COGR
Council On Governmental Relations
An Association of Research Institutions

MAY 2019 UPDATE

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Foreign Influence

Correspondence Between Senator Grassley and Federal Research Funding Agencies

A letter from Senator Chuck Grassley to NSF Director France Cordova dated April 15, 2019 includes a number of questions to "better understand NSF's current process for protecting taxpayer-funded research from foreign threats and to assess any forthcoming changes." COGR reported on a similar letter to NIH and the agency's response in the February 2019 COGR update. A letter has also been sent to the Department of Defense.

The NSF letter inquires about background checks on researchers and institutions, rules and procedures that exist to prevent foreign actors from acquiring or duplicating NSF-funded research data, audits and investigations of violations, enforcement mechanisms available to the agency, a list of entities under investigation, and the extent to which NSF engages with the Departments of Justice and State and the intelligence community to track, assess and analyze foreign threats.

In a response obtained by Science magazine and dated April 26, 2019, NSF Chief Operating Officer Fleming Crim noted the agency's engagement in international collaborations that are equitable and where there is reciprocity, while also noting efforts the agency has undertaken to maintain the integrity of federally funded research. The letter notes compliance requirements and reviews that may be conducted for receipt of federal awards and stricter requirements for domestic institutions conducting research at foreign campuses. The letter also describes the role of the NSF OIG in conducting audits, reviews and investigations of potential violations of rules and suggests that the OIG will respond to pertinent questions from Senator Grassley in a separate letter.

Remarks on Foreign Influence at the NIH Senate Budget Hearing

In an April 11 hearing on the NIH fiscal year 2020 budget request, Senator Blunt asked NIH Director Dr. Francis Collins about efforts the agency has made to address foreign involvement in U.S. research, such as duplicate labs in other countries and inappropriate sharing of information (22:18). Dr. Collins indicated that there have been "egregious instances" where NIH funding has been taken advantage of and that there were greater than 55 ongoing investigations at 55 individual institutions. These investigations were reported to have led to some investigators being fired from their institution or asked to leave. Dr. Collins suggested that institutions are recognizing that there is a problem and working in partnership with NIH to address these issues. Both Senator Blunt and Dr. Collins noted the benefits to the U.S. of training and retaining foreign talent and the importance of diversity in research.

Department of Defense Activities Related to Science and Security

The most significant update from what we previously reported is the issuance of a memorandum on March 20 from the Undersecretary of Defense on the further implementation of Sec. 1286 of the FY '19 NDAA. The memorandum requires proposers for all non-procurement transactions to submit detailed information on other current and pending support for all "key personnel." The information is to be included in a Senior Key Person Profile form included in all Funding Opportunity Notices (NFOs). The requirement was effective for NFOs 30 business days after issuance of the memorandum.

The memo cites (incorrectly) use of OMB R&R Form 4040-0001 (Senior/Key Person Profile). The form and instructions including the definition of "Senior/Key Person" may be found here. Our understanding is that DOD use of this form previously was restricted to certain medical research programs. According to the memorandum, "this information will be used to support protection of intellectual property, controlled information, key personnel, and information about critical technologies relevant to national security. Additionally, this information will be used to limit undue influence, including foreign talent programs, by countries that desire to exploit United States' technology within the DoD research, science and technology, and innovation enterprise."

No further information is available on the status of the pilot project to collect detailed personnel information on all personnel participating in DOD-funded projects that was discussed in our February Meeting Report.

Department of Energy Activities Related to Science and Security

The February Update discussed the DOE February 1 policy statement prohibiting DOE federal and contractor (including grantee) personnel from participating in talent recruitment programs sponsored by countries determined by DOE to be seeking to exploit U.S. scientific and technological expertise. We understand that DOE implementation of the policy for extramural researchers is proceeding slowly. The initial focus apparently will be on contractors that operate DOE lab user facilities. Broader implementation for grantees and contractors is expected to take some time.

