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### **Announcements**

# June 9-10, 2022, COGR Meeting: Registration Still Open

We are pleased to welcome COGR members back to Washington D.C. for the June 9-10, 2022, <u>COGR Meeting</u>. As our first in-person meeting since February 2020, we are truly looking forward to being together again. <u>Registration is still open</u>, and we have implemented a <u>Health and Safety Protocol</u> for all guests, speakers, and attendees, which includes a requirement to verify your vaccine status (must be fully vaccinated as <u>described by the CDC</u>) prior to attending the meeting. Attendees have been sent reminders from CrowdPass to verify their status, so if you have registered, please ensure you are watching for those emails (check your spam/junk folders) and get your vaccination cards uploaded and verified. Please contact memberservices@cogr.edu if you have any questions.

Back for this meeting, we will be using <u>Poll Everywhere</u>, an application that allows attendees to ask questions through their laptop or cell phone right from their seats. We recommend you download the <u>Poll Everywhere app</u> on your phone prior to arriving. We'll of course still have the standing microphone, but now you can choose to participate however you feel most comfortable.

### **Launching This Summer: COGR's Membership Portal**

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

# Research Security & Intellectual Property Management (RSIP)

## **Concerns Raised About SBIR/STTR (NEW)**

A classified DOD report last year raised security concerns about the Small Business Innovation Research Program (SBIR) Program. The report found that China is using state-sponsored methods to target DOD-funded SBIR companies. It includes eight case studies. They include examples of program participants who dissolve their American companies, join Chinese government talent programs and continue their work at institutions that support the People's Liberation Army, and instances of SBIR recipients taking venture capital money from Chinese state-owned firms and of working with Chinese entities that support the country's defense industry. The report concludes that the SBIR program needs a due-diligence process



to identify entities of potential concern that would then receive a more detailed review. The classified report was reviewed by the *Wall Street Journal* and discussed in a May 8 article. According to the article, it has been circulating on Capitol Hill.

A five-year reauthorization of SBIR and the related Small Business Technology Transfer Program (STTR) program is included in the House version of the COMPETES/USICA bill. If not reauthorized, the program will expire on September 30. Sen. Paul (R-KY) previously proposed an annual limit of 3 awards to individual SBIR companies. The Senator long has been a critic of what he views as SBIR "mills."

The SBIR/STTR program has been a significant source of support for startups, particularly those based on university technologies. If the program is not reauthorized, there will be adverse consequences for university technology transfer.

# **Controversy Continues Over Drug Pricing and March-In (UPDATE)**

The issue of drug pricing and march-in was raised again by Rep. Pocan (D-Wis) in a recent House hearing on the Department of Health and Human Services (HHS) 2023 budget. Rep. Pocan cited alleged price gouging on Xtandi and repeated the familiar canard that taxpayers were being made to pay twice. In response, the NIH Acting Director stated that pricing does not meet the march-in criteria and that the right tool must be used to address the concerns. The Xtandi march-in petition remains under consideration (see COGR March 2022 Update).

### President Zelenskyy Addresses AAU Presidents (NEW)

Ukrainian President Volodymyr Zelenskyy <u>addressed a group</u> of Association of American Universities (AAU) Presidents virtually on May 16, 2022. The focus was on how America's leading research universities, Ukrainian officials, and educators can work together to help rebuild and transform his country's decimated higher education sector. In his remarks President Zelenskyy focused particularly on students and the importance of making a choice to help make positive change, rather than being a bystander.

In an extended and wide-ranging Q & A with the AAU Presidents, one emphasis was on the importance of partnering in the postwar reconstruction of Ukraine. The need for expertise was cited by President Zelenskyy. Stanford is a partner in the <u>Ukrainian Global University</u>, which brings together an international network of institutions to help displaced Ukrainian students and scholars continue their education and research (President Zelenskyy will address the Stanford community on May 27<sup>th</sup>). However, President Zelenskyy also noted the importance of Ukrainian students and scholars returning to Ukraine to help with the rebuilding. Important priorities include cyber and IT, the defense sector, and the medical sector.



President Zelenskyy's administration envisions a postwar Ukrainian education sector with world-class research universities that drive scientific discovery and technological advancement, contribute to the nation's economy, and collaborate closely with American universities.

