COUNCIL ON GOVERNMENTAL RELATIONS
1200 New York Ave., NW, Suite 460, Washington DC 20005
(202) 289-6655; (202) 289-6698 (FAX)

September 2, 2016

TO: COGR Membership

FROM: COGR Staff

Click here for UPDATE SUMMARY

SUBJECT: September 2016 Update

TABLE OF CONTENTS

Procurement Standards (2 CFR 200.317-326): UPDATE

Based on our most recent correspondence with OMB in late August, the following represents expected next steps. Timing is important and COGR is in regular communication with OMB to pinpoint the status on official announcements.

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) and will be announced in the Preamble to Proposed Rulemaking.

2) The Proposed Rulemaking will invite comments specific to 2 CFR 200.320(a), Procurement by micro-purchases. The timeline for the Federal Register Notice is September/October 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).

As we noted in the June Meeting Report (dated July 1, 2016), concurrent legislative efforts are in motion that could create a statutory basis for establishing a more rational micro-purchase threshold. The Association of Independent Research Institutes (AIRI) is the lead and COGR is supporting AIRI's efforts. Once Congress reconvenes after Labor Day, we anticipate an update on the legislative front. We will keep the Membership updated on all developments.

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

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)

As we indicated in the letter, FAQs are designed to represent clarifying statements for sections of the Uniform Guidance that require additional clarification. They are not meant to be technical corrections or policy adjustments, though at times, there is a fine distinction between an FAQ

and a policy adjustment. We expect OMB to review and publish selected FAQs this Fall. We will keep the Membership updated on all developments.

HELP REQUESTED: Equitable Treatment of Off-Campus Research Centers in RFAs

As we reported in the June Meeting Report (dated July 1, 2016), a COGR Workgroup completed an analysis and forwarded it to NIH representatives. The emphasis of the analysis is to devise a more equitable mechanism for NIH to evaluate 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 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 also would include space and facility-related costs in the proposed budget.

Several individuals from this COGR Workgroup conferenced with representatives from the NIH Office of Policy for Extramural Research Administration (OPERA). They are interested in implementing solutions to restore equity; for example: 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.

However, OPERA would like data before they move forward. ***We need volunteers to provide the following data (either FY15 or FY16 data is fine):***

1) How many NIH awards do you have taking place in off-campus space?
2) What are the cumulative lease payment costs for these NIH awards?
3) Generally speaking, are these lease payments directly charged to the NIH award?
4) The assumption is you are collecting a 26% off campus rate on these awards, is that generally true for these NIH awards?
5) Generally speaking, what is the reason for these NIH awards being assigned to leased space rather than taking place in an on-campus building?

If you can help, please contact David Kennedy at dkennedy@cogr.edu. We would like to have this data by September 14th. Any help you can provide would be greatly appreciated!

HHS Office of Grants Policy and Closeouts: UPDATE

COGR continues to follow developments related to grants closeout. The June Meeting Report (dated July 1, 2016) included a recap of the presentation made at the Thursday, June 9 session by Jeffrey Johnson, Associate Deputy Assistant Secretary for Grants, Department of Health and

Human Services (HHS). COGR is in regular contact with the HHS Office of Grants Policy and Mr. Johnson and we will continue to engage, as appropriate, on the intertwined topics of HHS (including NIH) subaccounting (i.e., award-by-award accounting), the 120-day grant closeout model implemented by NIH, reconciliation between the Federal Financial Report (FFR) and the Federal Cash Transaction Report (FCTR) at closeout, the functionality of the Payment Management System (PMS), and the prospects for other HHS Operating Divisions joining the Research Terms and Conditions.

Some of the critical issues related to closeouts are being addressed internally by the HHS Office of Grants Policy and their "Closeout Workgroup". We expect the Closeout Workgroup to provide recommendations soon and our understanding is that the recommendations will be shared with COGR before finalizing the recommendations. COGR will remain actively engaged on these topics and we will keep the Membership posted on important developments.

2016 COGR F&A Survey: Preliminary Results Targeted for October 20 COGR Meeting

We initiated the 2016 COGR F&A On-line Survey on August 23rd. Per the August 23rd email to the COGR membership, we requested that each institution designate one person as the point of contact. We are encouraging institutions to complete the survey by September 30th, which will allow us to compile a critical mass of surveys prior to the October COGR Meeting and to provide preliminary results at that meeting.

F&A rates and related data will be shown by institution and be available to COGR MEMBERS ONLY. In addition, we are collecting "Negotiation Experiences". However this information will not be published by institution. Instead, this information will be available more generically; for example, one goal is to organize negotiation experiences by region, which can then be available when your institution is preparing for your F&A rate negotiation.

