

COUNCIL ON GOVERNMENTAL RELATIONS
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March 14, 2016

February 25-26, 2016 COGR Meeting Report

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RESEARCH & REGULATORY REFORM

Committee: Sara Bible, Chair, Stanford University, Cindy Kiel, University of California-Davis, Kerry Peluso, Emory University, Lois Brako, University of Michigan, John Ritter, Princeton University, Suzanne Rivera, Case Western Reserve University, Ara Tahmassian, Harvard University, Daniel Shapiro, University of Southern California, Robin Cyr, University of North Carolina-Chapel Hill, Lynette Arias, University of Washington, Naomi Schrag, Columbia University, Marti Dunne, New York University

Reform Efforts

Agency and University Efforts to Reduce Administrative Work Associated with Federal Awards

Jean Feldman, Policy Head, and Richard Buckius, Chief Operating Officer, National Science Foundation (NSF), discussed ongoing NSF efforts to reduce administrative burden for grantees. NSF recently conducted a survey to assess which efforts would be most helpful in reducing the level of administrative work. Among the top rated areas were proposals pre-populated with existing data; greater use of just-in-time; differentiating between solicitation-specific requirements and standard NSF proposal requirements; use of a common federal-wide biosketch; and broader use of preliminary proposals/streamlined proposal requirements. Pilot efforts were discussed, including one effort that would require only a budget justification at proposal submission, as well as proposal submission modernization, including migration from Fastlane to Research.gov and implementation of some of the efforts highlighted in the survey responses. Efforts to harmonize and standardize with other agencies were discussed as well as the possibility of allowing universities to use a draft notice of preliminary IRB approval for NSF projects lacking immediate plans for involvement of human subjects, their data, and/their specimens (pursuant to 45 CFR §690.118). We expect to provide additional information on the latter item in the coming weeks.

Also participating on the panel were Research and Regulatory Reform Committee members Sara Bible of Stanford, Ara Tahmassian of Harvard and Lois Brako of the University of Michigan. Each discussed broad initiatives as well as specific efforts that their universities are undertaking to streamline administrative processes and reduce the administrative workload for faculty and staff. This included specific examples in areas such as human and animal research. The committee is developing a list of best practices for reducing administrative work for distribution to COGR member institutions. Slides for both presentations can be found on the [COGR website](#).

Identifying and Reducing Regulatory Burdens at the U.S. Department of Agriculture (USDA)

We noted in the February COGR update that the USDA has issued a [notice](#) requesting comment on which regulations should be modified, expanded, streamlined, or repealed to make the USDA's regulatory program more effective or less burdensome. The agency is also seeking comment on measures that can be taken to increase flexibility. Comments are due March 28 and COGR intends to submit comments. Please contact [Lisa Nichols](#) with questions or comments.

Human Subjects Research

Common Rule

Dr. Jeff Botkin, Associate Vice President for Research at the University of Utah and Chair of the Secretary's Advisory Committee on Human Research Protections (SACHRP) presented on proposed changes to the Common Rule at the February COGR meeting. The presentation focused on proposed regulatory changes specific to secondary research use of clinical biospecimens. Dr. Botkin's presentation touched on legislation related to newborn blood spots, the difficulty of implementing the new consent provisions, and what is expected to be a substantial decrease in the availability and diversity of blood spots for research use. The high yield and low risk of secondary research use of de-identified biospecimens was discussed with no instances of welfare harms but a few instances of dignitary harms, including the Havasupai and Henrietta Lacks cases. There was discussion on transparency and public preferences. There is general support for biospecimen research but a need for greater transparency. Dr. Botkin discussed the Fair Transaction Model of informed consent, with respect to secondary research use of biospecimens which would seem to allow for limited disclosure when risks are low and autonomous authorization is not a realistic goal. In response to the proposed regulatory changes, SACHRP has proposed a system of notification of research practices and the opportunity to opt-out. It was suggested that this approach is appropriately calibrated to the level of risk and challenges and there is research that supports this approach. The details of opt-out and its implications for research are yet to be worked out.

COGR and APLU efforts to analyze the approximately 2,200 responses to the NPRM were discussed. Among the findings, universities and their affiliated academic medical centers as well as individual patients responding to the NPRM strongly oppose the proposed changes related to biospecimens. COGR will make the results of this review available to members once completed. Preliminary findings and Dr. Botkin's presentation are available on the [COGR website](#).

Accreditation

Elyse Summers, President and CEO of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), and Michelle Feige, Executive Vice-President, met with members of COGR's Research and Regulatory Reform Committee at the February COGR meeting. Elyse and Michelle discussed efforts to streamline their processes and provided the committee with data received in response to a recent member survey. Among other initiatives, AAHRPP has targeted reducing the time it takes to complete a site visit. The committee provided feedback on AAHRPP's accreditation and reaccreditation process in preparation for the meeting. Elyse expressed appreciation for the feedback and the desire to maintain an ongoing dialogue with committee members.

Animal Research

Matt Bailey, Executive Vice President, National Association for Biomedical Research (NABR), spoke with members of COGR's Research and Regulatory Reform committee recently on the issue of air transport of research animals. Opponents to animal research have engaged in efforts to end commercial air transportation of lab animals. NABR is looking for additional statements in support of animal research and the need for safe and reliable air transport. Please see the

[NABR website](#) for additional details (support statements are located at the bottom of the page) and consider lending your institution's support.

There was also discussion on a planned summer workshop that will examine the ethics of NIH's policies and procedures for all primate research. COGR will provide additional details as they become available.

