COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 460, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)

November 3, 2016

October 20-21, 2016 COGR Meeting Report

RESEARCH & REGULATORY REFORM

Committee: Sara Bible, Chair, Stanford University, Cindy Kiel, University of California-Davis, Kerry Peluso, Emory University, Lois Brako, University of Michigan, 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, Martha Jones, Washington University – St. Louis, Charles Greer, University of California-Riverside

National Institutes of Health (NIH) Policy on Good Clinical Practice (GCP) Training

COGR and NIH staff met by teleconference on October 28 to discuss concerns about GCP training requirements raised by COGR in an October 6 letter. We noted in our October update that NIH had issued a Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials on September 16. The policy, which goes into effect January 1, 2017, applies to investigators and clinical trial site staff responsible for the conduct, management and oversight of NIH-funded clinical trials. COGR has asked that the implementation date be extended to May 1; sought clarification on whether the policy applies to new awards or all active awards, advocating for the former; and expressed concerns about variations in how NIH defines "investigator" in the GCP policy and the financial conflict of interest regulations. NIH staff has requested additional information. We will keep members posted on the status of these discussions.

NIH Single IRB Policy for Multi-Site Research

On October 24, COGR, AAMC, AAU and APLU sent a letter to NIH requesting a one-year extension to the May 25 implementation date of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. The letter details some of the complexities of implementing the policy and the challenge of implementing it in an 11 month timeframe. In the letter, COGR, AAMC, AAU and APLU also inquire about yet to be published guidance; IT infrastructure grants to offset what for some institutions may be significant infrastructure costs; and whether additional funding will be made available by NIH to cover budgeted IRB costs so that investigators' funding for research is not reduced. The letter also highlights concerns with costing guidance and the ability of institutions to budget the full cost of a single IRB review. COGR has asserted that as institutions reorganize their IRB enterprise to comply with the new NIH policy, it will be imperative that the maximum costing flexibility is provided. COGR and NIH staff met by teleconference on September 30 in follow-up to a letter sent to NIH and OMB on September 23 detailing a number of costing related concerns and we anticipate further discussions. COGR and NIH staff also met by teleconference on October 28 to discuss a possible extension of the May 25, 2017 implementation date. NIH staff requested additional information. We will keep members posted on the status of these discussions.

Implementation of the NIH Single IRB Policy was the focus of a Thursday morning session at the October COGR meeting. Sara Bible, Stanford University, discussed some of the concerns raised with NIH in recent letters and discussions. Cindy Kiel; University of California Davis; Martha Jones, Washington University; and Kerry Peluso, Emory University, provided information on how their institutions are working to implement the NIH single IRB policy. UC Davis is conducting pilot studies to determine the cost and cost effectiveness of acting as the reviewing IRB for multisite studies of different size and risk. To date they have found that time to approval has doubled and investigator workload has increased.

Washington University is currently developing the infrastructure to act as the reviewing IRB where appropriate. This includes upgrades to their electronic systems; the possibility of new staff; changes in workflow processes; developing a costing model/fee schedule; and developing institutional policies and procedures. Emory University is currently negotiating with a commercial IRB to carry-out single IRB review of NIH-funded multisite studies. Kerry suggested that commercial IRBs have the necessary infrastructure to accommodate collaborations with others sites and that this arrangement makes it easier to identify costs and reduces liability.

At the Research and Regulatory Reform committee meeting on October 19, we discussed possible use of an adapted version of the SMART IRB Reliance agreement; removing informational text and streamlining the agreement to create a working template. Discussions with those that developed the SMART IRB agreement and with the Federal Demonstration Project are underway. There is agreement that the university community would benefit from a broadly accepted universal reliance agreement.

Federal Policy for the Protection of Human Subjects, "Common Rule"

HHS and NIH have indicated that a final rule will be published by the end of 2016. Unofficial sources suggest that a final rule may be submitted to the Office of Information and Regulatory Affairs for review by the end of this month, and that the final rule may not address overwhelming criticism of several of the proposed revisions and prominent recommendations.

As a reminder, the Secretary's Advisory Committee on Human Research Protections, in its comments on the Notice of Proposed Rulemaking (NPRM), recommended that "HHS conduct a comprehensive re-write of the NPRM through a concerted effort to simplify the proposed changes and to focus efforts on selected issues for which there is broad support by the public, investigators, IRB professionals, sponsors and other experts." The National Academies Committee on Federal Research Regulations and Reporting Requirements has suggested that the NPRM is "marred by omissions, the absence of essential elements, and a lack of clarity," does not "effectively address the breadth, depth, and import of unanswered questions" and that the current complexity of issues requires thorough consideration from a broad range of disciplines. The report recommends that the executive branch withdraw the Common Rule NPRM and "that Congress authorize, and the President appoint, an independent, free-standing national

commission modeled on the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research."

Discussions with Office of Science and Technology Policy Staff on Reform and Transition

Members of COGR's Research and Regulatory Reform committee met with Kei Koizumi, Assistant Director for Federal Research and Development, Office of Science and Technology Policy (OSTP), Executive Office of the President at their October 19 meeting. The committee discussed increasing regulatory requirements; a lack of responsiveness on the part of some federal agencies and with respect to particular regulations and policies; the Research Policy Board recommended by the National Academies; and how to engage most effectively with agencies and with the Research Business Models (RBM) working group in the absence of a Research Policy Board. RBM is a an interagency working group under the Committee on Science, part of the National Science and Technology Council, that was created over a decade ago to coordinate federal efforts to address "policy implications arising from the changing nature of scientific research." Most recently, the RBM produced the Research Performance Progress Report.