Also note, we are considering F&A Rates/Negotiation Experiences as Phase 1 of the survey. We are considering additional survey phases to address topics such as effective F&A rates, F&A recovery by type of sponsor, internal distribution of F&A recoveries, etc. We will discuss this more at the October COGR Meeting.

Finally, we want to extend a special "THANK YOU!" to those individuals and institutions that volunteered to Beta test the survey:

> Mark Daniel, (Broad Institute), Mark Perez (University of California, Merced), Alison Monroe & Klugh Jordan (Duke University), Bill Lambert & Josh Rosenberg (Emory University), Jonathon Jeffries (Georgia Institute of Technology), Sarah Axelrod & Peggy Mui (Harvard University), Barbara Cole (University of Miami), Leonor Rivera, Lisa DeStefano & Edward Kalaydjian (City University of New York Research Foundation), Nancy Daneau & Michael Miller (New York University), Gary Culpepper (Vanderbilt University), Danel Phelps (University of Washington). We value the contributions of all of our members and appreciate your continuing willingness to support COGR initiatives. Thank you for your help and participation!

If you have any questions on the survey, please direct them to both Toni Russo at trusso@cogr.edu and David Kennedy at dkennedy@cogr.edu.

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. The first link below is a press release with a summary of the settlement as written by the DOJ, U.S. Attorney's Office, Southern District of New York. The second link is the Stipulation and Order of Settlement and Dismissal and includes more details associated with the action.

> https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-95-million-settlement-columbia-university-improperly
>
> https://www.justice.gov/usao-sdny/file/875196/download

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 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 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, we do recognize it is an important issue for further discussion. We will pay close attention to any developments, and further expect to address this issue during the October COGR Meeting.

2016 Single Audit Compliance Supplement: Comments due October 31, 2016

The 2016 Compliance Supplement was released in August and is available at:

https://www.federalregister.gov/articles/2016/08/09/2016-18780/uniform-administrative-requirements-cost-principles-and-audit-requirements

Significant updates were made to Part 6 – Internal Control. Per the Federal Register Notice, Part 6 was updated to be consistent with the guidance contained in "Standards for Internal Control in the Federal Government" issued by the Comptroller General of the United States (Green Book) and the "Internal Control Integrated Framework" (revised in 2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Public comments can be made on Part 6, or any other section of the 2016 Compliance Supplement up until October 31, 2016. COGR is not certain whether or not we will respond. However, if you have any concerns with the 2016 Compliance Supplement, please contact David Kennedy at dkennedy@cogr.edu and we can explore the possibility of submitting comments.

Student Financial Aid (SFA) Cluster and the Single Audit

We have reported on this topic in the past several COGR Updates. At issue is whether a compliance audit is required on annual basis for the SFA cluster. The Department of Education (ED) position is that an annual compliance audit is required. This issue relates specifically to 2 CFR 200.518, Major program determination, and more broadly to the implementation of 2 CFR Part 200, Subpart F – Audit Requirements. COGR's understanding is as follows: if a Type A program (such as SFA) is determined to be low-risk, then a compliance audit is not required on an annual basis.

ED does not agree. On August 5, 2016, ED posted a Notice on the "Applicability of Single Audit Act Regulations to the Title IV Student Aid Programs". The ED Notice includes the following Resolution:

> *It is clear that the provisions of both the HEA and the implementing regulations require annual submissions of not only the institution's audited financial statements but also of the compliance audit of the institution's administration of the Title IV student aid programs. Therefore, an institution may meet this annual submission requirement by submitting annual audited financial statements and a compliance audit of the institution that were prepared either in accordance with the OIG audit guides or in accordance with the Single Audit Act requirements. In either case, the compliance audit must be submitted annually. Therefore, a submission prepared under the Single Audit Act requirements that does not include a compliance audit does not meet the HEA audit requirement.*
>
> *The Department continues to review issues related to the frequency of audit submissions and plans to include additional guidance in the 2017 Compliance Supplement applicable to audits of fiscal years beginning after June 30, 2016. Until further guidance is issued, institutions may continue to provide Single Audit submissions that were prepared using the standards in place prior to the Single Audit Act regulatory change referenced above. In addition, any institution that has already had an auditor prepare a Single Audit under the new OMB guidance referenced above, with a determination that the Title IV programs were low risk, should contact their respective School Participation Division.*

However, more clarity is necessary and COGR's perspective is that the Resolution posted by ED represents an interim resolution that requires more engagement and communication across all stakeholder communities. NACUBO, on behalf of the higher education community, has taken the lead on advancing the discussion with ED and OMB, and COGR will participate. We expect the 2017 Compliance Supplement to be the vehicle to provide official, final, and fair guidance, and COGR will engage, accordingly, as the 2017 Compliance Supplement is being developed.