# **AAU Presidents Briefing with Intelligence Agencies (NEW)**

In late April, a group of AAU Presidents met with several intelligence agency representatives at a briefing hosted by Sens. Rubio (R-FL) and Warner (D-VA). This was a follow-up to a briefing with similar participants several years ago. This time around the tone was different, with clear acknowledgment that universities are taking research security seriously and have established very good relationships with the FBI in particular. However, there also was recognition that China is seeking to acquire information arising from fundamental university research through a variety of tactics. Rather than seeking to identify particular technologies of concern, the focus perhaps should be more on these tactics. Discussions on these issues will continue.

### **Department of Education Webinar on Section 117 (NEW)**

The Department of Education (ED) has asked COGR and American Council of Education (ACE) to cosponsor a webinar for a discussion and an update on Section 117 Foreign Gift and Contract Reporting. ED will provide an overview of the Department's plans for Section 117, as well as answer some of the questions previously submitted. ED does not plan to focus on functionality issues with the reporting portal; ED representatives stated they are aware of them and are seeking longer-term solutions. The focus instead will be on the issues that were included in a list sent by ACE to ED about a year ago. This webinar may lead to an updated FAQ for Section 117 reporting. (Pending legislation that would lower the Section 117 reporting threshold also will not be discussed, but we noted to ED that should such legislation pass, the portal functionality problems will be greatly magnified.)

ED is seeking broad participation in the webinar, but it will not be completely open (and it will not be open to media). COGR and ACE are discussing how to handle invitations to participate. We expect participants will need to RSVP to participate, and it will be restricted to the COGR membership and other senior academic representatives. A date in early June is likely. We will keep COGR members informed of developments.

# **Research Security Legislation**

### **USICA/COMPETES Update**

The United States Innovation and Competition Act (<u>USICA</u>) and the House-passed America Creating Opportunities for Manufacturing, Pre-Eminence in Technology, and Economic Strength (<u>COMPETES</u>) Act now is in a House/Senate conference, with a very large number of conferees (107). <u>The committee held its first public meeting on May 12th.</u>



The Senate has passed a series of non-binding Motions to Instruct (MTI) the conferees. With respect to research security, the following MTIs were adopted:

- Paul motion to instruct conferees in relation to <u>H.R.4521</u>, USICA (Gain of Function Research). Agreed to by voice vote.
- Risch motion to instruct conferees in relation to H.R.4521, USICA (China Malign Influence). Agreed to by voice vote.
- Rubio motion to instruct conferees in relation to H.R.4521, USICA (Intel Review). Agreed to by voice vote.
- Scott (FL) motion to instruct conferees in relation to H.R.4521, USICA (ROI and Claw Back Provisions). Agreed to by voice vote.

As discussed in previous COGR updates and reports, it remains unclear how several of the research security provisions will be decided. There are a number of concerning Senate provisions, including Section 3138 on CFIUS, Section 6124 requiring faculty reporting of foreign gifts and contracts, Section 2308 requiring NSF to develop a plan to identify sensitive or controlled research areas and provide background screening, and Section 2526 mandating NSF to collect copies of any contracts, agreements, or documentation. Like the Senate bill, the House bill contains a prohibition on participation in foreign talent recruitment programs; however, the House provision is narrower in its definition of these programs focusing specially on prohibiting participation in 'malign' foreign talent recruitment programs.

We understand that Congressional leadership has asked for an update by May 25<sup>th</sup>. The goal is to have the conference process completed by mid-June so a final vote can be held before the July 4 recess. We will continue to keep the COGR membership informed of developments.

### Other Legislative Activities (NEW)

On May 16, Rep. Murphy (R-NC) released a discussion draft of his upcoming bill, the <u>Protecting Endowments from Our Adversaries Act</u> (PEOAA). The bill would impose a steep excise tax on private college and university endowments over \$1B that invest in "adversarial" entities on various government entity lists. The draft cites a National Association of College and University Business Officers (NACUBO) list of 80 private endowments over \$1B. We understand there is another draft bill that would prohibit DHS funding for any institution that maintains a Confucius Institute and contains other similar restrictions aimed at China.

### **Cybersecurity**

# NIST Plans Update to SP 800-171 (NEW)

At a recent cybersecurity conference, a National Institute of Standards and Technology (NIST) representative announced plans to update the <u>NIST SP 800-171</u> CUI security requirements as well as Special Publication 800-171A and Special Publication 800-172 ("enhanced security requirements" for



high-value assets), and its corresponding Special Publication 800-172A. The 800-171 Update will be Revision 3.

