COGR
Council On Governmental Relations
An Association of Research Institutions

February 13, 2018

TO: COGR Membership

FROM: COGR Staff

SUBJECT: February 2018 Update

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Working Through Frenzy in Washington: Thursday Morning Session on February 22nd

Never has a statement been so true; Working Through Frenzy in Washington is real, challenging, and has created lots of uncertainty. The session will cover a host of issues including the status of the federal and research budget, immigration reform, implications of tax reform, and other topics that are drawing significant attention in the Nation's Capital. Some of the discussion will be prospective, some retrospective, and all discussion will be around the common theme of how Washington currently is "functioning" and what to expect for the rest of 2018.

The panel with include: *Lizbet Boroughs* – Association of American Universities; *Megan Schneider* – National Association of College and Business Officers; *David Goldston* – Massachusetts Institute of Technology, Washington Office; *Matt Hourihan* – American Association for the Advancement of Science; and *Tony Mazzaschi* – Association of Schools and Programs of Public Health (ASPPH).

This is the kick-off session for the 2018 February COGR Meeting and should be a good opportunity to learn more and ask questions on the state of matters in Washington DC.

The Administration's Efforts to Cut F&A: WHAT'S NEXT?

We reported on this topic, extensively, in 2017, as prompted by the Administration's 2018 budget proposal to cap F&A costs on NIH awards. The Administration's 2019 budget proposal was released on Monday, February 12th. It appears as though F&A has not been specifically targeted in the 2019 budget proposal.

However, there are other areas of concern related to research priorities of the Administration in the 2019 budget proposal. We will monitor these developments, report back to the COGR membership, and continue to work closely within the Associations F&A Working Group, comprised of COGR, the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), the Association of Public Land-grant Universities (APLU), the Association of Independent Research Institutes (AIRI), the National Association of College and University Business Officers (NACUBO), and other partners.

In addition, and as we have previously reported, the COGR Costing Committee, with assistance from the RCA Committee, has organized around the development of an F&A White Paper to address many of the themes related to transparency, alternative models, education and myths. While this may not be a "hot issue" in the Administration's 2019 budget proposal, development of the White Paper remains a COGR priority. The focus of the paper will be to advocate, with an educational component, for fair F&A reimbursement policies across many stakeholder groups, including Federal agency leaders, Federal policymakers, our own Faculty, and even the Media. The White Paper also will attempt to memorialize key discussions and perspectives and talking points so that we can use it as resource when/if F&A comes under attack next time.

We are in the early stages of writing the White Paper, but we encourage the Membership to track down members of the Costing and RCA Committees during the upcoming COGR Meeting to share perspectives and other thoughts on this topic.

Procurement and the Micropurchase Threshold (MPT)

COGR members are preparing for implementation of the Uniform Guidance Procurement Standards, 2 CFR 200.317-326, to become effective on the first day of your new fiscal year. For many, this is July 1, 2018. For several, however, the effective date was January 1, 2018.

The two most significant issues for our community involve implementation of the Micropurchase Threshold (MPT):

1) Some auditors raised the concern that because the MPT has not been codified in the Uniform Guidance, the threshold defined in the National Defense Authorization Act (see below) is not applicable. While OMB has yet to clarify in writing, in correspondences between COGR and OMB, representatives from OMB are authoritative in stating the MPT per the NDAA is applicable and supersedes the Uniform Guidance. 2 CFR 200.101(b)(3) states: "… *in any circumstance where the provisions of Federal statutes or regulations differ from the provisions of this part, the provision of the Federal statutes or regulations govern*".

   COGR'S UNDERSTANDING IS THAT THIS ISSUE HAS BEEN RESOLVED AND THOSE AUDITORS THAT RAISED THE CONCERN HAVE SINCE RETRACTED THEIR POSITION.

2) A process for confirming an MPT greater than $10,000 still is not clear, despite straightforward criteria defined in the NDAA. At issue is what entity is empowered as the "*relevant executive agency*" per the NDAA. OMB continues to work on a solution and is aware that there is a sense of urgency and that several COGR members have a fiscal year that began on January 1, 2018. It appears as though OMB will not be the "*relevant executive agency*" to approve an MPT greater than $10,000. This suggests it will be either the institution's Cognizant Agency for Indirect Cost (i.e., CAS-HHS or ONR) or the institution's Cognizant Agency for Audit.

   THIS ISSUE REMAINS UNRESOLVED AND COGR WILL CONTINUE TO PURSUE.