We will continue to monitor this situation. In the meantime, we recommend working with your Single Audit team to determine further details and issues specific to your institution. Finally, although we do not expect issues, we would like to know if institutions have their SFA risk assessment questioned by their School Participation Division for FY16. Please contact David Kennedy at dkennedy@cogr.edu if you have issues or concerns.

COGR Meets with OMB/OIRA on Proposed Ed. Open Licensing Requirement

The December 2015 COGR Update discussed the Department of Education's proposed rule that would require Ed grantees to openly license to the public all copyrightable intellectual property created with Ed grant funds. COGR joined other higher ed. associations in commenting to the Department last December that a "one size" fits all open licensing approach would neither be appropriate nor effective. It would limit the ability of our members to transfer tested and validated educational technologies to the private sector. Subsequently a panel at the February COGR meeting discussed the pros and cons of open licensing (see COGR February 2016 Meeting Report; and click here for a "Fact Sheet" extolling the purported benefits of open licensing.

According to Reginfo.gov, the final version of the proposed rule was submitted to OMB/OIRA on July 12. We requested a meeting with OIRA to reiterate our serious concerns about the rule as proposed. The meeting was held on August 9. COGR, AAU and APLU participated as well as two university representatives. The university representatives provided specific examples of the issues raised for their institutions by the proposed rule. Besides OIRA, there were three Ed. officials in the room who took notes and asked questions as well as three more on the phone, along with representatives of the White House Domestic Policy Council and OMB.
From our perspective the meeting went well. However, we do not know the content of the final rule submitted to OIRA nor is it possible to infer the likely outcome. Previous COGR meetings with OIRA with regard to proposed agency rules appear to have been productive.

Bayh-Dole NPRM Expected Shortly

The May Update discussed an expected NIST NPRM that will contain a number of proposed changes to the Bayh-Dole Act regulations (37 CFR 400). The rule was expected to be issued in June, but has been delayed because of various levels of clearance necessary within the government. COGR recently was informed by NIST that the rule is expected to be published by the second week in September. NIST still is in the process of adjudicating agency comments.

NIST consistently has characterized the changes as minor and technical in nature. However, we understand informally that they may be more extensive than expected. The NPRM will not address recent concerns that have arisen over drug pricing and march-in rights. NIST has been

open about the process (see COGR February 2016 Update for a discussion of the likely changes). The changes that have been previously discussed by NIST appear to have relatively little impact on universities. However, there may be unintended consequences. The fact the process has been drawn out with agency comments is not particularly reassuring. We will notify the COGR membership when the NPRM is issued and provide an analysis.

NAS Report Addresses Invention Reporting

Chapter 10 of the recent NAS Report Part II on Federal Research Regulations and Reporting Requirements contains a number of recommendations related to invention reporting. It contains a number of criticisms of the iEdison reporting system and recommends that responsibility for iEdison be transferred from NIH to the Department of Commerce.

COGR long has had concerns about iEdison and federal invention reporting requirements generally (we summarized these recently in the June Meeting Report). We fully support the NAS recommendation to develop a uniform set of requirements for reporting of invention data applicable to all agencies. However, we believe that the lack of adequate resources and dedicated funding for the iEdison system is more the issue than the agency placement of iEdison. NIH should be given credit for managing the system under difficult constraints, and for making a number of recent improvements. It is not clear to us that transferring responsibility for the operation of iEdison to Commerce would provide more than marginal improvement in government-wide reporting of IP.

The June Meeting Report also discussed the AUTM Compliance Course in partnership with NIH to be held this October. A number of other agencies will participate. The conference also will be webcast. We also understand NIH is auditing invention reporting at 6 institutions. We plan to discuss possible follow up activities with AUTM, NIH, NIST and others (We had considered a possible survey of institutions on their invention reporting practices, but will defer for now).

NIH PMI Terms Remain Troublesome

We discussed in the February Meeting Report concerns about the terms in recent RFAs for the NIH Precision Medicine Initiative (PMI) Cohort Program. These terms include use of Other Transaction awards which are an exception to normal Bayh-Dole requirements, statements of intent to use Determinations of Exceptional Circumstances to prevent blocking public access to program outputs, and concerns about ownership of resources generated by the program including biospecimens and data. We also noted that President Obama had participated in a PMI forum where he alleged that researchers and universities were “hoarding” samples.

