COGR

NOVEMBER 2022

NIH Data Management and Sharing Policy: Cross Cutting Issues

Science & Security: Cross Cutting Issues

Research Security & Intellectual Property (RSIP)

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NIH Data Management and Sharing Policy: Cross Cutting

NIH Data Management and Sharing (UPDATE)

COGR's NIH Data Management and Sharing Readiness Guide has been updated to include Chapter 3 Part II: Implementation Roles & Responsibilities - Roles & Responsibilities Matrix. The Roles & Responsibilities matrix provides a comprehensive listing of the key activities throughout the lifecycle of Data Management & Sharing detailing the various stages in the process to support an institution's implementation of the NIH DMS Policy. Institutions are strongly encouraged to customize this tool based on the profile of the organization (e.g., organizational hierarchy, level of decentralization).

Additionally, the DMS working group released version 3.0 (released October 20, 2022) of the NIH Data Management and Sharing Policy Matrix to include three new NIH Supplements regarding sharing human participant data (NOT-OD-22-198, NOT-OD-22-213, and NOT-OD-22-214) and two changes to NIMH policy (NOT-MH-23-100 and NOT-MH-23-105). Please visit our resource page for more information on the NIH Data Management and Sharing Policy, including COGR and external resources.

We like to acknowledge the workgroup members who volunteer their efforts to this important initiative. The workgroup continues to develop materials for the remaining chapters and we will keep the membership updated on releases.

If you have questions about the Institutional Considerations document (Part I), the Matrix (Part II) or other feedback, please contact Krystal Toups at ktoups@cogr.edu.

NIH Data Management & Sharing Panel: Thursday Session at October COGR Meeting (NEW)

At the October 20, 2022, COGR Meeting, COGR presented a session[1] titled *Data Management & Sharing: Making Progress to January 2023.* The session was presented in two parts:

> **Institutional Perspective.** This discussion was led by Michelle Christy-COGR Partner; Jim Luther–COGR Partner, and David Kennedy–COGR Staff. The focus was institutional readiness, costing considerations, and advocacy.
>
> **NIH Perspective.** Michelle Bulls–Director, Office of Policy for Extramural Research Administration, National Institutes of Health (NIH) led this part of the discussion.

While there clearly are challenges institutions will face over the next several months in preparation for the January25 "go-live date" of the *Final NIH Policy for Data Management and Sharing* (and beyond), Michelle Bulls reiterated the NIH commitment to ongoing dialogue with research institutions and reasonable enforcement standards during the first year of implementation. Further, NIH is committed to

[1] *Session recordings are available to registered attendees.*

initiating an FDP demonstration project in 2023, which will be designed to identify issues and challenges during the policy implementation.

COGR will continue to develop educational resources and do advocacy leading up to, and after, implementation of the NIH policy. Contact Krystal Toups (ktoups@cogr.edu) and/or David Kennedy (dkennedy@cogr.edu) with questions or concerns.

Cost Impact: NIH Data Management & Sharing Policy Survey (UPDATE)

The Costing and Financial Compliance (CFC) Committee and the Contracts & Grants Administration (CGA) Committee have begun data analysis on the *Cost Impact: NIH Data Management & Sharing Policy Survey*. Thirty-four institutions completed the survey, and we are thankful for your participation! We presented initial findings at the Data Management & Sharing Panel session at the COGR meeting and expect to share additional findings soon. We will keep the Membership updated on all developments.

Science & Security: Cross Cutting

Research Security & Cost of Compliance: REPORT IS AVAILABLE (NEW)

After providing an update at the October COGR Meeting on the *Research Security and the Cost of Compliance, Phase I: Results from the Initial Phase of COGR's Survey on the Costs of Complying with Research Security Disclosure Requirements*[2] paper, it is now available to the COGR Membership. The paper went through a significant process of critical review and data analysis, with the intent of presenting results and conclusions that are both statistically sound and representative of the real cost impact on research institutions. Our primary finding is this:

> *The projected year one, average total cost per institution for compliance with the Disclosure Standards, regardless of institutional size, is significant and concerning. The figure ranges from an average of over $100,000 for smaller institutions to over $400,000 for mid-size and large institutions. Although some of these expenses are one-time costs, a sizeable portion will be annual recurring compliance costs. Overall, the cost impact to research institutions in year one is expected to exceed $50 million. Further, all research institutions will experience significant cost burden and administrative stress, and smaller research institutions with less developed compliance infrastructure may be disproportionately affected.*

The next steps will involve sharing and promoting the paper with various stakeholders, and we will keep the membership updated on all developments. If you have questions or concerns, please contact Kris West at kwest@cogr.edu or David Kennedy at dkennedy@cogr.edu.

