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TO: COGR Membership

FROM: COGR Staff

SUBJECT: October 2016 Update

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Procurement Standards and OMB Update at the COGR Meeting

As of this writing, the most recent [COGR Update](#) (dated September 2, 2016) on Procurement Standards remains unchanged and is summarized below.

- 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).

A representative from OMB will provide an update on the status of the Procurement Standards during the Friday morning session at the October COGR Meeting and we hope to learn more at that time. If we hear any news before the October COGR Meeting, we will provide an update.

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)

We also expect to learn more on the status of the FAQs during the Friday morning session with OMB at the October COGR Meeting. If we hear any news before the October COGR Meeting, we will provide an update.

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

The 2016 COGR F&A on-line survey was initiated on August 23rd. We will share preliminary results (de-identified) and also will address developments on the F&A rate negotiation

landscape. The panel will include University representatives and representatives from the Consulting firms who have a unique perspective on recent F&A rate negotiations and other F&A issues. This session also will cover F&A “hot topics” such as the status of F&A-related UG FAQs (i.e., DS-2, UCA), the intersection of lease costs and the appropriate F&A rate (i.e., recent DOJ settlement – see next section), direct charging of IRB costs under new NIH guidance, the recently released GAO report on the rate-setting process (see below), *and a recent development as it relates to the appropriate capitalization threshold for software.*

This session will be open to COGR members and representatives from the Consulting firms only, and we encourage you to share your institutional perspectives on these topics.

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

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% de minimus 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.

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 in any manner, institutions should pay attention to the extent that this may impact future F&A rate negotiations.

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

The [2016 Compliance Supplement](#) was released in August. The most 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 does not plan to respond; however, we can consider doing so if you have 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

This matter first arose in the Summer. NACUBO is the lead for the higher education community and COGR is actively engaged. Also, other stakeholders, including the National Association of State Auditors, Comptrollers and Treasurers (NASACT) and the AICPA are concerned. At issue is whether a compliance audit is required on an 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. COGR’s perspective is that the Resolution posted by ED represents an interim resolution that requires more engagement and communication across all stakeholder communities. Important questions must be addressed using a fair and collaborative approach. For example:

- What is the legal/statutory basis for ED’s position?
- How does ED’s position align with 2 CFR Part 200, Subpart F – Audit Requirements?
- What is OMB’s role as the “Gatekeeper” of rational regulatory oversight?

We are working with the other stakeholders to elevate this issue to appropriate leadership at OMB, the Office of Information and Regulatory Affairs (OIRA), and/or other appropriate oversight bodies. Also, 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 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.

NARA Issues Final CUI Rule

On September 14 the National Archives and Records Administration (NARA) [issued a final rule](#) on safeguarding Controlled Unclassified Information (CUI). The rule may be found at [The rule is effective November 14.](#)

The rule is primarily directed at federal agencies. However, it also applies to non-federal entities that handle, process, use, share or receive CUI. It requires compliance with NIST SP 800-171 security requirements for safeguarding such information. Agencies are to include these requirements in written agreements (contracts, grants, etc.) when CUI is involved.

The NIST 800-171 requirements apply to information, as distinct from FISMA requirements that apply where non-federal entities operate information systems “on behalf of” the government. In such cases other NIST requirements apply (SP 800-53). The CUI information will be either “Basic” (NIST 800-171) or “Specified” (with specified safeguarding requirements), as set forth in the [CUI registry](#). All CUI Basic categories are controlled at the “moderate confidentiality” level under NIST 800-171 standards. Agency controls must be consistent with the CUI standards (no more “SBU,” “FOUA,” etc. designations). There is extensive discussion in the rule of physical safeguarding requirements and methods for destroying or decontrolling CUI. NARA currently is developing marking requirements, which will include banners for each page containing CUI.

NARA also will develop a FAR rule which will apply government-wide and is supposed to supersede individual agency clauses (e.g. DFARS 252.204-7008, 7012, which were discussed in a panel at the COGR February 2016 meeting). Among other things the FAR rule will address situations where a contractor has outsourced part of the CUI processing to an external Cloud Service Provider (FedRAMP protections may apply in such cases). NARA has requested input from the FDP on several items that will be covered in the FAR rule. These include the oversight approach (certifications of various types), compliance plans, breaches and contractual liability. NARA also has asked for input as to the types of CUI that universities may have.