After consulting with COGR, the University of California raised a number of concerns with PMI representatives. An NIH representative met with the COGR CIP and RRR committees in June to further discuss these concerns. At that meeting she indicated that NIH supported Bayh-Dole and had not yet determined allocation of PMI IP rights (see June Meeting Report).

Unfortunately a subsequent PMI Funding Opportunity Announcement (FOA; OT-PM-16-003) contained similar terms, with government ownership of inventions, data and other products. Also, NIH has developed a PMI *Other Transaction Award Policy Guide* (cited in the

announcement) that provides for government ownership of inventions, participant data and biospecimens

The *Policy Guide* provides that except for participant data and biospecimens, awardees will own the rights to other data and materials resulting from projects. However, the FOA states that the government will own all rights to data and other products, including copyrightable works and software. This provision covers data submitted to NIH; the university may retain the raw data. NIH also will own and control biospecimens that have been submitted. Our understanding is that awardees may collect separate specimens for patient care purposes. FAR clause 52.227—13 applies to inventions, giving the government title. Awardees retain a revocable nonexclusive license. Presumably NIH could revoke the license if it is determined that it is being used in some way to block public access.

These PMI provisions are sufficiently different from normal NIH award terms that institutions may want to direct the attention of researchers to them. Also we suggest institutions consider including a cover letter in applications subject to these terms stating certain understandings. These might include that the institution may retain the original data for research, education and clinical care purposes and collect separate specimens for patient care. While the FOA closed August 29, future PMI RFAs and FOAs are likely to contain similar terms.

Export Control Developments

The NAS Part II Report on Research Regulations also contains a Chapter 12 on export controls. The report discusses the export control reform initiative, the non-applicability of the fundamental research exclusion to the conduct of research or research equipment subject to the ITAR, and concerns with other proposed ITAR changes. It recommends that the reform effort continue with stakeholder input. We agree; however, the Report cites approvingly the 2007 Deemed Export Advisory Committee report. We did not agree with all of the recommendations in that report (see COGR February 2008 Update).

Some changes to the export control regulations were published over the summer. On July 28 Commerce and State issued revised regulations on toxicological agents, medical countermeasures, and related items pursuant to the reform initiative. On August 17 the State Department clarified rules pertaining to the shipment of items subject to the EAR with items subject to the ITAR as part of the reform's harmonization objective. COGR did not comment on these changes, as they do not appear to raise particular policy issues.

Drumbeat Increasing over Drug Prices and Government-Funded Patents

A steady stream of articles and publications over the past couple of months has singled out the role of government-funded patents in high drug prices, and called for government action. Among the most recent with direct implications for university patents was an article in the August 24 LA Times advocating government exercise of march-in rights to address the high costs of certain Hepatitis C drugs. The article cites the Bayh-Dole Act "reasonable terms" provision as allowing the government to address drug pricing, although that interpretation was discredited by Sens. Bayh and Dole some years ago in a letter responding to a previous op-ed on the subject. Sen. Bayh also testified against that view of Bayh-Dole in a NIH march-in hearing

in 2004. Click here for another recent article along the same lines. In addition, articles from NPR and Boston Globe have published articles criticizing the role of patents although not necessarily in a university context.

The June Meeting Report discussed other recent articles, and the upcoming report of the UN Secretary General's High Level Panel on Access to Medicines. The report is expected to contain findings and recommendations that cite the role of patents in preventing access. (See a recently published article in the Orlando Sentinel for a contrary view from former Chief Judge Michel of the Federal Circuit).

The Congressional Research Service (CRS) issued a report on march-in rights on August 22 (R44597). The report does not make specific recommendations. It reviews the history of march-in petitions to NIH and the debate over the appropriate circumstances for exercise of march-in rights. It identifies a number of options for Congressional consideration. These include legislative clarifications of the circumstances that might trigger march-in such as cost concerns, transfer of oversight to an entity other than the funding agency to reduce bias, and a central database of inventions subject to Bayh-Dole to improve monitoring. Other possibilities might include restricting the ability of patent owners to legally appeal march-in determinations and limiting their current ability to select licensees by requiring open bidding auctions.

It appears likely that some action will be taken in the new Administration and Congress to address these drug pricing concerns. Any such action could affect patents generally and/or could be aimed at inventions resulting from federally funded research. We plan to work closely with AUTM and other stakeholder groups to monitor developments and respond to proposals that would adversely affect universities ability to transfer technologies for public benefit. (For an excellent example of a helpful response see the recent op-ed by the President of AUTM in the August 18 International Business Times.

