that the CGA Committee has recently reported and issues that we continue to follow:

> ***Reporting Harassment***. Several federal agencies have issued policies related to situations when an investigator has been removed from their position or disciplined due to harassment. NIH is the latest agency to announce such measures. Federal funding agencies approach these matters differently but reporting often must be completed on a relatively short timeline (e.g., 30 days). In addition, the process typically calls for coordination between human resources, the general counsel's office, and grant and contract administrators to notify the agency. CGA will be analyzing this issue to determine how COGR can assist institutions in complying.
>
> ***Diversity, Equity, and Inclusion***. CGA continues to monitor federal agency implementation of diversity and inclusion programs. Most recently, NIH has issued two calls for comment, and COGR's response letters[6] are posted on the website. In addition, we continue to monitor agencies' actions regarding improvements in access.

[6] *See COGR's April 3, 2022 letter in response to NIH's RFI on Suggestions on the Drat NIH Chief Officer for Scientific Workforce Diversity Strategic Plan for FY 2022-26 (NOT-OD-22-061) and COGR's April 14, 2021 letter in response to NIH's RFI on Suggestions to Advance and Strengthen Racial Equity, Diversity, and Inclusion in Biomedical Research and Advance Health Disparities in Health Equity Research (NOT-OD-21-066)*

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.

Contracts & Grants Administration (CGA)

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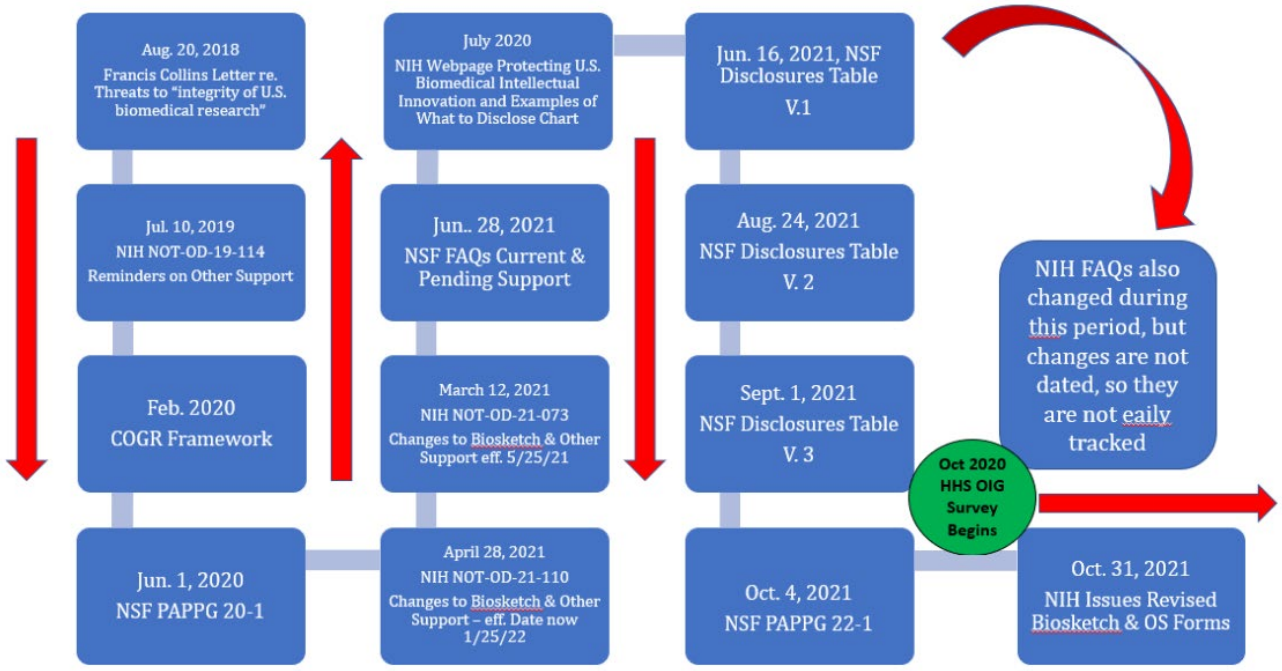
Appendix I

NIH & NSF Disclosure Guidance Timeline – Page 1 of 2



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