COGR
Council On Governmental Relations
An Association of Research Institutions

MARCH 2022 UPDATE

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Research Security & Intellectual Property Management (RSIP)

DOE Modifies Determination of Exceptional Circumstances (DEC) Terms (UPDATE)

Previous COGR Updates and Meeting Reports have discussed the Determination of Exceptional Circumstances (DEC) recently issued by the Department of Energy (DOE) to strengthen the Bayh-Dole Act domestic manufacturing requirement for DOE-funded inventions. We had expressed serious concerns about the potential adverse effects on university technology transfer of a requirement for government review and approval of any ownership changes involving inventions that receive government funding. A particular concern was the potential for these requirements to spread beyond DOE, with the Administration's emphasis on encouraging more domestic manufacturing.

COGR participated in several discussions with senior Administration officials on these issues. We expressed the need for balancing a desire for greater domestic manufacturing with the objective of encouraging innovation through commercialization of government-funded technologies. In our view, requirements like those in the DOE DEC would adversely affect technology transfer without necessarily promoting more domestic manufacturing. Fortunately, our concerns appear to have been heard. Based on recent discussions we do not expect the DOE requirements to proliferate to other agencies. We are continuing to discuss with senior officials options that the Administration might consider to facilitate domestic manufacturing while enhancing commercialization.

As announced at the COGR meeting on March 4, DOE is dropping the ownership review requirement in the current DEC and modifying it to only require notification. A COGR member institution received the new term on March 9. It states, "In the event that the Recipient or other such entity receiving rights in the Subject Invention undergoes a change in ownership amounting to a controlling interest, the Recipient or other such entity receiving rights shall ensure continual compliance with the (U.S. manufacturing requirement) …and shall inform DOE, in writing, of the change in ownership within 6 months of the change." There also have been clarifications to the waiver provisions.

We fully understand that concerns remain about the extension of the U.S. manufacturing requirement to non-exclusive licenses and worldwide sales. This may be particularly troubling in the event of breach of the requirement by a non-exclusive licensee. It appears this could lead to the termination of all non-exclusive licenses to the invention. It also appears under the revised terms that breach of the requirement for one subject invention could result in forfeiture of title to all subject inventions under an award. DOE also claims the right to nullify any license or other transfer where the licensee or transferee is in breach, which may raise legal issues. Further discussion with DOE may be necessary to clarify these terms. However, we believe this current modification of the DEC requirements addresses the most serious concerns.

March-In Petition Resubmitted to HHS (NEW)

A petition for HHS to "march-in" to require compulsory licensing for the prostate cancer drug Xtandi was filed last year by several prostate cancer patients. It requests march-in on the grounds of excessive pricing.

This matter has a long history. A similar petition was filed in 2016 and rejected (see COGR June 2016 Meeting Report). HHS/NIH consistently has taken the position that march-in is not an appropriate remedy for pricing concerns. The new petition reiterates the claim that march-in should be available for the petitioners' petition.

COGR long has had the view that exercise of march-in for price control purposes would undermine the Bayh-Dole Act and the ability of institutions to successfully commercialize federally funded technologies. The current petition essentially reiterates the arguments previously rejected by NIH.

We joined in a letter (along with almost 100 organizations) submitted by the Bayh-Dole Coalition on March 17 asking HHS to once again reject the march-in petition for Xtandi. The letter cites the contributions of the Bayh-Dole Act in commercializing technologies and points out that invoking march-in rights to address drug pricing is a clear misapplication of the law.

A number of members of Congress as well as some public interest groups have supported the petition. NIH is expected to complete its review this month.

DOJ Declares End of "China Initiative" (UPDATE)

On February 23, DOJ Assistant Attorney General Matt Olsen announced the new "Strategy for Countering Nation-State Threats," which will replace the China Initiative. It will take a more broad and comprehensive approach to address efforts by other nations which seek to undermine our core democratic, economic, and scientific institutions. In the speech, Mr. Olson cited concerns about ethnic bias and the chilling effect on the U.S. scientific enterprise resulting from the China Initiative. While current cases will continue, Mr. Olsen stated "In evaluating cases moving forward, (DOJ) will work with the FBI and other investigative agencies to assess the evidence of intent and materiality, as well as the nexus to our national or economic security. These considerations will guide our decisions — including whether criminal prosecution is warranted or whether civil or administrative remedies are more appropriate." He cited the NSPM-33 Guidance giving primary responsibility to research funding agencies for research integrity and security. While not directly mentioning "amnesty," Mr. Olson stated "Where individuals voluntarily correct prior material omissions and resolve related administrative inquiries, this will counsel against a criminal prosecution under longstanding department principles of prosecutorial discretion."

The decision to end the China Initiative was challenged by Sen. Grassley in a letter dated February 28. In the letter Sen. Grassley stated "that the communist Chinese government is clearly the greatest threat to the U.S. research field and the protection of our intellectual property. Your decision to shut down the China Initiative will negatively impact the whole-of-government approach to detecting, deterring and punishing these ever-present

threats from the Chinese Government." The letter criticized the decision as being driven by partisan pressure rather than promotion of national security.

COGR agrees that primary responsibility should be placed on the funding agencies for assuring research integrity and security. Civil or administrative remedies to address breaches or research grant fraud generally are more appropriate, except in rare cases. However, it also has come to our attention that the FBI continues to investigate researchers with ties to China. It may take time to assess whether the end of the China Initiative is more symbolic than real.