National Defense Authorization Act for Fiscal Year 2017. Sec. 217 (b): INCREASED MICRO-PURCHASE THRESHOLD FOR UNIVERSITIES, INDEPENDENT RESEARCH INSTITUTES, AND NONPROFIT RESEARCH ORGANIZATIONS.—Section 1902 of title 41, United States Code, is amended—

> *(A) $10,000; or (B) such higher threshold as determined by the head of the relevant executive agency and consistent with clean audit findings under chapter 75 of title 31, internal institutional risk assessment, or State law*).

COGR's position is that because the NDAA requires one of the three criteria to be demonstrated to use an MPT greater than $10,000, an institution that historically has used an MPT of, for example, $25,000, should be on safe ground if they continue to use $25,000. However, we continue to urge OMB to offer a reasonable solution that provides audit cover and NDAA compliance for those institutions whose MPT is greater than $10,000.

While OMB may not be the "*relevant executive agency*", we still encourage you to contact them with questions as concerns as they are the entity to determine who the "*relevant executive agency*" will be. Contact:

Rhea Hubbard at: Rhea_A_Hubbard@omb.eop.gov

Gilbert Tran at: hai_m._tran@omb.eop.gov

As necessary, COGR also recommends you consult with your Auditors and/or General Counsel at your institution. We will continue to pursue this issue with the intent of bringing clarity to the process. And as our

community moves toward implementation of the full suite of the Uniform Guidance Procurement Standards in 2018, COGR will be available to address concerns and raise these concerns with the appropriate federal officials.

NIH Notice NOT-OD-18-107 – NIH Enforcement of Closeout Policies: RESOLUTION

NIH released NOT-OD-18-107 on November 30th. In numerous forums over the past year, NIH has been adamant about the importance of timely closeout and its statutory mandate to be in compliance with the Grants Oversight and New Efficiency (GONE) Act. COGR supports NIH efforts to be in compliance with the GONE Act, though several concerns related to the framing of NOT-OD-18-107 were raised, including: 1) timing for initiating unilateral closeout (the Notice states: *Without prior approval from the awarding IC, NIH will initiate unilateral closeout for all awards that fail to meet closeout requirements within 120 days as required by the NIH Grants Policy Statement (NIH GPS) Section 8.6*), 2) better leveraging of 2 CFR 200.343(g), which allows agencies to complete agency closeout actions within one year of the acceptance of all reports, and 3) utilizing the most user-friendly approach to reminder letters.

After conversations with NIH policy leaders in early January; it was made clear that the intent of the Notice was to emphasize the NIH requirement for grantees to meet all closeout requirements within 120 days, and not to suggest that unilateral closeout actions would begin on day 121 if closeout requirements were not met. The NIH position is that NIH will initiate unilateral closeout within 180 days for all awards that fail to meet closeout requirements within 120 days. NIH will use FAQs to clarify NOT-OD-18-107.

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

COGR first tackled this issue in Spring of 2016 on behalf of several institutions that have been disadvantaged in proposal submissions to NIH relating to the treatment of lease costs. At issue has been Section 2.3.7.1 (see below) per the NIH Grants Policy Statement. While F&A costs are excluded from the direct cost limit, lease costs are not. Consequently, if an institution leases a building dedicated to research and the corresponding proposed lease costs would be allowable charges to the federal award, the proposed lease costs would be counted against the direct cost limit, which means fewer costs could be proposed for research staff and other direct research-related costs.

> **2.3.7.1 Applications That Include Consortium/Contractual F&A Costs**
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> *For FOAs that include a direct cost limit, **NIH policy excludes consortium/contractual F&A when determining if an applicant is in compliance with the direct cost limitation {emphasis added}.** This policy extends to all solicited and investigator-initiated applications and to all active announcements (Request for*
>
> *Applications and Program Announcements), involving consortium/contractual F&A costs, regardless of budget amount or budget format (e.g., modular and non-modular). While consortium F&A costs may be requested and awarded, applicants should not consider these costs when determining if a budget exceeds a direct cost limit.*
>
> *This policy impacts eligibility to submit a modular budget. The modular budget format is used for applications requesting $250,000 or less in direct costs per year. Consortium/contractual F&A costs are*

not factored into this direct cost limit; however, they may be requested in addition to the $250,000.

This policy also impacts applications requesting a budget of $500,000 direct costs or more for any year. These applications require prior approval from Institute/Center staff; however, the limit is exclusive of any consortium F&A costs. It does not affect any specific FOA that includes a total cost limit.