Future of Jason Group Uncertain

The Jason group is a network of distinguished academic scientists who informally advise the government on sensitive S&T matters, mostly military-related. It was established during the Cold War era and consists of 30-60 members. Most of its work typically has been done over the summer. It is funded through a contract with the MITRE Corporation.

Recent news reports have indicated that DOD was about to let the MITRE contract expire. However, in late April it was announced that the DOE National Nuclear Security Administration was awarding a short-term contract to MITRE to provide additional funding for the Jason group. Plans are for the Jason group to do approximately a dozen studies for DOD and DOE this summer. It also has been reported that NSF has reached out to the Jason group for a possible study of the foreign threat issue. The contract extension is through the end of January 2020.

Legislation Introduced to Impose New China-Related Visa Restrictions

On May 14 several Republican Senators introduced a bill (S. 1451- *People's Liberation Army (PLA) Visa Security Act* that would ban the issuance of visas to aliens employed, funded or sponsored by scientific institutions affiliated with the PLA. An annual list of such institutions would be published. Existing F or J visas of such individuals also would be revoked. The bill also would require a Security Advisory Opinion (Visa Mantis) review of any Chinese national who applies for a visa for research or graduate study in any field related to items controlled under the Commerce Export Administration Regulations.

We have long advocated the view that the primary vetting of foreign students and visitors to U.S. institutions should be done as part of the visa process. The bill appears consistent with that view. If enacted there may be implementation concerns, such as the basis for the institution listing and the effect on students and researchers already in the U.S. (although with existing Visa Mantis reviews the number of affiliated individuals presumably should not be large). However, it also has the potential to reduce institutions' role in the vetting process for foreign students and researchers.

Department of Education, Section 117 of the Higher Education Act

As evidence of foreign influence continues to rise, institutions are becoming increasingly sensitive to ensuring policies and procedures are being followed and compliance with laws and regulations are being met. Section 117 of the Higher Education Act requires institutions to file disclosures when an institution receives gifts or enters into a contract with a foreign source with an aggregate value of $250,000 or more per calendar year attributable to a particular country. The term "foreign source" in the statute is defined as "(A) a foreign government, including an agency of a foreign government; (B) a legal entity, governmental or otherwise, created solely under the laws of a foreign state or states; (C) an individual who is not a citizen or a national of the United States; and (D) an agent, including a subsidiary or affiliate of a foreign legal entity, acting on behalf of a foreign source."

As reported in the February Meeting report, the American Council on Education (ACE) sent a letter in January to the Department of Education seeking clarity on four issues. In partnership with ACE and the Association of American Universities (AAU), COGR attended a recent meeting with Department of Education representatives to discuss the issues raised in the ACE letter and reiterate the importance for clear guidance going forward. During this meeting we were told by the Department that guidance would be issued, however no date was given. COGR will continue to stay on top of this and will provide updates as necessary. For additional information, please contact Jackie Bendall at jbendall@cogr.edu

GAO Schedules Campus Visits as Part of Export Control Compliance Study

The February Meeting Report discussed the new GAO study of U.S. universities' implementation of export control regulations. It mentioned that COGR and AAU representatives had met with GAO staff involved in the study. Discussion centered on roles and responsibilities for export control compliance at universities and challenges that universities face. The GAO staff subsequently attended the AUECO annual meeting in March and held a number of one-on-one discussions with AUECO members, in addition to attending meeting sessions.

GAO now has arranged a number of campus visits and by the time you read this, will have actually had some meetings. They have developed a series of questions for various groups, including administrators, export control and facility security officers, designated officials and contracts and grants staff. The questions include roles and responsibilities, resources, sources of guidance, training and challenges. At each visit they also plan to meet with a group of faculty researchers. Fundamental research will be a topic for discussion with each group.

We understand that GAO has invited participants to raise other issues, including those pertaining to foreign influence. When we first met with GAO staff, we repeatedly encouraged them to maintain a focus on export

controls consistent with their charge. We were concerned that the discussion often spilled over into discussion of larger science and security issues. Apparently, that continues to be the case.

