COUNCIL ON GOVERNMENTAL RELATIONS
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May 30, 2017

TO: COGR Membership

FROM: COGR Staff

SUBJECT: May 2017 Update

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The FY2018 Federal Research Budget: Proposed Cuts to Research and F&A Reductions

The President's FY2018 Budget Proposal, released on May 23, includes major reductions for scientific research funding including over 20% in proposed cuts to the NIH budget and over 10% to NSF. While this creates significant concern, members of Congress on both sides of the aisle are largely dismissing the budget requests. An area of additional concern for institutions is that the President's Budget proposes to make these cuts to F&A costs with respect to the NIH budget. The following is an excerpt from the NIH section of the budget document "Major Savings and Reforms."

> "The Budget also proposes to reduce reimbursement of grantee administrative and facilities costs, referred to as "indirect costs", so that available funding can be better targeted toward supporting the highest priority research on diseases that affect human health. As a result of these changes to the reimbursement structure, significant reductions in 2018 will come from lower indirect cost payments. Increasing efficiencies within the NIH is a priority of the Administration. The Budget includes an indirect cost rate for NIH grants that will be capped at 10 percent of total research. This approach would be applied to all types of grants with a rate higher than 10 percent currently and will achieve significant savings in 2018. It would also bring NIH's reimbursement rate for indirect costs more in line with the reimbursement rate used by private foundations, such as the Gates Foundation, for biomedical research conducted at U.S. universities. In addition, the Budget proposes that NIH will streamline select Federal research requirements for grantees through targeted approaches. In tandem, the Budget supports burden reduction measures that will further reduce grant award recipient costs associated with research."

As COGR previously reported, Secretary of Health and Human Services, Dr. Tom Price, testified at a House Appropriations Committee budget hearing for the Department of Health and Human Services on March 29 that with respect to NIH funding the department would seek greater efficiencies, noting that 30% of grant funding is used for indirect expenses. COGR staff have been engaging with representatives from other associations to address misconceptions about indirect costs. Materials developed by the group are available on the COGR website.

The issue of indirect costs was raised in two recent hearings:

On May 17, 2017, the House Committee on Appropriations; Subcommittee on Labor, Health and Human Services, Education, and Related Agencies held the hearing *Advances in Biomedical Research* which included testimony from NIH Director Dr. Francis Collins and five NIH Institute Directors. Members of the committee praised NIH's work and expressed disappointment with proposed spending cuts to NIH initially outlined in the President's "skinny budget." While the hearing was not focused on F&A, there was discussion on this topic (specifically, at 1:20:20), with Representative Andy Harris questioning why the Federal Government was paying a higher rate than foundations. Dr. Collins indicated that foundation funding represents a small percentage of academic R&D and that universities are already heavily subsidizing federally funded research.

In a second hearing on May 24, the House Research and Technology and Oversight Subcommittees held a joint hearing titled: *Examining the Overhead Cost of Research*. COGR Board Chair, Jim Luther, Associate Vice President of Finance & Compliance Officer, Duke University, testified at the hearing. Other witnesses included Dale Bell, NSF Division Director,

Institution and Award Support, John Neumann, Director, Natural Resources and Environment, GAO and Richard Vetter, Professor of Economics Emeritus, Department of Economics, Ohio University and Director, Center for College Affordability and Productivity.

The hearing included an in-depth discussion on the role of F&A costs at research universities, including how NSF negotiates F&A rates; short and long-term trends in the rate of F&A reimbursement as a percentage of total awards at NSF, NIH and other agencies; how foundations reimburse F&A; and university's contributions to academic R&D, including unreimbursed indirect costs. Dr. Vedder proposed flat F&A rates of 10% or 20% and also suggested that agencies consider overhead costs when scoring an award. Jim Luther highlighted variations in costs due to location and the types of research conducted, neither of which would be accounted for in a flat rate, and that considering overhead when scoring an award would likely disadvantage universities with fewer resources. Jim highlighted the long standing federal university partnership, with universities contributing $16.7 billion in FY15, the latest federal data available, including $4.8 billion in unreimbursed indirect costs. Jim Luther's written and oral testimony are available on the COGR website. COGR will provide further updates on the Federal research budget, and related F&A issues, at the upcoming COGR Meeting on June 8-9.