This policy does not affect the SBIR and STTR programs since the statutory budget guidelines are based on total costs, not direct costs. It also does not affect any specific Funding Opportunity Announcement that has a Total Cost limit.

COGR's position was, and remains, that the NIH Grants Policy Statement should be amended to correct for the inequitable treatment of lease costs: both F&A and lease costs should be excluded from the direct cost limitation. However, that solution was not viable according to NIH policy leaders.

Instead, the solution that policy leaders from NIH facilitated was to intertwine this issue within the context of the institution's F&A Rate Agreement. NIH has discussed this issue with leaders from HHS – Cost Allocation Services (CAS) who are responsible for negotiating F&A rates with many COGR institutions. If an institution leases a building dedicated to research and the corresponding lease costs are allowable charges to federal awards, the NIH proposed solution is for the following language to be included under the Special Remarks section of the institution's F&A Rate Agreement:

F&A Rate Agreement: Section – Special Remarks:

The institution conducts research in leased space. The F&A rate applicable to this research is the negotiated Off-Campus rate. Lease costs are a facilities cost and are a direct charge to federal awards; the Off-Campus rate is not applied to these lease costs. For funding instruments that include a direct cost limit, lease costs are excluded when computing the direct cost maximum. NIH supports the institution's negotiated F&A rate agreement as required by NIH regulations and implemented by the NIH GPS. NIH will not define "off-campus" for grantees—that is done at the institution and is consistently applied regardless of the source of funds. Instead, the language in this Section II – Special Remarks is meant solely to define how lease costs are treated when computing the direct cost maximum for funding instruments that include a direct cost limit.

The solution is not perfect. Potentially problematic outcomes include: 1) Grants.gov has built in electronic checks that will continue to treat the lease costs as a direct cost that count against the direct cost limit, and 2) it is uncertain how HHS-CAS will respond when an institution requests that their F&A agreement be amended with the Special Remarks. However, NIH could be helpful with 1) by providing an approval letter stating that it is "acceptable" that the direct cost limit has been exceeded, and with 2) by confirming to HHS-CAS that the Special Remarks language is appropriate in F&A rate agreements for selected institutions.

The solution, by virtue of being supported by NIH, provides recognition by NIH that having lease costs be counted against the direct cost limit is inequitable to institutions that lease buildings dedicated to research and charge the lease costs to the federal awards housed in the building. Institutions still will have to finesse the checks and systems from the various NIH Institutes and Centers, and the potentially problematic outcomes described above will have to be addressed. However, NIH policy leaders are supportive of the solution to include the new language in the Special Remarks section of the F&A Rate Agreement.

COGR's position is that institutions that have been affected by the inequitable treatment of lease costs in NIH proposals should assertively work with NIH and HHS-CAS to amend their F&A Rate Agreements. Further, if/when there is an opportunity to revisit Section 2.3.7.1 of the NIH Grants Policy Statement, it may be appropriate to reexamine the core issue and work toward the ideal solution to address the inequitable treatment of lease costs in NIH proposals.

Payment and Reimbursement under 2 CFR 200.305 and the Compliance Supplement

As COGR has reported, auditors have challenged COGR member institutions by suggesting that grants and cooperative agreements should be subject to a strict interpretation of what constitutes payment/disbursement to a vendor. For example, one auditor position is that prior to billing a federal sponsor for reimbursement, the institution must have evidence that the institution's payment to the vendor has been cleared. This is in conflict with existing policy per 2 CFR Part 200.305(b): … *payments methods must minimize the time elapsing between the transfer of funds from the United States Treasury or the pass-through entity and the disbursement by the non-Federal entity.*

Predicating a request for reimbursement on when a payment to a vendor has cleared will make timely reimbursement inefficient, and in many cases, impossible. Furthermore, this discards longstanding, effective, and common-sense disbursement practices typically employed at research institutions where reimbursement is requested after an invoice from a vendor has been approved, identified for payment in the accounts payable system, and posted in the institution's official accounting records.

In response to a request for Public Comments to the 2017 Compliance Supplement, COGR sent a Comment Letter (dated October 20, 2017) to OMB, Gilbert Tran. Some of your institutions also sent letters, either documenting your unique circumstances or simply supporting the COGR letter. Our understanding is that OMB is reviewing the comment letters. A possible outcome is that this issue will be addressed in the 2018 Compliance Supplement. Interestingly, OMB is contemplating a "skinny" version of the 2018 Compliance Supplement (see below), which would focus only on the significant changes between 2017 and 2018. We will keep the Membership posted on all developments.