The committee discussed outreach with the next administration and regular meetings with OSTP. COGR is preparing materials for the presidential transition team. We also discussed the 2013 OSTP Public Access memorandum which directs Federal agencies to develop plans to make publicly available "to the greatest extent possible" final peer-reviewed manuscripts, published articles and data resulting from federally funded research. Institutions have strong concerns about meeting data requirements both with respect to investigator and administrative staff time and cost. There was discussion about the possibility of a federal data repository, such as data.gov. COGR pressed for further discussions between university and federal agency staff on the topic of data.

Maximizing Investigators Research Award (MIRA) and Other R35 Awards

The COGR Research and Regulatory Reform and Costing committees have been engaged in discussions with NIH on the use of the term "research effort" to establish the percentage time dedicated to the MIRA and other R35 awards. COGR initially raised concerns in an email dated June 3, 2016. COGR has indicated that "Institutional Base Salary" (IBS) is the operative metric for supporting time and effort and consistent with the Uniform Guidance and institutions' policies and procedures. COGR has provided NIH with examples detailing use of "research effort" as intended by NIH versus use of IBS that demonstrate the difficulty and increased burden that results from use of "research effort." The next call with NIH is scheduled for November 14. We will keep members informed of any progress.

National Science Foundation (NSF) Intergovernmental Personnel Act (IPA) Program

In March 2013 the NSF Office of Inspector General (OIG) published the report *Audit of Cost Associated with NSF's Use of Intergovernmental Personnel Act Assignees*. The report acknowledges the benefits of the IPA program but also highlights the additional cost of using IPAs instead of permanent employees

and makes recommendations for reducing costs. Among the recommendations were expanded use of telework and greater cost sharing by the home institution. In January 2016, the OIG submitted a *Follow-Up Review of Cost Associated with NSF's Use of Executive Level Intergovernmental Personnel Act Assignees* which focused on executive level IPAs. The review found that NSF had not reduced the cost of executive level IPAs and highlighted recommendations made in the 2013 report.

In response to the OIG reviews, NSF issued a bulletin on October 21 titled *Changes to Policies for Intergovernmental Personnel Act (IPA) Agreements for Personnel on Assignment to NSF*. The bulletin indicates that for all new IPA agreements in fiscal year 2017, 10% cost sharing of the IPA's academic-year salary and fringe benefits will be required; lost consulting payments will no longer be a reimbursable cost element; and that NSF-funded IPA travel to the home institution under the Independent Research/Development (IR/D) program will be limited to twelve trips per year. The bulletin indicates that this is a cost-sharing pilot. NSF has indicated that this is a 12-month pilot, the effects of which will be assessed by the agency as it considers possible changes to the program.

NSF is developing an agency-wide approach to managing the IPA program, a longstanding program authorized under the IPA Act that allows researchers and educators to take temporary assignments at federal agencies. In a presentation at the August National Science Board meeting, NSF staff indicated that there were 176 IPAs in FY15, primarily program officers and executives, with a cost that was approximately 2% over agency personnel costs. NSF noted that IPAs are not in executive positions at other agencies which have legislative authorities that allow for higher compensation packages, and that they are working to secure similar authorities which would allow them to hire executives in long-term appointments. NSF staff indicated that the agency is also looking to increase cost share as recommended by the OIG. NSF requests 15% cost share. However, in FY15 the actual percentage of cost share was 5%. An NSF IPA Steering Committee is considering issues related to cost-share, workforce and hiring authorities.

COGR has recently initiated conversations with institutions and NSF on the IPA program and NSF pilot. NSF's use of IPAs is greater than that of any federal agency. There is agreement among all parties that investigators, institutions and NSF benefit from the agency's use of IPAs both from a scientific perspective and with respect to greater communication between institutions and NSF leadership. NSF's Independent Research and Development Program allows IPAs to spend up to 50 work days a year on independent R&D. The 2013 OIG report indicated that of the 184 IPAs examined, 171 (93 percent) participated in the IR/D program in 2012 and NSF has indicated that 2015 data is consistent with this. Most IPA plans budget 1 day per week to research and IPAs return to their home institution regularly to attend to research and institutional obligations. The new pilot would limit paid travel to 12 trips per year but institutions can negotiate cost sharing to accommodate additional trips as necessary. NSF plans to issue guidance on travel and telework later this year. IR/D is considered part of an IPAs official duties at NSF and is included in the percentage effort committed (i.e., per NSF, 100% effort commitment includes IR/D). COGR and AAU will continue their discussions with NSF on the IPA program and pilot and work to identify mutually agreeable opportunities to sustain the current use of IPAs at NSF.

We are interested in your institution's experience with NSF's IPA program. Please contact Lisa Nichols if you have questions or concerns about the program and pilot effort.

