



**June 25, 2018**

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## **COSTING POLICIES**

Committee: Cindy Hope, University of Alabama (Chair) , Joseph Gindhart, Washington University-St. Louis, Lynn McGinley, University of Maryland-Baltimore, Jeffrey Silber, Cornell University, Cathy Snyder, Vanderbilt University, Michael Daniels, Northwestern University, Amanda Dotson, Texas A&M University, Michael Legrand, University of California-Davis, James Fortner, Georgia Institute of Technology, Sarah Axelrod, Harvard University, Nate Martinez-Wayman, Duke University, Marcia Smith, University of California – Los Angeles

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### **Procurement and the Micropurchase Threshold (MPT): GUIDANCE RELEASED**

The long-awaited OMB Memorandum to address implementation of the micropurchase threshold (MPT) was released on June 20, 2018. Specifically, [OMB Memorandum M-18-18, \*Implementing Statutory Changes to the Micro-Purchase and the Simplified Acquisition Thresholds for Financial Assistance\*](#), effectively implements the statutory changes set forth in the National Defense Authorization Acts (NDAA) for Fiscal Years 2017 and 2018.

As specified in the Memorandum *{emphasis added}*:

*In accordance with recent statutory changes set forth in the National Defense Authorization Acts (NDAA) for Fiscal Years 2017 and 2018, this memorandum raises the threshold for micro-purchases under Federal financial assistance awards to \$10,000, and raises the threshold for simplified acquisitions to \$250,000 for all recipients. Further, it implements an approval process for certain institutions that want to request micro-purchase thresholds higher than \$10,000. Agencies are required to implement these changes in the terms and conditions of their awards, and recipients of existing Federal financial assistance awards may implement them in their internal controls.*

Prior to the release of the Memorandum, the 2018 Compliance Supplement (CS) was released (see next section) and included audit guidance around the micropurchase and simplified acquisition thresholds within the context of NDAA for Fiscal Years 2017 and 2018. The June 2018 COGR Update included a “[COGR Analysis](#)” (see pages 4-5) on the 2018 CS. While the COGR analysis, at the time, was valid based on language in the 2018 CS, in light of the Memorandum, COGR’s interpretation is that where there are inconsistencies between the two, the Memorandum supersedes the 2018 Compliance Supplement. We believe OMB should further clarify.

### **Approval Process for an MPT Greater than \$10,000**

A key element of the Memorandum is the section titled: *Process for Requesting a Higher Threshold Under the NDAA for FY2017*. COGR has recognized the sense of urgency for those institutions that currently have an MPT greater than \$10,000 and the need to have a clear and timely “approval process”

to continue using their MPT greater than \$10,000. Finally, under this section of the Memorandum, guidance has been provided:

*Requests for approval should be submitted to the institution's cognizant Federal agency for indirect cost rates; however, institutions should contact the agency before sending the request to determine the correct point of contact. The cognizant Federal agency will assign review of the request to the appropriate office within the agency to determine whether to approve, and will maintain records and justification of all approvals. The request should include the threshold level being requested and the justification(s) for it based on the criteria above per Section 2 I 7(b) of the NDAA for FY2017.*

In a follow-up email from OMB, Gilbert Tran, additional clarification was given as to the **Points of Contact (POC)** to request approvals. In a June 20 e-mail from OMB to the stakeholders, Mr. Tran wrote:

*Hi Colleagues, I want to inform you that OMB has issued a memo regarding the implementation of the micro-purchase and simplified acquisition thresholds under the 2017 and 2018 NDAA. The link to the OMB Memo M18-18 is attached below.*

<https://www.whitehouse.gov/omb/management/office-federal-financial-management/>

*We are providing three POC for universities, nonprofit research organizations and independent research institutes to request a micro-purchase threshold higher than \$10,000.*

*For grantees under the Department of Health and Human Services (DHHS) cognizance for indirect costs, contact:*

*Andrea L. Brandon  
Deputy Assistant Secretary  
Office of Grants and Acquisitions Policy and Accountability  
Office of the Assistant Secretary for Financial Resources  
[Andrea.Brandon@hhs.gov](mailto:Andrea.Brandon@hhs.gov)*

*For grantees under the Office of Naval Research (ONR) cognizance for indirect costs, contact:*

*ONR Regional Administrative Contracting Officer (ACO) or  
Wade Wargo, Director, University Business Affairs  
[wade.wargo1@navy.mil](mailto:wade.wargo1@navy.mil) to identify the proper ACO*

*For grantees not under DHHS and ONR cognizance, contact Mary Tutman ([Mary.E.Tutman@omb.eop.gov](mailto:Mary.E.Tutman@omb.eop.gov)) or Gil Tran ([Hai.M.Tran@omb.eop.gov](mailto:Hai.M.Tran@omb.eop.gov)).*

*We also like you to remind all grantees that under the micro-purchase procurements with federal award funds (section 200.320 (a)), the purchases at or under the established threshold may be awarded without soliciting competitive quotations.*

*Regards,  
Gilbert Tran  
Executive Office of The President  
OMB/OFFM - 202-395-3052*

COGR members have diligently prepared for implementation of the Uniform Guidance Procurement Standards, [2 CFR 200.317-326](#). For several COGR members with a January 1, 2018 fiscal year start, the new standards already apply and the OMB Memorandum, unfortunately, is late. For many COGR members with a July 1, 2018 fiscal year start date, the OMB Memorandum, hopefully, provides enough time to implement key provisions related to the MPT and the Simplified Acquisition Threshold. For those COGR members with a fiscal year start date later in the year (e.g., September 1, 2018), the Memorandum may be timely.