EFF Launches New Campaign to Restrict University Relationships with Patent Trolls

The Electronic Frontier Foundation (EFF) has launched a new campaign to restrict university relationships with patent trolls. There are several aspects. One is **Reclaim Invention**, which seeks a Public Interest Patent Pledge from university leadership to check that a potential patent buyer or licensee does not match the patent troll profile. This builds on the AUTM Nine Points to Consider in Licensing University Technology which COGR and many other higher ed. associations and universities have signed. Last year working groups of both AAU and APLU reiterated the importance of restricting university relationships with patent trolls. The purpose served by another pledge in this area isn't clear.

Another and more disturbing aspect of the EFF campaign is a state legislative effort that involves introducing legislation in all 50 states that would require public universities to adopt a policy not to license or sell patents to trolls, and void the sale of any such patent (Reclaim Invention Act), read the proposed legislation here. While we agree that universities should avoid dealing with patent trolls as discussed in the AAU/APLU statements, legislation to this effect is too broad and has obvious adverse implications for university governance.

Harvard University has posted an explanation of why the university recently had initiated patent infringement litigation. This kind of public statement is a good rebuttal to allegations that in seeking to enforce patents universities are behaving as patent trolls. It explains the importance of technology development to society and the need to protect the rights of the researchers and the university. More media-focused efforts such as this may be helpful in responding to initiatives such as the EFF campaign and the persistent criticisms of university practices in this area.

COGR Partners with NACUA in Sponsored Research and Tech Transfer Workshop

As in previous years, COGR is serving as a cooperating organization for NACUA's November 2016 CLE Workshop on Academic Sponsored Research and Technology Transfer. The Workshop will be held in Washington November 16—18. We expect COGR staff will participate in workshop sessions. Other speakers include Kathy Partin, Director of ORI/HHS, and Mindy Bickel, Associate Commissioner for Innovation Development, USPTO.

Effective Practices Guide

COGR reported in the June update that the Effective Practices Guide is available on line and in print. Since June, COGR has sent out seven (7) spiral bound copies of the Guide to the Primary Representatives of each member institution. Additional copies of the EP Guide are available for $5.00. Send your request to trusso@cogr.edu for additional copies of the Guide.

HHS, Office of Research Integrity (ORI)

At the February 2016 COGR meeting, the Research Administration and Compliance (RCA) Committee met with Dr. Kathryn Partin, new Director of the Department of Health and Human Services Office of Research Integrity (ORI) to hear about her plans for developing strategic goals for ORI. Dr. Partin has accepted COGR's invitation to the October meeting along with her two Division Directors, Zöe Hammat, **Division of Education and Integrity** and Susan Garfinkel, **Division of Investigative Oversight** to provide an update on the "Developing the ORI Roadmap" and other ORI initiatives. COGR has been selected to participate on a September Planning Committee in preparation for a major ORI Conference in Spring of 2017.

Department of Labor Overtime Rule

COGR reported in its June update its plans to collect and share information about an institutions implementation choices related to Postdoctoral Scholars pursuant to the Department of Labor's new Overtime Rule effective December 1, 2016. COGR notified its members via the listserv on August 4th with a deadline date of August 17th. The survey results are being evaluated and an executive summary will be prepared in September for distribution to the membership. As previously indicated, responses from individual institutions will be kept confidential. To view a PDF of the survey questions, click here.

Conflict of Interest

On July 8th, COGR submitted a letter to the Office of Management and Budget (OMB) regarding the lack of harmonization of Conflict of Interest Policies amongst federal agencies. COGR

continues to work with individual agencies on a case by case basis in the form of teleconferences and formal letters as new policies and/or agency guidance present overly burdensome requirements. As in the past, OMB will continue to be copied on the correspondence as agency letters are submitted. COGR is currently working on a letter to address the COI policies and procedures of the Centers for Medicare and Medicaid Services (CMS) in September. The membership will be notified via the listserv when the letter is submitted. Stay tuned.

Webinar Hosted By Hogan Lovells on Drones Use on Campus: Navigating the FAA's New Small UAS Rule.

On Wednesday, September 21, 2016, Hogan Lovells will host a free webinar at 2 p.m. EST for anyone interested in learning more about FAA's new UAS Rule (Part 107) that became effective on August 29. Hogan Lovells Unmanned Aircraft System's lawyers will discuss the impact of the new rule to the higher education community and provide tips on how to make your campus compliant. Click here to register for this complimentary webinar.

Audit

NSF OIG on Personnel Services and the FDP Payroll Certification Pilot

The Office of Management and Budget (OMB) has issued a series of short webinars on the implementation of the Uniform Guidance. Topics include risk assessment; contract versus subaward determination; subrecipient monitoring; indirect cost rates; single audit; and personnel services.