NSF OIG Audit Reports

The NSF OIG issued a report dated September 29, 2016 that questions $2,710,238 of costs claimed on NSF awards by a member institution. The audit covered a three year period and more than $258 million in expenditures. Auditors questioned $2,242,477 in salary costs that "exceeded NSF's allowable limits"; $360,908 in unsupported ACM$ requests; and costs for equipment, travel and other expenses. Regarding unsupported ACM$ requests, the auditors indicate that the institution's "final funding requests for six NSF awards were based on the amount of funding remaining on the grant awards, rather than on the amount of actual disbursements that had been, or would be, made within three days, as required by NSF policy." The university disagreed suggesting that "because NSF often authorizes multiple no-cost time extensions on its awards, an award's POP [period of performance] is often extended past the related appropriation's fixed expiration date. In these cases, NSF notifies [the institution] of the date on which the cash management system will shut down…and states that the shutdown date will be [the institution's] last opportunity to draw funds on the award, even if the POP for that award extends beyond the shutdown date. As a result, [the institution] must calculate the projected remaining expenses that it will incur during the award's POP and then request the final payment prior to the shutdown date." The institution disagreed with the majority of the audit findings.

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, Amanda Dotson, Texas A&M University, Michael Legrand, University of California-Davis, James Fortner, Georgia Institute of Technology, Vivian Holmes, Broad Institute

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Procurement Standards and OMB Update at the COGR Meeting

A representative from OMB was scheduled to provide an update on the release of a new rule that would address our longstanding concerns with the Procurement Standards (2 CFR 200.317-326), and more specifically, the applicability of the micro-purchase threshold (200.320(a)) to procurement actions. ***However, the pending rule still is being processed though the Federal Register, and consequently, OMB was not able to attend the COGR Meeting.***

As of this writing, the rule has not been published in the Federal Register, though per our communication with OMB, the following can be expected:

1) An extension of the grace period for implementation of 2 CFR 200.317-326 is expected to be approved. The grace period will be extended to FY 2019 (i.e., July 1, 2018 for most institutions).

2) The Federal Register Notice will invite comments specific to 2 CFR 200.320(a), Procurement by micro-purchases. ***The timeline for the Federal Register Notice is early November 2016.***

3) Over the remainder of 2016 and into the first-half of 2017, the rulemaking process will unfold. Under this timeline and due to an extension of the grace period, regardless of any modifications, 2 CFR 200.317-326 will become effective in FY 2019 (i.e., July 1, 2018 for most institutions).

COGR will provide an update to the COGR Membership, via email, after the new rule is published in the Federal Register.

Uniform Guidance and Updates to the Frequently Asked Questions (FAQs)

We also expect updates to the FAQs, independent of the Federal Register Notice, to be released shortly. In August, OMB and the COFAR requested for COGR (as well as others from the grantee community) to submit FAQs so that an updated version of the Current FAQs (dated September 2015) could be made available. We addressed seven areas of the Uniform Guidance and provided both the "question" and the proposed "answer". The COGR Proposed FAQs are available on the COGR website. We addressed the following areas:

1) Safe Harbor for Pass-through Entities and their Subrecipients (2 CFR 200.331)
2) Use of the 10% De Minimis Rate and Flow-down of F&A Rate (2 CFR 200.331 & 2 CFR 200.414)
3) Public Advertisement of Competitive Bids (2 CFR 200.320)
4) DS-2 Approval Process (2 CFR 200.419)
5) Foreign Subrecipients and Single Audit Expectations (2 CFR 200.501)
6) Late Issuance of Management Decision Letters by a Federal Agency (2 CFR 200.521)
7) Process to Implement Changes to the Utility Cost Adjustment (Appendix III)

COGR will provide an update to the COGR Membership, via email, after the updated FAQs are made available.

Thursday AM Session: COGR F&A Survey, Negotiation Landscape, and Other F&A

This session was led by a panel that included: ***Cathy Snyder***, Director, Contract & Grant Accounting, Vanderbilt University; ***Jerry Fife***, Associate Vice President, Northern Arizona University and Principal – Point Consulting; ***Jeff Silber***, Senior Director, Sponsored Financial Services, Cornell University; and ***Jim Carter***, Managing Director – Huron Consulting Group. The PPT presentation is available on the COGR Website.

We covered an array of F&A "hot topics":

- COGR F&A Survey status. We shared preliminary results and described the process for rolling out reports. ***For those who have not initiated a survey, the on-line survey will be available through November 18th*** (contact Toni Russo at trusso@cogr.edu). Reports will be available beginning in early 2017.

- F&A Rate Negotiation Landscape. The four panelists each provided a unique perspective on the negotiation landscape, including experiences with obtaining an automatic, up to 4-year rate extension (see 2 CFR 200.414(g)). Also, soon-to-be-retirements by key personnel from HHS-CAS staff in the west coast region was addressed.

- Lease costs and the appropriate F&A rate. The thrust of this discussion was on audit risk in light of the recent DOJ settlement (see subsequent section). Also discussed were the varieties of "off-campus" rates that are used by institutions (several of those definitions are included in the PPT presentation), the use of a "Vicinity rate" (off-campus + library component) and a possible development where HHS-CAS may discourage future negotiation of this type of rate.

- Direct charging of Single IRB costs under new NIH guidance. We provided a brief introduction to this issue. The COGR Research & Regulatory Reform Committee is the lead on this issue (see applicable section of this Meeting Report for an update), with ongoing engagement by the Costing Policies Committee.

- Status of F&A-related UG FAQs (i.e., DS-2, UCA). We provided a brief reminder on the FAQs submitted by COGR, to OMB, on August 26th (see previous section).

- GAO report on the rate-setting process. We provided a brief update on this recently released report (see subsequent section).