Costing Policies Committee: Other Issues

The Costing Policies Committee continues its work on a wide range of other issues. Some of these are ongoing and have been covered in past COGR updates. As appropriate, each one will remain on our list for 2018.

2018 "Skinny" Compliance Supplement. As mentioned above, OMB is contemplating a "skinny" version of the 2018 Compliance Supplement. This would focus only on the significant changes between 2017 and

2018 with the intent of making for a more efficient update to the Compliance Supplement. Under this model, we would expect a return to the full version in 2019. We are in communication with OMB to determine the status of the Compliance Supplement.

Securing Student Information, Department of Education (ED). COGR has worked with several of our Association partners to raise concerns as to how ED has proposed audit objectives related to safeguarding

data specific to an institution's information security program (i.e., Safeguards Rule). ED withdrew their initial inclusion of overly-complex audit guidance from the 2017 Compliance Supplement. While COGR's position is that the Compliance Supplement is not the correct vehicle for this guidance, ED is now working with the community to include more manageable guidance in a possible release of a 2018 "Skinny" Compliance Supplement.

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

NSF to seek Public Comment on New Award Term regarding Sexual Harassment

After a tidal wave of sexual harassment allegations and litigation in academe and other organizations over the past year, federal agencies are paying close attention to their own policies and policies of those of who receive federal grant funding. On February 8, the National Science Foundation released Notice No. 144 to presidents of universities and colleges to condemn sexual harassment of any kind where NSF-funded science and education are conducted. The NSF will include a new term and condition requiring grantee institutions to report sexual harassment or any other kind of harassment from grantee personnel including the placement of the individual(s) on administrative leave. NSF will solicit feedback on this new award term and condition through its Proposal and Award Policies and Procedures Guide Federal Register process within the next several weeks.

Stay tuned for further updates on this matter.

Cannabis and Industrial Hemp Work Group

In December's update we notified the membership of a newly formed COGR work group on the barriers of conducting industrial hemp and cannabis research. Action items for the working group include the development of Frequently Asked Questions, a letter to members of Congress and/or the Drug Enforcement Agency as well as the development of a tracking system to capture research related activity in this area. COGR will convene a panel discussion at its upcoming February 22nd meeting Thursday afternoon. For additional questions, please contact Jackie Bendall at jbendall@cogr.edu.

Public Access to Federally Funded Research

In December, we mentioned plans to coordinate a response to the Open Science Community Interagency Working Group in follow-up to the October COGR Research Compliance and Administration Committee meeting. The letter was issued on January 19th via email to members of both the National Institutes of Health and the National Science Foundation. We understand that a Request for Information (RFI) will be forthcoming for public comment to which COGR will respond. Additional concerns or questions can be address to Jackie Bendall at jbendall@cogr.edu.

SRC JUMP Contract IP Provisions Raise Concerns

It was recently announced that the Semiconductor Research Corporation (SRC) has provided $200M funding through SRC's JUMP initiative for six collaborative university research centers (see

https://www.hpcwire.com/2018/01/16/src-spends-200m-university-research-centers/). The JUMP initiative is jointly funded by SRC and DARPA.

Each center includes multiple universities as participants, with subawards from the university prime contractors.

The subcontracts include 16 pages of IP provisions (#10—11). Of particular concern are provisions pertaining to background IP (BIP) provisions, which extend to non-contract performers. Notice and consent to license is required for all "implicated" background IP of non-contract performers at the institutions. A Due Diligence Process (DDP) must be developed by the contractor to identify such IP and provided to SRC for review and approval (#11.7). Additional detailed provisions address license terms and the conduct of the DDP.

These requirements raise serious compliance concerns. Accurate identification of all potentially "implicated" background IP through a DPP may prove extremely burdensome if not impossible, especially since it is not limited to IP of contract performers. In addition, extending the reach to non-contract performers raises serious policy issues for many institutions, as well as the possibility of creating conflict between contract performers and non-contract performers. We understand that four of the prospective university subs already have walked away, and others are considering similar action.

At this time COGR's role is to provide information to our member institutions. However, depending on developments, we might raise the issues with DARPA and/or central DOD research management, though it is not clear what DARPA could do, short of terminating the award to SRC. We understand that DARPA has discussed the issues with SRC and that some modifications may have been made in the original contract. Unfortunately, we also have heard informally that some SRC member companies now are insisting on similar BIP provisions, which raises similar administrative burden and liability issues. Companies tend to be concerned about assuring freedom to operate in collaborations with universities. The SRC IP provisions appear to be an extreme reflection of this concern.