In the webinar *Promising Practices in Implementation: Personnel Services*, Laura Rainey, Acting Director for Financial & IT Audits, Office of Inspector General (OIG), National Science Foundation (NSF), and NSF manager of the Federal Demonstration Partnership (FDP) payroll certification pilot, and Gil Tran, Policy Analyst, OMB, discuss the new flexibility for documenting personnel expenses resulting from the elimination from section 200.430 of the Uniform Guidance of examples included in A-21 and a focus on strong internal controls. Also discussed are the results and implications of NSF audits of two of the four FDP pilot sites which shifted to award-specific rather than personnel-specific certification and activity.

The NSF OIG indicates that the two institutions audited had good internal controls and policies and procedures, and a well-documented timeline for transition from the previous to the current (pilot) system. Audit findings were consistent with those under the previous effort reporting system, including that certifications and reconciliations were not timely and that the institutions did not always follow their own policies. NSF OIG advice for other institutions included reviewing existing systems for consistency with the Uniform Guidance and determining if, from a risk perspective, changing the system makes sense; documenting that this review was conducted and the institution's decision to retain the current system or implement a new system; documenting the policies and procedures of a new system, including the timeline for the transition from old to new; and that the institution follow its own policies. On the latter point, the NSF OIG indicated that with the shift from compliance to controls, auditors will look closely at an institutions policies and whether the institution is following them.

NSF Audit and the Two-Month Salary Issue

An NSF audit report published on July 8 reviewed costs totaling approximately $251 million charged to NSF over a three year period. The report indicates that auditors questioned $1,201,755 of costs claimed on 53 awards, including $774,976 in senior personnel salary charges that exceeded NSF's two-month limit and $343,794 in equipment, materials, and supplies expenses. The report indicates that the university was selected for audit because it is one of the largest recipients of NSF award dollars.

The university did not agree with $996,261 in questioned costs, including the full $774,976 in salary charges and $208,347 in equipment, materials and supplies charges. A recent issue of *Report on Research Compliance* indicates that in response to an audience members question at the NCURA Annual meeting held in August, the NSF acting assistant inspector general for audit, Marie Maguire, suggested that the NSF OIG will no longer question salary costs over the two-month cap as NSF has allowed the costs for a number of previous audits.

NSF Audit Resolution

In a letter to a member institution dated July 14, 2016, the NSF Division of Institution and Award Support determined that $780,636 of the $830,008 costs questioned by auditors for exceeding the NSF two-month salary limit will be allowed. The letter indicates that "the basis for the audit finding misinterprets the NSF faculty salary compensation policy." Other questioned costs in the amount of $49,372 were disallowed. NSF sustained and disallowed $47,116 in questioned costs based on the University's concurrence with the audit finding. The letter indicates that although there is no NSF or Uniform Guidance requirement, "the Agency recommends that the University consider enhancing its internal controls to address the allocation of equipment purchases at or near the end date (<90 days) of federal awards" and that "the development of a policy and procedure that addresses when PIs should consider obtaining an extension of the award end date (no cost extension) may also be helpful in preventing similar findings and cost disallowances in the future." The letter suggests that the university plans to develop an exception report to improve monitoring of late equipment purchases.

National Science Board Meeting

The National Science Board held a meeting August 9-10. Among the topics discussed was NSF's FY 2015 Merit Review Report. An annual report to the board on the merit review process. Prominent sections include the NSF merit review process and proposal and award data. NSF reports a 22% success rate for research grants, which made up 82% of competitive proposals, in FY15. This success rate does not include the roughly 4200 preliminary proposals acted on, 25% of which were invited to submit a full proposal. The report indicates that success rates have fluctuated from 19-22% over the last decade while the proposal count has been relatively stable over the last 4 years. "The annualized mean award amount was $170,605, a 0.5% decrease from FY 2014" and the duration just under three years. The average number of proposals an investigator submits before receiving an award was 2.36 for the 2013-15 period. The report also highlights $3.99 billion requested for proposals rated very good or higher that was not awarded due to budget constraints and provides data on ongoing pilot programs.

The Audit and Oversight portion of the NSB meeting included follow-up to an NSF review of the Intergovernmental Personnel Act (IPA) Program at NSF. NSF is looking to develop an agency-wide approach to managing the program, a longstanding program authorized under the IPA Act that allows researchers and educators to take temporary assignments at federal agencies. The review was conducted to assess NSF's progress toward reducing IPA costs following a 2013 OIG audit. The agency found that the number and costs of IPAs has actually increased since 2013, in particular with respect to executive compensation. 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 is also looking to identify opportunities for cost savings. The agency is looking at the use of cost share and engaging institutions with the goal of increasing cost share. NSF requests 15% cost share. However, in FY15 the actual percentage of cost share was 5%. The agency believes there is room to engage with institutions and seek a more robust contribution. The IPA program is viewed as offering significant benefits to both NSF and institutions/investigators.