Export Controls: New Russian Sanctions Announced (NEW)

On February 24, Commerce/BIS announced sweeping new sanctions against Russia in response to its invasion of Ukraine. They were formalized in the Federal Register on March 3 (87 FR 12226) and made effective against Belarus that day. The new rule also establishes comprehensive export/re-export/transfer restrictions on the so-called Donetsk People's Republic (DNR) and Luhansk People's Republic (LNR) regions of Ukraine and updates the existing restrictions for the Crimea Region of Ukraine. These controls primarily target the defense, aerospace, and maritime sectors. Additional sanctions targeting the oil refinery sector were announced on March 3 and formalized in the March 8 Federal Register (87 FR 12856). New sanctions also were announced by OFAC on February 24.

This is a fluid situation. We expect sanctions may continue to evolve. The new controls may not have substantial impact on COGR member institutions since physical exports to Russia typically have been infrequent and are screened for export review by most institutions. Given that the available license exceptions have been tightened, additional review of travel involving institutional equipment may be needed. Export analysis should be conducted with particular attention to the new sanctions and related controls including deemed exports.

Cybersecurity: Further Updates to CMMC; New Legislation (UPDATE)

CMMC

The November 2021 Update discussed changes to the DOD Cybersecurity Maturity Model (CMMC) program. On February 10, DOD announced further changes to CMMC 2.0 in an online town hall.

The principal change relates to the bifurcated assessment regime where third-party assessments were only needed for some Level Two CMMC contracts. Now all Level Two contracts will require third party assessments. DOD indicated that its analysis showed that all CUI included in such contracts needed a priority level of security. The Level One self-attestation requirement remains unchanged. Also announced was that the CMMC program has been formally moved from the Pentagon's acquisition arm to the DOD Chief Information Officer. Rulemaking for the CMMC is expected to be completed within two years. In a recent DFARS change, 204.7503 was revised to state that "In order to implement a phased rollout of CMMC, inclusion of a CMMC requirement in a solicitation during this time period [i.e., prior to September 30, 2025] must be approved by OUSD(A&S)" (Office of the Undersecretary of Defense for Acquisition).

It never was fully clear how the previous bifurcated assessment process would work in practice. This change appears at least to make things clearer. In another CMMC-related development, we understand that the Academic Advisory Council to the Advisory Board finally has met. And in a related development, NIST has announced plans to update the NIST SP800-171 security requirements later this year. This may include adding certain DOD-recommended practices. In addition, on March 15, NIST published new assessment procedures for the "enhanced security requirements" of NIST SP 800-172A.

Legislation

The August 2021 Update discussed concerns with the proposed Cyber Incident Notification Act, which would have required federal agencies, critical infrastructure operators, and federal contractors to report data breaches and security incidents to CISA. It would have required "covered entities" to report potential cyber intrusions. There were concerns that the legislation might be attached to the NDAA (which did not happen).

Recently Sen. Peters and Sen. Portman introduced the Strengthening American Cybersecurity Act, a package of cybersecurity directives, including new cyber incident reporting requirements. Notably, the cyber incident reporting requirements are directed only at critical infrastructure owner and operators. Unlike the previous version, the bill does not include federal contractors under the definition of "covered entity." Limiting compliance for the cyber incident reporting to critical infrastructure owners and operators is consistent with legislation reported out of the House Homeland Security Committee and is welcome news.

DOE Issues Revised Version of Order 142.3B (UPDATE)

The November Update noted that DOE was planning to revise Order 142.3B. The foreign national approval requirements under the previous version have been a continuing concern to COGR member institutions.

A revised Order was issued on March 2. It is labelled a "limited change." The only substantive change appears to be in Exemption (2)(c), which slightly changes the previous public domain exemption to "information which is already available to the public" and adds an exemption for information that "has been documented to be published and shared broadly within the scientific community." The Contractor Requirements Document Attachment also contains this changed and expanded exemption. Access restrictions continue to be based on DOE's (non-public) S&T Risk Matrix.

Accompanying FAQs indicate that the exemption "means that a specific laboratory action has been taken and recorded to release the information." They go on to explain that "since much of the unclassified work done at DOE laboratories is considered fundamental research as defined by National Security Decision Directive 189, the information covered by this exemption includes information that is "ordinarily...published or shared broadly within the scientific community."

Later the FAQs state "the DOE O 142.3B review can be required at any stage of the process depending on what the individual has access to. However, it is a best business practice to complete the review of a foreign national

and verify their approval to work on the proposal in advance of the proposal submission, to prevent any "last minute" surprises that would impact the ability to perform the work."

The practical effect of these changes is uncertain. It appears that fundamental research is within the exemption. This implies that foreign nationals participating in DOE-funded fundamental research will not need to be screened, which responds to the concerns expressed in our letter to DOE last July, and subsequent discussions with DOE officials. We have been advised by DOE that a response to our letter will be forthcoming shortly. COGR would appreciate hearing from our member institutions if they see a change in DOE approval requirements or behavior resulting from the revised Order – please contact Bob Hardy.