Associations Discuss University Tech Transfer with Administration

COGR has participated in two recent meetings between higher education association and Administration representatives. The first was in October of last year with the Office of American Innovation; the second was last month with the Office of Science and Technology Policy (OSTP).

Similar themes were discussed at both meetings. The Administration is looking for ways to increase the returns from federal R&D investments, and provide for more participation by the private sector. They are interested in tech transfer initiatives that will lead to "wins." Ways to replicate the success of institutions like MIT and Stanford are sought.

At both meetings we provided the Administration representatives with a set of recommendations. They include ideas such as providing new proof of concept (POC) funding through SBIR/STTR; expanding the I-Corps program; changes in tax law such as creating a collaborative R&D tax credit and more flexible standards for public-private use of bond financed facilities; revising the PHS conflict of interest (COI) requirements; and strengthening the U.S. patent system through a number of steps as well as reconstituting federal technology transfer oversight at the Commerce Department and simplifying and streamlining tech transfer reporting

requirements including the iEdison system (we understand NIST and NIH have a substantial redesign of iEdison underway—see October 2017 COGR Meeting Report).

Some of these recommendations would require legislative action. Moreover they may not lead to the quick "wins" that the Administration is seeking. We are continuing to discuss with the other associations possible additional recommendations.

NIST Announces New ROI Initiative

In early February NIST announced a new "Return on Investment (ROI) initiative to "Unleash American Innovation." NIST plans to use its convening function to work with a range of partners to identify improvements in federal technology transfer. The focus will be both on federal laboratories and federally-funded R&D at universities.

The review will include an assessment of federal principles and practices that should be protected and those that should be modified; reducing regulatory burdens to private sector investment; new partnering models; accelerating technology transfer in areas of strategic national importance; better metrics to evaluate impacts and outcomes; and new approaches to motivate increased technology transfer outcomes. An RFI will be issued next month, followed by three public forums. The (ambitious) goal is to complete the analysis with recommendations and action plans by June/July. Several interagency groups will support the effort. (For more information see www.nist.gov/tpo/ROI).

In remarks describing the initiative at a February 7 visiting committee meeting, the new NIST Director mentioned that the U.S. statutory framework for federal technology transfer (primarily the Bayh-Dole Act and Stevenson-Wydler Act) deals with U.S. rights only. That is an issue that should be among those reviewed, especially since other countries have adopted the Bayh-Dole Act with adaptations. He also mentioned conflicting federal and state policies as another area needing review. The intent is to build on earlier studies, and in particular to identify "low hanging" fruit.

In a panel discussion at the Feb. 7 meeting participants made a number of recommendations that track those we had provided earlier such as providing additional POC funding and expanding ICorps (see #s 2 above and 4 below). There also was extensive discussion of federal COI policies as a barrier to greater public-private sector relationships. Other specific problems identified include the requirement for federal exclusive licenses to be published in the Federal Register; the inability of federal employees to claim copyright which significantly inhibits the ability to transfer federally developed software to the private sector; and the patent fee structure.

The leadership role of NIST and the National Science and Technology Council (NSTC) was mentioned by OSTP in our meeting (see #2). The NIST Director also noted NSTC oversight of the ROI initiative. He plans to kick off the initiative in statements at the upcoming AAAS, LES and AUTM meetings. (He also described the initiative in a recent Congressional hearing; see Regulatory Reform Update). He also plans to hold small group meetings with stakeholders, and will meet with the COGR CIP Committee at our February meeting.

The emphasis of the ROI initiative seems more on the federal laboratories, although universities and the Bayh-Dole Act clearly will be included in the review. NIST also has announced a new "One NIST" initiative, to facilitate the ability of other organizations to partner with NIST. NIST may also seek authority to establish a

non-profit foundation, and may seek Other Transaction authority, which COGR traditionally has opposed. We will stay in close contact with NIST as the ROI initiative evolves, and plan to participate in the upcoming RFI process and public forums.

COGR Endorses I-Corps Expansion Bill

COGR has joined other higher ed. associations in endorsing the Innovators to Entrepreneurs Act of 2018, which Rep. Lipinski (D—IL) plans to introduce.

The bill would amend the American Innovation and Competiveness Act. It would expand the I-Corps program originated by NSF to allow any SBIR/STTR grantee from any federal agency to apply to participate and to use their grant funds to cover expenses. It also would allow any private citizen to apply to participate and pay out-of-pocket. The bill also would make the NSF pilot "I-Corps Go" business skills teaching program a nationwide formal component of I-Corps, and provides for a GAO assessment of the I-Corps program in two years.