NIST plans to issue a draft version ("pre-call") for public comments on all four publications later this year. The pre-call will ask for feedback on how stakeholders are using the 800-171 series. NIST will seek input on improvements and streamlining. The recent NIST request for information to update the cybersecurity framework is a model for the pre-call on the 800-171 series (although there have been some reports that NIST was disappointed on the lack of feedback on the framework). See here for more information.

### DOD Accelerates Timeline for Revised CMMC Implementing Guidance (UPDATE)

We have reported on the status of the DOD Cybersecurity Maturity Model (CMMC) program in recent COGR Updates and Reports (e.g. see March 2022 Update). At the cybersecurity conference mentioned above DOD announced it is accelerating by two months plans to implement changes to the CMMC program. The release of two interim final rules now is expected in March 2023. The expected timeline is two months earlier than DOD's plan announced in April to release the interim final rules by May 2023. DOD plans to start including the revised requirement in contracts in May following a 60-day comment period.

CMMC certifications received prior to the planned update to NIST 800-171 will need only to meet the requirements in the current version (Revision 2). DOD plans to conduct internal "tabletop" exercises to improve contracting officers' understanding of Controlled Unclassified Information (CUI). DOD is encouraging defense contractors to adopt CMMC early through getting an assessment completed by an approved certified third-party assessment organization before the rulemakings go into effect. (Third party assessments presumably will be necessary only for COGR member institutions that handle CUI.) We will continue to keep the membership informed on CMMC implementation.

# DOD/OIG Report on Contractor Compliance with NIST SP 800-171 (NEW)

On February 22, the DOD/OIG released a report (DODIG-2022-061) criticizing DOD contractors' compliance with DFARS clause 252.204-7012, "Safeguarding Covered Defense Information and Cyber Incident Reporting." That clause requires contractors that maintain CUI to implement security controls specified in 800-171. Based on an assessment of 10 (unspecified) academic and defense contractors, the report found that they did not consistently implement required cybersecurity controls to protect CUI stored on their networks from insider and external cyber threats, including use of multifactor authorization, physical access and other required controls. The report recommended that DOD contracting officers be instructed to verify contractor compliance.



# Research Ethics & Compliance (REC)

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

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 in the following areas: digital persistent identifiers, consequences for disclosure violations, information sharing, and research security programs. OSTP is working with agencies on the development of requirements and associated documentation, and agencies continue to work on implementation as well. Below is a summary of recent activities:

**OSTP Engagement Hours (NEW):** OSTP has been holding weekly "Engagement Hour" sessions with stakeholders to hear comments, concerns, and questions regarding research security program requirements under NSPM-33. OSTP will consider the information it obtains from these sessions as it develops standardized requirements for the research security programs that must be implemented by institutions receiving more than \$50 million in annual federal science and engineering funding. On May 9, COGR participated in an Engagement Hour with representatives from OSTP and numerous agencies (e.g., NIH, NSF, DOE, DOD). COGR presented on the following themes:

- Reaffirm Fundamental Research COGR urged OSTP to reaffirm the definition of Fundamental Research set forth in NSDD 189 and to acknowledge that research security program requirements are not intended to modify this standard.
- Ensure Inter-Agency Harmonization of Standards by Employing a Common Rule Approach

   COGR thanked OSTP for all of its work with agencies to promote harmonization and suggested that it consider a common rule-type regulatory approach, similar to that used in the area of human subjects research (see, 45 CFR Part 46). Under this approach, agencies would agree to adopt a single research security standard, rather than each agency developing and implementing its own standards in this area. If such an approach cannot be employed, COGR suggested that OSTP publish a chart highlighting differences across agency regulations and the reasons for those difference to assist institutions in their compliance efforts.
- Ensure that Controls are Commensurate with Risk COGR advocated for a risk-based approach to research security per which the type and number of controls increases commensurate with the security risk posed by research type.
- Work with Institutions to Address Costs Associated with Program Requirements COGR provided an overview of its current research security cost model survey and encouraged OSTP to discuss with institutions the costs involved and the development of shared solutions.