NIST Releases Final ROI Green Paper

On April 24 NIST released the final version of the Green Paper on the Return on Investment (ROI) Initiative, *Unleashing American Innovation*.

The final version contains relatively few changes from the previous draft. The draft version had responded positively to many of our comments and recommendations on the ROI RFI (see COGR December Update).

The principal change is to replace the *Intended Actions* in the draft version with *Findings*. Presumably this was done to provide a basis for subsequent implementing legislative or regulatory proposals. One positive change is deletion of the previous Intended Action 3 to extend the domestic U.S. manufacturing requirement to nonexclusive licenses. AUTM among others had strongly opposed this proposal. We had opposed the previous recommendation to establish a new "Research Transaction Authority" mechanism, which also has been deleted. However, the final version unfortunately contains a discussion under *Finding 9* of expanding OTA authority to other agencies. COGR long has been concerned about the proliferation of OTAs. While a written confirmation would be required from a procurement official that existing funding mechanisms could not achieve the goals of a particular R&D partnership transaction, it is not clear how or by whom this would be policed. *Finding 2* discusses the need to clarify the use of march-in rights, but it is less specific than the draft on the inappropriateness of their use to control the market price of products resulting from federally funded R&D. (In contrast, the discussion of the scope of the Bayh-Dole Act government use license under *Finding 1* remains very specific that it should not extend to third party distribution but only direct government use of the products of federal R&D.)

We understand NIST plans to submit legislative and regulatory packages to implement the Green Paper, but the timetable is not clear. There will be an opportunity for public comment on the packages. Even the "toned down" Finding on march-in rights has received strong criticism from consumer and public interest groups (see e.g. here and here).

The final version also contains a Finding (*Finding 13*) on the need to improve federal invention reporting requirements and systems. We understand informally that NIH and NIST may have completed the handover of iEdison invention reporting system responsibilities from NIH to NIST. The COGR CIP Committee plans to meet with a NIST representative at our June meeting to discuss the importance of stakeholder input to any system redesign.

Drug Pricing: Flurry of Legislative Activity Continues

We have been reporting on the recent legislative activities regarding drug pricing. We have now identified 26 bills that have been introduced in Congress that address some aspect of drug pricing. However, the focus of the more recent bills has tended to move away from remedies such as compulsory licensing of patents.

Both the House and Senate Judiciary Committee held hearings the week of May 6 that involved drug pricing issues. On May 7, the Senate Judiciary Committee held a hearing "Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition." The focus was on patent issues such as "pay for

delay" (settlements of patent infringement suits between generic drug and brand name drug manufacturers where the generic drug maker agrees to delay release of their drug for compensation), patent thickets, and "evergreening." There appeared little consensus on approaches. On May 9 the House Judiciary Committee held an oversight hearing on USPTO at which drug pricing issues also were mentioned.

Given the discord among legislators on the proper approaches it is unclear what may ultimately emerge. Some commentators believe House bills may be introduced shortly that bundle drug pricing measures with measures aimed at strengthening the Affordable Care Act.

Patent Law Developments.

Section 101. Discussions continue with Congressional staff about possible changes to Sec. 101 of the patent law (35 USC 101) on patent subject matter eligibility. The February Meeting Report discussed this issue and the comments of the higher education associations to USPTO. Sen. Tillis' Roundtable discussions now have resulted in a draft framework for a revision to Sec. 101. The plan is to introduce bipartisan legislation based on this framework early in the summer. We are continuing to discuss this issue with the assistance of several AAU university patent counsels.

Serial IPR Petitions. Senators Tillis and Coons sent a letter to USPTO about abusive serial *interpartes* review (IPR) petitions. The problem arises from multiple follow-on petitions attacking the same patent claims and asserting new or modified arguments. The Senators urged USPTO to find solutions to this problem. While we have not been active in discussions of this issue, we understand that some COGR member institutions have experienced problems with such serial petitions.