Management, Compliance and the Cost of the Data/IT Enterprise: Thursday Morning Session on June 8th

Many issues are swamping the Data/IT Enterprise: Public Access to research data, Safeguarding of Controlled Unclassified Information (CUI), the "Cloud" (including the treatment of F&A application), and other cybersecurity and related issues. This session will present an overview of these real and pressing day-to-day management challenges, with a focus on how institutions are balancing Compliance and Cost. The panelists for this session are:

Jack Suess, Vice President for IT and Chief Information Officer, University of Maryland, Baltimore County
Missy Peloso, Assoc. Vice President/Assoc. Vice Provost, Research Services, University of Pennsylvania (COGR Board Member)
Doug Backman, Director, Compliance, Office of Research and Commercialization, University of Central Florida
Brian Markham, Assistant Vice President, Information Security and Compliance Services, George Washington University

This diverse and expert panel will help to bridge dialogue across various university and research functions, while at the same time, advancing strategies to address the new, costly, and complex compliance requirements associated with managing and protecting sensitive data.

Procurement Standards: Grace Period Extended for One Additional Year

A May 17, 2017 Federal Register Notice confirmed a one-year grace period for implementation of 2 CFR 200.317-326 (Procurement Standards) has been approved. For most COGR members, this means that the 2 CFR 200.317-326 must be implemented on July 1, 2018. Per the Federal Register Notice:

For all non-Federal entities, there is an additional one-year grace period for implementation of the procurement standards in 2 CFR 200.317 through 200.326. This

means the grace period for non-Federal entities extends through December 25, 2017, and the implementation date for the procurement standards will start for fiscal years beginning on or after December 26, 2017.

Below are several observations and recommendations. We shared a version of these in our note to the COGR Listserve on May 16th, and have since updated. The first point is directly from OMB and the points that follow are COGR-specific understandings/interpretations:

1) Per OMB: *As many of you are aware, OMB in partnership with the COFAR was considering proposed changes to 2 CFR last Summer and Fall that have since been held up due to the ongoing government and regulatory reform efforts, therefore, we are granting one final grace period for non-Federal entities who choose not to implement the Uniform Guidance procurement standards. Non-federal entities who wish to take advantage of this grace period must document this internally, continue to follow the standards in prior OMB guidance, and begin preparing for implementation of the procurement standards prior to the end of this third and final extension*.

2) The procurement standards that you historically have used (premised on OMB Circular A-110) can continue to be used until the new implementation date.

3) The micro-purchase threshold that you are using (e.g., $5,000, $10,000, $25,000, etc.) remains effective until the new implementation date, though note the next point below.

4) For those institutions that exceed $10,000, the one-year extension gives you cover to continue following your policies implemented under OMB Circular A-110. However, we recommend documenting your justification for exceeding $10,000 so that you are in compliance with the National Defense Authorization Act (NDAA; i.e., *(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*). As necessary, COGR recommends you consult with your Single Auditors and/or General Counsel for your institution.

5) Update from the May 16th email to the COGR Listserve: Section 1902 of Title 41 of the United States Code codifies the NDAA language specific to: INCREASED MICRO-PURCHASE THRESHOLD FOR UNIVERSITIES, INDEPENDENT RESEARCH INSTITUTES, AND NONPROFIT RESEARCH ORGANIZATIONS. As such, the increase in the micropurchase threshold should be considered permanent, unless there is deliberate action by Congress to repeal this provision.

Also, per OMB: "*Any future changes to 2 CFR will be considered as part of the larger government and regulatory reform efforts and the final President's Management Agenda*." COGR anticipates there will be no revisions to 2 CFR Part 200, nor any new FAQs, in the near future. Therefore, COGR recommends that you start preparing for a July 1, 2018 implementation of the new procurement standards with the expectation that OMB may not be providing any implementing guidance. This will be especially important for those institutions that exceed the $10,000 micropurchase threshold per the NDAA.

Going forward, OMB will be focused on the President's Management Agenda. COGR will share its voice and hopes to work with the new Administration on these efforts. However, it is fair to say that the vehicle to affect change may not be 2 CFR Part 200. We will keep you posted on all developments and we expect to address more at the upcoming June COGR Meeting.

Costing Policies Committee: Other Issues

The Costing Policies Committee is working 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 2017 engagement.