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[2] *COGR's resource page on Science & Security can be found here: https://www.cogr.edu/cogrs-resource-page-science-and-security*

NSPM-33 and CHIPS & Science Act Research Security Provisions (UPDATES)

At the October 2022 COGR membership meeting, Rebecca Keiser, NSF Chief of Research Security Strategy and Policy, and Christina Eller, OSTP Asst. Director for Evidence and Policy, provided updates on the continued implementation of NSPM-33's disclosure and research security requirements and research security requirements included in the CHIPS and Science Act (P.L. 117-167). In addition to the proposed disclosure forms that NSF published for public comment (see discussion below), Dr. Keiser and Dr. Eller advised that OSTP and federal agencies continue to work on the standards and certification process for required research security programs, and they are expected to be published in the form of a request for information before the end of 2022. With respect to NSF's funding of the development of research security training modules, NSF announced that two of the three anticipated awards had been issued. One award is for a module regarding research security risk management and mitigation, and the second award is for a module regarding international collaborations.

NSPM-33 Implementation Guidance Disclosure Requirements & Standardization Forms: Thursday Session at October COGR Meeting (NEW)

This session discussed the recently released proposed common disclosure forms for the Biographical Sketch and Current and Pending (Other) Support. Jean Feldman, Head of the Policy Office within the Division of Institution and Award Support at NSF, and Michelle Bulls, Director of the Office of Policy for Extramural Research Administration at NIH, presented how their respective agencies plan to implement the forms.

NSF provided an update on the National Science and Technology Council's (NSTC) Research Security Subcommittee efforts related to disclosure requirements and standardization. Some important highlights of NSF's implementation plan for the common disclosure form include:

- The NSF Biographical Sketch and Current and Pending Support will align as close as possible to the common forms as documented in the PAPPG guide 23-1 (effective January 2023).
- NSF expects to handle any variances based on the feedback received through a public comment in the subsequent issuance of the PAPPG.
- NSF also discussed that SciENcv for the biographical sketch and current and pending other support will become mandatory in October 2023.
- NSF will require pre- and post-award disclosures for current and pending support information (CPS). An updated CPS will be collected before making funding decisions as requested by the NSF Program Officer. NSF is continuing to assess the possible use of just-in-time for CPS for a future iteration of the PAPPG. This would be a welcomed change and increase harmonization as it aligns with NIH's approach to collecting Other Support at the time of the award, narrowing the request only to applications under funding consideration.

NIH announced at the October COGR meeting that they are currently in the process of seeking OMB approval to revise the biosketch and other support forms to align with the common disclosure forms with

some agency-specific instructions (ex., page limits, personal statement, contributions to science, and hyperlink policy, methods for submitting supporting documents, etc.). NIH anticipates making the new forms available in January 2023. The electronic versions of the forms are expected to be made available in SciENcv in October 2023 to align with NSF's implementation.

During NIH's presentation, Michelle announced that NIH would post the Grant Policy Statement later this fall for public comment. NIH also expressed a commitment to do the same for NIH Policy Notices. This is a notable and much-appreciated opportunity.

COGR Submits Comments to NSF on Common Disclosure Forms (NEW)

In August, NSF, on behalf of the National Science and Technology Council (NSTC) Research Security Subcommittee, released for comment the proposed common disclosure forms for the Biographical Sketch and Current and Pending (Other) support. COGR submitted a response in an October 31 letter[3]. The letter expressed appreciation for the opportunity to comment on the proposed common disclosure forms and recognized the efforts by federal partners to harmonize disclosure requirements. COGR comments and recommendations are a cumulation of feedback from COGR member institutions as captured in a talking points document[4]. COGR's webinar Overview of the NSPM-33 Standardization Disclosure Forms for the Common Biographical Sketch and Current and Pending (Other) Support provided a synopsis of the forms and highlighted key considerations for institutions.

COGR's comment letter highlighted a need for agencies to provide the much-needed clarifications in crucial areas and to strike the right balance, ensuring that the information requested has a practical utility that meets the stated purpose and intent of the forms. The letter also highlighted that the estimation of burden included in the notice (1 hour for each form) is a significant underestimation of the actual time it takes to complete the forms. Polling results estimated the actual time to be at least double, if not four times greater. COGR recommended that agencies obtain an accurate estimation of the burden and pain points for researchers and consider working with organizations like FDP to gather this information. COGR's letter also highlighted the need for long-awaited clarifications for ambiguous terms like "in-kind," "appointments," and "positions," requesting that these terms be defined with qualifiers and examples. COGR also suggested an appropriate format be provided for these items in a non-project-based format, as the current common forms template requires disclosing these activities in a project-based format that includes such things as: start/end date, dollar value, time commitment, etc. COGR also highlighted the need to limit agency-specific information with a recommendation to collect this information outside of the common forms to maintain a truly common core form that can be applied across all agencies. In addition, we requested that changes to

[3] *Sent to COGR listserv via the COGR News Digest on November 2 and posted to COGR's website at https://www.cogr.edu/sites/default/files/FINAL%20COGR%20Letter%20for%20Request%20for%20Comment%20for%20Common%20Disclosure%20Forms.pdf*

[4] *Sent to COGR listserv on October 27 and posted to COGR's website at https://www.cogr.edu/sites/default/files/NSPM-33%20Implementation%20Guidance%20Disclosure%20%20Requirements%20%20Standardization%20Talking%20Points%20for%20Institutions.pdf*

the form be infrequent, in a workable and predictable time frame with sufficient advance notice to the community with opportunities to provide input.