Digital Accountability and Transparency Act (DATA Act) Section 5 Grants Pilot

Karen Lee, Chief of the Office of Federal Financial Management, Office of Management and Budget, and Mike Peckham, Director, Department of Health and Human Services DATA Act PMO, provided an overview of the execution of the Section 5 Grants Pilot. The pilot framework includes collecting feedback from grantees via the [National Dialogue](#) website, analyzing "data centric" forms, and testing models. These models include an online repository for grants-specific data standards, definitions, and context (the Common Data Element Repository or [CDER Library](#)); a test model that will allow grantees to submit the Federal Financial Reporting form through one system/portal, rather than multiple entry systems; a more streamlined approach to Single Audit reporting (SF-SAC/SEFA forms); a standardized notice of award cover sheet for Federal awards; and an online portal that provides federal grant lifecycle information ([Learn Grants](#)). COGR will continue to provide updates on the status of the pilot, including information and opportunities to engage. The presentation is available on the [COGR website](#).

Audit

The two-month salary saga continues with the release of another NSF OIG [report](#) with significant findings related to senior personnel salary. The auditors questioned \$ 2,003,109 of costs claimed on NSF awards including \$1,824,117 in senior personnel salary charges that exceeded two months. The university agreed with the facts for \$71,071 of the questioned costs. The NSF OIG also issued a [report](#) on the National Science Board's compliance with the Government in the Sunshine Act. The report suggests that the Board may have inappropriately used an exemption to close agenda items on topics such as pending legislation, NSF management challenges, and OIG recommendations, and increasingly used this exemption, and that retreat discussions may have been subject to Sunshine Act rules.

Precision Medicine Initiative: Data Security Policy Principles and Framework

On February 25 the White House released [Data Security Policy Principles and Framework](#) for organizations engaged in the Precision Medicine Initiative. The framework is based on the NIST Framework for Improving Critical Infrastructure Cybersecurity. [Comments](#) are due March 25th. Please contact [Lisa Nichols](#) with comments or questions.

COSTING POLICIES

Committee: Kim Moreland, Chair, University of Wisconsin, Joseph Gindhart, Washington University-St. Louis, Cindy Hope, University of Alabama, Lynn McGinley, University of Maryland-Baltimore, Jeffrey Silber, Cornell University, Cathy Snyder, Vanderbilt University, Michael Daniels, Northwestern University, Dan Evon, Michigan State University, Charles Hrcir, Texas A&M University, Michael Legrand, University of California-Davis, James Fortner, Georgia Institute of Technology, Vivian Holmes, Broad Institute

Streamlining and Facilitating Grants Closeout at NIH and HHS

As we wrote in the [February 2016 Update](#) (dated February 12, 2016), this persistent issue continues to be a priority for the Costing Committee and captures the intertwined topics of NIH/HHS subaccounting (i.e., award-by-award accounting), the new 120-day grant closeout model implemented by NIH, reconciliation between the Federal Financial Report (FFR) and the Federal Cash Transaction Report (FCTR) at closeout for all HHS Operating Divisions, and the functionality of the Payment Management System (PMS).

Tony Corio, Grants Policy Specialist (note, Michelle Bulls was not able to attend) from the NIH Office of Policy for Extramural Research (OPERA), provided an update during one of the Thursday morning sessions at the February 25th COGR Meeting. A representative from the HHS Office of Grants Policy attended the session as an audience participant and provided additional perspective during portions of the session.

COGR actively is engaged with NIH and HHS on a number of discussions, all of which relate back to grants closeout, and more specifically, “Streamlining and Facilitating Grants Closeout at HHS and NIH.”

- 1) FFR and FCTR reconciliation. Grants closeout is contingent on this reconciliation. However, as things currently stand, the FCTR requirements and the capabilities of PMS impede timely grant closeout. However, if the FFR could be accepted by NIH (and other HHS Operating Divisions) with the understanding that it will be reconciled to the FCTR at a later date, this could be a favorable development.
- 2) NIH/HHS and Unilateral Closeout. NIH Notice Number [NOT-OD-15-136](#) indicates unilateral closeout may be triggered at 180 days after the project end date. This creates a friction since the FFR and FCTR reconciliation normally cannot be completed in less than 180 days. Clarity on what is meant by unilateral closeout and how unilateral closeout actions are communicated could be a favorable development.
- 3) Consistent 120-day closeout model across HHS. NIH has adopted the 120-day model, as have NSF and DOD. COGR is engaging with HHS to understand if this model could be

applied to all HHS Operating Divisions (currently using the 90-day model). Our analysis is that a consistent 120-day policy will improve accuracy of filing closeouts and that timeliness will be improved since the need to file revised FFRs will be reduced.

- 4) Access to the PMS. Regardless of the 90-day or 120-day closeout model, PMS access beyond the closeout date is an important feature to have available. Our understanding is that HHS supports PMS remaining open beyond closeout; we are working with HHS to confirm that this is the intended functionality.
- 5) Budget versus Project Period Closeout. NIH continues to support the longstanding project period closeout model. However, other HHS Operating Divisions recently have implemented a budget period closeout model. Consequently, this has impacted access to PMS, which is particularly problematic when a budget period closeout model is used. We are working with HHS to address this situation.
- 6) Sync 45 CFR 75.381(g) with 2 CFR 200.343(g). The more restrictive HHS policy effectively gives HHS Operating Divisions 270 days to complete closeout actions (90 days to submit the FFR + 180 days), rather than the 455 days (90 days to submit the FFR + 365) allowed under the Uniform Guidance. While HHS Grants Policy may not be inclined to address this issue, closer review still may be appropriate.

45 CFR, 75.381(g):

The HHS awarding agency or pass-through entity should complete all closeout actions for Federal awards no later than 180 calendar days after receipt and acceptance of all required final reports.

2 CFR, 200.343(g):

The Federal awarding agency or pass-through entity should complete all closeout actions for Federal awards no later than one year [365 days] after receipt and acceptance of all required final reports.