COGR/AAU submitted comments to NARA last year when the CUI rule was proposed (see COGR [May 2015 Update](#) and [June 2015 Meeting Report](#)). Our principal concern was ambiguity in the proposed rule as to its application to non-federal entities and the compliance burden of NIST SP 800-171 with its 109 security requirements. The final rule includes gratuitous comments about the apparent non-compliance by academic and research entities with existing information security requirements and cites the importance of protecting sensitive information (NARA has apologized privately to COGR for the tone of these comments). It is critical that the upcoming FAR rule (which is not expected until sometime next year) adequately addresses issues such as liability for breaches, oversight responsibilities, etc. In many cases institutions will require substantial lead time to fully implement the NIST requirements, and this also should be factored in. Requirements such as multifactor authentication, mobile device encryption, and organizational incident response capabilities may be particularly challenging. The CUI rule also contains provisions for challenges to CUI designations and dispute resolution procedures which also should be incorporated in the FAR rule. Experience indicates that individual agencies may not necessarily implement the CUI requirements uniformly. The NARA rule requires that agencies establish processes to accept and manage challenges, with the right of appeal to NARA.

DOE Implements Waiver Process for Foreign National Approval Requirement

For some years COGR has been involved in seeking to resolve concerns about a requirement from the DOE National Energy Technology Lab (NETL) that all foreign nationals performing research on NETL-funded projects must be submitted to DOE for approval (see [COGR October 2013 Meeting Report](#)). 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”) but no other DOE facility appears to interpret the Order in this way.

After much discussion with DOE headquarters, a waiver process has been established, based on a memo signed by the Secretary of DOE. The memo delegates authority to the DOE Undersecretary for Science and Energy to issue waivers. Waiver requests must be submitted to the NETL contracting officer, stating that the awardee is an accredited institution of higher education, the research results will be published, are not expected to be controlled under federal export control regulations, and that if foreign nationals visit DOE facilities normal vetting requirements will apply. Additional statements affirming compliance with export control regulations and the lack of any need to access DOE information may be included. NETL has developed an (unnumbered) Request for Limited Exemption from DOE Order 142.3A form. The following clause also may be included in NETL awards:

*Notwithstanding any other term of this award, it may be in the Department's interest to provide exemptions from certain aspects of DOE Order 142.3A to institutions of higher education in connection with this award. **However, recipients must ensure that they do not allow foreign nationals to commence any work under this award unless and until an exemption is granted.** If an exemption is granted, DOE will modify this award to incorporate the terms of the exemption. No exemption to DOE Order 142.3A will be issued to any visit by a foreign national to any DOE site or facility.*

A number of COGR member institutions have submitted waiver requests. Institutions that plan on submitting requests may want to copy the DOE Undersecretary for Science and Energy (currently Adam Cohen Adam.Cohen@hq.doe.gov). We will report to the membership whether the waiver process appears successful.

Recent Contractual Issuances

- a. **DFARS Rights in Technical Data.** A [final rule was issued](#) on September 23 (). The changes were proposed in May (see [COGR June Meeting Report](#) for discussion). The major change is to expand the presumption that for major weapon systems, commercial items have been developed entirely at private expense. In such cases DOD receives only limited rights. No public comments were received.

The implications for COGR members should not be substantial (COGR has a brochure on the website *Rights and Responsibilities for Technical Data and Computer Software Under Federal Awards* that explains more fully the various kinds of government rights).

- b. **Government Contractor Employee Compensation.** A [final FAR rule](#) was published on September 30, revising the compensation cap to implement the 2013 Budget Act (PL

113-67). For contracts effective after June 24, 2014 the initial cap was \$487,000/year with annual adjustments. No further adjustment to this cap yet is available. There should not be substantial impact on COGR members.

- c. **Paid Sick Leave for Contractors.** A [final rule was issued](#) by the Labor Department on September 30. It establishes a floor of 7 days (56 hours) of paid sick leave annually for employees of government contractors, implementing Executive Order 13706. There were extensive public comments on the rule when proposed in February (COGR did not submit comments). It applies to contracts subject to the Davis-Bacon, Service Contract and Fair Labor Standards Acts but does not apply to grants or certain part-time employees. Where hours are not tracked (i.e. executive and professional employees) other methods are prescribed. The rule includes detailed provisions for requesting and documenting sick leave. COGR members may wish to assure that their HR staff are aware of the rule.