We understand that NSF will respond to comments. Considering NSF and NIH mentioned they are expected to launch the new forms in January 2023, we hope comments will be responded to before then. We will keep the membership updated.

COGR Joins Higher Ed. Association Letter to NSF on Standard Disclosure Forms (NEW)

COGR joined AAU, AAMC, APLU, and ACE in an October 31 letter[5] to NSF on behalf of the National Science and Technology Council (NSTC). The letter responds to a Request for Comment regarding the common disclosure forms for the biographical sketch and current and pending (other) support.

The joint letter recognized NSTC and the agency's efforts to align disclosure requirements and materials across federal agencies and noted the common disclosure forms as a positive step towards harmonization and consistency. The letter requested the following in the development of the common forms: 1) limit agency variation in required disclosure data elements and instructions, 2) ensure a transparent and uniform process for updating common forms, and 3) clarify definitions to facilitate compliance.

COGR 9/23 Webinar "Digging into DPIs" (UPDATE)

Digital persistent identifiers (DPIs or PIDs) are digital objects, maintained over a long period, that link individuals to various outputs, such as "ORCiD" IDs, which link authors to their scholarly publications. DPIs form a key mechanism for tracking scholarly publications, as well funding and data, and benefits of their use have been recognized in both the research security and data/publication sharing arenas. On September 23, 2022, COGR hosted a webinar with presenters from the University of Arizona's research office and libraries to provide insight into the practicalities of obtaining DPIs and their various uses. The slides are available on the COGR website and the webinar recording can be found in the COGR member portal for members who registered to attend the session.

COGR Presentation to National Academies (UPDATE)

On November 14-15, 2022, the National Academies of Sciences, Engineering, and Medicine (NASEM) hosted the workshop "Openness, International Engagement, and the Future of the Federally-Funded U.S. Science and Technology Research Enterprise." The workshop included representatives from academic institutions, higher education associations, and federal agencies who presented on benefits of promoting open science and international collaboration while addressing important research security issues and fostering the development of the United States' science,

[5] *Sent to COGR listserv via the COGR News Digest on November 4 and posted to COGR's website here: https://www.cogr.edu/sites/default/files/FINAL%20AAU%20AAMC%20APLU%20ACE%20COGR%20103122%20comments%20to%20NSF%20on%20standard%20disclosure.pdf*

technology, engineering, and mathematics (STEM) workforce. Presenters discussed topics including potential solutions to increase STEM workforce members, benefits and challenges of international collaborations, cybersecurity, and cooperation between the research security and law enforcement. COGR representatives participated in a panel with representatives from the Georgia Institute of Technology and Stanford University on "Practical Considerations and Risks/Benefits of Alternative Approaches." COGR's presentation focused on how institutions are implementing NSPM-33's requirements for disclosing biographical and research support and associated costs, as detailed in COGR's recent report Research Security and the Cost of Compliance – Phase I Report. COGR discussed the significant financial costs that institutions are incurring to address the Disclosure Requirements, and the need for discussions with federal partners on strategies for more equitable sharing of these costs.

SBIR/STTR "Foreign Risk Management" Provisions (NEW)

The SBIR/STTR reauthorization (S. 4900) passed by Congress in late September contains a number of provisions aimed at foreign influence and security risks.

Each SBIR/STTR funding agency is directed to establish a due diligence program to assess security risks posed by applicant small businesses. Two percent of the agency's SBIR funding may be allocated for this purpose, with an annual report submitted to the Congress.

A number of disclosure requirements are included for applicants. These include participation in a foreign talent recruitment program by all owners or "covered individuals" (those who contribute substantively to the R&D) of the small business; any joint venture or subsidiary affiliated with a "foreign country of concern" (China, North Korea, Russia or Iran); any current or pending financial or business arrangement with a foreign-owned enterprise; ownership by China or other foreign country of concern; percentage of investment by an entity affiliated with a foreign country of concern; any technology licensing or sales to a foreign country of concern during the preceding 5 years; or any related foreign business entity. Agencies may request true copies of any contract or financial agreement over the preceding 5 years.

Awards are prohibited to small businesses with owners or covered individuals party to a "malign foreign talent recruitment program" (as defined in other statutes) or affiliation with a research institution in China or other foreign country of concern or where there are conflicts of interest concerns, improper disclosures or national security concerns. Changes in disclosures must be reported to the funding agency. SBIR awardees may be required to repay awards where there are ownership changes or material misstatements posing security risks. STTR awardees are subject to similar requirements.