Sovereign Immunity. The September Update discussed the Federal Circuit decision finding against claims by a Native American tribe of sovereign immunity from patent challenges in IPR proceedings. On April 15 the tribe's appeal to the Supreme Court was denied. The result is that tribal sovereign immunity cannot be asserted in IPR proceedings. The implications for state sovereign immunity are unclear but as we noted in September, the Federal Circuit had stated "While we recognize there are many parallels, we leave for another day the question of whether there is any reason to treat state sovereign immunity differently."

Research Regulatory Reform

Exploring Regulatory Barriers to Innovative Academic Research

On April 2, 2019, the George Washington University Regulatory Studies Center held a one-day meeting in Washington, DC, to address Regulatory Barriers to Academic Research. The meeting was led by Bridget Dooling, a Research Professor at the Center, Susan Dudley, Center Director and a former Administrator with the White House Office of Information and Regulatory Affairs, and Dr. Andrew Morris, Dean of the School of Innovation, Texas A&M University. Staff from the Center will speak at the June 6-7, 2019 COGR meeting about the regulatory process and challenges specific to federally funded academic research, as well as potential outcomes and recommendations from the April 2 meeting to reduce regulatory barriers and create efficiencies in the oversight of federally funded research.

Research Regulatory Reform Activities of the Research Business Models Working Group

At the June 2018 COGR meeting, members of the Research Business Models Working Group discussed the group's May 25, 2018 report to Congress, *Reducing Federal Administrative and Regulatory Burdens on Research*, and planned initiatives. Members of the working group have been invited to the June 6-7, 2019 COGR meeting to provide an update on the status of these initiatives, including an anticipated report to Congress.

New National Science and Technology Council Joint Committee in Support of U.S. Research

On May 6, 2019, the White House Office of Science and Technology Policy announced the creation of a new joint committee of the National Science and Technology Council (NSTC). The committee, led by the NSTC Committees on Science and Science and Technology, will examine administrative burdens on federally funded research, research rigor and integrity, inclusive research settings and concerns about foreign influence and the protection of research assets.

OMB Guidance on Compliance with the Congressional Review Act

On April 11, 2019, Acting OMB Director Russell Vought sent guidance on compliance with the Congressional Review Act (CRA) to the heads of federal departments and agencies. The memorandum "reaffirms the broad applicability of the CRA to all Federal agencies and a wide range of rules; sets forth a process for OIRA to make major determinations" that took full effect on May 11, 2019; and "provides guidance for the type of analysis required for these determinations." Per the memo, "the CRA applies to more than just notice-and-comment rules; it also encompasses a wide range of other regulatory actions, including, *inter alia*, guidance documents, general statements of policy, and interpretive rules." "The CRA requires Federal agencies to submit a rule to Congress along with a report that includes OIRA's major determination and the proposed effective date of the rule."

The memo indicates that OIRA "does not consistently receive from agencies the information necessary to determine whether a rule is major" as some actions "are not submitted to OIRA through the centralized review process of Executive Order 12866." OIRA is therefore "instituting a systematic process to determine whether rules that would not be submitted to OIRA under Executive Order 12866 are major." That process is outlined in the memo. It does not explicitly refer to other regulatory actions.

Human Subjects Research

NIH Finalizes amendments to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

In an April 26, 2019, Federal Register notice, NIH finalized revisions to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines). The changes had previously been outlined in a notice dated August 17, 2018. COGR and other higher education associations submitted comments in response to the proposed changes.

In the revised guidelines, NIH eliminated human gene transfer (HGT) research protocol submission and reporting requirements to the NIH, and individual HGT protocol review by the Recombinant DNA Advisory Committee (RAC), in an effort to avoid duplicative oversight with the FDA; modified the role of Institutional Biosafety

Committees (IBCs) while noting that the roles and responsibilities of IBCs will be further considered; and eliminated the role of the RAC in HGT and biosafety.