At the conclusion of COGR's presentation, OSTP provided the following information in response to COGR's questions:

- OSTP plans on publishing proposed disclosure formats and instructions at the end of May for public comment, prior to adopting any standards.
- OSTP also will provide an opportunity for public review of research security program standards toward the end of August or beginning of September.
- OSTP will be tracking agency policies, guidance, and enforcement to determine if they are
  meeting the intended objective of promoting transparency and reducing undue foreign
  influence. OSTP will also look at how research security requirements impact collaborations
  and scientific output with the aim of preventing any discrimination based on nationality or
  xenophobia.
- OSTP did not directly address the issue of employing a risk-based approach to controls
  applied to research that poses differing levels of sensitivity. Rather, it asked DOD
  representatives to discuss the risk-based approach DOD is using to evaluate information that
  institutions are disclosing. DOD stated that it is reviewing disclosure information to identify
  conflicts of interest or commitment and determine whether they are manageable.
- OSTP advised that it is working to restore trust with institutions and to foster complete and transparent communications.

NSF Efforts Regarding Implementation of NSPM-33 (NEW): NSF updated its "Pre-Award and Post-Award Disclosure Relating to the Biographical Sketch and Current and Pending Support" chart to provide additional guidance regarding reporting of postdoctoral scholars, students, or visiting scholars (hereafter collectively referred as "Scholars") who are supported by an external entity. Scholars whose research activities are intended for use on the proposal/project should be reported under Facilities, Equipment and Other Resources. Scholars whose research activities are not intended for use on the proposal/project, but for whom there is an associated time commitment should be reported under Current and Pending Support, as well as in Project Reports, and as required per Post-Award Terms and Conditions. NIH and NSF are not completely aligned on this point, as NIH FAQs state that relationships that are solely a mentor/mentee arrangement (and thus, presumably require a time commitment), need not be reported if the Scholar is not performing research activities in support of senior/key personnel.

**DARPA Revision to FAQs (NEW)**: In January 2022, COGR hosted a webinar in which representatives from DARPA presented regarding the agency's Countering Foreign Influence Program. COGR members raised several questions during this presentation that were then provided to DARPA for further review and comment. DARPA provided answers to many of these questions in its May 12<sup>th</sup> update to its "Countering Foreign Influence Program (CFIP) Frequently Asked Questions (FAQ)". DARPA clarified the following points in these updated FAQs:



- Investigators are expected to disclose collaborations as current and pending support in Form SF424.
- DARPA is adopting the Implementation Guidance's approach regarding the disclosure of paid consulting, as well as the Guidance's exclusions from disclosure requirements.
- If institutions identify a need to submit corrections to inaccurate/incomplete investigator disclosures, they should contact the DARPA contracting officer and submit corrections no later than two business days after the notification.
- DARPA expects universities to review faculty members' personal contracts with foreign entities in accordance with their institutional policies.

**Department of Energy (DOE) Interim Financial Conflict of Interest (FCOI) Policy (FAL 2022-02) (UPDATE):** As of the date of this report, DOE has not yet issued the promised FAQs regarding its interim FCOI policy. DOE representatives have agreed to present on the policy at the upcoming June membership meeting, and COGR has provided the agency with questions on the policy ahead of the presentation.

# **Animal Research**

<u>USDA NPRM on Standards for Birds not Bred for Use in Research Under the Animal Welfare Act (87 FR 9880) (UPDATE)</u>

COGR submitted comments regarding this NPRM which, among other things, sets forth standards for research facilities' handling, care, treatment, and transportation of birds not bred for research. In its comments, COGR requested confirmation that the term "birds not bred for research" does not encompass wild-type birds that are bred in captivity. COGR asked USDA to specifically afford research institutions adequate time to address any changes required in the final rule in required change of operations and contingency plans. COGR also provided comments on several specific facility and handling provisions of the proposed rule and asked USDA to establish a regularly monitored email box to handle questions on the final rule.

Office of Laboratory Animal Welfare (OLAW) Request for Information (RFI) on Flexibilities for Conducting Semiannual Animal Program Review (NOT-OD-22-114) (NEW)

As a part of its continuing efforts under the 21<sup>st</sup> Century Cures Act to reduce administrative burden associated with animal research, OLAW recently issued a RFI on flexibilities for conducting semiannual program review. Flexibilities include items such as conducting reviews as a part of convened IACUC meetings, reducing the intervals at which standard operating procedures are reviewed, and utilizing

AAALAC International site visits to meet the requirements for a program review. REC has assembled a working group to review the RFI and submit comments, which are due on August 1, 2022.