The reauthorization also includes increased minimum performance standards for "experienced" SBIR firms. The existing standards are doubled for SBIR firms with more than 50 Phase I awards over a consecutive 5-year period. Those with more than 50 Phase II awards must average $250k of aggregate sales or investments and $450k if more than 100. There are restrictions on future awards if the standards are not met (and they

are not met simply by obtaining patents). GAO is directed to conduct an 18-month study of SBIR/STTR awardees with more than 50 Phase II awards over a 10-year period.

These requirements respond to a DOD report last year that found China was targeting SBIR/STTR companies. They also respond to longstanding concerns of Sen. Paul (R: KY) about SBIR "mills." Universities that are involved with SBIR/STTR through university startups should be aware of the new requirements. Foreign investments or affiliations of these companies should receive particular scrutiny.[6]

NASEM Report on Protecting Critical Technologies for National Security in an Era of Openness and Competition (NEW)

The report by the NASEM project committee on Protecting Critical Technologies for National Security was released on September 29. In this new report the committee reviews the protection of technologies that have strategic importance for national security in an era of openness and competition, considering policies and practices that relate to the production and commercialization of research in critical domains. Based on its analysis, the committee offers in this report recommendations for changes to technology protection policies and practices that reflect the current realities of how technologies are developed and incorporated into new products and processes.

There has been much discussion of the report. Some commentators have stated that it reaffirms NSDD-189 on fundamental research. In reality, the report appears more mixed and nuanced on the preservation of NSDD-189. Here is the actual report recommendation:

Recommendation 1: *The President, through an executive order, should clearly reaffirm that it is the policy of the United States that fundamental research, to the maximum extent possible, should remain unrestricted. In addition, the executive order should direct the Office of Science and Technology Policy, in coordination with federal agencies, to define criteria for open and restricted research environments within 120 days of issuance of the executive order. Furthermore, the executive order should direct federal agencies to designate the appropriate environment for work under a grant or contract prior to making the award, and to maximize the amount of sponsored work that can be performed in open research environments. In making this designation, agencies should state clearly that any restrictions or recommended restrictions apply only to the particular research grant or contract being funded, and not universally across the entire institution receiving the funding.*

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[6] *For more information and commentary see: https://www.defensenews.com/congress/2022/09/29/congress-reauthorizes-dod-innovation-grants-with-new-china-safeguards/ and https://breakingdefense.com/2022/09/congress-saves-sbir-program-at-the-last-minute-with-strings-attached/.*

With regard to NSDD-189, the report states:

"…it should be recognized that NSDD-189 reflects the era of U.S. dominance in science and technology during which it was issued. It is focused on restrictions on the products or results of research rather than the research process itself and on restrictions on the production, sale, trade, or use of technologies. It is informed by risk acceptance position that the costs of losing some information of commercial or national security importance to other countries is outweighed by the benefits of openness. The policy simply does not envision the potential need to protect the U.S. position as the leader in R&D and the development of new technologies or the underlying conditions that are responsible for the nation's leadership. As a result, the directive does not address the need to protect access to top talent or to preserve open environments that foster disruptive discoveries. While NSDD-189 remains an important statement of principle for U.S. policy, then, its sole focus on protection of the information and technology outputs of the R&D process through such restrictions as classification limits its usefulness in a more competitive global environment."

Much of the report discusses different control mechanisms, the risks associated with shared platforms, etc. It includes a number of case studies. The bottom line is that the report is not an unequivocal endorsement of the fundamental research policy expressed in NSDD-189. It remains to be seen what impact the report may have on government policy.

Research Security & Intellectual Property (RSIP)

Selected Committee activities related to Science & Security are reported above under the Cross Cutting Issues section of the COGR Update. Other items being followed by RSIP are covered below.

RSIP COGR Committee Holds Informal Discussion with DOD (NEW)

During its October meeting, the RSIP Committee met informally with a DOD representative. It appears that DOD plans to adopt the NSPM-33 common disclosure forms with some individual service component variances. DOD also is planning to adopt the ORCHiD DPI. The Defense Science Board currently is developing a report on "Balancing Openness and Security Across the DOD Academic Research Enterprise." This may have implications for DOD practices. Historically DOD has found a low level of conflicts of interest or commitments among its investigators (1-2%). Requirements for security of federal contract information (i.e., CMMC Level 1) should not apply to fundamental research. While DOD views universities as doing well on research security overall, there is a need for more training of investigators. Our discussion was constructive and reassuring.

New Export Control Rules on End Users and Semiconductors (NEW)

On October 13th, the Department of Commerce, through its Bureau of Industry and Security (BIS), released two new rules through the Federal Register.

The first is a final rule announcing revisions to the BIS Unverified List which include criteria that make it easier for BIS to move a party to the Entity List. As required by the Export Administration Regulations, BIS conducts regular end user checks with both domestic and international companies to verify U.S. export controls compliance. Under this new rule, if BIS determines that it cannot conduct an end user check within 60 days of providing notice, BIS may begin the process of placing the party on the Unverified List if they determine that it is due to a sustained lack of cooperation by the host foreign government. If after an additional 60 days BIS is still unable to conduct an end user check, BIS may begin the process of moving the party to the Entity List. This new timetable for adding parties to the restricted lists increases the importance of institutions adopting a restricted party screening program to properly manage export control restrictions that may apply to a foreign collaborator or supplier.