- 7) Research/Class exemption from the FCTR requirement. COGR's understanding is that the FCTR is necessary if the award includes a cash advance. However, if it is a cost-reimbursement award, which is what we generally receive for research, the FCTR no longer is necessary since all the cash balance and related information is available in the subaccount. A Research/Class exemption could be a favorable development.
- 8) DATA Act Section 5 Pilots. As presented during the Friday morning session of the COGR meeting, Karen Lee from OMB and Michael Peckham from HHS addressed the five pilots that have been defined. One of those would address streamlining the submission of the FFR and the FCTR. We will follow this development and determine how/if items 1) and 7) above may intersect with this particular pilot.
- 9) Grants Oversight and New Efficiency ([GONE](#)) Act. This legislation was signed into law by the President on January 28th and requires OMB, in coordination with HHS, to submit to Congress by December 31 a report that captures various metrics related to timely closeouts of all Federal agency grants (our understanding is that the first report will be

due December 31, 2017). It is uncertain how non-compliance with timely grants closeouts will intersect with the GONE Act.

- 10) Federal Awardee Performance and Integrity Information System (FAPIIS). Requirements under FAPIIS no longer are applicable to contracts only; FAPIIS now encompasses grants. As of February 16, 2016, NIH officials began using information in [FAPIIS](#) as part of the risk assessment process for making grant awards. It is uncertain how non-compliance with timely grants closeouts will intersect with FAPIIS.

We will learn more on all of the above as we continue our engagements with NIH and HHS. We will keep the Membership posted, accordingly.

Uniform Guidance and the Procurement Standards: COGR and AIRI to Meet with OMB

David Mader, OMB Controller and Acting Deputy Director of Management, presented the key-note, post-lunch presentation at the February 25th COGR Meeting. Mr. Mader focused his presentation on brief comments, leaving significant time for Q&A with the COGR membership. Concerns related to implementation of the procurement standards (effective FY2018, i.e., July 1, 2017 for most research institutions) dominated the Q&A.

COGR submitted a letter to OMB requesting “Implementation of Sensible Procurement Standards”. Mr. Mader acknowledged the letter during his presentation. The [COGR letter](#), dated January 20, 2016, is available on the [COGR home page](#).

We made three specific requests in the letter:

- 1) Establish a “Grantee Exemption” process from 2 CFR 200.317-326; similar to the exemption offered to States.
- 2) Fix those sections of 2 CFR 200.317-326 that require common-sense improvements.
- 3) Increase the Micro-purchase threshold from \$3,000 to \$10,000, with an option, based on institutional risk assessment, to set a higher threshold.

The COGR letter, in combination with advocacy by the Association of Independent Research Institutes (AIRI) and strong and compelling anecdotes raised by the Membership during Mr. Mader’s Q&A, may have borne fruit. Representatives from COGR and AIRI have been invited to meet with OMB at the end of the month to further discuss implementation of the procurement standards. And while we are aware of several legislative efforts to influence how the micro-purchase threshold should be set as it applies to grants, we recognize that the OMB meeting may be one of the last, best chances to influence the implementation of the procurement standards before the go-live date in FY 2018.

Uniform Guidance: Beyond Procurement

The presentation and Q&A session with David Mader extended beyond procurement. An important take-away from the session was Mr. Mader’s invitation for COGR to share with OMB additional areas of concern related to the Uniform Guidance implementation.

While we expect the focus of the upcoming OMB meeting (see previous section) to be on procurement, COGR will take the opportunity prior to the meeting to submit a letter to Mr. Mader and present those other areas of continued concern. For example, Subrecipient Monitoring, F&A-related (1.3% UCA and DS-2), Conflict of Interest, and Agency Deviations (F&A rates, Cost sharing) top the list. Several other items we expect to raise are applicability of the 10% diminimis rate to for-profit entities, codification of the FAQs and the original Preamble, resurrecting the concept of an “Ombudsman” (i.e., an OMB direct-access troubleshooter), and encouragement to OMB to support “uniformity” via the Research Terms and Conditions.

Parallel to raising these issues in a letter to Mr. Mader, COGR has contemplated the idea of preparing a “Year 1 Report Card” on the Uniform Guidance. As we have previously written, some of the questions the research community should be asking include: Where has administrative burden been reduced? Where has administrative burden increased? Has the PI-climate improved? (i.e., family-friendly, productivity and efficiency, goodwill and common sense improvements, etc.). Can we quantify cost impacts? FTE impacts?

How OMB responds to the remaining open items could influence our approach to a Year 1 Report Card. We encourage you to continue sharing your institutional perspectives and experiences with COGR staff. Send comments to David Kennedy at dkennedy@cogr.edu or Jackie Bendall at jbendall@cogr.edu.

2016 DRAFT Compliance Supplement and the Single Audit

Mandy Nelson, a Partner at KPMG and a National Expert on the Single Audit, provided an update during one of the Thursday morning sessions at the February 25th COGR Meeting. Single audits applicable to FY2016 will represent the first time that institutions will be required to comply with [2 CFR Part 200, Subpart F – Audit Requirements](#).

Ms. Nelson addressed the following developments:

- 1) Major program audit requirements under Subpart F and the impact on auditing R&D as a “Type A” program (e.g., if R&D is not considered high risk, it could be eliminated from the audit in a given year; a “Type B” program may be selected).
- 2) Possible new emphasis on internal controls applicable to identifying special provisions / terms and conditions in federal awards.
- 3) Part 6, Internal Controls. Part 6 still is not available in the DRAFT version of the 2016 Compliance Supplement. This is a critical section as it directly relates to the new standards defined in [2 CFR 200.300, Internal controls](#). When finally made available, there is concern there may be ambiguity on what the expectations are for an institution to document its system of internal controls.
- 4) Part 3, Compliance Requirements and the DS-2. OMB asked COGR to provide suggestions related to clarifying the DS-2 review and approval process. We shared with OMB our concern that Part 3 is inconsistent with [2 CFR 200.419\(b\), Cost accounting standards and disclosure statement](#) and the related [COFAR FAQs](#). According to Ms. Nelson, COGR’s suggestions are being reviewed.

- 5) Possible, future initiative to simplify/consolidate the Data Collection Form and the SEFA.