Research Ethics & Compliance (REC)

Implementation of the Presidential Memorandum on United States Government-Supported Research and Development National Security Policy ("NSPM-33")

Background: On January 4, 2022, the National Science and Technology Council (NSTC) issued the Guidance for Implementing National Security Presidential Memorandum 33 on National Security strategy for United States Government-Supported Research and Development ("Implementation Guidance"), which outlined basic requirements for each of the five broad research security areas set forth in NSPM-33:

- Disclosure Requirements and Standards
- Digital Persistent Identifiers
- Consequences for Violation of Disclosure Requirements
- Information Sharing
- Research Security Programs

Engagement Hours (NEW): The Implementation Guidance states that OSTP will engage with stakeholders regarding Guidance requirements for 90 days following the Guidance's publication. In line with this directive, OSTP announced that it will host stakeholder Engagement Hours on Mondays between March 28th and May 30th consisting of two 30-minute sessions at 12 to 12:30 p.m. and 12:30 to 1:00 p.m. (ET). OSTP will continue to hear community input after the initial Engagement Hour period ends, but scheduled sessions will shift to once or twice per month.

During these Engagement Hours, representatives from institutions, associations, and other interested parties will meet with members of OSTP and the NSTC Subcommittee on Research Security. Government representatives will not have prepared presentations but will listen to concerns and answer questions raised by stakeholders. Stakeholders must schedule their appearance at an Engagement Hours, and as many as three separate organizations may present at a single session. Stakeholders should come prepared with questions and/or slide presentations that may be shared in advance with OSTP and the Subcommittee.

COGR will schedule its participation in an Engagement Hour and work with COGR Committee members to develop questions and presentation materials. Institutions that want to individually participate in an Engagement Hour may contact OSTP by email at MBX.OSTP.ResearchSecurity@ostp.eop.gov to express their interest in doing so. OSTP will respond with details regarding scheduling and meeting logistics.

Next Steps Regarding NSPM-33 Implementation (NEW): At the March COGR membership meeting, Dr. Rebecca Keiser, National Science Foundation (NSF) Chief of Research Security Strategy and Policy and Co-Chair of NSTC's Subcommittee on Research Security, provided an update on next steps concerning the Implementation Guidance. Her presentation primarily focused on overarching concerns regarding research security programs and next steps regarding the program requirements outlined in the Implementation Guidance. Major points from the presentation are highlighted below.

Research Security Program Requirements: Dr. Keiser reported that although NSPM-33 contains a broad definition of "foreign talents programs" (FTP), NSF is considering use of definition that focuses on indicators in participation agreements of "malign" FTPs (MFTP) including:

- Requirement that a foreign institution or funding agency always be acknowledged first in publications
- Ability for the researcher to cancel the participation agreement only in extraordinary circumstances
- Negative impact on the researcher's capacity to fulfill responsibilities concerning grants or contracts awarded by U.S. funding agencies
- Substantial scientific duplication or overlap
- Requirement to transfer non-public information to a foreign government or entity
- Requirement to apply for/receive research funding from foreign government funding agencies per which the foreign institution will be the awardee

Importantly, Dr. Keiser emphasized the distinction between MFTP and permitted international collaborative activities such as participating in scholarly collaborations and publishing information that is not otherwise controlled; participating in international conferences and exchanges; engaging in research projects that are open and reciprocal; advising and providing letters of recommendation for foreign students enrolled in a researcher's home institution; and participating in similar scholarly and academic activities as defined by federal funding agencies.

Dr. Keiser referenced the definition of MFTP contained in Section 10651 of the America Competes Act of 2022 and sought feedback from COGR members as to whether such a definition is useful, the specifics of the definition, and how such a definition might be best addressed in policy and/or guidance if it is not adopted legislatively. In this respect, she also described an "International Collaboration Catechism" that outlines questions that researchers and institutions should consider when evaluating international collaborations. The clear overarching theme of the Catechism is full transparency regarding the nature, purpose, participants,

funders, deliverables, and other details of the collaborative activity. As with the definition of MFTP, Dr. Keiser requested feedback regarding the Catechism and how information regarding appropriate and inappropriate international collaborations can best be disseminated to the awardee community.

Disclosure Requirements: Dr. Keiser reported that Michelle Bulls, Director of the National Institutes of Health (NIH) Office of Policy for Extramural Research Administration, and Jean Feldman, Head, Policy Office, Division of Institution and Award Support at NSF, are leading a working group that is developing the standardized grant application forms and instructions that researchers will use to disclose the appointments, affiliations and sources of research support outlined in the Implementation Guidance. Per the Guidance's timetable, these forms are expected to be completed during the first week of August 2022, 120 days after the Implementation Guidance was issued.

Financial Threshold Triggering Application of Research Security Program Requirements: NSF will be providing a list of entities that meet the $50 million threshold for establishment of a research security program based on award funding as shown in USAspending.gov and in lists maintained by the National Center for Science and Engineering Statistics. Notably, in determining the amount, each of the two prior fiscal years will be considered individually, as opposed to combining awards received during those years.

Certification: The Research Security Subcommittee is considering one of the following two approaches to institutional certification regarding research security programs: (a) annual certification on an institutional basis via SAM.gov; or (b) certification on a proposal basis. Dr. Keiser advised that her preference was for annual certification.

Training: NSF has issued a solicitation for the development of research security training modules, and responses to the solicitation are due on May 23, 2022. Per the solicitation, modules will be funded via the issuance of one to three cooperative agreements with total anticipated funding of $1.5 million. Funding for the cooperative agreement will be provided by NIH, NSF, Dept. of Defense (DOD), and Dept. of Energy (DOE), and technical support for the modules will be provided by the FBI. Training modules are expected be internet based and widely accessible to end users. Each proposal must address one of the following topic areas:

- Why is research security an important issue?
- What is a disclosure policy and how will it be used?
- What actions can federally funded research recipients take to manage and mitigate risk?
- Is institutional collaboration encouraged?