I-Corps has been widely viewed as a very successful model for encouraging greater commercialization of federally-funded research through providing entrepreneurial education and mentoring experiences. It has built a national network of science entrepreneurs and contributed to a cultural shift in recognition of entrepreneurship as an important career track for scientists and engineers. Rep. Lipinski's bill would allow a significant expansion of the program, particularly through use of SBIR/STTR funding.

Sovereign Immunity Claims in Patent Cases Continue to Receive Attention

The December 2017 COGR Update and earlier COGR reports discussed concerns about sovereign immunity claims by state institutions and others in patent cases. Another recent case involved a graduate student's claim of inventorship against a state institution. The claim initially was dismissed on sovereign immunity grounds and the dismissal was upheld on appeal.

While decisions in recent cases have favored state institutions, judges have noted that the Supreme Court *Florida Prepaid* case upholding state sovereign immunity from patent infringement claims now is nearly 20 years old. At that time state universities were not as heavily involved in seeking and enforcing patents as is the case today. The unsuccessful petition for *cert.* in the above case cited these points and alleged that "States have repeatedly and extensively abused Eleventh Amendment sovereign immunity to gain litigation advantages against private entities in the patent arena and deprive private citizens of their patent rights." While the argument was unsuccessful, it is possible that at some point courts may prove more responsive to these arguments, especially given perceived abuses of sovereign immunity by rentals of patent rights such as discussed in the December Update.

Updates

Controlled Unclassified Information (CUI). The oft-postponed due date for the draft FAR CUI clause has been postponed again, until March 14, 2018. This is nine months past the original due date. NARA recently issued guidance for non-FAR-covered CUI requirements in information sharing agreements with entities outside the federal government. While the guidance is directed to executive agencies, it

includes requirements and best practice recommendations for other entities. The NARA website also includes new recommendations for CUI training.

Bayh-Dole Criticisms. Another in the seemingly never-ending series of articles and papers criticizing Bayh-Dole was recently published *Is the Bayh-Dole Act Stifling Biomedical Innovation?* The authors point to findings that firms that received NIH SBIR funding were less likely to commercialize their technology than similar firms that did not partner with universities. They believe the Bayh-Dole Act is the "culprit." In their view it distorts the innovation system. By inhibiting the open flow of knowledge, it allegedly is a significant contributing factor to declining biomedical research productivity. The authors do not provide any data to support these assertions. They ignore the long record of university success in transferring federally-funded technologies to the private sector under Bayh-Dole as shown by AUTM surveys and other studies. The article is one of a long line based on the philosophic belief that ideas created with public funding should be freely available. This argument goes back to the beginning of Bayh-Dole, and has never really gone away.

Dept. of Ed. Open Licensing Requirement. The requirement was to be phased in beginning last October. We have asked a number of COGR institutions whether they have received grants subject to the requirement. We are hoping to receive more information. If any COGR member has received such an award from Ed. please let Bob Hardy at COGR know.

Health and Human Services

Common Rule Delay

Health and Human Services (HHS) Office for Human Research Protections (OHRP) Director Dr. Jerry Menikoff will join us at the February COGR meeting to discuss the Common Rule, including the recent delay and request for comments, and will take questions from meeting participants.

On January 22, 2018, 16 federal departments and agencies filed an Interim Final Rule (IFR) titled "Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects". The IFR delays both the effective and compliance dates of the revised rule, published on January 19, 2017, to July 19, 2018 for these agencies and for the Consumer Product Safety Commission which adopted the rule on September 18, 2017. The notice cites a request from AAMC, AAU, APLU, and COGR, as well as a request from SACHRP a number of months ago to delay the rule. The request from COGR and the other higher education associations sent in June of this year was for a one-year delay in the compliance date, with no delay in the effective date, and this was highlighted in a two-page document and discussions with staff from the Office of Information and Regulatory Affairs and the HHS OHRP in December.

A one-year delay of the compliance date alone would have allowed institutions to move forward with implementation of certain provisions of the revised final rule (including those expected to reduce administrative burden) and to delay implementation where additional guidance and education is needed. This would have been particularly helpful as institutions had to be prepared to move forward with the revised rule prior to the publication of an IFR. With a delay in the effective date, as indicated in the notice, "regulated entities are not allowed, prior to July 19, 2018, to comply with the 2018 Requirements in lieu of the pre-2018 Requirements."