The second is an interim final rule announcing new export controls for advanced computing and semiconductor items, supercomputer and semiconductor end use, and entity list modification. Public comments will be accepted until December 12, 2022. BIS also created a website that includes FAQs and other information related to these new controls. This new interim rule comes in response to rising U.S. government concerns that China is using these technologies in advanced weapons development and as a means to enable human rights abuses. It is long and complicated and does not lend itself to a quick summary.

The new export controls differ in scope from traditional controls in that they are specific to one country, unilateral in nature, and apply to commercial items that are in earlier stages of development and production. The scope of these new export controls includes both traditional and novel controls that fall into four categories:

1. New and modified Export Control Classification Numbers (ECCNs) to control high performance integrated circuits, other items that contain these circuits, and any associated technology and software;
2. New restrictions on U.S. person activities that support the development or production of advanced node semiconductors or semiconductor production equipment even when the activities or items are not subject to the U.S. export control regulations;
3. End use controls on commodities, software, and technologies subject to the export regulations that relate to the development, production or use of integrated circuits, semiconductor production equipment, or supercomputers; and
4. Expansion of the Entity List and foreign direct product rules to target transactions with specific entities in China to the extent that they relate to newly controlled technology, software, or production equipment.

We understand AUECO is developing comments on the interim semiconductor rule. Due to the complex nature of these new export controls, we expect additional corrections and guidance from BIS following the public comment period. The implications for fundamental research currently are unclear.[7]

March-In Calls Continue (UPDATE)

Many COGR updates and meeting reports over the years have discussed the misguided calls for use of the Bayh-Dole march-in provisions to address high drug costs. The September Update mentioned the joint higher ed. association letter to HHS Secretary Becerra last July in response to a Congressional letter urging him to use the Bayh-Dole march-in and government use rights to lower prescription drug prices.

While there has not been a response to the letter, recent news reports indicate that Sec. Becerra has stated that use of march-in rights is not "off the table.[8]"

On October 27, the Bayh-Dole Coalition held a webinar on "The Three-Pronged Attack on U.S. Innovation and Intellectual Property. In addition to misuse of march-in rights, the other "prongs" discussed were inappropriate use of 28 USC 1498 as a price control mechanism, and expansion of the current TRIPS waiver on COVID-19 vaccines to include therapeutics and diagnostics as well. A distinguished panel including Retired Chief Judge Susan Braden of the U.S. Court of Federal Claims addressed these issues. The webinar discussion is a useful reality check on the problematic consequences of exercise of any of these three actions.

Research Ethics & Compliance (REC)

Selected Committee activities related to Science & Security are reported above under the Cross Cutting Issues section of the COGR Update. Other items being followed by REC are covered below.

Request for Information (RFI) Regarding Cannabis Research (UPDATE)

COGR and the Association of American Medical Colleges (AAMC) submitted a joint response letter to the NIH's recent "Request for Information (RFI): Investigators' Interests in and Barriers to Research Studies on the Health Effects of Cannabis and its Constituents" (NOT-AT-22-026). The letter provided comments on the "barriers, scientific interests, and needs associated with therapeutic cannabis or cannabinoid research from investigators conducting or interested in conducting research on cannabis, cannabinoid phytochemical, and related compounds (synthetic compounds, terpenes etc.)." The response stressed how the federal government classification of marijuana as a Class I Controlled Substance makes it that extremely difficult for researchers to gain access to strains of marijuana currently used by the public in states that

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[7] *For additional perspective see https://www.csis.org/analysis/assessing-new-semiconductor-export-controls.*

[8] *In addition, misguided calls for use of march-in have continued in various media (e.g. https://undark.org/2022/11/03/the-public-shouldnt-pay-for-drugs-twice/; for a more balanced view see https://www.bakerbotts.com/thought-leadership/publications/2022/october/march-in-rights-implications-from-the-covid-pandemic).*

permit the medicinal/recreational use of the drug. The letter also discussed the difficulties that researchers have in navigating the Drug Enforcement Administration's (DEA) registration requirements and the FDA's process for obtaining an Investigational New Drug application for research involving human subjects. COGR and AAMC recommended that NIH work with FDA and DEA to establish an interagency work group to examine the cannabis research environment and mechanisms for fostering stakeholder input and engagement on new policies and processes.