Dr. Keiser advised that institutions will have the flexibility to use the modules as their sole means for satisfying the research security program training requirement, or in conjunction with institutional materials,

or not at all. She also reported that although the modules will be available on-line, at present there is no plan to generate a training record or attendance certificate, although institutions are free to do so.

Session Regarding NSPM-33 Security Program Requirements at March COGR Membership Meeting (NEW)

The Implementation Guidance does not require institutions that meet the $50 million funding threshold to implement a research security program until one year after final program requirements have been announced. Nevertheless, institutions have already started to consider the program requirements set forth in the Implementation Guidance. During the March meeting, four institutions – Brown University, University of Chicago, University of Pittsburgh, and Washington State University – reported on the steps they are taking to prepare for the upcoming program requirements. A common theme among all presenters was the evaluation of existing institutional policies, processes, and infrastructure in place for cyber-security, international travel security, export controls and research security training, with an eye to leveraging existing resources to comply with the new requirements.

NSF SORN Response (UPDATE)

In December 2021, COGR provided comments in response to a System of Records Notice (SORN) published in the Federal Register by NSF regarding the use of its new data analytics tool NSF-77, which will be used to compare information from researcher disclosures against publicly available publication and patent information to identify inconsistencies. COGR subsequently met with both Dr. Keiser and staff for the House Science, Space and Technology Committee's Research and Technology Subcommittee to discuss concerns regarding the SORN. On March 9th, NSF provided a written response to each of the points that COGR raised in its written comments.

In this response, NSF emphasized that it would publish "internal research security guidelines that will provide guidance to staff on reporting, validation, and sharing processes for research security concerns" arising from use of the tool. These guidelines will address roles and responsibilities in the use of the tool and details regarding the validation process that will be employed when inconsistencies are identified. Although these guidelines will not be provided for public comment prior to implementation, NSF emphasized that they will be subject to an iterative improvement process and that "validation activities and routine uses beyond sharing information with OIG will not be implemented until the guidelines are published." Additional important points NSF included in its response are: (a) NSF will consider proactive validation mechanisms as a future enhancement to the tool; (b) the NSF-77 tool and associated guidelines is "a living document and will undergo further refinement as the agency better understands what categories [of information] are critical for accomplishing the listed purposes"; and (c) NSF will consider suggestions from COGR on alternate methods and data sets that NSF should use to validate the "accuracy, relevance and completeness of self-reported publication data provided by PIs."

Department of Energy Interim COI Policy (UPDATE)

The DOE issued Financial Assistance Letter 2022-02 (FAL), an interim financial conflict of interest (FCOI) policy for grant awardees. Unfortunately, DOE representatives were unable to present at the March COGR meeting, but they did meet with COGR staff to discuss the policy and consider questions regarding the policy that COGR provided in advance. Significant points from this discussion include the following items:

- Upcoming FAQs: DOE will be publishing a set of FAQs that provide clarifications regarding the policy, including the application of the 180-day compliance period reference in Section C of the FAL. DOE stated that it hoped that these FAQs would address many of the questions provided by COGR including those regarding the meanings of various terms used in the FAL and review and reporting requirements.
- Notice of Proposed Rulemaking (NPRM): Ultimately, DOE will publish an NPRM for a final rule, but the timetable for publication is not yet known.
- Harmonization with Public Health Service (PHS) Financial Conflict of Interest Regulations (42 CFR Part 50, Subpart F) and Program Office Discretion: DOE reported that much of the interim policy is patterned after the PHS regulations, but the agency wants to preserve flexibility to address the differences across various DOE programs and the differing levels of sensitivity in the information that these programs handle. DOE also stated that this need for flexibility underlies the interim policy's provision of discretion to program offices to apply stricter requirements on an award basis (e.g., expanding the definition of "investigator" to include "any person who participates in the purpose, design, conduct or reporting of a project" funded/proposed for funding by DOE).
- Investigator Certification: DOE advised that institutions should use verbatim the certification language set forth in Section IV(d)(4) of the interim policy. It also stated that institutions may use current institutional systems and processes for obtaining investigator certification, and that additional information will be provided in the upcoming FAQs.
- Organizational Conflict of Interest Requirements: Section VI of the interim policy includes requirements for non-federal entities regarding organizational conflicts of interest. DOE reported that these requirements are primarily directed to private organizations with parent/subsidiary relationships in the procurement context.
- Reporting: DOE stated that for the present there will not be a uniform electronic portal for reporting; rather, program offices will manage reporting logistics
- Sub-awardees: DOE advised that it expects prime awardees to flow-down requirements to sub-awardees, and it does not generally expect prime awardees to review sub-awardee disclosure. DOE representatives, however, would not rule out the possibility of different requirements in specific Funding Opportunity Announcements (FOA).

COGR has extended an invitation to DOE to present at COGR's June membership meeting, and DOE representatives indicated a willingness to do so.

Scientific Integrity RFI (NEW)

As a follow-up to NSTC's scientific integrity task force's report "Protecting the Integrity of Government Science," OSTP issued an RFI entitled "To Support the Development of a Federal Scientific Integrity Policy Framework." Similar to OSTP's July 2021 RFI, this RFI seeks input on the improvement of scientific integrity policies/processes in place at government agencies, and the collected information will be used "to develop a framework for regular assessment and iterative improvement of agency scientific integrity policies and practices." The RFI seeks information on how such policies/practices can be developed/updated to address diversity/equity/inclusion, new technologies, emerging modes of science, and coordination with related policy areas, such as research security. The RFI also seeks information on metrics for evaluating and improving scientific integrity policies and ways to ensure "long-term viability and implementation of Federal scientific integrity policies, practices and culture through future Administrations."