Single IRB and Direct Charging. We recently have reported on FAQs (dated 1-30-2017) posted by NIH to provide additional clarification to the June 2016 NIH Notice Number: NIH-OD-16-109. Notably, FAQs 6 and 7 seem to provide flexibility for institutions to remove all IRB costs from an indirect cost pool and, in turn, establish a direct charging methodology. While use of a Specialized Service Facility (SSF) is suggested in FAQ 6, at the February COGR meeting NIH representatives indicated a more generic recharge center model also could be appropriate. We understand that updated FAQs may be released soon. The COGR Research & Regulatory Reform (RRR) Committee is the lead on this issue, with ongoing engagement by the Costing Policies Committee.

Equitable Treatment of Off-Campus Research Centers in NIH RFAs. A COGR Workgroup has worked closely with NIH for over a year with the goal devising 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. Off-campus research centers are at a competitive disadvantage; i.e., by including the lease costs against the direct cost maximum, fewer costs can be proposed for research staff and other direct research-related costs. Since this impacts only several COGR institutions, the new solution being considered by NIH is to note this situation in the "Special Remarks" section of the F&A Rate Agreement and to cross-reference this to section 2.3.7.1 (Applications That Include Consortium/Contractual F&A Costs) of the NIH Grants Policy Statement. We hope to resolve this longstanding issue soon.

SINGLE AUDIT: Reimbursement/Advance Payment Methodology. Recently, several auditors have challenged COGR member institutions by suggesting that grants and cooperative agreements should be subject to a strict interpretation of the reimbursement methodology. Specifically, the 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 the normal practice where reimbursement is requested after a vendor has been billed and the transaction has been posted in the Accounts Payable system. The source of this new audit approach seems to have been generated by the IG community. COGR is working with Federal government representatives, and representatives from KPMG and PwC, to address this issue.

SINGLE AUDIT: Securing Student Information, Student Financial Aid (SFA) Cluster. This was the new section proposed by the Department of Education in the DRAFT version of the 2017 Compliance Supplement. COGR has worked with association partners to raise our objections to OMB and the Department of Education. Included in the coalition are

NACUBO, EDUCAUSE, the National Association of Student Financial Aid Administrators (NASFAA), the National Association of State Auditors, Comptrollers, and Treasurers (NASACT), the AICPA, and leaders from the Single Audit firms. In April, we received notification from OMB, based on the recommendations of our coalition: the Department of Education has agreed to delay new requirements for "Securing Student Information" in the SFA cluster until the 2018 Compliance Supplement. According to OMB, the delay will avoid confusion for this year's audit and allow for better planning and execution on future year audits. We expect to re-engage on this issue later in the year once the 2018 Compliance Supplement begins to be vetted.

SINGLE AUDIT: Annual Compliance Audit, Student Financial Aid (SFA) Cluster (NO NEW UPDATE). The four Associations, the National Association of State Auditors, Comptrollers and Treasurers (NASACT), the American Institute of Certified Public Accountants (AICPA), the National Association of College and University Business Officers (NACUBO), and COGR, continue to monitor this issue. We were concerned that the Department of Education (ED) position (requirement for a separate annual compliance audit of Title IV Student Aid Programs) might be included in the 2017 Compliance Supplement. However, our understanding is that it will not be included. Still, ED is using its *Dear Colleague Letter* from last August as the basis for their position that an annual compliance audit is required. More to come on this issue.

2017 Compliance Supplement Status. This publication is relevant to number of issues addressed above. We believe it will be available soon.

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.

Associations Request Further Delay of Ed. Open Licensing Requirement

We previously reported that the Department of Education (Ed.) announced on March 21 that the effective date of the open licensing requirement will be delayed two months until May 22 to allow the Department an opportunity for further review of the final regulations. The requirement was to go into effect on March 21.

On April 20 COGR joined the other higher ed. associations in requesting a further delay in the effective date. This followed an informal teleconference held the day before with several Ed. representatives where we reiterated our concerns about the requirement. The letter cited our ongoing concerns. It stated our belief that the interests of the Department and the stakeholder community would best be served by setting a new effective date beyond May 22, 2017. This would allow for additional consideration informed by further dialogue between the Department and stakeholders.

In the informal teleconference we discussed concerns about the new broad exemption process. The Ed. representatives indicated they deliberately wanted it to be ambiguous, to remain flexible. We noted that the problem was the resulting uncertainty. We also raised questions about how decisions on exemptions would be made, especially with regard to potential compromises of IP rights. The Ed. reps mentioned experience with the TAC open licensing program at Labor that

showed that posting of assessments was the biggest concern, not IP. This seems similar to the concerns about disseminating unvalidated materials resulting from the open licensing policy.