The Compliance Supplement is a unique document that does not move through the normal Federal Register / Public Comment process. Instead, it is developed and vetted between OMB and representatives from the audit community (e.g., AIPCA, Public Accounting firms, Audit-centric Associations, etc.). OMB historically has provided COGR with a copy of the DRAFT version and the opportunity to provide comments. As we patiently wait for a DRAFT version of Part 6, as well as feedback on COGR's recommendations for Part 3, we will be sure to keep the Membership updated on all developments.

Affordable Care Act (ACA) Compliance and Graduate Research Assistants

The American Council on Education (ACE) and the College and University Professional Association for Human Resources (CUPA-HR) are the lead Higher Ed associations and are working closely with the IRS and the Department of Treasury to advocate for a fair and reasonable implementation of the ACA as it relates to higher education institutions. The two primary issues that COGR has followed are: 1) treatment of student employees, including research assistants, and 2) compliance of a Student Health Insurance Plan (SHIP) with the ACA.

The treatment of student employees concerns an institution's capacity to maintain documentation that the 30-hour threshold, which triggers ACA coverage, has not been reached. For research assistants (RAs), COGR has worked with ACE and CUPA-HR to show how effort reporting or other payroll confirmation systems might serve as a safe harbor. For example, if the RA appointment is for 19 hours, an effort report could serve as the confirmation that the 30-hour threshold was not reached. Similar safe harbors are being pursued for teaching assistants, residential life advisors, and recreational sports students. To date, IRS/Treasury does not appear to be receptive to these safe harbors; however, ACE and CUPA-HR will continue to pursue solutions over the remainder of the year.

In regard to SHIPs, a recent [IRS Notice](#), *Application of the Market Reforms and Other Provisions of the Affordable Care Act to Student Health Coverage, Notice 2016-17*, states that schools will receive one more year of transitional relief before they are required to bring their SHIPs into compliance with the ACA. Therefore, existing SHIPs can be offered through the 2016-2017 academic year; after that, it is uncertain. As with the treatment of student employees, ACE and CUPA-HR will continue to pursue solutions. If you have questions, COGR can connect you with the appropriate contacts at ACE and/or CUPA-HR.

NIH Salary Limitation (Cap): Policy Update and Treatment of NIH Contracts

[NIH Notice Number: NOT-OD-16-045](#) was posted on December 24, 2015; *Notice on Salary Limitation on NIH Grants, Cooperative Agreements, and Contracts*. Per the Notice, the Federal budget resolution for FY 2016 (signed into law on December 18, 2015) maintained the NIH Salary Cap at the Executive Level II. And effective January 10, 2016, the Executive Level II increased from \$183,300 to \$185,100. Also included in the Notice is a link to the [Salary Cap history](#) (FY 1990 to Present).

[NIH Notice Number: NOT-OD-16-059](#) was posted on January 28, 2016; *Notice of Correction to Salary Limitation on NIH Grants, and Cooperative Agreements*. The correction notice removes all references to NIH extramural research and development contract awards. ***However, the NIH salary limitation still is applicable to contracts.***

According to representatives from the NIH Division of Acquisition Policy and Evaluation, the *Notice of Correction* was issued to emphasize that application of the NIH salary limitation to contracts is handled differently than grants. For grants, the salary is required to be annualized to determine if the salary limit has been exceeded. For contracts, annualization is not required. Also, as it relates to consultants, for grants, the salary limit is not applicable to consultants (though the standards of reasonableness and consistency must be met). For contracts, the salary limit is applicable to consultants (though again, annualization is not required).

[Salary Rate Limitation Q&As](#) can be found on the NIH web site. The NIH Division of Acquisition Policy and Evaluation recognizes that there may be confusion due to the different application of the salary limit to contracts versus grants. As necessary, they will provide additional clarification for the community.

Other Recent NIH Notices of Interest (Fiscal Policy)

The following recent [NIH General Policy Notices](#) affecting NIH fiscal policy should be noted:

[NOT-OD-16-062](#) (January 26, 2016): Revised: Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2016

[NOT-OD-16-054](#) (January 20, 2016): Clarification: New Salary and Research Cost Allowances for K08 and K23 Career Development Awards

[NOT-OD-16-046](#) (January 20, 2016): NIH Fiscal Policy for Grant Awards - FY 2016

[NOT-OD-16-044](#) (December 24, 2015): Notice of Legislative Mandates in Effect for FY 2016 (note subsequent correction per [NOT-OD-16-048](#), December 31, 2016)

Please contact COGR staff for additional detail, if needed.

Equitable Treatment of Off-Campus Research Centers in RFAs

We wrote about this topic last year and are reviving the discussion based on feedback from several institutions. COGR hopes to work with these institutions and NIH to devise a more equitable mechanism for comparing proposed costs between on-campus and off-campus research centers. Specifically, at issue is the treatment of “space and facility-related costs” when a Research Funding Announcement (RFA) or policy regarding Investigator initiated proposals limits maximum costs in terms of maximum Direct Cost.

In the case of an off-campus research center, space/lease costs and other facility-related costs are considered a direct cost, which means that the off-campus research center will disproportionately have to propose these types of costs in comparison to an on-campus research center. In effect, the off-campus research center is at a competitive disadvantage because fewer costs can be proposed for research staff and other direct research-related costs. The inequity is compounded when a

proposed collaborator is associated with an off-campus research center; in this situation, the potential subrecipient would include space and facility-related costs in the proposed budget.