- ***Software capitalization threshold.*** This is a new development as the HHS-CAS west coast region has interpreted a strict $5,000 capitalization threshold for all forms of software acquired

with federal funds. We addressed this development in the session and shared COGR's interactions with OMB on this topic (see subsequent section).

We expect each of these issues to require ongoing engagement and we will keep the Membership updated on all developments.

DOJ Settlement: F&A Recovery in Connection with Federal Research Grants

A July 2016 settlement between a research university and the Department of Justice (DOJ) resulted in a $9.5 million settlement related to F&A costs charged to NIH research awards. At issue was the appropriate F&A rate to be charged to NIH research awards taking place in space owned by a third-party entity. A Press Release summary by the DOJ, U.S. Attorney's Office, Southern District of New York is available and the Stipulation and Order of Settlement and Dismissal includes more details associated with the action.

Central to the settlement is the following definition, which is standard in many F&A rate agreements:

> *For all activities within a 50 mile radius of the campus and performed in facilities not owned and operated by the institution* ***and to which rent is directly allocated to the project, the off-campus modified rate will apply {emphasis added}.*** *For all activities outside a 50 mile radius of campus the off campus rate will apply. Grants or contracts will not be subject to more than one indirect cost rate. If more than 50% of a project is performed off-campus, the appropriate off-campus rate will apply to the entire project.*

COGR's understanding is as follows: NIH research grants in question took place in a facility owned by a third-party and rent was not paid (***i.e., not directly allocated to the project***) for the use of the donated space. In the course of developing its F&A rates, the institution included these NIH projects in the on-campus research base, which inflated the denominator and resulted in a lower calculated F&A rate. Under the long-established "averaging concept" used to develop F&A rates under OMB Circular A-21 (and subsequently, 2 CFR Part 200), the aggregate F&A recovery for all Federal programs should be neutral (i.e., perceived over-recovery on certain projects is offset by perceived under-recovery on other projects).

COGR's view is that this practice should not lead to inappropriate aggregate F&A charges to federal grants, though we do recognize it is an important issue for further discussion. ***In the Thursday morning session at the October COGR Meeting we addressed audit risk*** and emphasized that institutions should review internal policies and practices for establishing rates for off-campus projects and clinical trials, including projects in leased space and donated space (e.g., affiliated hospitals, VA, etc.). The recent DOJ settlement apparently was initiated by a whistle-blower, which sometimes suggests the possibility of copycats. It is not clear if HHS-CAS, ONR, the IG community, or other federal oversight bodies see this

as an issue that needs pursued. COGR will pay close attention to all developments, and we encourage you to contact COGR staff if you have concerns related to this issue.

GAO Report: Indirect Cost Rate-Setting Process

The United States Government Accountability Office (GAO), in September 2016, released GAO-16-616, *Agencies Involved in the Indirect Cost Rate-Setting Process Need to Improve Controls*. The GAO study was requested by the House Subcommittee on Oversight and Investigations, Committee on Energy and Commerce.

The report focuses on processes and controls specific to the rate-setting processes at Cost Allocation Services (CAS-HHS), the NIH Division of Financial Advisory Services (NIH-DFAS), and the Office of Naval Research (ONR-DOD). The NIH-DFAS negotiates rates for approximately 190 for-profit organizations, while CAS and ONR are the two rate-setting organizations that historically have negotiated rates for universities, nonprofit research institutes, and hospitals. CAS negotiates rates for approximately 460 universities, 150 nonprofit research institutes, and 90 hospitals. ONR negotiates rates for 25 universities and 5 nonprofit organizations.

GAO found that while CAS, NIH-DFAS, and ONR had designed controls for setting indirect cost rates, deficiencies in the design of some of these controls could result in the waste of federal resources. GAO made 12 recommendations to improve controls; HHS concurred with the GAO's 7 recommendations to CAS and NIH-DFAS and described ongoing and planned actions to address them. DOD concurred with 4 recommendations to ONR and partially concurred with 1. While the report is not directed at our community, institutions should pay attention to the extent that this may impact future F&A rate negotiations.

Software Capitalization under the Uniform Guidance

The HHS-Cost Allocation Services (CAS) west coast office has raised the issue that acquisitions of software and internally developed software projects acquired with federal funds (or projects that could have repercussions for F&A recovery) must be capitalized using a $5,000 threshold. HHS-CAS seems to be utilizing a "one-size-fits-all" definition of software. This raises issues about the application of F&A and the treatment of diverse software-related acquisitions. With that said, HHS-CAS is at a disadvantage as they are working with definitions from the Uniform Guidance (2 CFR Part 200) that are inconsistent and can lead to multiple interpretations.

The COGR Costing Committee met with OMB to share our concern and has constructed our position as follows:

- There are many categories and classification schemes for software, and currently there are no universally agreed-upon definitions; therefore, a "one-size-fits-all" approach is not appropriate.

- Currently, institutions (appropriately) have varying definitions of both software and the corresponding capitalization thresholds. Depending on the definition/type of software, capitalization thresholds can range from $5,000 to $1 million, or more. This approach is consistent with GAAP and is consistent with how it is applied across the institution.

- The relevant definitions in the Uniform Guidance are: 200.12 – Capital assets, 200.33 – Equipment, 200.58 – Information technology systems, and 200.59 – Intangible assets. While 200.33 and 200.58 specify software is equipment (tangible asset) and must be capitalized at a $5,000 threshold, 200.12 and 200.59 support that software is intellectual property, which normally is considered an intangible asset.