Responsible and Ethical Conduct of Research Changes (NEW)

At the COGR October membership meeting, Jean Feldman, head of the NSF Policy Office, Division of Institution and Award Support, reported on NSF's implementation of changes in its responsible and ethical conduct of research (RECR) requirements. Section 10337 of the CHIPs and Science Act calls for NSF to require RECR training on mentor/mentorship, research security threat awareness, and export controls and to expand RECR training to include not only undergraduate/graduate students, but also "postdoctoral researchers, faculty, and other senior personnel." Ms. Feldman advised that the RECR changes described in the 2023 Proposal and Award Policies and Procedures Guide (PAPPG 23-1) would go into effect July 31, 2023. Meeting attendees asked if the CHIPS and Science research security RECR requirements would become effective in July 2023, even though the NSF-funded training modules on these topics are not expected to be available by the date, and NSF took these points under consideration. In follow-up with NSF, Ms. Feldman advised that the text of PAPPG 23-1 on RECR requirements is correct and will remain unchanged. Specifically, proposals submitted on or after July 31, 2023, must conform to PAPPG 23-1's requirement to expand RECR trainees to include "faculty and other senior personnel" and to add training to address "mentor training and mentorship." In response to the concerns that were raised, NSF will not require RECR training to include research security training topics until after the NSF research security training modules are available, and NSF noted that the text of PAPPG 23-1 does not address these requirements.

Animal Research (UPDATE)

During its October 19th meeting, REC met with Dr. Axel Wolff and Dr. Neera Gopee from the Office of Laboratory Animal Welfare (OLAW) to discuss OLAW's progress in fulfilling the 21st Century CURES Act's (P.L. 114-255) mandate to identify areas for potential reduction of administrative research burden on animal research, OLAW enforcement activities, and other OLAW initiatives. OLAW representatives reviewed areas in which the agency acted to reduce administrative burden and noted that OLAW soon would be issuing three additional requests for institutional input on administrative flexibilities in the following areas: use of existing IACUC review flexibilities, exemptions from IACUC review, and reporting of non-compliance. OLAW also advised that it would be conducting a survey of research institutions regarding the efficacy of OLAW's efforts in reducing administrative burden. On the topic of enforcement, OLAW discussed its conduct of announced site visits. These visits, which are conducted over the course of a few days, provide OLAW representatives an opportunity to visit animal care and use facilities in which PHS-funded animal research is conducted and to review compliance with the PHS Policy on Humane Care

and Use of Laboratory Animals. ("PHS Policy"). Other notable items raised by OLAW during this meeting include:

- NASA's adoption of the PHS Policy and the expansion of that policy to certain higher order cephalopods; and
- OLAW's work with the Federal Demonstration Project (FDP) to develop a standard procedure & universal protocol repository to assist researchers.

Human Subjects Research

Certificates of Confidentiality (NEW): On October 11, REC members met with Dr. Adam Berger, Director of Clinical and Healthcare Research Policy at NIH, to discuss the uses and limitations of certificates of confidentiality ("Certificates") in research involving human subjects. REC members were particularly concerned with protections that Certificates afford to individuals of child-bearing age, given the potential criminal liability for abortion in some states following changes in federal law. Dr. Berger noted that Certificates follow the research and its data and that Certificate requirements should be clearly communicated to data recipients. Dr. Berger also advised that NIH's data sharing policy allows for exceptions in cases in which the sharing of data may violate an individual's privacy or put their safety at risk. However, he cautioned that Certificates may not be used to circumvent mandatory state reporting requirements, and researchers must clearly inform subjects of the limitations of Certificates. Although Certificates are automatically in place for NIH-funded research, researchers must apply to NIH if they want to obtain a Certificate for research that is privately funded. NIH may grant such Certificates in its discretion, and it does not maintain public statistics on how many such Certificates it grants, or the timetable for their processing. Dr. Berger stated that if a researcher wants to obtain a Certificate for a privately funded study, application should be made to NIH at least three months before enrollment in the study is to begin.

Recent FDA Guidance Document on Expanded Access (NEW): The FDA issued new draft guidance on expanded access to investigational drugs -- Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers – that will be of interest to Institutional Review Boards that oversee compassionate use requests. The guidance notes that expanded access is considered to meet FDA's definition of a clinical investigation and a sample informed consent template is provided.

OSTP Request for Information: Clinical Research Infrastructure and Emergency Clinical Trials (NEW)

COGR has been participating in discussion with representatives from OSTP on ways in which the federal government can improve and speed the conduct of clinical research during emergency circumstances, such as the recent COVID-19 pandemic. Discussions encompassed topics such as improving the recruitment of more diverse research sites, easing completion of case report forms using data from medical records, and developing in advance agreed-upon terms and conditions for clinical trial agreements. Using information from these discussions, OSTP developed and issued an RFI seeking formal public comment on these topics and others. REC will develop a response to this RFI that will reflect on the importance of ensuring

regulatory flexibility during public health emergencies and developing mechanisms to permit healthcare facilities that are leading the clinical response in such emergency situations to effectively participate in associated research endeavors.