NIH has provided a link to the full comments submitted and the Federal Register notice includes responses from the agency. Among the comments submitted by higher education associations was a recommendation that NIH adapt Appendix M-1-A (4; a-f) as guidance for HGT Risk Assessments. NIH eliminated Appendix M while noting that "Because NIH/OSP sometimes issues guidance or points to consider on specific topics relevant to the NIH Guidelines when requested by the community, NIH/OSP will make available the parts of Appendix M–1–A that are still relevant, in light of the final changes to the NIH Guidelines, *as a separate resource* [emphasis added] for institutions, IBCs, and investigators on the types of information that institutions and IBCs may wish to consider in the review of HGT protocols." The higher ed letter also suggested that "A revised Appendix M should include specific instruction to local IBCs to develop a collaborative process with their IRB of record to ensure input and oversight from both the IBC and IRB perspectives on SAE reporting and informed consent." In the Federal Register notice, NIH suggests that "institutions may expand the scope of IBC review of protocols and safety reports beyond that outlined by the NIH Guidelines, but in general, review of adverse events and informed consent documents is the purview of other oversight entities." The notice indicates that the RAC will be renamed the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC), and that NIH will release a revised charter of the committee. It also notes that "the NIH will continue to consult, as needed, with the NExTRAC or other relevant advisory committees regarding issues of emerging biotechnologies, biosafety, or when proposing changes to the NIH Guidelines or other relevant policies." Regarding establishing a point of contact to address questions that previously would have been considered by the RAC, the notice indicates that "NIH/OSP continues to serve as a resource for guidance, which it provides to investigators, institutions, biosafety professionals, and members of the public on a daily basis" and suggests that questions should continue to be directed to NIHGuidelines@od.nih.gov.

Comments from COGR and other higher education associations included a recommendation for a comprehensive review of the NIH Guidelines by a task-force of scientists from the regulated community with appropriate expertise to ensure that the Guidelines appropriately address relevant newly emerged and emerging technologies. Per the notice, "NIH is undertaking a long-term effort to consider further updates to the NIH Guidelines, building upon the July 2017 workshop, NIH Guidelines: Honoring the Past, Charting the Future. The NIH will continue to solicit input and facilitate transparent discourse to consider these and similar issues." Specific details on the individual revisions/amendments to the Guidelines can be found in the notice.

Higher Education Associations Send a Letter to OHRP Regarding Legal Interpretations of Compliance with the Single IRB Requirements Under the Revised Common Rule

COGR and other higher education associations sent a letter to Dr. Jerry Menikoff, Director of the HHS Office for Human Research Protections, on May 1, 2019, expressing concern about recent OHRP interpretations of compliance dates for cooperative research under the revised Common Rule. As noted in the letter, "the final revised Common Rule (2018 Requirements) indicates that the rule is effective July 19, 2018, with a general compliance date of January 21, 2019, and a compliance date of January 20, 2020 for cooperative research. The research community understood this to mean that studies approved by an IRB on or after January 20, 2020, would be subject to the requirements for cooperative research." However, recent email correspondence from OHRP staff

has indicated that cooperative research studies subject to the 2018 Requirements are required to come into compliance beginning January 20, 2020, such that studies that have already been approved by local IRBs and may be ongoing would need to be identified, paused, and undergo a new single IRB review.

The letter notes that this is contrary to the language in the preamble and has not been previously communicated in presentations and guidance. The letter asks that HHS reassess this recent interpretation or address the issue by exempting cooperative research projects approved after the Common Rule's effective date but prior to the compliance date from single IRB review as permitted by Section 114(b)(2)(ii) of the revised Common Rule. COGR will continue to seek a resolution.