UN Report on Access to Medicines Blames IP for Access Issues

The [final report](#) of the UN Secretary General's *High-Level Panel on Access to Medicines* was released on September 14. As expected, it places primary blame on IP for the lack of access to health technologies by poorer countries. It singles out the Bayh-Dole Act for particular criticism, asserting that "limiting access to academic discoveries can obstruct follow-on innovation and force taxpayers to pay twice for the benefits of publicly-funded research." It calls for non-exclusive licenses, IP donations, and other open models of innovation. It also calls for compulsory licenses to meet public health needs. Other recommendations address the need for public health considerations in assessments of patentability, more transparency in pricing of health technologies and clinical trials, the delinking of drug prices from R&D costs, and prioritization of health in trade agreements.

On September 16 the higher ed. associations including COGR [issued a statement](#) pointing to the success of Bayh-Dole and strongly criticizing the assertions in the report about the limited access to academic discoveries. The U.S. State Department also [strongly criticized the report](#), citing the narrow mandate of the Panel and the complexity of the issues. It criticized the panel for not properly recognizing the role of IP in incentivizing drug development and expanding access to medicines ("there can be no drugs that have not been developed"). It cited the concerns of several Panelists who had practical experience in managing medicine R&D that the Panel recommendations could have significant unintended negative consequences.

BIO, PhARMA, and others also have criticized the report, pointing to infrastructure issues, corruption and lack of health care workers as crucial factors in the lack of availability of medicines in poorer countries. It also should be noted that 95% of the drugs on the WHO Essential Medicines list are off-patent. It is not clear whether the UN General Assembly will adopt the report (the Secretary General has not fully endorsed the report recommendations). However, it adds to the controversy over links between university tech transfer and drug prices (some of the language in the report such as "taxpayers paying twice" is identical to that used by critics of Bayh-Dole in the U.S.). It may put the US in a defensive posture at future meetings of international bodies such as WTO and others.

March-In Rights Continue To Receive Attention

We mentioned in recent updates and meeting reports claims that the march-in provisions of the Bayh-Dole Act should be used to address concerns about drug pricing. In a recent “[Memo to the President](#),” Alfred Engelberg stated that Bayh-Dole is “ill-suited to the current world” and recommended a new public-private partnership to replace it. The partnership would be structured according to the recommendations of a Presidential commission. Mr. Engelberg was formerly counsel to the generic drug industry and a major drafter of the Hatch—Waxman Act. He also is a well-known philanthropist who founded the Engelberg Foundation as well as centers at Brookings and NYU.

The Congressional Research Services recently [issued a report](#) on *March-In Rights Under the Bayh-Dole Act*. It reviews the history of march-in rights and the Bayh-Dole Act. It does not make recommendations but presents options for Congressional consideration. These include further defining Bayh-Dole provisions related to march-in, such as “reasonable terms” and “health and safety needs,” transfer of oversight to other than the funding agency, establishing a centralized database of Bayh-Dole subject inventions, and open bidding auctions for licenses. The report concludes by citing the need to strike a balance in terms of benefits from commercialization of federally funded research.

HHS, Office of Research Integrity (ORI)

Dr. Kathryn Partin, Director of HHS, Office of Research Integrity will be present October 20th to discuss the ORI Roadmap. Division Directors, Zöe Hammat, **Division of Education and Integrity** and Susan Garfinkel, **Division of Investigative Oversight** will provide an overview of other ORI initiatives. COGR recently participated on the ORI Planning Committee in preparation of the ORI 2017 Quest Conference. More details to follow from HHS.

Department of Labor Overtime Rule

COGR reported in the last update its plans to release an executive summary of the FLSA Postdoctoral Research Survey results conducted in August. The executive summary has been finalized and can be found on [COGR's website](#).

Conflict of Interest

In a previous update, COGR informed the membership of its plans to send a letter to the Centers for Medicare and Medicaid Services (CMS) regarding their onerous conflict of interest requirements. The letter was submitted to CMS on October 4th, sent to COGR's membership listserv. To view a copy of the CMS letter, [click here](#).