COGR still would like to see OMB be proactive in working with those institutions where their fiscal year has started, as well as those institutions that are up against a tight deadline with a July 1, 2018 fiscal year start date. We propose that OMB support the following for institutions requesting an approval to maintain their current MPT greater than \$10,000:

- 1) institutions can initiate the approval process as described in the Memorandum;
- 2) institutions are permitted, with a fiscal year start date of July 1 or prior, to continue using their existing MPT that is greater than \$10,000; and
- 3) upon approval, have it be clearly communicated to institutions that the approval is retroactive to the start date of their fiscal year. For institutions with a fiscal year start date of, for example, September 1, the same approach would be necessary if approval is not received before their fiscal year start date.

We expect there will be questions that arise. We encourage you to contact Gilbert Tran at OMB (202-395-3052, [hai\\_m\\_tran@omb.eop.gov](mailto:hai_m_tran@omb.eop.gov)) or Mary Tutman at OMB (202-395-1703, [Mary.E.Tutman@omb.eop.gov](mailto:Mary.E.Tutman@omb.eop.gov)) if you have questions or concerns. Also contact David Kennedy at COGR at [dkennedy@cogr.edu](mailto:dkennedy@cogr.edu) for additional insights and COGR perspectives.

### **2018 Compliance Supplement and Audit Related Issues**

As we addressed in the June 2018 COGR Update, OMB released the [2018 Compliance Supplement](#) (CS). This year's edition was published as a "skinny" CS (251 pages) and includes only significant updates to applicable sections. In effect, auditors will use the 2017 CS and the 2018 CS together to guide their audits.

Below is an update to the topics we addressed earlier in June:

**Procurement and the Micropurchase Threshold (MPT).** See previous section. As we noted above, while the COGR Analysis, at the time, was valid based on language in the 2018 Compliance Supplement, in light of the OMB Memorandum M-18-18, COGR's interpretation is that where there are inconsistencies between the two, the Memorandum supersedes the 2018 Compliance Supplement. We believe OMB should further clarify.

**Payment and Reimbursement under 2 CFR 200.305.** This is not addressed and remains a concern. According to some in the audit community, the IG position is that “recipients will be reimbursed without ever paying their invoices” if reimbursement requests are made before issuing payments. In response to a request for Public Comments to the 2017 Compliance Supplement, COGR sent a [Comment Letter](#) (dated October 20, 2017) to OMB, Gilbert Tran. Some of your institutions also sent letters, either documenting your unique circumstances or simply supporting the COGR letter. COGR views this as an open item and hopes to pursue it further at a Single Audit Roundtable meeting later this year.

**Securing Student Information, Department of Education (ED).** COGR has worked with several of our Association partners to raise concerns as to how ED has proposed audit objectives related to safeguarding data specific to an institution’s information security program (i.e., Safeguards Rule). ED withdrew their initial inclusion of overly-complex audit guidance from the 2017 CS. COGR’s position has been that the CS is not the correct vehicle for this guidance. This issue was not addressed in the 2018 CS, but will be revisited in the 2019 CS. We will continue to track this issue.

**Annual Compliance Audit, Student Financial Aid (SFA) Cluster.** Throughout 2017, we regularly reported on a 2016 Department of Education [Dear Colleague Letter](#) that formed the basis for an ED position that an annual compliance audit of the SFA is required. Our understanding is that the Department of Education, at least for now, has backed off of this position.

**Revenue Recognition of Grants and Contracts by Not-for-Profit Entities.** This new FASB rule will impact how private institutions account for revenue and expense. A summary of the new [FASB revenue recognition rule](#) is available at the FASB website.

In the course of reviewing the 2018 CS and other audit related issues, please contact David Kennedy at [dkennedy@cogr.edu](mailto:dkennedy@cogr.edu) if you identify any issues of concern.

### **Costing Policies Committee: Other Issues and Areas of Interest**

Below is a summary of other issues in which the Costing Policies Committee is engaged, and/or topics that might be of interest.

**F&A Update and COGR White Paper.** F&A currently is not under heavy scrutiny, as it was at this time last year. Still, COGR continues its participation in the Associations F&A Working Group, comprised of COGR, the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), the Association of Public Land-grant Universities (APLU), the Association of Independent Research Institutes (AIRI), the American Council on Education (ACE), the National Association of College and University Business Officers (NACUBO). And as we reported at the June Meeting, the COGR Costing Committee, with assistance from the RCA Committee, has organized around the development of an F&A White Paper to address many of the themes related to transparency, alternative models, education and myths. We expect to make major progress this Summer and will keep the Membership posted on status.

**NIH Salary Cap for 2018.** Two NIH Notices published on May 16, 2018; [NOT-OD-18-180](#) and [NOT-OD-18-181](#), implement NIH fiscal policies and legislative mandates for FY2018. As

published on the website of the Office of Personnel Management (OPM), [Salary Table No. 2018-EX](#) shows the Executive Schedule salary rates, effective January 2018. Per the Executive Schedule, the NIH salary cap (Executive Level II) increases from \$187,000 to \$189,600. The two NIH Notices further confirm the March 7, 2018 NIH guidance; NIH Notice Number: [NOT-OD-18-137](#), Guidance on Salary Limitation for Grants and Cooperative Agreements FY2018.