In section III, *Good Cause for Interim Final Rule*, agencies indicated that "a notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest." Per the notice, "Without a delay, and without guidance, institutions that have expected a delay who hastily attempt to implement the revised rule without adequate preparation are bound to make mistakes, the consequences of which may jeopardize the proper conduct of research and the safety and wellbeing of human subjects." The IFR notes categories of activities that have been deemed not research and five new exemption categories as among the areas that will require significant guidance, noting feedback from SACHRP with respect to the latter.

The notice goes on to indicate that "…the federal departments and agencies named in this interim final rule are developing a notice of proposed rulemaking in order to fully engage regulated entities and the public regarding further delay of the 2018 Requirements until January 21, 2019. The additional time provided by the six month delay in this interim final rule will allow sufficient time for the notice and comment rulemaking process to be completed. Issuance of this interim final rule avoids the possible result of having the federal departments and agencies propose an implementation delay but be unable to complete the rulemaking process and publish a final rule that would be effective by January 19, 2018."

An eleventh hour delay of both the effective and compliance dates, however well-intentioned, presented a challenge to institutions which had strived to comply with the revised final rule by January 19, 2018 as required by regulation prior to the publication of an IFR. Continued uncertainty about the final effective and compliance date with the proposal of additional rulemaking will add to that challenge. A proposed rule and request for comments is expected to be specific to an additional 6 month delay, as indicated in the notice, which may be more complex than the across the board delay of the effective and compliance dates implemented with this IFR. Comments on the IFR are due March 19, 2018. Still listed on the OIRA website is proposed rulemaking titled "Federal Policy for the Protection of Human Subjects: Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year." COGR will continue to update members on the status of forthcoming rules and guidance as information becomes available.

NIH Clinical Trial Case Studies

We previously reported that COGR, AAMC, AAU and APLU sent a letter to Dr. Michael Lauer, NIH Deputy Director for Extramural Research, on September 17, 2017, expressing concern that NIH's definition of "clinical trial" has been significantly expanded through the set of case studies published by the agency in the summer of 2017. Associations have had subsequent exchanges with Dr. Lauer on this topic, including discussions on alternative reporting structures for basic health research involving human subjects.

The Federation of Associations in Behavioral and Brain Sciences (FABBS) recently provided an update on progress that has been made with respect to the NIH clinical trial case studies and on January 22, a dialogue on this topic between Jeremey Wolfe, immediate past president of FABBS, and Mike Lauer was published in Nature Human Behaviour. The dialogue addresses related concerns that have been raised by the community, providing information and clarifications that should be helpful to investigators. Related correspondence from several different authors and perspectives are included.

As indicated in the FABBS blog, and by Dr. Lauer, in a post to his blog dated January 17, case studies 18 a-f have been revised in response to feedback from the research community. As of this writing, there does not appear to be anything in case 18 that would suggest that basic health research involving fMRI is a clinical trial. This would appear to include fMRI research involving manipulations that result in transient changes to physiology or behavior with no therapeutic intent. Further, case studies 24 and 26, which have been of concern, have been removed from the website and could potentially be under revision. We remain concerned about other case studies that capture basic health research, including case studies 9 and 14 as highlighted in our letter, and those that continue to occupy grey areas and further stretch the boundaries of what has traditionally been defined as a clinical trial. Earlier versions of published case studies from October 2014 and April 2015 seemed to closely adhere to what has traditionally been characterized as a clinical trial while later versions of the case studies, including September 2016 and, in particular, more recent versions, have been much more ambiguous.

COGR will continue its dialogue with NIH and other associations and societies engaged on this issue and seek further revisions as necessary. In the meantime, investigators should continue to consult the case studies. As indicated in Nature Human Behaviour article, those uncertain of whether their research meets the definition of a clinical trial should reach out to their program officer. Per Dr. Lauer in the Nature article, "If you follow your program officer's opinion, your grant proposal will not be disqualified for being on the wrong side of the clinical trial definition."

New HHS Secretary Confirmed

The Senate voted to confirm Alex Azar as Secretary of the Department of Health and Human Services on January 24. Azar steps into the role vacated by former Secretary Tom Price. As reported previously by the NY Times, Washington Post and other news outlets, Azar is a lawyer that has previously served at HHS in the role of General Counsel and Deputy Secretary under George W. Bush, and more recently served as a senior executive at Eli Lilly. He is described as a conservative who is very knowledgeable of the department, health policy, and the regulatory process.