Regulatory Reform

COGR Analysis of the National Academies Report and the OIG Response

We noted in our June 2016 COGR Update that the National Academies Committee on Federal Research Regulations and Reporting Requirements released Part 2 of its report, *Optimizing the Nation's Investment in Academic Research; A New Regulatory Framework for the 21st Century*, on June 29. The full report includes Parts 1 and 2 and is available online. COGR has previously commented on Part 1 of the Committee's report. COGR's analysis of Part 2, which serves as a review and also offers COGR's position on many of the recommendations, was posted to our website on September 1. Part 2 of the report addresses federal regulations governing human subjects research, the "Common Rule," and proposed revisions to the rule; export controls; select agents and toxins; intellectual property and technology transfer reporting; and consideration of how to operationalize the proposed regulatory framework and Research Policy Board (RPB) recommended in Part 1.

Not previously reported here and of potential interest is the NSF and HHS OIG's response to Part 1. Of note, the OIGs indicate that "OIGs are required to report audit findings to Congress on a semiannual basis and to post issued audit reports on their websites within 3 days of their being publicly available. If OIGs reported ONLY the results of final audit resolution (and not the actual findings and recommendations), they would not be in compliance with the [Inspector General] Act." The Academies report recommends that Congress encourage all federal inspectors general to report only final audit resolution findings on their websites and in their semi-annual reports to Congress. This would require modification of the Inspector General Act.

Regarding disclosure statements the letter indicates that "Eliminating the requirement to file changes to DS-2s, would violate the UG requirement to follow CAS, which requires amending DS-2s when there is a proposed change in accounting practices. In addition, CAS requires that amendments and revisions to Disclosure Statements be accurate and approved by federal

agencies." The letter further suggests that "Adequate DS-2s provide the basic regulatory foundation that prevents IHEs from charging indirect costs as direct, or double charging costs both as direct and indirect expenses."

The letter responds individually to the "five recommendations for actions Congress should require OIGs to take." Regarding the recommendation to "Resolve issues regarding their interpretation of agency polices and priorities with the agency before conducting formal audits of research institutions…" (e.g., with respect to the NSF two-month salary limit for senior personnel). The letter states that "If OIGs accepted agency interpretations of applicable criteria that were inconsistent with their own interpretations, OIGs would lose their mandated independence." Given that the agency writes the policy COGR would suggest that it is not an interpretation. The letter further states that "Issuing repeated findings and questioning associated costs, knowing that the agency will not sustain them, is consistent with audit mandates in the IG Act to report questioned costs because of 'an alleged violation of a provision of a law, regulation, contract, grant, cooperative agreement, or other agreement or document governing the expenditure of funds,' or 'a finding that the expenditure of funds for the intended purpose is unnecessary or unreasonable'."

Regarding the recommendation that OIGs "Provide to Congress and make publicly available information generated each year on the total costs (agency and institutional) of Inspectors General audits of research institutions…" the letter states that "Audit offices have limited resources, and use a risk-based approach to select auditees that are the highest risk of misuse of taxpayer funds. Given the constraints of the audit process, verification of agency and institutional costs per audit would utilize resources that otherwise could detect serious flaws in internal controls at the agency…" Regarding re-examining the risk-based methodology that OIGs use in identifying institutions as candidates for audit, the letter indicates that "What may begin with fairly simple risk factors (e.g., number and size of awards, total dollar amount at risk) may become more sophisticated with the use of supervised (predictive or directed) modeling, such as decision trees and neural networks; and unsupervised (descriptive or undirected) modeling, such as Kohonen networks and K-means clusters." Interesting.

Government Accountability Office (GAO) Report on Federal Research Grants

GAO released the report *Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements* on July 22. Recommendations for executive action address the need to standardize administrative research requirements; reduce pre-award administrative workload and costs; PHS conflict of interest; purchasing; and subrecipient monitoring. COGR will issue a full review and analysis in the coming weeks.

COGR Checklist for Reducing Administrative Burden

As previously reported, COGR has distributed a checklist with over 100 actions that have the potential to reduce the administrative work associated with sponsored awards at member institutions. We are very interested in hearing about actions your institution has implemented or may implement; actions that might be added to the list; and, how your institution incentivizes burden reduction. Your institution's participation would be very much appreciated. Completed

checklists can be returned to Lisa Nichols. If possible we would appreciate having completed checklists returned by September 30. However there is no deadline for returning the checklists.