**HHS/NIH Policy Update: Financial Reporting.** We are paying close attention to developments in the area. As we have reported, we believe there is an opportunity to pursue issues including: Facilitating and/or eliminating the quarterly Federal Cash Transactions Report (FCTR, SF-272); consistent grantee close-out requirement of 120 days applicable to all HHS operating divisions; and addressing weaknesses in the Payment Management System (PMS). We will keep the Membership posted on all developments.

**NIH pooled accounts in the Payment Management System.** As the conversion to subaccounting almost is complete, some institutions are sharing with COGR discrepancies between the amount that PMS indicates as available in the pooled account versus the remaining awarded/authorized funds recorded in the institution's financial system. It is not clear how these discrepancies are to be resolved, but as appropriate, COGR will engage with federal officials.

**NRSA Stipend Levels and Regional Cost of Living Differences.** Stipend levels under the Ruth L. Kirschstein National Research Service Awards (NRSA) program are published annually by NIH. While the level may increase on an annual basis, there is no recognition of regional cost of living differences. COGR informally is surveying the Membership to determine if this is an issue of broad concern.

We will keep the Membership posted on all developments related to the above issues. We encourage you to raise issues not covered to the COGR staff or to members of the Costing Committee.

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## RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Pamela Webb, University of Minnesota (Chair); Michael Ludwig, University of Chicago; Jeffrey Friedland, University of Delaware, Walter Goldschmidts, Cold Spring Harbor Laboratory, David Norton, University of Florida, Jennifer Lassner, University of Iowa, Steven Martin, Indiana University – Bloomington, Lisa Mosley, Yale University, Allen DiPalma, University of Pittsburgh; Jeremy Forsberg, University of Texas-Arlington, Stephanie Endy, Case Western Reserve University, Twila Reighley, Michigan State University

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### USDA Records Freeze (Update)

As previously reported on COGR's listserv, many of our members confirmed receipt of a [letter](#) from USDA notifying recipients of funds from *certain* USDA components including Agricultural Research



Service (ARS), Economic Research Service (ERS) and National Agricultural Statistics Service (NASS) of a records disposal freeze. Subsequently, NIFA posted an [update](#) on their website notifying entities of the freeze associated with eight (8) USDA offices. There has been confusion both within USDA and extramural grant community whether the records freeze applied to the other five agencies mentioned on NIFA's website since no "official" letters were received from those USDA Offices unlike the letter from Ars, ERs, and NASS.

On May 21<sup>st</sup> COGR was notified by the records management officer that USDA attorneys have lifted the freeze for external cooperators and grantee copies of the record. Pursuant to the correspondence received, we consider this to be no longer an issue for our members. Please contact [jbendall@cogr.edu](mailto:jbendall@cogr.edu) should you require additional information.

### **NSF PAPPG Out for Comment**

COGR reported that the Proposal and Award Policy and Procedures Guide (PAPPG) is out for comment in the Federal Register. Comments are due July 13. COGR will be responding and invites your comments to be submitted to [jbendall@cogr.edu](mailto:jbendall@cogr.edu) no later than July 6, 2018.

### **NSF Presentation on Harassment Reporting**

On Friday COGR reported that the [joint comment letter](#) submitted in response to the [Federal Register Notice](#) had been reviewed by NSF. Jean Feldman, Bob Cosgrove and Rhonda Davis, Office of Diversity and Inclusion (ODI) gave an update and presentation on the background and context of the new term and condition, the role of ODI and information pertaining to Title IX Compliance Reviews. Of significant importance during the presentation was NSF's willingness to host COGR and other associations for a small round table discussion on July 24<sup>th</sup> prior to implementation of the proposed new requirements. The round table discussion was mentioned in COGR's comment letter and we're truly appreciative that NSF has agreed to host. COGR will update the membership on any new developments pertaining to the new policy and will also comment on the section in the draft PAPPG that addresses the reporting requirement. Stay tuned for updates.

### **SAM.gov Update on Registration**

The Research Compliance and Administration Committee (RCA) hosted Nancy Goode, Director of Outreach and Stakeholder Engagement and Christy Hermansen, Project Lead, of the General Services Administration to gain clarity around the issues from the extramural grant community associated with the registration and renewal process in the System for Award Management (SAM). Previously, GSA had announced via the [Federal Register](#) on May 25<sup>th</sup> new plans to require a notarized letter as a means to reduce fraudulent activities of certain bad actors from impersonating legitimate entities. The new process will require an officer or other signatory authority of each institution to formally appoint an Entity Administrator for registering or recertifying in SAM. The original, signed and notarized letter is mailed to the Federal Service Desk for SAM prior to the registration's activation or re-registration.

COGR was notified in May that there were a handful of institutions that had submitted in accordance with the new requirements, but were awaiting renewal of the certification. Nancy and her team members were invited to FDP to update the membership of the new requirement. During the



presentation, members were informed that letters would be processed within two (2) days of receipt, however the volume of approximately 50,000 registrations were causing a backlog causing GSA to recommend that institutions submit six weeks ahead of time. For those entities that had time, the adjustment may not be an issue, but those with proposal deadlines in May were prevented from submitting proposals and receiving awards. This issue was discussed during the RCA Committee meeting. COGR was advised at the time to send an email to Ms. Goode for institutions who were waiting for approval. We were also informed that new guidance would be issued by the GSA that would alleviate the problem. For information on the new notarized letter process change effective June 11<sup>th</sup>, [click here](#).