Department of Energy – Pre-award Information Sheet

COGR has received [the Pre-award Information Sheet](#) from members (required at the time of application for financial assistance awards) and has reached out to the DOE for a response. We are aware that you may see these forms/templates through the year and ask that you forward them to COGR at your earliest convenience. We have notified the OMB who will contact the DOE for more information. We will keep the membership informed as we know more.

Human Subjects Research

Department of Health and Human Services (HHS) Clinical Trial Results Submission

HHS issued a [final rule](#) on Clinical Trials Registration and Results Information Submission on September 16. This follows the publication of a Notice of Proposed Rulemaking on November 19, 2014. The National Institutes of Health (NIH) issued its [policy](#) on clinical trials reporting the same day. Both describe applicability and requirements for submitting clinical trials results information to ClinicalTrials.gov and are effective January 18, 2017. A [summary](#) of the final rule and NIH policy is available on the NIH website. A [summary of changes](#) from current practice and of data elements with shorter reporting timeframes is also provided. As indicated in an NIH announcement, ClinicalTrials.gov will be offering a series of [webinars](#) with information about the Final Rule.

The Final Rule applies to clinical trials with one or more U.S. sites; that study a drug, biological, or device product manufactured in the U.S. and exported for use in clinical trials outside the U.S.; and/or conducted under a Food and Drug Administration (FDA) investigational new drug application or device exemption. The rule also applies to pediatric postmarket surveillances of a device product ordered by FDA. It does not apply to Phase 1 trials of drug and biological products or feasibility studies of device products. The final rule provides an approach for evaluating applicability. The requirements apply to the sponsor or designated principal investigator. The rule also specifies the approach for determining who will be considered the sponsor, how a sponsor can designate a principal investigator as the responsible party, and how responsibility reverts to the sponsor if the investigator is unable to fulfill the requirements.

The final rule addresses statutory requirements for the submission of results information for applicable clinical trials of approved drug and device products, but also extends the requirement beyond statute to products not approved, licensed, or cleared by FDA. In addition to summary data, the rule requires the submission of the full protocol and statistical analysis plan as well as a summary of adverse events, and that all submitted information be updated at least annually if there are changes. Non-compliance can result in civil monetary penalties of up to \$10,000 per day and “jeopardize grant funding and future funding to the grantee.” Estimated costs to implement the rule are \$59.6 million annually.

The NIH policy released in conjunction with the final rule applies to *all* clinical trials, regardless of study phase or type of intervention, funded in whole or part by NIH, regardless of whether the trials are subject to the Final Rule. Compliance with the policy will be a term and condition of the award. Applicants are required to submit a plan outlining how they will meet the policy's expectations. Non-compliance will be posted on the clinical trial record and may lead to enforcement actions, including termination of funding.

In an overview of public comments, NIH acknowledges concerns that the policy will create additional work for investigators, but suggests results submission as directed by the policy is an ethical obligation and will maximize the public's investment in research, and that for these and related reasons NIH has “not changed the essential contours of the policy.” NIH was “also not persuaded that the timeframe for results information submission should be longer for academic investigators” and suggests that the “timeframe of 12 months from the primary completion date should provide enough time for investigators to organize their data and submit results information.” NIH expressed that they were “confident that academic institutions can develop central support services as necessary to assist investigators should they need it.” The policy does

allow for delayed submission of results information for up to two years beyond the initial deadline with a certification that regulatory approval of the product is being sought. The policy also allows for extensions for good cause. The policy suggests that “In terms of the costs of complying with the policy, grantees are permitted to charge the salaries of administrative and clerical staff as a direct cost. Such staff could assist investigators in meeting their responsibilities under the policy.”

We are concerned that recent NIH policy developments are not responsive to the concerns of grantees. While the intent of a policy may be admirable, failure to appropriately balance benefits and costs - in this instance, the submission of information that is of greatest benefit to the public and research community versus investigators research time and funding and the cost of implementation to institutions – can be detrimental to the research enterprise. While NIH takes considerable time to describe grantee comments, few if any changes are made to the final policy.