- Industry norms and the University Industry Demonstration Partnership (UIDP) recently have designated software as a separate category of assets under intellectual property.

- GASB 51 and FASB ASC 350 both recognize that institutions should categorize software as intangible property, rather than equipment.

- And as institutions have worked with their internal and external auditors to refine thoughtful and institutionally appropriate definitions of both software and the corresponding capitalization thresholds, the correct and fair outcome would be for institutions to continue managing software capitalization under their current policies and practices.

Any mandate that would involve institutions to follow one policy for software acquired on federal awards and a separate policy for all other software acquisitions would be a costly and burdensome requirement. OMB appears to be receptive to COGR's position and we have incorporated our position into a letter to OMB (see www.cogr.edu for a copy). We will continue to advance this discussion and keep the Membership posted on all developments.

F&A Recovery: Nonprofit Disease and Research Foundations

FasterCures is a DC-based center of the Milken Institute, which "*works across sectors and diseases to accelerate the process by which great advances in science and technology are turned into meaningful medical solutions for patients*." *FasterCures* is leading a diverse workgroup of representatives from nonprofit disease and research foundations, and research universities, to address issues of common ground that can enhance the partnership between these organizations. Issues related to data sharing, intellectual property and licensing were among the first to be addressed, and a current initiative is being explored to develop better methodologies for recovering F&A-related costs.

Several leaders from the COGR Contract & Intellectual Property (CIP) Committee have taken a leadership role in the *FasterCures* workgroup and have asked the COGR Costing Committee to participate in the discussions related to F&A recovery. This may be a good opportunity to address the longstanding issue of under-recovery of F&A costs and to considerer new solutions that will be workable for all parties.

HHS Office of Grants Policy: Closeouts, Grants Policy Statement, Other Developments

Jeffrey Johnson, Associate Deputy Assistant Secretary for Grants, Department of Health and Human Services (HHS) presented at a session during the June 9 COGR Meeting. We included a recap of that session in the June Meeting Report (dated July 1, 2016). Since then, COGR has been in regular contact with the HHS Office of Grants Policy and Mr. Johnson.

COGR has a longstanding relationship with NIH and we are encouraged by the growing and productive relationship with the HHS Office of Grants Policy and all of the HHS Operating Divisions (HHS ODs). Some of the issues we have raised, to date, with the HHS Office of Grants Policy and Mr. Johnson include: 120-day grant closeout model across all HHS ODs, functionality of the Payment Management System (PMS), the prospects for other HHS ODs to join the Research Terms and Conditions, and applicability of the 10% deminimis rate to foreign recipients and training grants. Discussions on these topics have been productive.

Also, some of the critical issues related to grant closeouts are being addressed internally by the HHS Office of Grants Policy and their "Closeout Workgroup". We expect the Closeout Workgroup to provide recommendations later this Fall and our understanding is that the recommendations will be shared with COGR before finalizing the recommendations. Finally, the HHS Grants Policy Statement (last updated in 2007) is being revised and we expect to engage with the HHS Office of Grants Policy as this gets closer to completion. COGR will remain actively engaged on these topics and we will keep the Membership posted on important developments.

Equitable Treatment of Off-Campus Research Centers in NIH RFAs: UPDATE

A COGR Workgroup continues its work with NIH to devise a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. At issue is the treatment of lease costs when a Request for Application (RFA) or policy regarding Investigator initiated proposals limits costs in terms of maximum direct cost. COGR's position is that off-campus research centers are at a competitive disadvantage because by including the lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. Note, when lease costs are not counted against the direct cost maximum and treated similarly to F&A costs for on-campus research centers, the total cost of the research at on and off-campus facilities is relatively comparable.

Last month COGR provided a cost impact analysis to NIH, which demonstrated the potential effect on the NIH budget if the treatment of lease costs in NIH budgets was changed. While lease costs still would be proposed in the project budget, they would be excluded against the direct cost maximum allowing other direct research-related costs to be proposed, resulting in more total costs being proposed for off-campus research centers, and hence, a potential cost impact to NIH.

Based on data collected from over 20 institutions, and extrapolating the results, COGR determined the overall cost impact to NIH to be less than $20 million. Based on feedback from the COGR membership, it appears that less than a dozen institutions conduct significant research at off-campus research centers and a relatively small amount of lease costs are being directly charged to NIH awards. Therefore, with only a slight cost impact to the NIH budget, coupled with a resolution to the inequitable treatment, COGR suggests that an NIH policy change would be appropriate.

If you are interested in viewing the COGR analysis, contact David Kennedy at dkennedy@cogr.edu. We will keep the Membership posted on developments.

Student Financial Aid (SFA) Cluster and the Single Audit: UPDATE

We have followed this issue since it arose in the Summer. The most recent COGR Update (dated October 11, 2016) a summary and a description of the core issue: The Department of Education (ED) maintains that an annual compliance audit of the SFA Cluster is required, despite the fact that this appears to be inconsistent with the requirements under the Higher Education Act of 1965, the Single Audit Act Amendments of 1996, and the *Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards* (2 CFR Part 200).