**On or about June 29, 2018, GSA will be inaugurating a new login process for SAM.gov.**

Organizations are strongly encouraged to confirm the email address associated with their current SAM.gov user accounts prior to June 29. Failure to have an accurate email address might cause a delay in updating or renewing an existing registration after June 29.

**NIH Clinical Trial Fixed Rate Subawards**

COGR and FDP have been working for the last few months to request elimination of NIH prior approval for fixed price (fixed-rate) clinical trial site subawards, as well as eliminating the need to obtain approval to exceed the Simplified Acquisition Threshold on those same transactions.

**Please see the email below from Samuel Ashe, Director of the Division of Grants Policy approving this change.** As expected, if other conditions requiring NIH prior approval apply (e.g., foreign entity, change in scope), then prior approval for those aspects would still be needed.

Per a conversation Pamela Webb had on June 8, 2018 with Michelle Bulls, institutions may use this flexibility immediately, and may rely on Sam's email below as backup for this until the formal guidance can be issued. NIH intends to issue their guidance in the form of an NIH Guide Notice within the next few weeks or so and will also incorporate the change into the next Grants Policy Statement.

Both COGR and FDP continue to work on other ways to streamline the subaward process. Please contact Jackie Bendall of COGR and Stephanie Scott, Co-Chair, FDP Subawards Subcommittee and Jennifer McAllister, FDP Subawards Subcommittee for additional questions.

----- Forwarded message -----  
From: **Ashe, Samuel (NIH/OD) [E]** <[samuel.ashe@nih.gov](mailto:samuel.ashe@nih.gov)>

Thank you for sending forward the proposed language. Based on our review, NIH will issue guidance clarifying the distinction between a fixed amount subaward and a fixed-rate agreement which is commonly used by Clinical Trial Coordinating Centers to distribute capitation funds. In a fixed amount subaward, the total value of the award is negotiated upfront. This requires the pass-through entity to know both the unit price and the total number of units that will be provided. However, in a fixed-rate agreement, while there is a negotiated cost per unit, e.g., per patient cost in a clinical trial, the total amount of the award may be unknown when the agreement is created. Since this type of agreement is based on a "fixed rate" as opposed to a "fixed amount" as defined by 45 CFR Part 75.201, prior approval will not be required to enter into this type of agreement provided there are no other factors that

would require NIH prior approval consistent with [NIHGPS Chapter 8.1.1.4](#). In addition, the simplified acquisition threshold cap will not apply to these types of agreements since they are not based on “fixed amounts”. By issuing this clarification NIH will acknowledge that we have not made any changes to our current clinical trial capitation award funding model.

### **Environmental Protection Agency Federal Register Notice, “Strengthening Transparency in Regulatory Science”**

COGR, along with other associations intends to put out a joint response to the EPA’s NPRM, “[Strengthening Transparency in Regulatory Science](#)”. This proposed controversial rule effectively prevents the EPA from evaluating the *best available* evidence when developing regulations specifically aimed at protecting human health. COGR has been a longtime advocate of transparency, reproducibility, and open science participating with NIH and other associations on public access initiatives and forums. COGR disavows EPA’s stance that scientific research lacks merit or value if the data, for legitimate purposes, cannot be made publicly available or reproduced. The public comment period for the proposed rule published in the Federal Register has been extended to August 16, 2018. A public hearing will be held on July 17, 2018. Please submit your comments to [jbendall@cogr.edu](mailto:jbendall@cogr.edu).

### **Office of Management and Budget (OMB) – President’s Agenda**

COGR was fortunate to host OMB staff Rhea Hubbard and Nicole Waldeck, Policy Analysts with OMB on Thursday to present to the Membership the [President’s Agenda](#). There are many opportunities for COGR to insert its expertise to assist OMB with grant challenges under this initiative. Areas of focus for OMB include but are not limited to conflicting guidance, fragmentation, burden, the need for improved coordination across lines with businesses and programs, opportunities to improve access to and quality of data, and unstandardized business process. We look forward to partnering with OMB in the coming months. A formal stakeholder outreach strategy is forthcoming and will be posted to the OMB Grants Community of Practice page. COGR will update the membership on additional details as they become available.

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## CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Patrick Schlesinger, University of California-Berkeley (Chair), Alexandra Albinak, The Johns Hopkins University, Elizabeth Peloso, University of Pennsylvania, Kevin Wozniak, Georgia Tech Research Corporation, David Winwood, Louisiana State University, Fred Reinhart, University of Massachusetts, John Ritter, Princeton University, Wendy Streitz, University of California, Jennifer Ponting, Harvard University, Dan Nordquist, Washington State University, Cindy Kiel, University of California, Davis

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### **COGR Committees Meet with Director of DOD Basic Research Office**

On June 6 the COGR CIP and RRR Committees met with Dr. Bindu Nair, Acting Director of the DOD Office of Basic Research, and Jason Day, Subject Matter Expert in the Office. We discussed concerns about the access of foreign nationals to DOD-funded research. Some of the concerns were prompted by a recent visit of the DOD Deputy Secretary of Defense to a DOD-funded activity at MIT where he observed a number of foreign nationals participating in the research. This has led to considerable discussion at DOD of the proper balance between scientific openness and the need for greater security. Dr. Nair and her office have sought to communicate the long history and value of DOD-funded open science. Classification based on NSDD-189, which defines fundamental research, has been viewed as the proper response to national security concerns. However, the concerns today more involve economic security, where DOD is not best positioned to take the government lead.