Several options to restore equity that have been discussed are: 1) Allow the off-campus research center to exclude space and facility-related costs when the RFA includes a maximum Direct Cost limitation, or 2) Allow the off-campus research center to state maximum costs in terms of Total Cost instead of Direct Cost when the RFA includes a maximum Direct Cost limitation. If interested in participating in this discussion, please contact David Kennedy at dkennedy@cogr.edu.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Alexandra McKeown, Chair, The Johns Hopkins University, Cindy Kiel, University of California-Davis, Elizabeth Peloso, University of Pennsylvania, Patrick Schlesinger, University of California-Berkeley, Kevin Wozniak, Georgia Tech Research Corporation, David Winwood, Louisiana State University, Cathy Innes, North Carolina State University, Fred Reinhart, University of Massachusetts-Amherst, John Ritter, Princeton University, Wendy Streitz, University of California, Wendy Montgomery, University of Maryland, Melanie Roewe, Washington University – St. Louis

COGR Submits Comments on DFARS Safeguarding Rule

On February 29 COGR/AAU submitted a joint comment letter on the second interim rule on *Safeguarding Covered Defense Information* (DFARS Clauses 252.204—7008 and 7012; see [COGR February Update](#) for a discussion of the rule). COGR/AAU commented on the previous version of the DFARS safeguarding requirements in October, 2015 (letter posted on COGR website). The DFARS requirements also were discussed in a panel session on cybersecurity at the February COGR meeting.

The letter expressed appreciation to DOD for delaying implementation of the requirements until December 31, 2017. We also expressed appreciation for clarifying that the flowdown of the requirements applies only to subcontractors who handle covered defense information or provide operationally critical support. However, we pointed out that the 7008 clause requires contractors to represent that by submitting offers they either will implement the NIST SP 800-171 security requirements by December 31, 2017 or implement alternate security measures approved by the DOD Chief Information Officer (CIO). The revised 7012 clause requires contractors to notify DOD (CIO) within 30 days of any NIST requirement not implemented (or approved alternative measures). While under both clauses the NIST requirements or approved alternatives must be fully implemented by December 31, 2017, the discussion in the rule states that the requirement for CIO acceptance prior to award is removed in the 7012 clause. We pointed out that this appears somewhat contradictory, and may lead to confusion. Also there appears little incentive for contractors to submit alternative measures if only a notification is required prior to that date.

The comment letter also reiterated the concerns we previously expressed about the potential impact on fundamental research. We again urged DOD to clarify that contracted research

projects determined to be fundamental research do not involve covered defense information. We suggested that the definition of Export Control included in Covered Defense Information in the 7012 clause be changed to apply to information “subject to” the export control regulations rather than “identified in,” which would bring in the protections for fundamental research in the regulations. We also suggested the 7012 clause be revised to state that where the contractor is expected neither to receive nor produce covered defense information, the 7012 requirements will not apply until such time as covered defense information is received or produced. This would allow fundamental research to proceed without lengthy negotiations to remove the 7012 clause or uncertainty as to whether the 7012 clause is self-deleting (the position taken by DOD during the panel discussion at the February COGR meeting; see below).

[A copy of the comment letter](#) is posted on the COGR website.

Panel Discusses Cybersecurity Challenges

The panel session on cybersecurity at the COGR meeting included representatives from the National Archives and Record Administration (NARA), NIST and DOD. During the panel discussion the DOD representatives expressed some sympathy for the need to more clearly address fundamental research in the revised DFARS safeguarding rule. They also appeared to acknowledge the need to address concerns about the “self-deleting” nature of the DFARS 7012 clause. The NARA representative indicated that it was not the intent to incorporate regulatory definitions into descriptions of categories of Controlled Unclassified Information (CUI; [COGR October 2015 Meeting Report](#) for a discussion of the CIP Committee discussion with NARA). However the DFARS experience will be useful for developing the pending FAR clause, which will apply security requirements for CUI government wide.

In addition to the DFARS discussion, the NARA representative discussed the pending rule for non-federal CUI, which now is being finalized. It will be followed by the FAR clause. NARA teamed with NIST in developing the SP 800-171 security requirements, which are set at the moderate confidentiality level. The NIST representative indicated that in developing the requirements NIST was concerned with assuring adequate confidentiality when CUI moves out of nonfederal space. The requirements are derived from NIST 800-53 federal controls, which are far more extensive. They apply when CUI is processed, stored or transmitted by non-federal entities. (Slides of the NIST presentation will be posted to the COGR website).

In discussion it was suggested that NARA/NIST consider partnering with the FDP in developing the FAR clause. The compliance implications of the NIST SP-800-171 controls were raised by COGR member representatives. Concern was reiterated that COGR member institutions are receiving DOD contracts for fundamental research that include the revised 7012 clause. Hopefully the government representatives will be responsive to these concerns.

Open Licensing Pros and Cons Discussed by Panel

[The December Update](#) discussed the comment letter submitted by COGR/AAU/APLU/AUTM on the Department of Education’s open licensing proposed rule. The comment letter expressed concern about the “one size fits all” approach adopted by Ed. in the proposed rule. We noted the result would be to limit the ability of our institutions to transfer tested and validated educational technologies to the private sector for further development and dissemination. We suggested that Ed. reconsider the proposed requirement and explore ways to work with stakeholders such as our

institutions and faculty to develop more carefully calibrated provisions that would not foreclose proprietary management of copyrightable materials when that is the best option to ensure wide dissemination and public benefit.

Ed. received about 200 public comments on the proposed rule, fairly evenly split between “pros” and “cons.” We have reached out to the Association of Research Libraries (ARL) and other proponents of open licensing suggesting the need for continued dialogue. To that end a panel session was organized at the COGR meeting that included ARL, SPARC Open Access, and Creative Commons representatives. It was moderated by Fred Reinhart, Immediate Past President of AUTM, and also included an AAU representative.

The panel discussion recognized the difficulty of the issue for universities. They share the goal of disseminating knowledge and information with proponents of open licensing, but also often need to secure private funding for further development to assure dissemination, particularly with the current pressure to commercialize technologies. The ARL representative acknowledged the tension. While supporting the concept of making educational tools and technologies broadly accessible through open licensing, there is a need for flexibility. It was noted that Ed has never exercised the government purpose license to materials developed with its funding. The SPARC representative cited the issue of affordability of educational materials, and that with digital availability publishers are no longer needed for public access. The Creative Commons representative discussed open source software business models. With the increasing uncertainty about patenting of software that has resulted from recent court decisions, the Bayh-Dole Act is not highly relevant to the discussion.