Meeting with John Claud, Assist. Director of the U.S. Department of Justice (DOJ) Consumer Protections Branch (NEW)

In February, REC hosted attorney John Claud, Assist. Director of the U.S. Department of Justice (DOJ) Consumer Protections Branch, at its monthly meeting to discuss DOJ's recent clinical trials fraud initiative. This initiative is aimed at criminally prosecuting certain research misconduct in clinical trials, including data falsification in federally funded clinical trials and clinical trials supporting FDA new drug or device applications. Mr. Claud provided an overview of the initiative and noted that many of DOJ's cases in this area come from due diligence by contractors, whistleblowers, and referrals from the FDA. Mr. Claud emphasized, however, that an FDA referral does not necessarily result in a criminal prosecution. Mr. Claud advised that DOJ carefully reviews each case that it receives to determine if it should be handled administratively, civilly, or criminally and noted the following factors that may lead to criminal prosecution: harm to humans; impact on vulnerable communities; evidence that indicates research results were completely fabricated; and presence of a high level of fraud and/or money at stake. Mr. Claud also noted that in addition to prosecution under the Food Drug and Cosmetic Act, the DOJ also may bring charges in these cases under mail and/or wire fraud statutes.

Meeting with Dr. Liza Bundesen, Deputy Director, Office of Extramural Research, NIH (NEW)

On March 8th, REC and CGA members met with Dr. Liza Bundesen, Deputy Director, Office of Extramural Research (OER) at NIH. Dr. Bundesen advised that among the projects/initiatives for which she has primary responsibility are overseeing the implementation of the NIH Advisory Committee to the Director recommendations on rigor, reproducibility, and translation in pre-clinical research and handling OER's

response to General Accounting Office (GAO) audits. Although she is not a member of the group responsible for NIH's implementation of NSPM-33, she is part of the team that manages research integrity issues/cases arising from peer review, research misconduct, and human and animal subject research.

When asked about OSTP's recent RFI concerning federal agencies' scientific integrity programs (discussed above), Dr. Bundesen stated that Dr. Lyric Jorgenson of NIH's Office of Science Policy is taking the lead on this project. Dr. Bundesen does not anticipate that the information collected in response to this RFI will result in changes to the PHS regulations on research integrity or financial conflict of interest, but she did note that the Department of Health and Human Services is working toward cross-unit harmonization with respect to internal policies in this area. She also noted that GAO reports regarding scientific integrity and political interference are expected to be published soon.

The group also discussed with Dr. Bundesen the stress placed upon workers and the workplace by the COVID-19 pandemic. She advised that NIH continues to review the pandemic's impact on the agency activities, particularly with respect to the following themes:

- Work force, staffing, and remote work
- Operations, including supply chain
- Infrastructure, particularly IT infrastructure
- Communications and collaborations

U.S. Department of Agriculture (USDA) NPRM "Standards for Birds Not Bred for Use in Research Under the Animal Welfare Act" (NEW)

REC is reviewing the USDA's NPRM proposing additions and changes to the Animal Welfare Act's implementing regulations (9 CFR Part 2) to address birds not bred for research. The regulations encompass dealers, exhibitors, carriers, intermediate handlers, and research facilities. Birds that will be subject to the proposed rule include those that are "obtained from their natural habitat and used or intended for use for research, teaching, testing, or experimentation purposes," while birds "bred in captivity" that are being used or are intended for use in research, teaching, testing, or experimentation purposes are excluded. A summary of the proposed rule is available here, and REC is developing comments that will be submitted to USDA.

NIH Guide Notice on Changes to RCR Instruction Requirements (NOT-OD-22-055) (NEW)

On February 17, NIH issued NOT-OD-22-055 requiring awardees to incorporate changes into their RCR instruction for the 2022-23 academic year and for new/renewal applications for research training, career development, research education & dissertation grants beginning with September 25, 2022, due dates. The Guide Notice requires the incorporation of the following new subject matter areas in mandatory RCR training:

- **Conflict of Commitment**– Allocating time, effort, or other research resources
- **Safe Research Environment** – Promoting a workspace free of sexual, racial, ethnic, disability & other forms of discriminatory harassment
- **Peer Review** – Responsibility for maintaining confidentiality and security
- **Data Analysis**
- **Lab tools** – Tools for analyzing data, creating, or working with digital images and recordkeeping practices, including methods such as electronic lab notebooks
- **Secure and Ethical Data Use and Data Confidentiality**

Notably, although the reference to the requirement for eight contact hours in delivering instruction has been deleted, the Guide Notice specifies that video conferencing may be used to partially, but not completely, fulfill the requirement for face-to-face interaction among faculty and participants, except for "short term training programs or unusual/well-justified circumstances." When meeting with Dr. Bundesen, REC members requested additional clarification on what constitutes "face-to-face" interaction and pointed out that participants may feel more comfortable in raising questions in video conferencing settings, as opposed to in-person settings.