A draft options paper developed by Dr. Nair's office was discussed at the meeting. Option 1 involves DOD developing topic areas of sensitive research and a list of adversary nations from which to protect such research. Solicitations would restrict foreign nationals from those nations from being funded by DOD, and DOD approval would be required of any publications. Option 2 involves greater classification of critical topic areas. Option 3 would prohibit funding to research performers who participate in foreign talent programs from adversary nations with an exemption for fundamental research, and also establish a forum for discussions between DOD and law enforcement officials, and the university community. Pros and cons for each option are discussed in the paper in a fairly balanced way.

In discussion we noted that option 1 essentially would prohibit DOD funding of fundamental research in the critical topic areas. By definition fundamental research cannot involve restrictions on publications or on access to the activity. Many institutions will not accept funding subject to such restrictions. One CIP member estimated the effect on her institution would be to lose \$100M--\$125 M in DOD funding. More data of this kind might be helpful. While we would not encourage greater classification, option 2 at least would preserve the current system. Option 3 preserves the current system but raises issues as to

what constitutes a “foreign talent” program and how this might be certified by an institution in proposals. We pointed out that it also might be affected by pending legislation (see [COGR June Update](#)). Dr. Nair’s office has been discussing with the National Academy of Engineering establishment of a forum such as proposed in option 3. The plan would be to hold two meetings annually between senior DOD and academic representatives. The need to identify possible fundamental research “champions” to interact with DOD leadership also was mentioned. The options memo currently is an internal draft. Dr. Nair requested that we identify whether any other major option might be missing. Further input on the pros and cons also would be helpful.

We will be discussing possible further COGR responses.

### **NIST Holds Last of Public Hearings on ROI/RFI**

On June 14 NIST hosted the last of four public meetings on the Return on Investment RFI initiative (see [COGR May Update](#)). [The RFI](#) was released on May 1. It asks for comments on four questions: 1) core federal technology transfer principles and practices that should be protected or changed; 2) challenges to effective transfer of technology and knowledge resulting from federal R&D; 3) proposed solutions to these challenges; and 4) other ways to improve technology transfer resulting from federal R&D.

NIST had held three previous regional public meetings on the RFI, in San Jose, Denver and Chicago. Our understanding is that most were sparsely attended. 120 people registered for the fourth meeting held at NIST headquarters. Only about half that number actually attended, although additional people viewed the webcast.

COGR has been working on a joint response with AAU, APLU and AAMC. Jessica Sebeok of AAU made a statement at the June 14 meeting on behalf of the associations. In her statement Ms. Sebeok pointed to the importance of preserving the Bayh-Dole statutory framework. She suggested a number of possible improvements to the implementation. These included providing more government funding specifically for commercialization, addressing compliance burdens associated with invention reporting and the U.S. manufacturing requirement, and improving the balance in conflict of interest regulations between addressing conflicts and incentivizing partnerships with industry. She also suggested the need to strengthen the U.S. patent system through providing more clarity on Section 101 patent eligibility, assuring against misapplication of Bayh-Dole march-in rights, and harmonizing court and PTAB claim construction standards. She also made a number of tax code suggestions pertaining to facilities financed with tax exempt bonds and the R&D tax credit. Finally she emphasized the importance of taking a broad view in defining measures of success for technology transfer.

There was a great degree of commonality in the comments of other participants in the June 14 meeting. None were critical of Bayh-Dole. Many cited the need for greater speed and timeliness throughout the federal R&D process, from the proposal stage on to the establishment of public—private partnerships for commercializing resulting technology. Much of the discussion involved the federal labs. The need for responses on a timeframe more attuned to business needs, and to overcome impediments through regulatory changes and more exposure to commercialization culture such as through entrepreneurs in residence programs, etc. was repeatedly cited.

We are developing a detailed joint association response along the lines of Ms. Sebeok's statement, with greater elaboration of some of the key points. We plan to have a draft available for COGR members by the end of this month. We encourage COGR member institutions to submit their own responses, and to consider use of the joint association response as a template. Comments are due July 30.

### **NIST Director Speaks at COGR Meeting**

Dr. Walter Copan, Director of NIST, spoke to the COGR membership at the June meeting on "Unleashing American Innovation". He discussed the mission and goals of NIST and NIST program activities. He discussed NIST's role in technology transfer, and the ROI Initiative. He described the cross-agency priority (CAP) lab-to-market goal of the President's Management Agenda, and implementation of the goal. He concluded by summarizing a number of systemic challenges. These map well to the issues raised at the June 14 meeting, and that we plan to address in our response to the RFI (e.g. march-in rights, conflicts of interest restrictions, lack of access to maturation funding to advance promising technologies).

Dr. Copan's [presentation is posted](#) on the COGR website.

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### **RESEARCH & REGULATORY REFORM**

Committee: Lois Brako, University of Michigan (Chair), Kerry Peluso, Florida State University, Suzanne Rivera, Case Western Reserve University, Ara Tahmassian, Harvard University, Robin Cyr, University of North Carolina-Chapel Hill, Lynette Arias, University of Washington, Naomi Schrag, Columbia University, Marti Dunne, New York University, Martha Jones, Washington University – St. Louis, Charles Greer, University of California-Riverside, Mary Mitchell, Partners, J.R. Haywood, Michigan State University

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### **Association Meeting with the FBI to Discuss National and Economic Security Concerns**

The COGR CIP and RRR committees met with FBI officials Susan Thompson, Office of Private Sector; Edward You, Weapons of Mass Destruction Directorate, Biological Countermeasures Unit; Peter Lapp, Washington Field Office; and Tom Harper from the Department of Education Office of Inspector General (OIG) who serves as a task force officer with the FBI on cyber-crimes. The discussion focused on national and economic security, cybersecurity, intellectual property (IP) theft and other areas of concern. Burt Seearam and Gloria Zaborowski from the FBI, and Rodolfo Gonzalez and Lourdes Agosto from the Office of the Director of National Intelligence also attended. COGR committee members were joined by AAU, APLU and ACE staff and members of the AAU CFR and APLU CGA.