As noted the discussion was informal, and the Ed. representatives were constrained by the rulemaking process. We hope that there will be a further delay in the effective date.

COGR Requests Clarification of Fundamental Research and Covered Defense Information

The February Meeting Report discussed concerns raised by the October 2016 amendment to the DFARS 252.204—7000 clause. The clause was amended to provide that fundamental research "by definition cannot involve any covered defense information" (7000(a)(3)). The discussion in the final rule states "A contract or project that is appropriately scoped as fundamental research will not contain any covered defense information." The determination that a project is fundamental research must "ensure that it is clear that no covered defense information is involved." The amendment attempted to respond to concerns that COGR previously had expressed to DOD that our member institutions were inappropriately receiving safeguarding requirements in fundamental research projects.

The definition of "covered defense information" (DFARS 7012 clause) encompasses both "controlled technical information" (CDI) and "other information" described in the NARA CUI Registry. Controlled technical information is technical information with military or space application that is subject to access or disclosure controls. "Other information" is information subject to other CUI Registry controls such as Privacy controls (e.g. Health Information or Student Records).

The problem arises because it is possible for fundamental research to involve both types of information as inputs where unrestricted dissemination of the research results is intended. For example, one of our institutions reported receiving funding for DARPA projects where the Principal Investigator attends program meetings in which controlled technical information is discussed. Such information will not be included in the project outputs nor will it be disseminated to the team participating in the project on campus at the institution. However DARPA has taken the position that under the revised 7000 clause, the project may no longer be considered fundamental research because of this limited exposure to CDI. Another example is a project involving military medicine where access to Health Information is required as part of the research. Again there is no intent to disseminate such controlled unclassified information in the research results, but under the 7000 clause it is not considered fundamental research.
DOD/DPAP had asked that we bring such situations to their attention. We responded with these examples.

We also pointed out that the necessary safeguarding or dissemination controls for the particular information can be ensured while still providing for unrestricted dissemination of the research results. Our institutions have a clear understanding and experience with this concept in complying with the export control interpretation of fundamental research that distinguishes the research outputs from either input or conduct. However, this is inconsistent with the revised DFARS rule.

We requested that DOD clarify the DFARS guidance to address these types of situations. We also invited DPAP representatives to meet with the COGR Contracts and Intellectual Property Committee at our meeting next month for further discussion. We are awaiting a response.

BIS Critical Facilities Survey Raises Concerns

We understand that a number of COGR institutions have received this survey. It is difficult if not impossible for universities to respond to some of the questions. Similar issues arose with the BIS Deep Dive Space Industry Survey 5 years ago. At that time COGR arranged a conference call with BIS. However, we understand that there are ongoing discussions with BIS about the need to revise the survey. We also understand that the survey is supposed to have been sent only to institutions with cleared classified research facilities. At this time there does not appear to be a clear COGR role beyond sharing information.

Citizenship Restriction in NNSA Solicitation

The National Nuclear Security Administration (NNSA) recently issued a SSAA solicitation that is for fundamental research, but requires that the PI be a US Person, sponsor approval for all non-US Persons, and submission of a list of non-US person citizenship information as part of the proposal. In discussions with NNSA we understand there was a suggestion that these might become DOE-wide requirements.

COGR called the matter to the attention of the DOE Under Secretary for Science and Engineering. He indicated that NNSA programs do not fall under the Under Secretary for Science and the foreign national approval waiver of DOE Order No. 142.3A requirements does not apply to them. However, to date there has been no similar change in citizenship requirements for other DOE science programs. NNSA will post q's and a's on their website shortly on these requirements.

Association Representatives Meet with USPTO Director

On May 1 COGR participated in a meeting of higher education representatives with Michelle Lee, U.S. Patent and Trademark Office (USPTO) Director. The meeting was held at Ms. Lee's request. She stated an interest (which she also has stated previously) in encouraging more interaction between universities and USPTO. She mentioned two specific areas where input from universities would be welcomed. One is the new Patent Trial and Appeal Board (PTAB) Procedural Reform Initiative. The other is the ongoing Enhanced Patent Quality Initiative. Among other topics she mentioned was the biennial patent fee adjustment process.