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### **Human Subjects Research**

Secretary's Advisory Committee on Human Research Protections (SACHRP) Meeting (NEW)

At its <u>March 2022</u> meeting, SACHRP members <u>presented</u> on potential changes to the definition of being "engaged in research," including a potential exception for:

Parties (a) who do not have a key role in designing the research, conducting the research, or analyzing and interpreting the research results; and (b) whose participation in the research is "substantively similar to its regular activities, or otherwise of such a nature, that its participation presents no significantly heightened risk to subjects.

SACHRP's discussion included a number of case studies illustrating application of the potential exception, and REC has invited SACHRP member Mark Barnes to meet with Committee members to review these examples.

SACHRP members also <u>presented</u> on possible recommendations regarding changes to the definition of "support," as that term is used in conjunction with the need for coverage under a Federal Wide Assurance, i.e., "federally supported means the U.S. Government is providing any funding or other support." One recommendation concerned expanding the definition to encompass research "conducted with any significant assistance or support from HHS funding, including infrastructure support for 'centers' or 'core services.""

SACHRP did not make any final decisions on these recommendations, and members agreed to bring these topics back to the next meeting for further discussion.

### Guidance on Clinical Trial Informed Consent Posting (NEW)

OHRP posted <u>additional guidance</u> for NIH funding recipients on the posting of IRB-approved clinical trial informed consent forms to satisfy the requirements of the 2018 Common Rule (45 CFR §46.116(h)). The guidance discusses the websites at which forms may be posted (<u>ClinicalTrials.gov</u> or <u>Regulations.gov</u>); deadline for posting (including a definition of "last study visit"); who may post the form; and the version of the form that should be posted.



COGR Response to "NIH Request for Public Comments on DRAFT Supplemental Information to the NIH Policy for Data Management and Sharing: Responsible Management and Sharing of American Indian/Alaska Native Participant Data" (NOT-OD-22-064) (NEW)

COGR submitted a <u>response</u> to this request for comments and suggested that the document explicitly state that its provided examples of appropriate data sharing/management are not exclusive. Recognizing Tribal Nations' rights to apply their own requirements to research conducted within their jurisdiction, COGR also suggested that the Guidance recommend full and open discussions between researchers and Tribal Nations prior to proposal submission to identify any requirements or restrictions on use/sharing of research data. Finally, COGR recommended that the Guidance include examples of any data-sharing restrictions or limitations that NIH would not permit for NIH-funded projects.

Publication of NIH Guidance "Informed Consent for Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing" (NEW)

COGR submitted comments in response to an NIH RFI, Developing Consent Language for Future Use of Data and Biospecimens (NOT-OD-21-131), some of which were incorporated into this <u>final guidance</u>. Notably, the Guidance encompasses both "individually identifiable and deidentified data and biospecimens." Sample consent language including test covering withdrawal of consent for storage/sharing, as well as the potential for commercial application of biospecimens/data.

Meetings with OSTP re. Development of Model Clinical Trial Agreement for Use in "Emergency" Research (UPDATE)

The COVID-19 pandemic pointed up the need for research institutions and federal funding agencies to work quickly on clinical research required to understand and combat emerging infectious diseases and other rapidly developing public health emergencies. In this vein, OSTP representatives have been meeting with COGR and other associations to discuss the development of clinical trial agreement templates that might be used as part of these efforts. These discussions have included prior efforts in this area and templates that might be leveraged (e.g., templates developed by the Federal Demonstration Project). Periodic meetings are continuing.

### **Research Environment**

REC has been closely following efforts by NIH and other agencies to ensure appropriate protections within the research environment against sexual harassment and bullying in the research environment. One example of recent agency action in this area is NIH's publication of "Requirements for Notification of Removal or Disciplinary Action Involving Program Director/Principal Investigators or Other Senior/Key Personnel" (NOT-OD-22-129). This notice was issued to implement provision of the 2022 Consolidated



<u>Appropriations Act (P.L. 117-103)</u>. Beginning on July 28, institutions will need to notify NIH of the removal of a PD/PI or any other senior/key personnel from their position, or any other disciplinary action taken against such individuals "due to concerns about harassment, bullying, retaliation, or hostile working conditions." Notice must be provided to NIH by the Authorization Organization Representative within 30 days of the disciplinary action.