NIH Releases a New Template for Human Behavioral and Social Science Research

NIH released a new template tailored to clinical trials with a behavioral or social intervention or manipulation on March 28, 2019.The template is based on the NIH-FDA Phase 2/3 IND-IDE Clinical Trial Template. It has been integrated into the NIH Clinical E-Protocol Writing Tool. Use of the template is voluntary.

The protocol template, NIH Notice and a related blog post can be found here under "Clinical Trial E-Protocol Tools and Template Documents." The blog post discusses suggested benefits of template use and requests feedback on user experience. Questions about the template can be sent to the NIH Office of Science Policy at SciencePolicy@od.nih.gov.

Research Involving Animals

Staffing Changes in NIH OLAW's Division of Policy and Education (DPE)

The NIH Office of Laboratory Animal Welfare has reported that Neera Gopee, DVM, PhD, has been appointed the Director of DPE. Dr. Gopee, who joined OLAW in 2016, has replaced Susan Silk. Susan retired at the end of 2018 but continues to direct the Interagency Collaborative Animal Research Education (ICARE) Project under contract to OLAW. The announcement also indicates that Dr. Nicolette Petervary, VMD, has joined DPE as a Veterinary Medical Officer.

COGR-FASEB Webinars on Institutional Administrative Requirements for Animal Research and Federal Agency Responses to Webinar Questions

We previously reported on two webinars conducted by COGR and the Federation of American Societies for Experimental Biology (FASEB) which included the participation of staff from research institutions and from NIH OLAW and the USDA APHIS. The first webinar, *Streamlining Institutional Requirements for Animal Research*, which targeted research and IACUC administrators, was held on March 18. The second, *Understanding Federal Versus Institutional Requirements for Animal Research*, was more specific to investigators and was held on March 25. The archived webinars can be found here.

The webinars highlighted findings from a survey of COGR members on actions that institutions can take to reduce administrative burden associated with animal research and institutional animal care and use committees. The webinars addressed areas of the report where institutions had not taken action and where a review of federal requirements and flexibilities might facilitate a change in practice. This included areas such as protocol review, animal numbers, literature searches, and pain and distress classifications.

The survey results suggested that institutions are more likely to take action to reduce administrative burden when federal agencies provide clear directives and address uncertainty, and when agency regulations are harmonized. COGR has provided NIH, USDA, and FDA with the summary results of the survey to assist in their efforts to reduce administrative burden. In addition, webinar participants, including federal agency staff from NIH OLAW and USDA APHIS, have provided written responses posed during the webinar. The questions and responses can be found here.

NIH Proposed Information Collections

On April 12, 2019, NIH published a Federal Register notice on proposed information collections to be submitted to OMB for review. Per the notice, "Starting in January 2020, NIH will require applicants and recipients to address Human Fetal Tissue requirements within the SF-424 R&R and the Research Performance Progress Report (RPPR) due to Congressional ((Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2)) and Department of Health and Human Services (45 CFR 46.204and 46.206) mandates regarding human fetal tissue research. Applicants and recipients will be required to comply with Federal and state laws concerning the acquisition of human fetal tissue (including cell lines) as well as include a concise description of the proposed characteristics of the human fetal cells/tissue outlining the procurement budget details, and how the applicants/recipients will document the processes for how they will use the human fetal tissues and cells." The notice also refers to "collection of more structured information" to "facilitate NIH's development of data systems to facilitate oversight of clinical trials as well as understand where gaps in the research portfolio may exist." The public has 60 days to comment.

National Academies Report on Reproducibility and Replicability in Science

The National Academies Committee on Reproducibility and Replicability in Science released its report and recommendations on May 7, 2019. Harvey Fineberg, Chair of the committee, led a webinar to present the findings and recommendations. Dr. Fineberg suggested at the outset that there is not a reproducibility crisis, but that this is also not a time for complacency and that improvements are needed.