Bayh-Dole does not apply to copyrighted materials. Many issues were raised at the panel session, including the relationship of the proposed Ed requirement to the terms of foundations that may also be involved in materials development, questions having to do with modifications such as attribution and liability (Creative Commons has a license which requires attribution and identification of modifications), and the global implications. We intend to continue the dialogue with the proponents and other stakeholders.

HHS Responds to House Letter Regarding March-In

By letter dated March 2 HHS responded to the letter from Rep. Doggett (D—TX) co-signed by over 50 other House Democrats requesting that NIH develop guidelines for the exercise of Bayh-Dole Act march-in rights to address drug price gouging ([see COGR February Update](#)). The letter discussed a number of measures taken by HHS to address rising drug prices. However, it noted that the purpose of march-in authority is to “ensure that a government-funded invention that covers a drug does not block it from entering the market.” According to the letter, march-in is strictly limited to situations where an agency determines that the specific criteria for march-in are met, such as alleviating health or safety needs or when effective steps are not being taken to achieve practical application of an invention. The letter mentioned previous cases where NIH considered use of march-in to address drug pricing concerns, and determined that march-in was not justified under the statutory requirements. However, the letter stated that NIH “is prepared to use its authority if presented with a case where the statutory criteria are met regarding the commercialization and use of an NIH-funded, patented invention, and where march-in could in fact alleviate health or safety needs or address a situation where effective

steps are not being taken to achieve practical application.....” The letter concluded that the statutory criteria are sufficiently clear and additional guidance is not needed.

We are pleased that NIH continues to interpret march-in as not an appropriate mechanism to address drug pricing concerns. It appears that based on the letter NIH also is likely to respond negatively to the march-in petition recently filed on the prostate cancer drug Xtandi since the issues raised are identical to those in previous cases considered by NIH (we do not role what role if any DOD will play with respect to that petition). However, we note that the HHS response letter does not completely bar the use of march-in in all cases involving drug pricing issues.

NIH Plans Issuance of DEC for Precision Medicine Initiative

On February 8 NIH issued two RFAs (RFA-PM-16-001 and 002) for the Precision Medicine Initiative (PMI) Cohort Program. Both contain a notice that NIH intends to issue a Determination of Exceptional Circumstances (DEC) to assure that patents directed to inventions made under the award “cannot be used to block access by the research public to this important resource and associated technology.” The RFAs also state that NIH will own the resources generated by the Cohort Program as well as biospecimens and data, and may take exclusive custody and control of them at its reasonable discretion upon termination or expiration of the cooperative agreement. (The closing date for proposals was February 16).

After consulting with COGR, the University of California raised three questions with the designated PMI team about these provisions.

- 1) With regard to the first question about the details of the DEC, NIH/PMI responded that “There are a variety of approaches the NIH could potentially adopt. The agency may discuss the programmatic objectives and proposed DEC with applicant(s) when an application is being considered for potential award, after applications have been reviewed, and it may further discuss its options over the length of the grant.”
- 2) The second question had to do with whether institutions could retain the right to use biospecimens for patient care and research purposes. NIH/PMI responded that “All biospecimens collected for the PMI Cohort Program will be sent by partner HPOs to the PMI Cohort Program biobank for storage. These specimens will be collected under standardized protocols for the use of the Program and are not intended for clinical care. .. Organizations may also maintain their own parallel biospecimen collections (which would not be subject to PMI use), but these do not replace or substitute for the PMI cohort collections.”
- 3) The third question involved the implications of NIH’s exclusive custody and control of data. The NIH/PMI response was that “Data collected specifically through the PMI Cohort Program, including specific core data that will be extracted from EHRs and sent as copies to the coordinating center, will be housed centrally in the coordinating center. For data directly submitted to the PMI cohort program by an organization... In the spirit of transparency and collaboration, individuals and organizations that provide data to the PMI cohort should, as a general policy, have unrestricted rights of access to their own

submitted data. ... The Data Access working group of the Steering Committee will develop policies for data use and access for all qualified users.”

On February 25 President Obama participated in a White House Forum on the Precision Medicine Initiative. During the course of the Forum the President alleged that the best researchers and best universities often are “hoarding their samples” and that “the basic model of research at universities is having your samples, that’s really valuable because that’s how you get grants.” He contrasted that with having samples available to researchers worldwide, with the associated time and cost savings. (see <https://www.whitehouse.gov/blog/2016/02/25/precision-medicine-health-care-tailored-you>).

It appears these concerns about biospecimen “hoarding” are reflected in the PMI provisions on biospecimen and data control and ownership. They may present a challenge to COGR member institutions as the PMI unfolds. The NIH response to the question about the details of the planned DEC essentially is a non-response. It also implies NIH may seek to modify the DEC on an ongoing basis after award. This appears inconsistent with the Bayh-Dole Act, and may present additional challenges. We also are concerned that these developments as well as the open licensing initiative at ED and other agencies may portend a shift by the government with regard to rights in federally-funded technologies, materials and data.

PCORI Contract Terms Continue to Raise Concerns

We previously have discussed concerns about the contract terms in agreements from the Patient-Centered Outcomes Research Institute (PCORI). A group of COGR representatives met with PCORI leadership in May of 2013 to discuss these issues ([see COGR May 2013 Update](#)). Issues and concerns with PCOR contracts remain. Discussions have continued between COGR representatives and PCORI. Many of the issues that institutions seem to be facing with PCORI could partially be attributed to the fact that they were (and still are) a young organization and started to fund programs immediately rather than wait until they had mature processes and procedures in place. The Contract for Funded Research Projects is in version “CR8.” PCORI states that the current version has taken into consideration a lot of feedback they have received. It was suggested that additional feedback before they roll out the next version might be a good idea. The initial PCORI awards primarily involved pilot projects. These agreements were fixed price agreements and only allowed F&A on salaries and wages (which was a principal point of discussion three years ago). All PCORI research agreements are now cost reimbursable and pay 40% overhead.