Costing & Financial Compliance (CFC)

Measuring Cost of Compliance on Targeted Federal Regulations: NSPM-33 (UPDATE)

At the March 2022 COGR Meeting, we presented a session titled, *Cost of Compliance: NSPM-33, New Disclosure Requirements, and Research Security Plans*. A copy of the slide deck is available. The session was in a case study format, focusing on four thematic areas:

- Leveraging Technology, Processes & Systems
- People and Training
- Size & Scope Matter
- How Much will it Cost—and How to Pay

Each thematic area was led by one of the four panelists: Elizabeth Peloso, Assoc. V.P./Assoc. V. Provost, Research Services, University of Pennsylvania; Craig Reynolds, Assist. V.P. for Research Sponsored Projects, University of Michigan; Gerald Mauck, Exec. Dir., Research & Sponsored Programs, University of Denver, and Jeffrey Silber, Sr. Director, Sponsored Financial Services, Cornell University. David Kennedy, from COGR, moderated the session.

The COGR Costing Committee, in partnership with the COGR Research Ethics & Compliance Committee, are analyzing the new NSPM-33 disclosure and research security requirements using a cost of compliance lens. During the session, we also shared a survey methodology COGR has used with ten member institutions, to date. Initial findings of the survey were presented. The data COGR has collected (de-identified) will be shared with

federal agency leaders to support further discussions on administrative burden, harmonization opportunities, and how to pay for this new unfunded compliance mandate.

We now are expanding the survey beyond the original ten member institutions. If you are interested in participating, please contact Kris West at kwest@cogr.edu or David Kennedy at dkennedy@cogr.edu.

Anticipated Retirement of the FCTR (NEW)

As of this writing of this report, we have not received official word for the retirement of the Federal Cash Transactions Report (FCTR), OMB Standard Form 272. However, an official notice by NIH and/or HHS is expected. Retirement of the FCTR will solve the longstanding and problematic reconciliation issue between the FCTR and the Final FFR by eliminating the edit check barrier for submitting a Final FFR. It also will reduce administrative burden by cancelling the FCTR, which has been redundant and unnecessary ever since HHS/NIH introduced "subaccounts" more than five years ago. Our understanding is institutions should begin to receive guidance from HHS/NIH in the spring and final action will be applicable for the quarter ending June 30, 2022. We encourage you to reference the Notices of NIH Policy Changes webpage to follow the official release of the anticipated retirement. COGR also will update the membership when we have official notice.

Treatment of Procurement and Related Rebates (RESOLUTION)

We were first made aware of this issue last fall in response to comments made by representatives from Cost Allocation Services, U.S. Department of Health and Human Services (CAS/HHS) at several conferences. At issue has been 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. These rebates often are associated with strategic sourcing agreements, established by an institution's procurement office, which ultimately result in cost savings on all procurements and 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 of 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 in the February 2022 Update should be a helpful resource.

No-Cost Extension for HEERF Awards (NEW)

Institutions are receiving guidance letters from the U.S. Department of Education indicating that "*the Department will automatically extend the performance period of all open HEERF grant awards that have balances over $1,000*." Also indicated is that the new performance period end date will be June 30, 2023, and that "*no further action is required*" to receive the extension. Still, COGR recommends you contact a program officer at the Department of Education to confirm details and/or address other questions you may have.

Audit Update: Single Audit and Federal Developments (ONGOING)

COGR continues to follow audit developments both on the single audit and the federal Office of Inspectors General (OIG) fronts. Below is a summary of developments (also reported in the February 2022 Update):

- ***The 2021 Compliance Supplement (CS)*** was released in three separate postings and is now completed for the current single audit cycle. These documents are available per the links below and also are available on the OMB–Office of Federal Financial Management (OFFM) website. The 2021 Compliance Supplement was released on August 25, 2021, and on August 30, COGR submitted a comment letter to address several topics (i.e., HEERF reporting, cash management, and audit reasonableness) of potential concern. Addendums 1 and 2 were released in December and January (respectively) and provide additional guidance on programs associated with the American Rescue Plan.

- ***The Department of Health and Human Services, Office of Inspector General (HHS-OIG) Workplan*** can be followed at the HHS-OIG website. Of potential 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 on January 21st titled Promising Practices for NSF Award Management. The report was prepared by NSF OIG contractor Cotton & Company LLP as an NSF OIG 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 expects to meet with NSF OIG staff to share its concerns.

Also note the next section below, *Resolution to NSF OIG Audit Finding*. This has been an ongoing item COGR has engaged, and below is a summary of the resolution.

Resolution to NSF OIG Audit Finding: Application of the F&A Cost Rate (RESOLUTION)

This issue arose last year when institutions were cited by the NSF Office of Inspector General (OIG) for applying an "incorrect" (lower) F&A cost rate to NSF awards. On May 14, 2021, COGR wrote a letter to the National Science Foundation to address these audit findings concerning the application of the F&A cost rate to a new award (and in some cases, with a PI transfer). Specifically, the NSF OIG cited the following example as an audit finding: 1) an F&A cost rate was proposed at 52 percent, 2) at the time of award a new F&A cost rate of 54 percent had been negotiated, and 3) institutional policy allowed the proposed 52 percent F&A cost rate to be used on the award. ***A common institutional policy*** is to permit the lower 52 percent F&A cost rate to be used, which allows proposed direct costs for the PI to be maintained—and there is no harm to NSF.

NSF Management supported the common institutional policy in an NSF Management Response to an External Audit (dated December 2, 2021), though emphasized 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. Additional details to this resolution also were included in the February 2022 Update.