REC is discussing agency expectations in this area, as well as actions that institutions are taking to promote safer research environments and plans a presentation on this topic at the October membership meeting.

# Costing & Financial Compliance (CFC)

## Cost of Compliance & Research Security: NSPM-33 (NEW)

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. We will continue this discussion at a session on Friday, June 10<sup>th</sup> — Research Security & the ROI. This will be a closed session and will provide an update on COGR's "Research Security Costing Model" Survey. To date, twenty-six institutions have participated in Phase I of the survey, focusing on the cost impact of the new researcher disclosure requirements (note: Phase II will focus on implementation of the institution's research security program). In addition to presenting results of Phase I, we also will explore the survey results within the context of the goals of NSPM-33, i.e., what have been the benefits to the research community at large in light of the significant investments that are being made by research institutions?

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

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

This initiative culminates a 5-year+ process of engagement between COGR, NIH, and HHS, and solves the longstanding and problematic reconciliation issue between the FCTR and the Final FFR. It also further reduces administrative burden—by cancelling the FCTR, it eliminates the redundant and unnecessary step of completing the FCTR, which became obsolete ever 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.



## **2022 Compliance Supplement is Available (NEW)**

The 1,968 page 2022 Compliance Supplement was posted on May 11<sup>th</sup> (at least three months early compared to previous years) on the OMB, Office of Federal Financial Management (OFFM) website. Comments on the 2022 Compliance Supplement, as specified in the Federal Register Notice, are due to OMB by July 11, 2022 (late comments will be considered to the extent practicable). Comments will be addressed in the development of the 2023 Compliance Supplement. However, COGR's view is that if there are significant issues, we will advocate for comments to be addressed sooner. Several items of note are:

- Applicability of 2 CFR Part 200 FAQs (p. 28 and p. 1778). As COGR requested upon the original release of 2 CFR 200, the FAQs applicable to 2 CFR Part 200 (the Uniform Guidance) are recognized in the Compliance Supplement.
- Part V: R&D and SFA Clusters (p. 1776 and p. 1781). COGR reviews the Compliance Supplement for updates to the R&D Cluster—there appear to be no significant changes to the R&D Cluster.
- Appendix IV: "Higher Risk" programs (p. 1931). This section updates the list of COVID-19 programs that have been determined as "higher risk."
- Appendix VII: Federal Audit Clearinghouse transition (p. 1959). This section provides the timing for the Federal Audit Clearinghouse transition from Census to GSA, effective October 1, 2022.

COGR will consider submitting comments to OMB regarding the 2022 Compliance Supplement. If you have any issues or concerns, please contact David Kennedy at <a href="mailto:dkennedy@cogr.edu">dkennedy@cogr.edu</a>. You may also reach out to the OMB Grants Team at <a href="mailto:GrantsTeam@omb.eop.gov">GrantsTeam@omb.eop.gov</a> with questions.

### Audit Update: Single Audit and Federal Developments (NEW & ONGOING)

COGR follows audit developments both on the single audit and the federal Office of Inspectors General (OIG) fronts. Below is a summary of audit developments we are following:

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



- Department of Health and Human Services, Office of Inspector General (HHS OIG) Workplan. In addition to the CAS initiative above, the HHS OIG Workplan can be followed at the HHS OIG website. Also of interest to some COGR members is a new initiative to look at compliance associated with the Provider Relief Funds and billing requirements for out-of-network patients.
- The National Science Foundation, Office of Inspector General (NSF OIG) released a report on January 21<sup>st</sup> titled Promising Practices for NSF Award Management. The report was prepared by NSF OIG contractor Cotton & Company LLP and designed as a resource for the research community to identify "promising practices" gleaned from eighteen separate NSF OIG audits. COGR has raised two concerns: 1) the report does not include management responses, audit resolution, or any other counter to the auditor perspective, and 2) "promising practices" could unintentionally transform into new audit standards. COGR met with NSF OIG officials to share our concerns, and while we were assured the intent was not to create new audit standards, COGR members still should take note of this NSF OIG report.
- Resolution to NSF OIG Audit Finding and Following Other NSF OIG Developments. We have reported in recent COGR Updates on the favorable resolution as to how F&A rates can be applied to new awards in select situations. In an NSF Management Response to an External Audit (see Resolution 19-1-013), the common institutional policy—allowing the proposed lower F&A cost rate to be used despite the negotiation of a new higher F&A cost rate now in effect—was affirmed. This allows proposed direct costs for the PI to be maintained, and there is no harm to NSF. Also emphasized was the importance of internal controls to ensure that the F&A cost rate applied to a new award does not exceed the F&A cost rate in effect at the time of the award. Other NSF OIG developments and recent audit reports can be found on the NSF OIG Reports & Publications page.