Universities did not provide comments on the proposed rulemaking last fall ((81FR68150). She also mentioned two patent subject matter eligibility roundtables held last fall (there was university participation in the second one, held at Stanford). We mentioned the Ed. open licensing requirement, and subsequently furnished a copy of our letter to the Secretary requesting reconsideration of the rule. We also briefly discussed IP responsibilities in the new Administration. Ms. Lee mentioned the White House National Trade Council and the Intellectual Property Enforcement Coordinator in OMB as possible contact points along with Commerce.
COGR will continue to discuss with other associations possible mechanisms to provide more input to USPTO. AUTM may be best suited to lead this effort, with its strong ties to patent practitioners.

March-In Continues to March Along

On April 19 KEI submitted a new petition jointly to HHS and DOD requesting reconsideration of the denial of the petition by the Obama Administration last year for march-in on the prostate cancer drug Xtandi (see June 2016 Meeting Report; related developments were discussed in the September, October and December Updates as well as the February 2017 Meeting Report and April Current Developments). In the petition KEI again asserted that the price of Xtandi is excessive and that march-in is an appropriate remedy. A meeting was requested.

We are not aware of any response to the latest KEI petition. However, recently there have been press reports of high level Administration discussions of possible "recoupment" to NIH of royalties on NIH-funded inventions. Also we understand the state of Louisiana is considering asking HHS both to obtain voluntary licenses to drugs for treatment of hepatitis C that could make medications available at a deep discount to poorer populations, and to invoke 28 USC 1498, which provides for government use of any patented invention for "reasonable compensation." That authority has been used before by the government, particularly DOD.

COGR and several other higher ed. association representatives met several months ago with some of the researchers who are working with Louisiana in developing the request to HHS. Much of that discussion also centered on possible use of Sec. 1498 to address public health concerns about drug availability and pricing. There are a number of challenges associated with use of the authority, such as determining "reasonable" compensation. It should be noted that the statutory provision applies to **all** patents, not just those that are federally-funded. Thus it does not pose the same degree of immediate threat to the Bayh-Dole Act that is raised by march-in. We understand the state of Louisiana may seek public comments before proceeding with a request to HHS.

AAU/APLU Post Tech Transfer Infographic

AAU/APLU have developed a new advocacy infographic and fact sheet *How Tech Transfer Transforms Society*. This one pager illustrates the important role university technology transfer plays in moving ideas from lab to market, and how patent protections are essential to this process. AAU/APLU are making available both a PDF of the general document the associations will be using for advocacy purposes, and also a customizable version.

NIST Issues Funding Opportunity on Technology Commercialization Best Practices

On May 11 NIST posted a Notice of Funding Opportunity (NOFO) for *Maximizing Technology Commercialization of Federal Research Investments through Best Practices at Innovation and Economic Prosperity Universities*. The program will support one project for one year (approximately $300,000), focused on evaluating commercialization practices at universities that have been designated by APLU as Innovation and Economic Prosperity Universities (IEPUs), "for their approaches to innovation and technology commercialization and to review and evaluate existing technology-based collaborations between IEPUs and technology development entities, including Federal research laboratories (FRLs).

NIH Issues Reminder of Need for Approval of Invention Disclosure Extensions

Also on May 11 NIH issued a Notice (NIH-OD-17-065) reminding awardees that NIH approval is required for extensions of time to disclose inventions, elect title or file initial patent

applications. Enhancements have been made to the iEdison system to facilitate approval requests. Included in the Notice is a link to detailed instructions including FAQs.

Research Regulatory Reform

Joint Association Letter to Office of Management and Budget (OMB) Director Mick Mulvaney

COGR, AAU and APLU submitted a joint letter to OMB Director Mick Mulvaney on April 26, 2017 requesting that OMB quickly begin the process of establishing the Research Policy Board mandated by section 2034 of the 21st Century Cures Act. The Cures Act, enacted on December 13, 2016, directs OMB to establish the new Board, and the process by which members of the Board will be appointed, within one year of enactment. As directed by the Cures Act, the Board, consisting of federal and non-federal members--including university representatives and affiliated non-profit organizations--will advise the federal government on the effects of federal research regulations and reporting requirements and recommend ways to modify, streamline and harmonize them. As conceived by the National Academies Committee on Federal Research Regulations and Reporting Requirements in their report, *Optimizing the Nation's Investment in Academic Research*, the Board would also prospectively advise on proposed rules and draft policies and guidance. We understand from an association meeting with OMB staff on May 18 that there is some movement on establishing the Board. COGR will continue to engage with OMB and other federal agencies and offices on the implementation of regulatory reform provisions included in Cures.