NIH Policy on Good Clinical Practice (GCP) Training

NIH 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, “establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice.” Per the policy, recipients are expected to retain documentation of their training. The policy applies to investigators and clinical trial site staff responsible for the conduct, management and oversight of NIH-funded clinical trials. COGR has submitted a [letter](#) to NIH expressing concern about the definition of “Investigator” in this policy which appears to be based, in part, on FDA’s definition of “Investigator” but is significantly different from the definition of “Investigator” in the Public Health Service financial conflict of interest regulations. The letter also seeks clarification on whether the policy applies to all active awards or only to proposals submitted and awarded on or after the effective date and requests that the implementation date be extended to May 1, 2017.

NIH Policy on Funding Opportunity Announcements (FOA) for Clinical Trials

Effective September 27, 2017, grant applications for clinical trials can only be submitted in response to clinical trial-specific funding opportunity announcements per an [NIH Policy](#) issued on September 16. Per the policy, this will ensure that “key pieces of trial-specific information are submitted with each application, and uniformly apply trial-specific review criteria.”

Research with Animals

NIH Workshop on Research with Non-Human Primates

NIH held a workshop on September 7 on *Ensuring the Continued Responsible Oversight of Research with Non-Human Primates* to discuss the oversight framework governing the use of non-human primates in NIH-funded research. Officials from NIH have expressed that from their perspective the workshop, which included a discussion of the science, but also the ethics, regulations and philosophy related to this research, went very well. NIH officials do not anticipate making significant changes to the agency’s approach to non-human primate research. An [archived webcast](#) of the workshop is available on the NIH website.

Research Regulatory Reform

House Research and Technology Subcommittee Hearing on Academic Regulatory Reform

On September 29, the Research and Technology Subcommittee of the House Committee on Science, Space and Technology held the hearing [*Academic Research Regulatory Relief: A Review of New Recommendations*](#). The hearing is available for viewing on the committee's [website](#). The hearing focused on recommendations from the National Academies report [*Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*](#) and the GAO report [*Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements*](#). Among those testifying were COGR Board Chair Jim Luther, Associate Vice President for Finance and Compliance Officer, Duke University; Larry Faulkner, President Emeritus, The University of Texas at Austin and Chair of the National Academies Committee on Federal Research Regulations and Reporting Requirements; John Neumann, Director, Natural Resources and Environment Team, Government Accountability Office (GAO); and Angel Cabrera, President, George Mason University.

Subcommittee Chairwoman Barbara Comstock (VA-10) and Ranking Member Dan Lipinski (IL-3) have introduced [H.R. 1119](#), the *Research and Development Efficiency Act*, and [H.R. 5583](#), the *University Regulatory Streamlining and Harmonization Act of 2016*, respectively. H.R. 1119 would create a federal working group to make recommendations on how to minimize regulatory burden on research institutions. H.R. 5583 would implement many of the recommendations made in the National Academies report, including the creation of a Research Policy Board composed of federal and university officials charged with reviewing existing and proposed regulations with the goal of reducing regulatory burden. The bill also calls for the appointment of an Associate Administrator for the Academic Research Enterprise for unified oversight.

Government Accountability Office Report on Federal Research Grants

We reported in the September COGR update that the 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; and target requirements to areas of greatest risk, particularly with respect to conflict of interest, purchasing, and subrecipient monitoring. A [preliminary review](#) of the report is available on the COGR website.

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. We have received a number of completed checklists and appreciate the time that institutions have taken to complete them and the commitment to reducing administrative burden. We understand that many institutions are still working to complete the checklists. Completed checklists can be returned to [Lisa Nichols](#).

Audit

National Science Foundation (NSF) Office of Inspector General Reports

In what would appear to be a departure from recent audits, an [NSF OIG report](#) dated August 25 details the audit of an institution that is not a major recipient of NSF funding, auditing \$15.4 million charged to NSF awards over a three year period. Among the questioned costs were “expenses that were not reimbursable in accordance with [the institution’s] internal policies and procedures, which require expenses to be reimbursed within the fiscal year in which they are incurred”; salary costs exceeding two-months which the university has agreed to return; and costs for air travel that did not comply with the Fly America Act. Recent [audit resolution findings](#) for another institution determined that \$538,348 of \$568,130 in questioned costs will be allowed, including \$444,966 for senior salary over two-months. The letter indicates that the audit finding misinterprets the NSF faculty salary compensation policy.