FBI officials expressed concern about data security, data theft, and the role of F1 and J1 student visa holders in research and their possible engagement in data theft on behalf of foreign intelligence offices. They emphasized a shared responsibility between the government and academia in protecting data and IP and discussed a number of specific incidents of foreign student theft. The book "Spy Schools" by Daniel Golden was cited as a good source of information about these activities.

The white paper [Higher Education and National Security: The targeting of Sensitive, Proprietary, and Classified Information on Campuses of Higher Education](#) was distributed. Agents indicated that the FBI has [64 field offices](#) across the country and that institutions should make contact with their local field office and reach out to them with security/cybersecurity and environmental health/biosafety concerns. They noted that this helps to identify large-scale efforts involving issues such as theft of proprietary information, software, articles, data, and student's personally identifiable information and email accounts, all of which have occurred recently, as well as other potentially multi-institutional efforts. FBI officials suggested that "data is the new oil" and that the data the U.S. is "hemorrhaging" today is the IP of tomorrow. Officials strongly recommended two-factor authentication which they suggested would have prevented theft in as many as 80% of recent cases. It was suggested that institutions consider who they contract with regarding DNA sequencing and other health and related efforts that generate valuable, and sometimes sensitive, data and consider contracting only with domestic sources.

FBI officials indicated that they understood the need for open communication and sharing of data and ideas in science, and that they were not suggesting greater protectionism, but that institutions need to be aware of these very real security threats and address them. They also suggested that institutions need to make their faculty and students aware of these threats, possibly through existing training. There was some discussion on data sharing and federally required data sharing and plans. The fact that the government appears to be sending mixed messages was mentioned by university representatives. Institutions suggested that the FBI connect with NIH, NSF and other federal agencies engaged in the interagency working group on public access.

The June meeting follows a May meeting with COGR and other higher education association staff to discuss lines of communication between the FBI and other security offices and agencies and academia. The FBI is planning further meetings with university groups for similar discussions.

## **Human and Animal Research**

### **Common Rule**

On June 18, 2018, the Department of Health and Human Services and 16 other federal departments and agencies issued a [final rule](#) to delay the Common Rule general compliance date until January 21, 2019. The final rule adopts the proposals put forward in an April 20, 2018 notice of proposed rulemaking. The rule maintains the current effective date of July 19, 2018. As described in the NPRM and final rule, institutions cannot implement the new rule until January 21, 2019 with the exception of three burden reducing provisions:

- The revised definition of "research," which deems certain activities not to be research;
- The allowance for no annual continuing review for certain categories of research; and,
- The elimination of the requirement that institutional review boards review grant applications.

Studies for which institutions choose to implement any or all of the three provisions must implement the full 2018 requirements beginning on January 21, 2019. COGR and other higher education associations [supported](#) the proposals described in the April 20, 2018 NPRM while also stressing that associated guidance should be issued promptly to allow institutions time to adjust their policies, procedures, and technology in advance of the general compliance date.

### Update on the NIH Clinical Trial Case Studies

COGR and several other organizations met with NIH Principal Deputy Director Dr. Larry Tabak and other NIH staff on May 2 to discuss concerns that NIH has broadened its definition of “clinical trial” through its most recent set of case studies published in late summer 2017. Notes from the May 2 meeting can be found [here](#). [Higher education associations](#) and other groups such as the Federation of Associations in Behavioral and Brain Sciences had previously expressed significant concerns with the case studies and the implications of defining basic research involving humans as clinical trials. On June 17, after consulting with NIH and congressional staff, Dr. Tabak sent a document outlining the agency’s [plans](#) to address the treatment of basic science research categorized as clinical trials under the current case studies. Under the plan, NIH proposes the following:

- NIH will issue a Guide Notice stating that for “basic science studies” NIH will delay enforcement of the policy on registration and reporting, the [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#), through July 1, 2019. The policy will still be enforced for studies that do not meet the definition of basic science.
- The plan indicates that the NIH Guide Notice will describe a “flexible, lenient, implementation of other policies for basic science research.” The agency will announce that it is in an implementation phase and will “monitor, refine but not penalize through July 1, 2019.” The plan indicates that NIH will “continue to expect registration and reporting for basic science trials, with added flexibility to allow reporting on existing basic science portals, and with the expectation that data will eventually be transported to [clinicaltrials.gov](#)...” NIH has been working with Brian Nosek to determine how [clinicaltrials.gov](#) can interface with the Open Science Framework (OSF) to allow information in OSF to upload directly to [clinicaltrials.gov](#).
- The plan indicates that NIH will issue a request for information, open for 90 days, to determine the reporting standards best suited for basic science research.
- The plan also indicates that NIH will issue a basic science funding opportunity announcement (FOA) for “fundamental human studies that meet the NIH definition of clinical trial” no later than October 30, 2018.