PCORI has started a new program, the Eugene Washington PCORI Engagement Award Program Agreement. These programs are intended to be smaller, non-research initiatives and will have different terms than research agreements. Funding may go to universities or community organizations for projects which encourage patient/community engagement. PCORI does not view the terms as negotiable; however, it is doubtful that one contract will work for the variety of programs they seek to fund under this program. A workshop agreement would/should be very different than a short, proof-of-concept data collection, for instance.

PCORI is developing a survey that all Authorized Representatives in their system will receive. Among other questions, they will ask something to the effect of “...Over the past 18 months, what is the impact of the F&A policy on your institutions...” They indicated they are seeking

good data so that they can address the F&A issue, particularly with respect to subawards (F&A is applied only to the first \$25K of ALL subs). They recognize that PCORI is funding some very large projects with many subaward sites and that universities are being impacted by this policy. PCORI also is very open to accepting feedback on the invoice procedures and templates.

COGR plans to provide PCORI with a white paper that contains a comprehensive discussion of the issues with a red line version of their research and engagement agreements.

Challenges in Foundation Funding of University Research Spark Discussion

Foundation funding of University research continues to grow as do the challenges associated with agreement terms. Starting with a meeting at Stanford around two years ago (discussed in the [COGR May 2014 Update](#)), there has been a series of meetings sponsored by or involving *Faster Cures*, one in Boston, one in New York City, a meeting at the BIO 2015 annual meeting in Philadelphia, and a special interest group meeting at the recent 2016 AUTM annual meeting in San Diego.

These meetings have helped increase understanding of the needs and concerns of each side. For example, university representatives explained to the foundation representatives that most if not all license agreements have meaningful diligence provisions and universities have strong incentives to see results commercialized. Foundation representatives explained the competitive aspects and challenges of raising funds from donors who want them to pay low indirect costs and capture a share of future licensing revenue.

There has been convergence in areas such as reporting, publication, removing march-in clauses, sharing of results and materials, greater involvement by the foundations in marketing and licensing efforts, and royalty sharing. However, an informal survey of the audience taken during the CIP Committee report revealed three continuing problem areas: indirect costs, intellectual property, and indemnification. Approximately 60 people indicated that they are involved with foundation grant agreements and almost all feel they are problematic. *Faster Cures* has a toolkit for foundation—university partnerships on its website (<http://train.fastercures.org/toolkits/foundation-university-partnerships/>). It includes model templates addressing three issues that are a result of the meeting discussions: Early-Stage Research, Commercialization of Inventions, and Royalty Sharing. It also includes sample agreements from three different foundations that represent varying approaches, priorities, and level of complexity. Additional templates address issues such as access to research tools, milestones and deliverables, progress reporting, confidential disclosure, materials transfer (the AUTM toolkit) and research consortia. *Faster Cures* also has developed principles for IP negotiation (<http://www.fastercures.org/reports/view/24>). We understand further templates and principles may be developed.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Michael Ludwig, Chair, University of Chicago; Jeffrey Friedland, Princeton University, Pamela Caudill, Harvard University, Walter Goldschmidts, Cold Spring Harbor Laboratory, David Norton, University of Florida, James Tracy, University of Kansas, Pamela Webb, University of Minnesota, Jennifer Lassner, University of Iowa, Steven Martin, Indiana University – Bloomington, Lisa Mosely, Arizona State University, Allen DiPalma, University of Pittsburgh

New Effective Practices Guide

Managing Externally Funded Sponsored Programs: A Guide to Effective Management Practices has been updated for the university community on effective financial, compliance, and administrative practices in research administration. The revised guide incorporates 2 CFR 200 (UG) and other updated regulations. Last revised July 2009, the new version is now available and posted on COGR's website with hyperlinks throughout to relevant information and cross cutting sections. The online version will be updated twice a year or as applicable when new regulations are effective. [Click here to access the revised Guide.](#)

New Listserv for the Office of Science Policy (OSP)

OSP has recently launched a new listserv that will allow stakeholders to receive timely updates on policy areas including biosafety and biosecurity, clinical research, genomic data sharing, technology transfer, innovation policy, scientific reporting, and much more. The listserv will also provide subscribers with information on upcoming OSP and trans-governmental meetings and workshops related to important science policy topics.

To subscribe to the listserv, please click [here](#) and then choose the “subscribe” option. You may also subscribe by sending an email to listserv@list.nih.gov with the message: Subscribe OSP_News

As a reminder, the OSP blog “[Under the Poliscope](#)” written by the NIH Associate Director for Science Policy, Dr. Carrie D. Wolinetz presents a unique take on major science policy issues OSP deals with. To subscribe to the blog, simply follow this link: <http://osp.od.nih.gov/under-the-poliscope>

Meeting with Kathryn Partin, Office of Research Integrity (ORI)

The RCA Committee met with Kathryn Partin, the new Director of ORI on Wednesday, February 24th. Dr. Partin made it clear that she believes optimal oversight occurs when there are active partnerships between institutions and their regulators. Previously a full professor in neuroscience at Colorado State University, she went on to become part of the Office of the Vice

President of Research at CSU, eventually serving as Assistant Vice President for Research Integrity.

Having assumed the Directorship of ORI on December 28, 2015, she is still learning her office operations and in the midst of a “listening tour” before she sets strategic priorities. She prefers small groups (not more than 15) for these types of sessions whenever possible. Dr. Partin stated that she is a strong advocate of Responsible Conduct of Research (RCR) training, though she recognizes that data are not yet available to determine the effectiveness of RCR training.