Administration Efforts to Reform the Federal Government

OMB Director Mick Mulvaney issued guidance on "Reforming the Federal Government and Reducing the Federal Civilian Workforce" to agency heads on April 13 in follow-up to a March 13 Executive Order. The Executive Office of the President is seeking feedback from the public on these reform efforts. OMB staff indicated in recent conversations that in addition to ideas for restructuring the federal government, COGR and others should submit proposed regulatory reforms to the site. As reported previously, the Administration issued Executive Order 13777 on February 24 enforcing and augmenting existing Executive Orders involving retrospective review of federal agency regulations in a stated effort to reduce regulatory burden and enforce regulatory reform. COGR recently submitted proposals for reforming research regulations, including elimination and modification, to White House staff at their request. These and other proposals developed by COGR will be submitted to this website as suggested by OMB. Proposals for reform will also be posted to the COGR website and regularly updated.

NIH Actions to Stabilize the Biomedical Research Enterprise

On May 2 NIH hosted a call to discuss how the agency plans to stabilize the biomedical research enterprise. A recording of the May 2 call is available for those interested by sending an email to nmb@od.nih.gov.

In response to language in section 2021 of the 21st Century Cures Act, *Investing in the Next Generation of Researchers*, which calls for "improving opportunities for new researchers and promoting earlier research independence," as well as concern for flat or negative funding trends for early and mid-career investigators and a large proportion of NIH funding currently being directed to a smaller number of more established investigators, NIH discussed plans to cap

funding to any individual investigator with three R01s or their equivalent. How this will be accomplished is still being worked out. Investigators would be assigned scores by NIH using a new tool, the Grant Support Index (GSI), which is still in the works. An R01 might equal seven points with a cap at 21 points (three R01s or equivalent). The GSI was previously referred to as the Research Commitment Index (RCI) and described in a January 26 blog post which provides a sense for how the scores could be derived. However, the blog has since been updated to note that "*the table used on this page does not reflect the finalized Grant Support Index values, discussed in the May 2 2017 blog, "Implementing Limits on Grant Support to Strengthen the Biomedical Research Workforce." Community input will be used in developing the final Grant Support Index."* This initiative, which could potentially be implemented for applications being accepted in September 2017, will not affect current funding and is expected to free up approximately $500 - $650 million in funding for 1500-1600 new awards.

Dr. Collins released a statement about the proposed change on May 2 and NIH Deputy Director for Extramural Research Mike Lauer posted a blog on this topic which has received over 350 comments to date. Dr. Lauer is scheduled to discuss the GSI at the Council of Councils Meeting on May 26 and will discuss current thinking on the GSI in a meeting with COGR committee members on June 7.

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

The NIH Office of Science Policy will hold a workshop on the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* July 18-19 in Rockville, MD. The purpose is to examine the "current biosafety oversight framework, and discuss the future direction of biosafety oversight." The Guidelines are 40 years old, if written today, what would they look like? "Where would they fit within the current policy and regulatory landscape? What would be the role of the Recombinant DNA Advisory Committee (RAC)?" Those interested in attending can register via the workshop website.

Human Subjects Research

Secretary's Advisory Committee on Human Research Protections (SACHRP) Meeting

The HHS Secretary's Advisory Committee on Human Research Protections is meeting May 25-26. A link to the agenda and webcast is available here. SACHRP will discuss the final revised Common Rule, in particular, the effective date provisions, exemptions involving benign behavioral interventions, the expedited review list and broad consent. In opening remarks, Jerry Menikoff, Director, Office for Human Research Protections (OHRP), emphasized the importance of SACHRP's comments on the notice of proposed rulemaking in shaping the outcome of the final rule. There was discussion on the new administration's review of rules published at the end of the last administration. COGR has previously reported on the January 20 White House memorandum to freeze new or pending regulations to allow the new administration time to review them. Dr. Menikoff indicated that the Common Rule is part of that administrative review, although there are no indications that specific concerns have been raised with respect to the rule. OHRP hopes that they will hear soon that the review has been completed but had no information on the timeline. One possible outcome could be a delay in the implementation of the rule.