Costing & Financial Compliance (CFC): Other Issues (NEW & UPDATES)

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

2020 NSF Higher Education Research & Development (HERD) Survey. The 2020 HERD was released on December 27th 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.

Heritage Foundation: Report on F&A. In January, the Heritage Foundation released a report titled *Indirect Costs: How Taxpayers Subsidize University Nonsense*. Rather than attempt a serious analysis on the role of F&A costs at colleges and universities, the report instead takes a political jab at institutions of higher education. In 2019, COGR published a paper titled *Why the System Works*, which provides an alternative and balanced analysis of the history, role, and importance of a reliable mechanism for recovering F&A costs.

Facilities and Administrative (F&A) Cost Rates Under COVID-19. COGR also released the paper, *F&A Cost Rates and Reimbursement Pressures Under COVID-19* in April 2021. This paper builds on the 2019 paper, with a focus on how the pressures of the COVID-19 pandemic impacted issues around F&A cost rates and reimbursement.

NSF OIG: NSF Award Recipient COVID-19 Audits and Capstone Report. As we have reported in prior updates, the NSF OIG released a *Capstone Report (OIG-21-6-003): Observations on the OMB COVID-19 Flexibilities (prepared by Cotton & Company LLP, August 3, 2021)*. On Page 1 of the report (page 6 per the PDF), the NSF OIG summarized "*WHAT WE LEARNED": NSF award recipients used the COVID-19 flexibilities to continue performing essential research and services during the COVID-19 pandemic, as summarized in Appendix II,* ***and were generally prudent in their stewardship of federal resources [COGR emphasis added].***

Uniform Guidance (UG) and FAQ Reminder. Electronic versions of 2 CFR Part 200 (Uniform Guidance) and the corresponding UG FAQs (May 3, 2021) are available and easily accessed at the links above.

Please contact David Kennedy at dkennedy@cogr.edu to further discuss any of these issues above, or other items that have not been covered.

Contracts & Grants Administration (CGA)

COVID-19 Vaccine Mandate Status (UPDATE)

COGR continues to monitor the status of federal government regulations and guidance regarding COVID-19 mandates. On December 7, 2022, the U.S. District Court for the Southern District of Georgia issued a nationwide preliminary injunction of EO 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors that directs executive agencies to ensure that contracts and contract-like instruments covered by the order include a clause requiring contractors and subcontractors at any tier to comply will all Task Force guidance. On December 17th, the Eleventh Circuit Court of Appeals upheld the injunction. The White House has appealed the decision. Oral arguments are set to be heard the week of April 4. For now, and according to the Task Force Guidance, enforcement of the clause is on hold until further written notice by the Court and federal government. Note however, that independent parties can contract between themselves and agree to voluntarily comply with the provisions of the proposed rule. In such cases, agreements would be enforceable as long as relevant state and/or local jurisdictions do not prohibit the mandate. Institutions should closely review agreements to ensure compliance with associated provisions.

The US Supreme Court also halted OSHA's Emergency Temporary Standard (ETS) rule for private businesses with 100 or more employees. OSHA subsequently withdrew the ETS. Although it is withdrawn, the ETS proposed rule still exists "in theory" perhaps to be modified at a later date; any modification or new proposal would have to go through a notice and comment period.

On Jan. 13, 2022, the US Supreme Court approved the Centers for Medicare & Medicaid Services (CMS) enforcement of its interim final rule requiring many Medicare- and Medicaid-certified providers and suppliers to vaccinate their staff for COVID-19. Covered providers are now subject to three different key compliance deadlines, depending on their location as indicated in the final guidance memoranda released January 14 and January 20, 2022, respectively.

Diversity, Equity, Inclusion and Accessibility (DEIA) at NIH (UPDATE)

Dr. Marie Bernard, NIH's Chief Officer for Scientific Workforce Diversity (COSWD) presented during COGR's March membership meeting on Strengthening Diversity, Equity, Inclusion and Accessibility at NIH. The slide deck and areas of discussion focus on three topics, the Government-wide DEIA Strategic Plan, the NIH UNITE initiative and the NIH COSWD DEIA Strategic Plan ("COSWD Plan") for DEIA for fiscal years 2022-2026. NIH has issued an RFI seeking comments and suggestions for the COSWD Plan framework. Comments are due April 3, 2022. Section four of the Government-wide DEIA Strategic Plan contains a road map for DEIA agency action. Agency plans are to be delivered by March 23rd. Prior to the release of the Government-wide Strategic Plan, NIH had already begun work on the COSWD Plan and negotiated with Congress a due date for late spring/early summer. The COSWD Plan is meant to articulate NIH's vision for DEIA while also addressing the White House Government-wide Strategic Plan. Overarching principles of NIH's plan will be based on internal and external stakeholder feedback from comments and suggestions

received in response to the RFI. The COSWD Plan will in broad scope articulate NIH definitions for DEIA, contain example accomplishments, convey five-year goals, and address accountability via measures of progress NIH will put in place.

For background, UNITE's five committees were established to address racism and discrimination in science and develop methods to promote DEIA across the biomedical enterprise. The NIH Common Fund will be used to address health transformative research in health disparities and health equity research. The Common Fund has committed up to $58M over the next five years. This funding will support multiple programs and awards, including eleven awards in 2022.