COGR is working closely with NACUBO, the National Association of State Auditors, Comptrollers and Treasurers (NASACT), the AICPA, and other stakeholders to elevate this issue to senior leaders at OMB and ED. We expect the 2017 Compliance Supplement to be the vehicle to provide official, final, and fair guidance, and we will engage, accordingly, as the 2017 Compliance Supplement is being developed. We encourage you to continue working with your Single Audit team to determine issues specific to your institution, and we will keep you posted on all developments.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Alexandra McKeown, Chair, The Johns Hopkins University, 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; Michael Moore, University of North Dakota

DOD Issues New Cybersecurity Regulations

On October 21 DOD issued a final rule amending the Defense Federal Acquisition Regulations Supplement (DFARS) requirements for safeguarding covered defense information and cyber incident reporting (81FR72986).

An important feature of the final rule is an amendment to the DFARS 252.204—7000 *Disclosure of Information* clause. This clause has been of longstanding concern to COGR members. The amendment provides that fundamental research by definition cannot involve any covered defense information. This directly responds to concerns COGR had expressed to DOD that institutions were receiving safeguarding requirements in fundamental research projects, particularly in flowdowns from prime defense contractors (see COGR February 2016 Meeting Report).. The effect is to reinforce that fundamental research projects are not subject to the safeguarding requirements. While helpful, it heightens the need to obtain determinations from DOD contracting officers that contracts have been scoped and negotiated as fundamental research by the contractor and research performer, in accordance with 7000 (a)(3). The safeguarding requirements are mandatory flowdowns when covered defense information is involved. We understand that prime contractors are including them in subcontracts regardless of the nature of the project. This should help institutions in pushing back.

The other main feature of the final rule is a revision of the 252.204—7008 *Compliance* and 7012 *Safeguarding Covered Defense Information and Cyber Incident Reporting* clauses. The 7012 clause now explicitly links the definition of "Covered Defense Information" with the NARA CUI Registry (see COGR October 2015 Meeting Report). It provides that the NIST SP 800-171 requirements apply to contractor information systems that process, store or transmit covered defense information. The requirements must be implemented no later than December 31, 2017. Prior to October 1, 2017 contractors must notify the DOD Chief Information Officer (CIO) within 30 days of contract award of any NIST requirement not implemented by the time of award (after October 1 the notification

requirement does not apply, since contractors should be preparing for full implementation by December 31).

Requests to vary from any of the NIST requirements must be submitted to the DOD CIO, with an explanation of why the requirement is not applicable or how an alternative measure will be used to compensate to provide equivalent protection (see 252.204—7008(c)(2)). The CIO will adjudicate these requests prior to contract award, with accepted variances incorporated in the contract. The revised 7008 *Compliance* clause also provides that by submitting offers offerors represent that the NIST requirements will be implemented by December 31, 2017.

It is not clear from the revised 7012 clause as to whether the notification and variance requirements should be read conjunctively or as separate requirements. However, the discussion in the preamble to the final rule states that "Separate and distinct from the process to vary from the security requirements in NIST SP 800—171, the 30-day notification requirement …requires the contractor to provide the DOD CIO with a list of the security requirements that the contractor is not implementing at the time of award (5.a.; p. 72990). Also, in the preamble to the second interim rule amending the 7008 and 7012 clauses, DOD indicated it was delaying the requirement for full implementation of the NIST security measures until December 31, 2017 because of concerns expressed by industry (see COGR February 2016 Meeting Report). Therefore it appears that contractors have the choice of either notifying DOD of any non-compliance within 30 days of the contract award with the understanding there must be full implementation by December 31, 2017, or requesting a variance prior to the contract award. If the variance is approved, presumably the December 31 date no longer will apply with regard to the particular requirement(s) covered by the variance. The variance procedures also apply to subcontractors.

Two other features of the final rule involve cloud service providers and cyber incident reporting. If a cloud service provider is used to store, process or transmit any covered defense information, the provider must meet the security requirements established for the Federal Risk and Authorization Management Program (FedRAMP) as well as the cyber incident reporting requirements of the 7012 clause. The cyber incident reporting requirements have not significantly changed from the interim version. "Malicious software" discovered in connection with a cyber incident now must be submitted to the DOD Cyber Crime Center (DC3), not the contracting officer. Cyber incidents must be reported within 72 hours of discovery to http://dibnet.dod.mil/ . Contractors must obtain a medium assurance certificate for this purpose, and must complete (and update) Incident Collection Forms.

The rule was effective upon issuance. As we discussed in the most recent COGR Update, NARA is developing a FAR CUI rule that is expected to be issued next year. While it is supposed to supersede the DFARS (and other agency) clauses, our guess is it may closely track the DFARS requirements (covered defense information is one category of CUI). DOD has specific statutory requirements which required issuance of the DOD rule prior to development of the FAR rule. The NIST SP 800-171 requirements that may be of most concern to COGR member institutions are those involving multifactor

authentication, encryption and organizational incident response capabilities. The final rule clearly states that DOD will not provide any funding for compliance costs (4.b.-p. 72989).

COGR Committees Discuss NETL Foreign National Approval Requirement

The October Update discussed the new waiver process for the requirement of the DOE National Energy Technology Lab (NETL) in Morgantown that all foreign nationals performing research on NETL-funded work must be submitted to DOE for approval. The requirement has been applied to fundamental research projects performed on campus even where the foreign nationals have no access to NETL-provided information or DOE facilities. It is based on DOE Order No. 142.3A ("Unclassified Foreign Visits and Assignment Program--https://www.directives.doe.gov/directives/0142.3a-BOrder/view) .