National Science Foundation

American Innovation and Competitiveness Act (AICA) Hearing

On January 30, 2018, the Senate Commerce, Science, and Transportation Committee held the hearing "One Year Later: The American Innovation and Competitiveness Act." NSF Director France Cordova and NIST Director Walter Copan testified at the hearing, which examined the agencies implementation of the Act. Dr. Cordova highlighted several areas of her written testimony during oral testimony and discussion, including a Request for Information on Mid-Scale Research Infrastructure, and programs to expand STEM opportunities.

During the hearing lawmakers expressed enthusiasm for the work of NSF and federal support for the agency's efforts. Many cited findings from the National Science Board's recently released Science and Engineering Indicators; noting that China is the second largest investor in R&D and that the country's investments are growing at a much higher pace than that of other nations and may soon eclipse U.S. investments. It was noted that some have suggested that the U.S., which contributes 0.7 % of GDP to R&D, should contribute 2%, and Dr. Cordova was asked what would happen if the U.S. R&D investment was 2%. Dr. Cordova noted that a lot of

R&D investment is in development and that if there were an increase, the emphasis should be on growing that Nation's investment in basic research, which she suggested are the root of technology and tech transfer and would be transformational. Dr. Cordova noted, as examples, that much of the technology behind self-driving cars is based on NSF discoveries and that the very first grants for gene editing were NSF grants. Both Cordova and Copan were asked about short-term funding measures and lapses in funding and their effect on agency operations. Both indicated that it was a challenge, and Dr. Cordova noted that NSF had to cancel 10 merit review panels during a recent shutdown and that travel was significantly disrupted.

While acknowledging that OSTP and OMB were directed to reduce administrative burden under the AICA, Dr. Cordova was asked what efforts NSF is taking to reduce burden. Dr. Cordova noted that the NSB had a task force on administrative burden several years ago and identified a number of ways to reduce burden in its report. NSF is implementing recommendations specific to the agency and has its own internal groups focused on reducing burden, including streamlining processes and practices and streamlining merit review to reduce burden on proposers (e.g., standardizing solicitations and deadlines). NIST Director Copan also mentioned use of common practices and opportunities to enhance return on investment, including expanding review of federal tech transfer to reduce administrative burden and unintended barriers to commercialization.

Dr. Cordova was asked if she could provide some insight into the recommendations that might be made by the National Research Council to improve reproducibility of scientific data. Section 116 of the AICA required NSF to "enter into an agreement with the National Research Council to assess research and data reproducibility and replicability issues in interdisciplinary research; to make recommendations for improving rigor and transparency in scientific research; and to submit to the Director of the Foundation a report on the assessment..." Dr. Cordova noted that on March 8, 2017, NSF established an agreement with the National Academies to conduct a study to assess reproducibility and replicability in science. A committee of 15 experts held its first meeting in December and will hold four additional meetings in 2018. Dr. Cordova expressed that science is very heterogeneous and that she hoped the committee would take a nuanced approach to the different fields and the individual challenges that they face and provide best practices that can be publicized and shared.

National Science Board's Science and Engineering Indicators

On January 18, 2018, the National Science Board issued its biennial Science and Engineering Indicators Report for 2018. The report includes U.S. and international R&D trends and data on academic R&D among other areas. On February 1, the Board released a companion policy statement to indicators *Our nation's future competitiveness relies on building a STEM-capable U.S. workforce* and accompanying press release. A member of the National Science Board and/or NSF staff will discuss the report at the February COGR meeting.

COGR Session with the NSF Office of Inspector General

National Science Foundation Assistant Inspector General for Audit Mark Bell, and Deputy Assistant Marie Maguire, will speak about ongoing changes to how the OIG assesses risk and conducts audits, including updates to the OIG's risk matrix, greater use of internal auditors, enhanced flexibility with external audit contracts, addressing issues consistently identified in audit, and early communication with NSF staff on the merit of potential findings. Recent reports, including the OIG's report on responsible conduct of research; ongoing or

recently completed audits, including reviews of single audit and subrecipient monitoring; and planned audits that impact grantees will be discussed.

Grant Reporting Efficiency and Agreements Transparency Act

Rep. Virginia Foxx (R-N.C.) and Rep. Jimmy Gomez (D-C.A.) introduced the Grant Reporting Efficiency and Agreements Transparency Act, or GREAT Act, on February 1. The bill seeks to standardize data elements reported on federal grants and cooperative agreements and to reduce duplication and administrative work through use of technology and standards. The bill would also amend the Single Audit Act "to provide for grantee audits to be reported in an electronic format consistent with the data standards". Ultimately the goal is greater transparency in federal spending. The GREAT Act is viewed as a continuation of the work initiated by the DATA Act and related pilot program.