On June 19, COGR inquired about the following in a follow-up email to Dr. Tabak:

- How is NIH defining “basic science”? Will NIH be using its current definition of “[basic research](#),” (Systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind.)?
- The plan indicates that NIH will delay enforcement action of the [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#), which established the expectation that investigators conducting clinical trials will ensure that the trials are registered and reported in [ClinicalTrials.gov](#), until July 1, 2019. The plan also indicates that NIH will “continue to expect registration and reporting for basic science trials with the added flexibility to allow reporting on existing basic science portals and with the expectation that data will eventually be transported to [clinicaltrials.gov](#)...” Is it anticipated that NIH will have the ability to draw data and information



from any existing portal? Will NIH be providing examples of existing portals while expressing that any portal that accomplishes registering and reporting will be acceptable?

- With respect to “flexible, lenient implementation of other policies,” does this suggest that basic science research will not be subject to related policies including the [Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials](#), [New Review Criteria for Research Project Applications Involving Clinical Trials](#), and the [NIH Policy on Funding Opportunity Announcements \[FOA\] for Clinical Trials](#)? Regarding the latter FOA policy, the plan indicates that NIH will issue a basic science parent FOA no later than October 30, 2018. Will basic science no longer be required to respond only to clinical trial specific FOAs, including prior to publication of the basic science FOA?
- We remain concerned that NIH continues to refer to basic science as “trials” and with regard to NIH’s interpretation of “intervention.” An issue not addressed in the plan is the broadening of the NIH definition of “clinical trial” through the case studies published last summer. Categorizing basic research as clinical trials is confusing to the scientific community and agency staff and will be confusing to the public as well. We urge you to address this issue.
- We would be interested in knowing the anticipated timeframe for publishing the NIH Guide Notice(s).

NIH staff have indicated that the points COGR raised, such as “confirming the [existing NIH definition for basic science research](#),” are expected to be addressed in the guide notices and that the notices and request for information are expected to be published within the next three weeks. We will keep members informed of any further progress.

#### Animal Research Reform Efforts and the Farm Bill

COGR and other higher education associations submitted a [letter](#) to the Ranking Member and Chairman of the Senate Committee on Agriculture, Nutrition, and Forestry in support of consideration for efforts to provide regulatory relief by allowing flexibility on the timing of research facilities inspections under the Animal Welfare Act. The Senate is currently considering the farm bill.

Higher education associations had previously sent a [letter](#) to Representative David Rouzer expressing appreciation for an amendment to H.R. 2 that would revise the timing of research facilities inspections. A similar amendment has not been offered in the Senate to date.

#### Audit

##### HHS and NIH OIG COGR Session on the FDP Payroll Certification Pilots

Laura Rainey, Audit Manager and National Single Audit Coordinator, NSF Office of Inspector General, and Lori Pilcher, Regional Inspector General for Audit Services, Atlanta, HHS OIG, discussed the Federal Demonstration Partnership Payroll Certification Pilots and compensation compliance under the Uniform Guidance at the June 7-8 COGR meeting. Lisa Mosley, Executive Director, Office of Sponsored Projects, Yale University, and Co-Chair of the University Cohort on Alternatives to Effort Reporting served as moderator.

There was acknowledgement that payroll certification and other alternatives to effort reporting were completely allowable under the Uniform Guidance and the discussion centered on how to ensure that institutions were compliant. Laura discussed the NSF audits of George Mason University and Michigan Technological University and Lori the HHS audits at the University of California Irvine and Riverside for which both described joint agency approaches and work. Laura noted that most NSF payroll costs are for graduate students and allocable to one award. This is in contrast with HHS where the salaries of faculty and others may be charged to multiple awards. It was suggested that this impacted the risk assessment and focus and conclusions of the audits. Laura described the use of system bimonthly reconciliations, budget to actual analyses every two months, at GMU as being a vital/key control that supports the numbers at the end of the year and the need to conduct analyses and certifications timely and in accordance with institutional policy. Michigan Tech required time sheets for graduate students and monthly reconciliations. It was suggested that making full allocations available would also be a good control. Both OIGs presented key takeaways from the audits.

The OIGs suggested that institutions use their payroll systems to detect and investigate anomalies and utilize the GAO's Green Book and COSO's Internal Control Integrated Framework as guidance in developing appropriate internal controls. In terms of whether the OIGs intend to audit compensation, HHS did not have immediate plans to explicitly audit compensation. NSF described its risk-based approach and noted that if data analytics identify compensation as a risk at a particular institution it would be something that they would review within the context of a larger audit. Detailed slides from the presentation are available on the [COGR website](#).

### **COGR Session on the European Union General Data Protection Regulations**

Mark Barnes, Partner, Ropes and Gray LLP, led a discussion on the implications of, and compliance strategies for, the EU's [General Data Protection Regulations](#) at the June 7-8 COGR meeting. The regulations became effective May 25, 2018. The GDPR apply not only if the institution is established in the European Economic Area (EU member states and Iceland, Liechtenstein and Norway) and acts as a data controller and processor, but also to U.S. based institutions offering goods and services to, or monitoring the behavior of, individuals in the EEA, whether residents or not. Mark discussed applicability, authority or legal bases to process data, consent, and hypothetical questions of interest to institutions. These include whether it is necessary to re-consent for ongoing clinical trials initiated prior to the GDPR effective date and whether data from previous studies may be used for secondary research purposes.