At the October meeting the CIP and RCA Committees met with Adam Cohen, DOE Under Secretary for Science and Engineering. He informed us that NETL's interpretation of the DOE Order is based on the view that all information pertaining to DOE-funded projects is protected DOE information. The Secretary of Energy has issued a letter approving a waiver process for accredited institutions of higher education for fundamental research projects where the information generated will be published and the results will not be export controlled. The waiver process applies to situations where no foreign national access to DOE/NETL sites, information, technologies or equipment is contemplated. As noted in the Update, waiver requests must be submitted through NETL to Dr. Cohen.

At the meeting Dr. Cohen stated that he has approved all waiver requests submitted to him so far. In response to concerns we expressed that the waiver process might not survive a change in DOE leadership, he indicated that a change in the DOE Order was being drafted. COGR/AAU followed up with a letter to Dr. Cohen expressing appreciation and encouraging him to advocate for a permanent inclusion of the exemption within DOE Order 142.3A. In a response Dr. Cohen has indicated that the permanent change has been drafted and in the approval process for the Secretary. Hopefully it will be issued in the next several weeks.

This issue has been under discussion with DOE leadership for three years. No other DOE facility appears to follow NETL's strict interpretation of the Order (which Dr. Cohen conceded in his meeting with us). We are grateful that an interim solution has been found and a more permanent fix may be in the works. However, the inability of DOE to resolve the situation with NETL for this length of time despite assurances from DOE leadership remains troubling. We also subsequently were informed by Dr. Cohen that the Secretary's letter could not be released. Also, while Dr. Cohen mentioned several waiver approvals, we had not yet had verification from any COGR member institution of a successful waiver request. (If you have received a waiver please notify Jackie Bendall or Robert Hardy of the COGR staff).

AAU/APLU Joint Survey of University Technology Transfer Management Policies

On October 21 AAU/APLU jointly sent a survey to all their member institutions regarding their technology transfer and intellectual property management policies.

The survey is intended to gauge the extent to which the member universities have implemented the university technology transfer policy recommendations made by the AAU Working Group on Technology Transfer and Intellectual Property and the APLU Task Force on Managing University Intellectual Property last year (see COGR May 2015 Update for a summary of the recommendations). The recommendations emphasized that a primary mission of universities is to ensure discoveries made on their campuses are developed and distributed for the benefit of the public. The recommendations also encouraged universities to strengthen their policies to ensure that institutional intellectual property management and technology transfer practices align both with the public interest and with the institutions' core research, education and service missions. One specific recommendation was that universities should not deal with patent trolls, and should have policies in place restricting such dealings. The survey is short, consisting of six substantive questions. One asks about the TTO's relationship with the university. Another asks about mission and policy statements on management of intellectual property, and another involves policies addressing the Nine Points. Question #6 asks specifically whether institutions have in place policies prohibiting or restricting licensing university patents to patent assertion entities (patent rolls). The final two questions concern metrics for successful technology transfer and other useful policies or practices.

We have repeatedly discussed in COGR Updates and Reports concerns about university dealings with patent trolls. The cover memo to the AAU/APLU survey mentions the Electronic Frontier Foundation's recent campaign to restrict such relationships (see COGR September 2016 Update; see http://techtransfercentral.com/2016/10/26/ttos-largely-silent-about-new-effort-pressuring-universities-to-cut-ties-with-patent-trolls/ for a further update). Also, a recent study claimed that a number of universities that have endorsed the Nine Points still licensed hundreds of patents to a well-known patent assertion entity.

AAU/APLU believe that an effective way to avoid legislative action on this matter is to put in place clear and transparent written policies stating that the institution's technology transfer goals and objectives align with the interests of the public. This includes policies meant to ensure university intellectual property is licensed or assigned only to entities that intend to develop and disseminate patented university innovations, and not to entities whose primary business model is based on nuisance or abusive patent assertion practices. We will report on the institutional responses to the AAU/APLU survey.

NIST NPRM on Federally Funded Inventions

We have mentioned in a number of recent Updates and Reports NIST's plans to issue an NPRM revising the federal regulations that implement the Bayh-Dole Act (37 CFR 401). The NPRM initially was expected in June but has been delayed. It is one of the final activities under the Administration's Lab to Market Initiative (see COGR February 2016 Update).

NIST has been very open in this process, and consulted frequently with COGR. They have been determined to "do no harm" to Bayh-Dole while improving the infrastructure for technology transfer within the federal government. Most of the delay evidently has involved resolving the input from other federal agencies as to the proposed changes. The revisions do not address matters of recent concern such as march-in rights.

We (and NIST) had expected the NPRM to be published by now. NIST is planning to hold a public meeting and webinar on the proposed changes on November 21. Requests to participate in person must be submitted to http://www.nist.gov/tpo/bayh-dole and received by November 14. COGR anticipates participating in the meeting.

We will update the COGR membership as to the content as soon as it is released. We expect it will be very shortly.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Pamela Webb, Chair, University of Minnesota; Michael Ludwig, 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, , Jennifer Lassner, University of Iowa, Steven Martin, Indiana University – Bloomington, Lisa Mosely, Arizona State University, Allen DiPalma, University of Pittsburgh; Jeremy Forsberg, University of Texas-Arlington

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HHS, Office of Research Integrity (ORI)

The October Update mentioned that Dr. Kathryn Partin, Director of HHS, Office of Research Integrity would be present at COGR's October 2016 meeting to present her findings collected from external listening sessions conducted over the past several months. During her presentation she shared the feedback she obtained from associations and societies, including COGR, RIOs and RCR experts, federal interagency groups, NIH intramural RIOs, NIH Leadership, and the NSF Inspector General.