Retrospective Review of Regulations

Federal agencies have published their latest "lookback" or retrospective review reports. The reports identify and take action on opportunities to streamline, revise, and eliminate unnecessary regulations. A White House blog post from Office of Information and Regulatory Affairs (OIRA) Administrator Howard Shelanski touting some of the achievements of this initiative did not highlight areas related to the regulation of research. A review of the latest HHS Retrospective Report found nothing noteworthy.

Implementation of the Digital Accountability and Transparency Act of 2014 (DATA Act)

The Office of Management and Budget and its executing agent, the Department of Health and Human Services (HHS) needs your help to improve federal financial award and reporting processes. HHS is still actively seeking university participation in the Section 5 Grants Pilot Test Models. Details on the test models can be found on the HHS DATA Act PMO webpage www.hhs.gov/datactpmo. If you or others at your institution are willing to participate please contact the HHS DATA Act Program Management Office via email at DATAActPMO@hhs.gov.

As part of the implementation of DATA Act requirements, the Department of Treasury is seeking feedback on the USAspending.gov open beta site. Please forward this message and link to faculty or administrators at your institution that might utilize the USAspending website and seek to comment on its reorganization. Among the new functions added, the website will allow users to see the amount of federal dollars awarded by location, recipient and program/agency.

Human Subjects

Recent Meeting with OIRA and Federal Agencies to Discuss the Clinical Trials Registration and Results Submission Proposed Rule

COGR met with staff from OIRA and federal agencies on August 22 to discuss key concerns with the Proposed Rule for Clinical Trials Registration and Results Submission. The final rule is currently under OIRA review. Staff from COGR member institutions, including Lois Brako and Diane Wilson from the University of Michigan, Robin Ginn from Emory University and Blair Holbein, a faculty member from the University of Texas Southwestern Medical Center, participated by phone. COGR provided OIRA and agency staff with background materials and a summary of key concerns, among them that the timeframes for reporting are overly stringent and inconsistent with the logistics and realities of research conducted at academic institutions, making it difficult to fully comply in a timely manner, and that the greater the volume of data requested, the less time scientists can dedicate to conducting research.
COGR recommended that §11.44 (a) be modified to allow 18 (rather than 12) months after the primary completion date to report results; that 30 day reporting timeframes should remain restricted to correcting errors in the record and changes to overall recruitment status and

completion and all other necessary updates restricted to12 month reporting requirements; and that the regulations should not exercise the option to include results reporting for unapproved products and should not add additional requirements to upload protocols or create lay summaries or detailed scientific summaries. A final rule is anticipated this fall.

Health and Human Services Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) Draft Guidance on IRB Written Procedures

OHRP and FDA published a notice announcing the availability of Draft Guidance on IRB Written Procedures on August 2. The draft guidance is intended to assist institutions with preparing and maintaining written procedures. As indicated on the FDA website "The draft guidance provides an IRB Written Procedures Checklist that incorporates the FDA and HHS regulatory requirements for IRB written procedures and additional topics that FDA and OHRP recommend including in IRB written procedures." Once finalized, the draft guidance will supersede existing guidance from OHRP (Guidance on Written Procedures, 2011) and FDA (Appendix H: A Self-Evaluation Checklist for IRBs, 1998). Comments are due by October 3. COGR will submit comments.

Human Stem Cell and Chimera Research

COGR, AAU and APLU submitted joint comments on Proposed Changes to the NIH Guidelines for Human Stem Cell Research and the Proposed Scope of an NIH Steering Committee's Consideration of Certain Human-Animal Chimera Research to NIH on August 25. NIH proposed to revise the Guidelines to expand existing prohibitions and to establish a steering committee, made up of federal employees, to provide programmatic input on this area of research. NIH is requesting public comment on the proposed changes to the guidelines and the scope of research the steering committee would consider. COGR, AAU and APLU generally supported the proposed changes and encouraged NIH to consider having the newly created steering committee include non-federal members and consider what criteria would need to be met before allowing introduction of human cells into non-human primate embryos. Additionally, our organizations asked that NIH take into account the implications of this funding prohibition on similar research using gene editing tools. Comments are due September 6.

Animal Research

NIH Office of Laboratory Animal Welfare (OLAW) Releases Updated Brochure

NIH OLAW has updated its brochure, *What Investigators Need to Know About the Use of Animals*. The updated brochure can be found here.