Mike Ludwig, Associate Vice President for Research Administration, University of Chicago; Mary Mitchell, Corporate Director of Research Compliance, Partners Healthcare; and Ara Tahmassian, Chief Research Compliance Officer, Harvard University, discussed their institutions' approaches to implementation. Institutions are identifying and categorizing applicable data and updating policies, forms (including language in consent forms), contracts and agreements as needed. Internal structures have been created to address the GDPR, including steering committees and local coordinators, and IT, communications and General Counsel are engaged. Training is focused on building awareness of GDPR applicability and one institution described high-level training for researchers, including guides, as well

as training for staff. Special categories were described as a significant challenge as well as exempt research that involves EU collaborations. Institutions described reaching out to IRBs their institution serves, determining whether data in vendor systems meet GDPR requirements, and addressing research conducted under study abroad programs. Detailed slides from the session are available on the [COGR website](#).

### **NIH Advisory Committee to the Director June 2018 Meeting**

The NIH Advisory Committee to the Director (ACD) met on June 14-15, 2018. Agendas, links to the archived webcast, presentations and other materials can be found on the [ACD website](#). The meeting included discussions on the Next Generation Researchers Initiative, rigor and reproducibility, and NIH's sexual harassment policies and procedures, as well as a number of other topics.

A presentation from the ACD working group on the Next Generation Researchers Initiative noted the text in the 21st Century Cures Act calling for the establishment of the initiative and the charge to the committee which included assisting the NIH ACD on the development of a trans-NIH Next Gen policy. Draft recommendations were presented on modifying the original NGRI definitions and policy, including expanding the time period for defining Early Stage Investigators from 10 years to 12-15 years, or starting the clock at the date of first independent position and ending approximately 6-7 years later, and evaluating EEI together in peer review. With respect to Early Established Investigators (EEI), shifting the focus to supporting highly meritorious "at risk" investigators. Other recommendations include developing methods to identify and support ESIs and "at-risk" investigators, including in funding mechanisms beyond the R01; enhancing diversity in a meaningful and sustainable way, including unconscious bias training for reviewers, program officers and trainees; more clearly defining the target distribution of investigators across career stages, including modeling the "carrying capacity" of the NIH system; and assessing productivity through a multifaceted approach, including a holistic assessment of an individual's contributions to science (e.g., outside of publications) and recent contributions to science. The working group will continue to develop draft recommendations and expects to issue a final report at the December 2018 ACD meeting.

Dr. Michael Lauer, NIH Deputy Director for Extramural Research spoke about the work of the ACD Rigor Working Group, which was required under section 2039 of the 21st Century Cures Act to develop and issue recommendations to enhance rigor and reproducibility of scientific research funded by NIH. Dr. Lauer discussed recommendations, including providing resource links in application instructions, including both NIH-produced and external resources; clarifying "scientific premise" in the instructions; providing examples of authentication plans; integrating training in rigor throughout training applications so that it contributes to score; and continued outcomes evaluation to assess adherence to the policy by applicants and reviewers. Dr. Lauer noted that currently less than 30% of methods include a description of randomization and less than 1% information on sample sizes. He noted that PCORI's second-level review includes a rigorous methodological review. NIH doesn't currently do this. There was discussion of two kinds of rigor, that of the supporting data and the proposed experiments.

### **Nonprofit Funder Research Institution May 16 Workshop Follow-up**

We previously indicated in the [June 2018 pre-meeting update](#) that COGR, the [Health Research Alliance](#), and [Faster Cures](#) led a day-long workshop on May 16 to discuss guiding principles and beneficial practices to build and foster effective relationships between non-profit research-funding organizations and research-performing institutions. The meeting was supported by the National Academies Government University Industry Research Roundtable.

A website is currently under development and meeting materials, including an archived webcast, will be made available. A follow-up meeting has now been scheduled for November 7, 2018 at the National Academies Keck Center in Washington, DC.

### **Research Regulatory Reform**

#### **COGR Session on the Research Business Models (RBM) Working Group and Report**

Theresa Grancorvitz, Deputy Office Head, Office of Budget, Finance and Award Management and Co-Chair of the RBM, and RBM members Jean Feldman, Head, Policy Office, Division of Institution and Award Support, NSF, and Michelle Bulls, Director of the Office of Policy for Extramural Research Administration, discussed the working group's May 25, 2018 [report](#) *Reducing Federal Administrative and Regulatory Burdens on Research* in a session at the June COGR meeting. COGR included a summary of the report in the [June 2018 update](#). RBM members sought feedback from COGR meeting participants on how the RBM working group might reduce research regulatory burden and discussed having regular meetings with COGR and other associations that represent research institutions and researchers. Slides for the session are available on the [COGR website](#).

#### **COGR Session with OIRA Administrator Neomi Rao**

Office of Information and Regulatory Affairs (OIRA) Administrator Neomi Rao was a guest speaker at the June 7-8 COGR meeting. OIRA oversees the review of federal regulations and approval of information collections, as well as the regulatory reform process. Administrator Rao leads the President's efforts to streamline, simplify, and reform the federal government's regulations and regulatory process.

Neomi Rao spoke about Executive Orders aimed at reducing regulatory burden and successes in reducing the number of new regulations. She also spoke about the [Spring 2018 Unified Agenda of Regulatory and Deregulatory Actions](#) where agencies identify ineffective regulations for revision and repeal; private market solutions; net benefits of regulations to the public; and ensuring that rules don't exceed statutory authority. OIRA is also seeking to change the regulatory culture around guidance, which Rao suggested should provide explanation but should not be a backdoor to regulation. Agencies are cataloguing guidance and there is work government-wide to streamline and eliminate guidance as necessary.

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