RCA Committee members then discussed with the ORI Director some of the specific issues they had experienced with ORI in the past, including:

- a. *Advice given to an institution orally by ORI when discussing how to handle a case was then later reversed by ORI after the institution had followed that advice.* This causes institutional frustration and awkwardness.
- b. *Institution completes a case and takes action against a faculty member, then submits it to ORI only to have ORI decline to pursue the matter.* (ORI’s term for the latter is “DTP”) This not only causes institutional frustration, but may also have legal consequences for the institution if the faculty member decides to sue the University and wishes to use ORI’s declination as justification that the University’s decision was an overreach. Dr. Partin said there are several reasons for a DTP, including that cases submitted to ORI need to be stronger. 20-30% of cases are rejected because the University didn’t follow its own published policy and procedures. In other cases, the institution followed its own procedures perfectly, but there can be a disconnect between the University’s policy/procedural standards (based on a reasonable preponderance of evidence) and the legal standards ORI must use.
- c. *It sometimes takes ORI a very long time to respond.* This may be a workload issue for ORI. Dr. Partin noted that she’s learned that it is taking a long time to get new positions filled, as HR has been outsourced. In addition, she needs to review internal processes to look at how they may become more efficient. Dr. Partin is very aware, however, that speed of resolution is important – she noted that an allegation, even unsubstantiated, can ruin a young scientist’s career.

Dr. Partin discussed some areas that she is beginning examine:

- a. *Improved guidance to public regarding trends and patterns.* She recognizes that more data would be helpful about published case studies, levels and trends. This will help institutions be able to better focus their training efforts and oversight efforts. ORI is working on FAQs now.
- b. *Enhancing understanding and guidance through conference proceedings/outcomes.* Dr. Partin’s office funds conferences on ORI topics, including two upcoming ones on retractions (Colorado State) and sequestration (U of Indiana). On the latter conference, there is work time planned for on the last day of the conference aimed at creating a Best Practices Guide on sequestering data that are part of an investigation.

- c. *ORI would like to review the laws and regulations around Scientific Misconduct to see if they need to be updated.* One example was the definition of “significant” misconduct, and what “significant” is intended to mean.
- d. *Internal ORI processes will be reviewed to determine if improvements are needed.*

Dr. Partin indicated that she would be very open to being invited back after she has been in the job a bit longer, and she asked that we include her director of investigations, Susan Garfinkel, at that time. She invited us to send her written suggestions or recommendations for things we would like to see changed and also on what areas we’ve had a hard time obtaining general guidance from ORI, or what ORI data we would like to see published. She is also interested in hearing about State data openness laws and how Universities apply them, and what exceptions exist to sharing of data. She indicated that it would be optimal to have our recommendations by early May, when her listening tour is complete.

COGR will follow up with ORI Director Partin and if you have comments or suggestions please contact Jackie Bendall at jbendall@cogr.edu.

Meeting with Wade Wargo and Debbie Rafi, DoD

Together with the Costing Policies Committee, RCA met with Wade Wargo and Debbie Rafi. Wade is Grants Policy Staff Specialist, Assistant Secretary of Defense for Research and Engineering, and Debbie is Director of University Affairs for ONR.

Mr. Wargo reported that we will soon see an updated set of DODGARS (DOD Grants and Agreement Regulations). They expect to send that to OMB by early March, and it is likely to go out for public comment within ~2 months after that. They are planning a 90 day comment period. The DODGARS will call for:

- A standard agreement format and award terms
- A standard location for definitions
- Migration to Title 2 from title 32
- Prescriptions given to the DOD grants officers about when to use certain award terms (similar to how the FAR prescriptions work)

Some DOD components are already using the updated award terms as their model, and he expects that others will do so shortly (ARO in March, AFRL and Wright-Paterson AFB in April.)

Some specialist topics of high interest that were also discussed include:

- *Conflict of Interest* – standardizing this across DOD agencies.
- *Setting of F&A rates for for-profit (and foreign) subrecipients.* We discussed the question of handling for-profit subrecipients that do not have a negotiated F&A rate, but who want more than 10% de minimus F&A called for in the Uniform Guidance, but the pass-through institution is not amenable to negotiating a rate with the subrecipient (usually because of lack of resources to do this.) Historically, DCAA or the institution’s ACO would be willing to help verify a subrecipient’s F&A / profit

rates even when the pass-through entity couldn't get the numbers directly from the subrecipient, but these resources are no longer available. Debbie Rafi concurred that the budget cuts over the past decade have meant that these entities often aren't available, or aren't available for these purposes any longer. There was some discussion about potentially distinguishing between cost analysis (requiring a detailed line-item analysis of a for-profit entity's budget) and price analysis (is the bottom line reasonable).

- *Micro-purchase threshold.* The group took this opportunity to ask for reconsideration of the micro-purchase threshold for the DODGARS and the DOD research terms and conditions. This led to a discussion of the work FDP is doing in this regard, but also a desire (by COFAR) to see more data – for example, how many transactions exist between the \$3,500 threshold and the \$10K threshold, and what is the dollar exposure for those transactions? Are there data that showcases dollar exposure and transactional benefit at various dollar levels between \$3500 and \$10K? Ms. Rafi also indicated that she is aware that the Federal-wide RTCs are considering asking for a \$10K micro-purchase threshold exemption, or an overall exemption for research recipients similar to the exemption provided to State agencies.

COGR will continue these discussions with DOD staff, and please contact Jackie Bendall at jbendall@cogr.edu if you have questions or comments.

Legislation Introduced to Ease Restrictions on University Use of Drones

Senators Gary Peters (D-MI) and Jerry Moran (R-KS) introduced legislation on March 3 that would allow colleges and universities to operate small unmanned aircraft systems (sUAS) for educational and research purposes, including the instruction of students. Under current Federal Aviation Administration (FAA) regulations, colleges and universities are treated the same as commercial drone users. This means that to use such systems, students and professors must apply for approval from the FAA, obtain a pilot's license, and use only pre-approved aircraft. The Higher Education UAS Modernization Act [aims](#) to allow students and educators at colleges and universities to operate unmanned aircraft without requiring specific approval from the FAA by meeting certain requirements. COGR along with other Associations and individual faculty have written to the bill's sponsors to indicate our support.