The main talking points were as follows:

- ORI values its relationship with COGR and considers the organization a key stakeholder;
- Division of Investigative Oversight (DIO) is measuring misconduct activity, and ORI is publicizing the data to promote research misconduct;
- There are a number of Division of Education and Integrity (DEI) outreach activities, but probably the most important are the 5 RCR conferences that will be announced soon via ORI's website and newsletter;
- In addition to administrative actions against Respondents, ORI performs compliance actions against institutions that fail to follow their assurance;
- The "listening tour" has been completed and what was reported is as follows: Fully staffing the DIO, providing technical assistance to RIOs, measuring workflow for efficiencies, examining trends of misconduct findings and administrative actions, continue to deliver RIO boot camps and consider adding advanced topics, participate in discussions on retractions, review institutional compliance activity;
- Next steps for ORI: provide customer satisfaction surveys to RIOs and RCR Program Managers, assemble and compare Federal Misconduct Policies matrix, strategic planning by fall, finalize ORI Roadmap by end of calendar year.

Statements from the COGR audience are as follows:

- Strong RCR need prior to a misconduct act is just as important – ORI agrees
- Need to train research associates, since they perform misconduct but don't get training – unfunded mandate problem
- Federal harmonization is needed in misconduct and RCR policies
- Getting timely updates from ORI is important
- More guidance should be available in the area of "confidentiality". What can be said about a case, before, during and after?

National Science Foundation (NSF), Proposal and Award Policies and Procedures Guide (PAPPG)

The National Science Foundation has released the newly revised NSF *Proposal & Award Policies & Procedures Guide* (PAPPG), (NSF 17-1) effective for proposals submitted, or due, on or after January 30, 2017. The PAPPG has been modified in its entirety, to remove all references to the *Grant Proposal Guide* (GPG) and *Award & Administration Guide* (AAG).

Other revisions include:

- Addition of new sections on Special Processing Instructions and Types of Proposals, including two new types, RAISE and GOALI;

- Additional instructions for proposers on completion of the Collaborators and Other Affiliations information;
- Supplemental guidance on submission of proposals by organizations impacted by a natural or anthropogenic disaster;
- Implementation of 45 CFR 690.118 for applications and proposals lacking definite plans for involvement of human subjects;
- Update on the type of information that NSF may request from proposers with regard to Federal environmental statutes;
- Supplemental information regarding treatment of NSF awards with canceled appropriations; and
- Numerous other changes and clarifications throughout the document.

Webinars to brief the community on the new PAPPG will be held on November 7th and January 19th at 1pm EST. Registration is required on the outreach events website.

Please send your comments to jbendall@cogr.edu. COGR will decide whether to respond based on the number of responses we receive from the membership.

Pre-Award Information Sheet Requirements with DOE

In the October update COGR mentioned receiving the Pre-award Information Sheet from members (required at the time of application for financial assistance awards). This is a 12-page sheet required of applicants to the DOE Office of Energy Efficiency & Renewable Energy. At the October meeting RCA and CIP met with Dr. Adam Cohen, DOE Under Secretary for Science and Engineering. During this meeting we pointed out that the Sheet does not appear to have OMB approval for the requested information, and that much of the information requested is redundant and unnecessary for universities that routinely received financial assistance awards from the government. Dr. Cohen promised to take the Sheet under advisement and directed us to an individual at DOE for further discussion purposes. COGR will continue to advocate against this issue over the next few weeks.

Data Transfer and Use Agreements Working Group

The RCA and CIP Committees met jointly to hear about the efforts underway by the Federal Demonstration Partnership (FDP) to establish Data Transfer and Use Agreement templates necessary for contractually managing the influx of incoming and outgoing datasets from academic and other non-profit institutions, federal agencies and private industry. The data both identified and non-identified are necessary components of conducting scientific research and as such may be subject to confidentiality provisions (when necessary) while promoting transparency pursuant to applicable laws, regulation, federal requirements and University policy. As this is one aspect of the broader Public Access initiative, it is important to establish open communication in this process early on to reduce to the extent possible the growing administrative burden in managing and complying with public access mandates.

Dual Use Research of Concern

The NIH Office of Science Policy is asking for Stakeholder input regarding the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern . More than a year after its effective date of September 24, 2015, the government is interested in knowing how researchers and institutions are implementing the policy. What are the challenges being encountered? Are there best practices for identifying DURC or managing risks? The USG has asked the National Science Advisory Board for Biosecurity (NSABB) to solicit feedback by hosting a series of regional stakeholder meetings. These meetings will focus on how institutions are implementing the DURC policy and what challenges they are facing.

The NSABB will discuss this new task at its next full Board meeting, a teleconference on November 4th, 2016 from 12:00 pm – 3:00 pm ET. This teleconference is open to the public and time will be reserved on the agenda for public comments. If you can't participate on Nov. 4th, there will be additional opportunities to engage the NSABB to discuss the institutional DURC policy in the coming months. Interested stakeholders can submit comments to the NSABB at any time by emailing nsabb@od.nih.gov. COGR will continue to monitor this issue and will submit comments as appropriate. If you have any concerns or comments, please contact Jackie Bendall at jbendall@cogr.edu.