Dr. Bernard and colleagues have communicated extensively with external stakeholders by holding listening series webinars, issuing opportunities for input, such as a March 2021 Request for Information (RFI) seeking suggestions to advance and strengthen racial equity, diversity, and inclusion in the biomedical research workforce and advance health disparities and health equity research. Click here to read COGR's response to the RFI.

NIH New and Updated Other Support FAQs (UPDATE)

On March 10, NIH released new and updated FAQs addressing other support made in the last sixty (60) days. The answers to these questions and other new and updated FAQs can be found on the NIH Other Support FAQ page.

NIH Data Management and Sharing (UPDATE)

COGR was pleased to welcome back to COGR's March membership meeting Drs. Lyric Jorgenson and Greg Farber along with colleagues Taunton Paine and Cindy Danielson from NIH to discuss the latest goings on related to NIH's Final Policy on Data Management and Sharing going live on January 25, 2023. The slide presentation is available here.

New resources are expected to be forthcoming by NIH to supplement the final policy. COGR members can expect to see guidance around budget considerations, (e.g., things to consider when developing proposal budgets including tools and models for estimating costs when data management and sharing practices go beyond the scope of a project), how to store, manage, and curate data, and how data is submitted to a repository.

NIH also continues to explore the area of persistent identifiers, ways to give credit to researchers who are "good" data sharers (more on this in subsequent blogs on Open Mike), harmonization of plans to lessen the burden on researchers of having to submit plans with varying requirements to twenty-seven I/Cs, and to study data-reuse to determine value added.

As training materials for program staff are being finalized at NIH, the Office of Data Science and Strategy has been setting up a series of generalist data repositories that will be accessible to the research community to improve upon the infrastructure needs for researchers to share data. Internal discussions have taken place at NIH regarding the SF 424 form and whether having a fillable form for data management and sharing plans would be more optimal than having researchers create plans organically. The intent for NIH is to keep the flexibility that is built into the

Final policy with the goal of helping researchers prospectively plan how to share data. It was also mentioned that fillable forms can often constrain researchers by forcing explanations into boxes that may not fit a particular situation.

When asked about how NIH will handle the volume of data management plans as a result of the Final policy, it was stated that NIH intends to have a small group of staff conduct initial evaluations as a means to speed up the review for program officers. A summary of the initial review will be provided to the program officers who will conduct subsequent reviews (e.g., in RPPR) via reporting intervals to ensure compliance with the policy.

NIH discussed its relevant work in the area of security. Considering certifications for uses that go beyond the Genomic Data Sharing policy has been brought up. Members should expect to see more on the topic of security and can expect additional RFIs, including the most recent NIH RFI on Proposed Updates and Long-Term Considerations for the NIH Genomic Data Sharing (NOT-OD-22-029). Click here to read COGR's response.

Lastly, NIH would like to hear more from institutions about their experiences in working with National Science Foundation (NSF) directorates and whether implementing the data management and sharing requirements with NSF directorates is easier than with NIH I/Cs. For questions related to the NIH Final Policy on Data Management and Sharing and how to be involved in COGR's working group, please contact Michelle Christy at mchristy@cogr.edu.

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)

Walter Goldschmidts (Chair)	Cold Spring Harbor Laboratory
Stephanie Endy	Brown University
Jeffrey Friedland	University of Delaware
Stephanie Gray	University of Florida
Charles Greer	University of California Riverside
Jennifer Lassner	University of Iowa
Steven Martin	Indiana University
Bruce Morgan	University of California Irvine
Lisa Mosley	Yale University
Twila Reighley	Michigan State University
Craig Reynolds	University of Michigan
Jennifer Rodis	University of Wisconsin-Madison
Pamela Webb	University of Minnesota
Jackie Bendall	Director, COGR

Costing & Financial Compliance (CFC)

Jeffrey Silber (Chair)	Cornell University
Sarah Axelrod	Harvard University
Jeremy Forsberg	University of Texas Arlington
Joseph Gindhart	Washington University - St. Louis
Vivian Holmes	Massachusetts Institute of Technology
Cynthia Hope	Georgia Institute of Technology
Michael Legrand	University of California, Davis
Nate Martinez-Wayman	Duke University
Gerald Mauck	University of Denver
Jennifer Mitchell	Northwestern University
Julie Schwindt	University of South Alabama
Marcia Smith	University of California, Los Angeles
Renotta Young	Columbia University
David Kennedy	Director, COGR

Research Ethics & Compliance (REC)

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Lynette Arias	University of Washington
Theresa Colecchia	Johns Hopkins University
Keri Godin	Brown University
Grace Fisher-Adams	California Institute of Technology
Karen Hartman	Mayo Clinic
J.R. Haywood	Michigan State University
Mary Mitchell	Mass General Brigham
Deborah Motton	University of California
Kerry Peluso	Florida State University
Brian Smith	University of California - San Francisco
Geeta Swamy	Duke University
Ara Tahmassian	Harvard University
Debra Thurley	Pennsylvania State University
Kristin West	Director, COGR

Research Security and Intellectual Property Management (RSIP)

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Alexandra Albinak	Johns Hopkins University
Allen DiPalma	University of Pittsburgh
Cindy Kiel	Stanford University
Sophia Herbert-Peterson	Georgia Institute of Technology
Michael Moore	Augusta University
Dan Nordquist	Washington State University
Jennifer Ponting	University of Chicago
Kenneth Porter	University of Maryland
John Ritter	Princeton University
Fred Reinhart	University of Massachusetts
Janna Tom	University of California
Robert Hardy	Director, COGR