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

# **Costing & Financial Compliance: Other Issues (ONGOING)**

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

*Proposed NASA Term and Condition and Procurement.* COGR sent a Comment Letter to NASA on April 21<sup>st</sup> raising a concern with a proposed NASA term and condition. While COGR fully supports robust and proactive initiatives to expand procurement opportunities for small minority businesses, women's business enterprises, and labor surplus area firms, the proposed term would be problematic on several fronts and be inconsistent with 2 CFR 200.321, Contracting with small and minority businesses, women's business enterprises, and labor surplus area firms. We are following the status of the NASA proposal.



NIH Notice of Legislative Mandates, FY2022. This annual Notice (NOT-OD-22-117 for the FY2022 fiscal year)—released soon after the fiscal year appropriations budget is approved by Congress—describes statutory provisions applicable to NIH funding. Embedded in the this Notice are links to related NIH Notices applicable to statutory and related provisions covering other key policy topics for FY2022—NOT-OD-22-105 (Fiscal Policies), NOT-OD-22-076 (Salary Limitation), and NOT-OD-22-108 (rescinded version) & NOT-OD-22-132 (Ruth L. Kirschstein, NRSA & corrected version).

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

No-Cost Extension for HEERF Awards. We reported in the March Update that institutions have received 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.

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

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



# Contracts & Grants Administration (CGA)

# **National Science Foundation PAPPG: (NEW)**

On April 13, 2022, the National Science Foundation announced proposed changes to its Proposal & Award Policy & Procedure Guide (PAPPG), expected to become effective in January 2023. The Guide includes several proposed changes, and members are encouraged to review the NSF Policy Office <u>marked-up version</u> of the Guide in detail.

COGR is preparing comments in time for the June 13th deadline and will share those with the membership as soon as they are complete. The proposed new PAPPG includes:

- Several revisions to support the transition from Fastlane.gov to Research.gov
- Several proposed changes to implement the <u>requirements in NSPM-33</u>, including a new <u>research security</u> section, warnings and penalties for noncompliance with NSF requirements, reporting of participation in foreign talent recruitment programs, strong encouragement for recipients to use <u>ORCID</u> as a digital persistent identifier, submission of Current & Pending Support through <u>SciENcv</u>, certification that information is complete and accurate (also through SciENcv), and other changes.
- New requirement for a <u>Plan for Safe and Inclusive Field/Vessel/Aircraft Research</u> for projects that involve off-campus field research, aimed at keeping researchers safe from harassment.
- Various changes to bring NSF practices in alignment with NIH, including reporting only <u>current positions</u> on the biosketch (currently "all positions"), the submission of revised <u>Current & Pending Support</u> before award, and the possibility <u>for certain exceptions</u> for the longstanding data sharing requirements
- Changes to support the new NSF <u>TIP directorate</u>, including introducing new forms of awards in addition to grants and cooperative agreements (e.g., Broad Area Announcements (BAAs)), and changes to the eligibility criteria to allow other types of organizations to submit proposals.
- The introduction of two new tools <u>BAAM</u> (Broad Agency Announcement Management) and ProSPCT (Program Suitability and Proposal Concept). The ProSPCT tool would be <u>required for various types of submissions</u> at the planning stage before full submission. It appears the tools will also be used to provide early feedback on a proposed project for prospective PIs.
- New statements about the time frame for approval of annual reports and final reports and a specific statement that the program officer must approve the annual report.
- New references to several new areas of compliance, including <u>dual-use research</u>, <u>environmental considerations</u>, and <u>an expansion</u> of the definition of significant financial interest to include private equity venture and other capital.