ORI RFI Regarding Research Misconduct Regulations (UPDATE)

The Secretary of Health and Human Services (HHS), through the Office of Research Integrity (ORI), has issued a "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct." ORI is considering revising the 2005 regulations on research misconduct (42 CFR Part 93) and requested input on which sections of the regulations should be unchanged, removed, or modified. REC and the Association of Research Integrity Officers (ARIO) submitted a joint response to this RFI that included the following major points regarding the current research misconduct regulations:

- Retain the current definition of "research misconduct," and do not expand it to include other research integrity related issues that should be address under separate policies.
- Provide institutions with greater flexibility to terminate proceedings at the assessment or inquiry stage of proceedings.
- Delete or substantively revise the "subsequent use" exception at §93.105(b)(1).
- Clarify the concept of "need to know" as it applies to the confidentiality of research misconduct proceedings.
- Clearly define all state-of-mind terms used in the research misconduct regulations, including, the term "recklessly."
- Eliminate the current deadlines for the conduct of inquiries and investigations and acknowledge that proceeding timelines depend on the facts and circumstances of each case.
- Eliminate Subpart E and revise the current federal appeals process to call for direct appeal to the Assistant Secretary of Health.

REC will continue to closely follow developments regarding any changes to the Research Misconduct Regulations.

OSTP Webinar on Open Access Policy (NEW)

In early November, OSTP conducted a webinar on the memorandum it published in August 2022 on "Ensuring Free, Immediate, and Equitable Access to Federally Funded Research." The webinar reviewed each element of the memorandum and detailed the timeline that OSTP will follow in implementing the policy. Under this timeline, federal agencies providing more than $100M in federal R&D awards must provide OSTP with their plans for achieving free, equitable and immediate access to publications and data from federally funded research ("Public Access Plans") by February 2023, while agencies providing $100M

or less in such funding will have until August 2023 to develop such plans. Agencies must publish policies for implementing Public Access Plans by December 31, 2024, with an effective date of no later than December 31, 2025. As OSTP officials were unable to present at COGR's October meeting, the invitation will be re-extended for the February membership meeting.

Conflict of Interest (COI) Publication (UPDATE)

REC continued its work on updating the COGR publication "Recognizing and Managing Personal Financial Conflicts of Interest." COGR hopes to have the update completed by the end of 2022.

Costing and Financial Compliance (CFC)

Selected CFC activities related to Science & Security and NIH Data Management & Sharing are reported above under the Cross Cutting Issues section of the COGR Update.

F&A Cost Rate Negotiations and Engagement with Cost Allocation Services (ONGOING)

As we reported in the September Update, COGR members and other institutions that negotiate F&A cost rates (and fringe benefit rates) with Cost Allocation Services (CAS), have been concerned about not being able to complete timely negotiations and receive final rate agreements. CAS has a unique placement in the U.S. Department of Health and Human Services (HHS) as an entity under the Program Support Center (PSC). According to the PSC website: "PSC is a shared services organization dedicated to providing support services to help its customers achieve mission-critical results. More than 40 services and products support three crucial business areas."

One of the sub-organizations under PSC is Indirect Cost Negotiations, and as what has become common knowledge across the COGR membership, CAS is experiencing significant staff shortages. In fact, these shortages have been exacerbated by the fallout from the COVID-19 pandemic. Consequently, this has led to long delays in completing timely negotiations and receiving rate agreements from CAS. COGR and CAS recently have engaged with one another with the goal of finding solutions to reduce these long delays, and explore other opportunities that could be beneficial to the community. We will keep the membership updated on how we progress.

COGR F&A Cost Rate Survey, Revisited (NEW)

The Costing and Financial Compliance Committee is planning to conduct a new F&A Cost Rate Survey of the COGR Membership. The last survey was conducted in 2016-2017[9]. Additional details and logistics will be shared over the next several months, with an expected launch date of January 2023.

[9] *The 2016-17 Survey can be found on COGR's website here: https://www.cogr.edu/cogr-2016-17-fa-survey-results*

Cost of Compliance Studies: Science & Security and Data Management & Sharing (ONGOING)

The Costing Committee has been heavily engaged in two cost of compliance surveys: Science & Security and Data Management & Sharing. Both are described in previous sections of this COGR Update. As cost of compliance and its associated cost burden have been highlighted for these two federal compliance requirements, the importance of data-driven evidence to support claims about significant cost and administrative burden is essential. The two surveys take two different approaches to documenting the cost of compliance. As the need continues to complete these types of surveys, we encourage the COGR membership to share feedback on any challenges for completing the two recent surveys, as well as any other input that could be helpful to how COGR implements such surveys.

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:

Comment Letter to Small Business Administration (SBA). On November 8th, COGR wrote a comment letter to the SBA in response to a Federal Register Notice (Document Citation: 87 FR 55642, Pages 55642-55678), dated September 9, 2022—*Ownership and Control and Contractual Assistance Requirements for the 8(a) Business Development Program*. We raised a concern that the SBA proposed rule could result in a new requirement for research institutions to provide line-by-line documentation of indirect costs in certain subcontracting engagements with small businesses. The comment letter is available on the COGR website.