Dr. Menikoff indicated that there seemed to be some confusion about the current implementation date. He reiterated that the current Common Rule remains in effect until the revised rule is implemented on January 19, 2018. Provisions of the new rule cannot be implemented unless they are consistent with the current rule (e.g., adding information to the consent form).

NIH e-Protocol Writing Tool and Final NIH-FDA Clinical Trial Template

NIH issued a notice on May 2 announcing the release of the Final NIH-FDA Clinical Trial Template for Phase 2 and 3 IND/IDE Studies. NIH also released a Clinical e-Protocol Writing Tool to facilitate the development of these protocols. The tool allows for collaborative writing and review.

COGR Submits Comments and Questions on NIH Single IRB FAQs

COGR submitted comments and questions to NIH on March 16 on the document "NIH Single IRB Policy FAQs for [the] Extramural Community." Comments are indicated throughout the document in red italic text. In an email dated April 18, NIH representatives indicated that NIH has revised the FAQs based on feedback from COGR and others and expects to upload a revised version in a few weeks.

DATA Act

The Treasury Department launched the Beta.USAspending.gov website on May 9. This is a new version of USAspending.gov that should allow the public to more clearly track how tax dollars are spent. The "Beta" site will run concurrently with the existing version of the USAspending.gov website over the summer to minimize disruptions, allow for additional changes and corrections and to add historical data to the beta site. OMB expects to issue its report to Congress on the DATA Act Section 5 pilot, which included opportunities to reduce regulatory/administrative burden, in early August.

Audit

National Science Board Committee on Oversight

The National Science Board met May 9-10. The archived webcasts are available here.
The NSB Committee on Oversight briefly discussed the NSF OIG semiannual report to Congress. The Board is in the process of reviewing the report and the NSF management response and plans to submit both to Congress by the end of May. Few specifics were discussed, among them, concerns about a decline in the quality of single audit and an indication that the semiannual reports will now include a table with research misconduct statistics. NSF OIG staff has been spending more of their time on reports of fabrication and falsification although cases of misconduct generally are not increasing as noted by NSB Chair Maria Zuber. The OIG has noted that more investigators themselves are conducting plagiarism, although the total number of cases is not increasing. Investigators have suggested that they weren't aware that they were engaging in plagiarism and the OIG is considering how they might provide information to the community to assist universities in educating research staff and preventing misconduct. The OIG intends to publish a report in the next few weeks on a review of how officials at over 50 universities have implemented required responsible conduct of research training. NSF implemented the requirement as directed by the America COMPETES Act. The OIG will also issue reports on

negotiations of the NEON project and on NSF internal controls over conflict of interest for rotators in the next few weeks.

NSF Chief Financial Officer Marti Rubenstein reported on the implementation of the DATA Act. The Treasury department's beta site Beta.USAspending.gov went live on May 9. As required by the DATA Act it expands reporting elements such that 100% of NSF appropriations and expenditures are detailed on the website. The public will be able to view federal spending at the zip code level. NSF is currently identifying issues and bugs and reporting them to Treasury. The new beta site has data from the most recent quarter. Historical data will be added to the site by the fall.

Stevens Amendment

As a result of the Ivy League Flunkers report, certain members of the US Senate have asked that the GAO launch an investigation on taxpayer transparency violations related to Public Law 114-113 which states the following:

> "When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state—(1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources."

The Senate letter to the GAO concluded that many federal grant recipients failed to disclose the percentage and dollar amount of total costs of a USG funded project.
COGR would like your feedback regarding compliance with this law and will continue to monitor the status as more information is made available. Please submit your comments to jbendall@cogr.edu

Public Access Working Group

As previously mentioned in the April 2017 Current Updates, The AAU and APLU Public Access Working Group (PAWG) held a meeting on April 11-12 that hosted representatives from the NIH and the NSF for the purposes of engaging in consensus building around data access issues. To date, the group has developed both agency and institutional guidance that will be released in the coming months and is considering a Whitepaper as a potential deliverable. Stay tuned for further updates as progress continues.

National Academies Report on Research Integrity

On April 11th, after five years in the works, the NRC released its new, "Fostering Integrity in Research" report, providing recommendations and best practices following its previous report in 1992. The NRC was challenged with looking at the impact on changing trends in scientific research, modern day science, and advantages and disadvantages in terms of educational efforts. The NRC committee gathered stakeholder input from five groups: researchers, research institutions, research sponsors, journals, and societies ultimately producing checklists for each.