### **NIH Data Management and Sharing (UPDATE)**

The COGR NIH Data Management and Sharing (DMS) Workgroup released the first section of an NIH DMS Readiness Guide: Briefing Sheet for Institutional Leadership – in collaboration with the Association of Research Libraries. The Briefing Sheet is an introduction to the requirements to help research administrators get the conversation started with senior leadership and key stakeholders across campus about the status of the institution's readiness to comply with these new requirements. The DMS Workgroup recommends that institutions modify the Briefing Sheet with specific information about their institutions, including the key players and available resources. Contact memberservices@cogr.edu if you would like an editable copy of this document to customize for your institution. As a reminder, the new NIH-wide data management and sharing policy will be effective for all NIH institutes and centers no later than January 2023.

Additional sections of the Readiness Guide will be released over the summer, including a policy matrix of all NIH policies, by institute and center, detailing the specifics requirements for the management plan, how it will be monitored, frequency of the data upload, and other components of the NIH policy. Other sections of the guide will include a discussion of Roles and Responsibilities, Culture Change, Costing Issues, Compliance, and more.

At the June meeting, COGR will host a session focused on how institutions are implementing the NIH DMS policy now. We hope you will join us for that panel discussion. For more information on the NIH DMS Policy, please visit <u>COGR's Resource page</u>, including the policies, COGR Updates, meeting materials, policy letters, and additional resources.

Finally, related to this topic, NIH is requesting comments on its draft supplemental information to the NIH policy for data management and sharing on <u>protecting privacy when sharing human research participant</u> data. Comments are due June 27, 2022, and COGR plans to respond.

# Transition from DUNS to Unique Entity Identifier (UEI)

Several COGR members reported issues registering new entities or renewing their registrations in SAM.gov. The changeover started on April 4<sup>th</sup>, 2022, after which institutions began reporting problems when validating their institution's address. The General Services Administration (GSA), which runs SAM.gov, reported that there was a problem bringing over the addresses from the old system to the new system, which caused the validation issues. This, in turn, caused a backlog at the help desk. The result was that some institutions had trouble receiving payments and validating UEIs for proposal submission. Other institutions reported delays in issuing new subawards to institutions that did not previously have a DUNS or UEI.

Several institutions were helped by a fix that GSA implemented around self-certification of the institution's address. NIH issued a 30-day extension for new UEIs for some grant-related activities. We were also informed that OMB issued blanket 30-day extensions on expiring registrations. While many



issues were resolved related to existing entities, problems persist with registering new entities in SAM.gov for new EUIs. COGR will continue to monitor this.

### Federal Other Transaction Authority Agreements (NEW)

COGR members report a significant increase in the number of federal awards arriving at their institutions in the form of an Other Transaction (OT) type agreement. This is a unique funding mechanism typically issued by sponsors to non-traditional recipients or when non-standard terms and conditions are needed to support new types of programs. OTs are flexible agreements that can offer significant benefits to allow the research team to deliver on new types of collaborations and projects. At the same time, recipients must ensure that their award includes basic terms and conditions such as ownership of intellectual property and the ability to recover their negotiated F&A and fringe benefit costs.

A new working group is being formed to develop helpful guidance for research institutions on important points and key terms to consider when negotiating and managing OTs. Please contact <u>Michelle Christy</u> with any questions about the new working group.

### Additional Notices CGA is Monitoring (NEW)

CGA is also monitoring these topics:

<u>Implementation FAQs related to DARPA's implementation of the Foreign Influence Risk Rubric See</u> more about the DARPA rubric for assessing research risk at the award stage in the Research Ethics & Compliance section of this Update.

June 2022 Updated eRA RPPR Module and Instruction Guide: Action Required for In-Progress Budget Forms

On May 13, NIH announced that it expects to release new RPPR forms and instructions to allow for the additional information required for Other Support.

In addition, note that NIH updated the following compensation limits and NIMH Special Council Review Procedures:

Correction to Stipend Levels for Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2022

Guidance on Salary Limitation for Grants and Cooperative Agreements

### Modifications to the NIMH Special Council Review Procedures

NIMH is updating its policy concerning extremely well-funded PIs, stating that those with funding of more than \$2 million in total costs (previously \$1.9M in total costs) must receive special council consideration before awarding a new project.



Finally, NIH issued a <u>Notice of Legislative Mandates in Effect for FY 2022</u> that includes these compensation notices, as well as policy reminders related to grant and contract management. See more in the Costing & Financial Compliance section of this Update



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

## **Contracts & Grants Administration (CGA)**

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