Treasury Offset Program. This is an ongoing issue that has affected almost every (if not every) COGR member at some point in time. At issue are delinquent institution debts, often identified to the VA or other student tuition reimbursements, which then get "offset" against non-related federal research awards. In addition, these delinquent institution debts also can result in a hold on issuing a federal award. The challenge with the Treasury Offset Program is that there is no easy way to intervene when a federal research award is affected. COGR will continue to pay attention to this longstanding issue, and if/when there are opportunities to voice concerns, we will do so.

Proposed NASA Term and Condition Regarding Procurement. COGR sent a comment letter to NASA in April raising a concern about a proposed NASA term and condition. The last we heard, 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 would 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. We continue to report on this issue as it continues to resurface in selected situations. In the fall of 2021, Cost Allocation Services (CAS, HHS) raised

an issue on the treatment of rebates associated with institutional p-cards and similar lump-sum procurements. CAS maintained these rebates should be identified to individual federal awards. 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.

Retirement of the FCTR by the U.S. Department of Health and Human Services. On April 1st, the U.S. Department of Health and Human Services (HHS) retired the Federal Cash Transactions Report (FCTR), i.e., OMB Standard Form 272. This was announced in NIH Notice NOT-OD-22-099 and further promoted in an HHS-department wide announcement. 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.

Federal Office of Inspectors General (IG) and Single Audit Developments. We encourage COGR members to follow the HHS OIG Workplan and the NSF OIG Reports & Publications page. Further, the NSF Management Responses to an External Audits is a helpful resource for reviewing NSF OIG audit resolutions. COGR members are welcomed to contact COGR when audit issues arise, and when appropriate, we can connect institutions and/or provide feedback that may be relevant to the issue at hand.

NSF Higher Education Research & Development (HERD) Survey Developments. The results for the 2021 HERD are expected to be released before the end of the calendar year. We will provide an update when the results are available. In addition, we are tracking a possible addition to the HERD Survey, which would focus on capturing R&D capital expenditures. Our understanding is that this is a pilot question for the 2022 HERD, and if your institution has been selected to complete this pilot question, we encourage you to contact COGR.

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

Contracts & Grants Administration (CGA)

Selected Committee activities related to Science & Security & NIH Data Management and Sharing are reported above under the Cross Cutting Issues section of the COGR Update. Other items being followed by CGA are covered below.

NSF Proposal & Award Policies & Procedures Guide (UPDATE)

On October 26, 2022, NSF released the revised version of the PAPPG 23-1. As previously reported, COGR responded to NSF's request for comment on the proposed PAPPG in a June 13, 2022, letter. A notable comment addressed in the final version of the PAPPG is the request to delay the mandatory use of SciENcv for a year. As reflected in the PAPPG 23-1, the mandatory use of SciENcv will go into effect in October 2023.

NSF provides a Summary of Changes that includes several notable items, including:

- New sections added to the PAPPG that address:
  - Disclosure Requirements
  - Research Security
  - Scientific Integrity
- New certification requirements for the:
  - AOR and senior personnel relating to NDAA 2023, Section 223
  - Responsible and Ethical Conduct of Research (RECR) for proposals after July 31, 2023. This replaces existing certification, expanding the training requirement to faculty and other senior personnel and mandating that the training cover mentor training and mentorship (as mentioned above in Science & Security: Cross-Cutting Issues)
  - AOR to certify that any organization proposing to conduct research off-campus or off-site has a plan in place for this proposal regarding safe and inclusive working environments
- Effective for proposals submitted on or after January 30, 2023, senior personnel will certify that the information provided in their Biographical Sketch and Current and Pending Support documents are accurate, current, and complete.
- The Biographical Sketch and Current and Pending (Other) Support are revised to align with the common disclosure forms.

Grant & Contract Administration: Other Issues (UPDATES)

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

Executive Order 14042. As shared through the COGR News Digest, on October 19, 2022, the administration issued updates to the Safer Federal Workforce guidance for Federal Contractors. The U.S. Office of Management and Budget (OMB) issued guidance for agencies regarding the federal government's enforcement of Executive Order 14042 ("EO 14042"). The guidance reaffirms the federal government's decision not to enforce any contract clauses implementing EO 14042 and directs agencies not to include an implementing clause in any new contracts and solicitations.

Other Transactions Authority. CGA continues to monitor the use of Other Transactional Authority (OTA) as an award mechanism utilized by a number of federal research organizations. OTA is designed to provide flexibility and leverage resources to meet time-sensitive needs and is a mechanism that the newly established Advanced Research Projects Agency for Health (ARPA-H) may utilize as it moves ahead based on lessons learned from the Defense Advanced Research Projects Agency (DARPA).

As reported in COGR's June 2022 update, COGR has formed a workgroup of members with OTA experience across multiple federal agencies to develop points and strategies that will streamline and improve the OTA process for agencies as well as partnering and responding organizations. We hope that these suggestions and observations will serve as a resource document that will be available for members in early 2023 and will enable conversations with agencies seeking guidance and input from us regarding OTAs.

COGR would like to thank COGR Board Chair Jeffrey Silber (Cornell University) 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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