Among the many recommendations including but not limited to providing mentoring training for faculty, expanding RCR to all faculty, providing better tracking on RCR outcomes (both positive and negative), and improved RCR statistics, the Committee suggest the creation of a Research Integrity and Advisory Board (RIAB). COGR will be hosting senior executives, including the Chair of the NRC Committee at its upcoming meeting for a panel discussion that will provide an overview and various perspectives of the report.

NIH Reporting on Preprints

As a reminder, May 25th kicks off the NIH's Guide notice on "Reporting Preprints and Other Interim Research Products." Citing Interim research products is not a mandatory requirement however is encouraged. The NIH reminds applicants and awardees in its notice to list the interim research product type in the citation and to explicitly state in the preprint text that the work IS NOT peer reviewed.

COGR recently followed up with Dr. Neil Thakur upon release of the guide notice with a few follow-up questions. As a result, no additional guidance is planned for applicants, however guidance is being considered for peer reviewers and scientific review officers. COGR was concerned about the negative impact this might have on investigators who've just received their first R01 coupled with the time it takes to get published. We fear that investigators may hold off on submitting a publication instead listing various preprints which peer reviewers may perceive as less advantageous from those who have published articles. Dr. Thakur indicated that this shouldn't be perceived as a negative by a peer reviewer and would consider adding this to the peer reviewer guidance. NIH will monitor the workload this new guidance creates and will have more statistics of its findings in the coming months. COGR will consider inviting Dr. Thakur to the October meeting for a status update.

Update to RTCs Agency Implementation Statements

On May 4th, the NSF released a revised Agency Implementation Statement updating the US. Department of Homeland Security's implementation date of the Research Terms to October 1, 2017. The next agency to follow prior to October is the US. Department of Agriculture/National Institute of Food and Agriculture (NIFA) beginning June 1, 2017.

NSF Seeks Comments on Revised Proposal & Award Policies and Procedures Guide (PAPPG)

On May 24, 2017, the NSF published a notice in the Federal Register announcing the availability for comment the revised draft *Proposal & Award Policies & Procedures Guide (PAPPG)*. The Foundation is accepting comments by regular mail or email from the external community until July 24, 2017. As a courtesy to the community and for the purposes of facilitating review, NSF has once again highlighted in yellow with explanatory comments throughout the document clarification, changes or additional where appropriate. COGR seeks your feedback for a written response to the NSF no later than July 13th and will respond on or before July 24, 2017. Please submit your comments to jbendall@cogr.edu.

National Science Advisory Board on Biosecurity (NSABB) Discusses DURC & Gain of Function Research

The NSABB hosted a public teleconference May 11th to present the Blue Ribbon Panel draft report on the 2014 small pox incident at the National Institutes of Health Bethesda MD campus.

During this meeting, stakeholders were also offered the opportunity to engage in the USG policy on DURC. Since the time that the government put a pause on gain-of-function (GOF) research for pathogens that could potentially create a national pandemic, the NRC and the NSABB have developed guidance for federal agencies that would lift the pause of GOF studies if such guidance is adopted and followed. OSTP released this guidance in January 2017.

A few things to note from the guidance and teleconference:

- The NSABB voted and received full consensus to send the draft Blue Ribbon report to NIH leadership;
- NIH will be releasing a Guide Notice soon along with FAQ's on GOF guidance.
- The purpose of the NSABB teleconference was to also finalize agenda for the next stakeholder meeting Sept 25-26 in Chicago on DURC. The meeting will be open to the public, more details to follow. The NSABB will re-convene after September meeting.
- An excellent summary of critical contributing factors for the small pox incident can be found in Table 2, page 26 of the report. Factors include lack of policy for abandoned materials housed in labs, lack of clarity on oversight between FDA and NIH, lack of proper inventories, lack of responsibility for materials, **improper packaging by research institutions, leadership at the highest levels must hold researchers responsible, institutions should conduct clean sweeps, etc.**
- The OSTP Guidance is not binding at this time

Click here for additional meeting materials.

Additionally the National Academies hosted a workshop on Committee on Dual Use Research of Concern: Options for Future Management for the purposes of exploring options for managing and communicating DURC results. The report is pending but expected to be released in the summer.

For concerns around DURC or GOF, please contact Jackie Bendall at jbendall@cogr.edu.