Noting inconsistencies across fields, the committee proposed definitions of *reproducibility* and *replicability*. The committee recommended that NSF "in harmony with other funders, endorse or create code and data repositories and "consider funding tools, training, and activities to promote computational reproducibility." The committee highlighted the role of meta-analyses and research synthesis in the assessment of replicability. The report includes detailed recommendations regarding transparent methodological reporting and recommends "training in the proper use of statistical analysis and inference." Members of the committee suggested during the webinar that there is growing adoption of reproducible science, including among journals and through the use of badges. The committee also noted challenges, including inadequate record keeping and lack of resources or incentive to work in a reproducible way. It was also suggested that with different tools and computational environments, capturing information in a lab notebook is no longer feasible. and that investments in infrastructure are needed to support reproducibility.

The committee assessed public confidence in science as part of its charge. Citing NSF data, it notes high-levels and sustained trust in scientists and science as an institution, and stable, if not wide-spread, knowledge of the

scientific process and methods. The committee suggests that it is unclear whether the idea of a reproducibility "crisis" has "registered very deeply with the general population."

Detailed recommendations can be found in the report. David Allison, Dean of The Indiana University School of Public Health-Bloomington and a member of the committee, will present the committee's findings and recommendations at the June 6-7 COGR meeting.

Nonprofit Funder – Research Institution Partnership May 22 Meeting

COGR and the Health Research Alliance (HRA) will hold a day-long workshop of the Nonprofit Funder – Research Institution (NFRI) Partnership on May 22, 2019 in Washington, DC. The workshop will facilitate ongoing discussions and efforts around four key elements of foundation-institution relations: (1) Streamlining administrative requirements; (2) Indirect costs/research project support costs; (3) Intellectual property and tech transfer issues; and (4) overall principles for successful partnerships between nonprofit funders and research institutions. This is the third in-person NFRI partnership meeting. The draft agenda for the May 22 meeting can be found here. The link to registration can be found here. Details on current and planned partnership initiatives were presented at the February 2019 COGR meeting and included in the meeting report.

National Science Board May 2019 Meeting

The National Science Board is scheduled to meet May 14-15. The agenda for the meeting can be found here and a link to register for a live webcast here.

The Board is seeking nominations for its class of 2020-2026. Information regarding nominations can be found here.

Combatting Sexual Harassment in Science

COGR will once again host representatives from the National Science Foundation (NSF) at the June meeting to discuss the latest developments since last October's implementation of the term and condition on sexual harassment. COGR also anticipates having a representative from the National Institutes of Health (NIH) to discuss new developments underway at the NIH including a new website portal for filing complaints of sexual harassment and the latest developments from the Advisory Committee to the Director's (ACD) working group on sexual harassment.

On May 16th, NIH is having a public listening session put on by the ACD working group on Changing the Culture to End Sexual Harassment. The working group convened for its first meeting in February. Deliverables from the group will include an interim report to Dr. Collins in June and final report in December 2019. During the public listening session, registrants will hear firsthand from women who have been subjected to harassment or gender discrimination as they provide input for the Working Group as it develops its recommendations. Click here for additional information regarding the public session. The session will also be videocast and archived.

Confidentiality Scenarios Related to Responding to Allegations of Research Misconduct

The COGR ad hoc working group on Confidentiality Issues in Research Misconduct has submitted the aforementioned confidentiality scenarios to the Board for final review and input before posting it to the COGR website. Members will be notified via the listserv once the document becomes available. COGR especially thanks the Association of Research Integrity Officers (ARIO) and the following members of the work group for their dedication and support of the work product: Ann Pollack - UCLA (Chair), Grace-Fisher Adams - UCLA, Sheila Garrity - George Washington University, Lauran Qualkenbush - Northwestern University, Emily Sobiecki - Partners, Gretchen Brodnicki - Harvard, Naomi Schrag - Columbia, Gerri Sands - Fred Hutchinson Cancer Research Center, Dave King - University of Kentucky, Kristen West - Emory University, Eric Everett - UNC, Lois Brako - University of Michigan, Ray Hutchinson - University of Michigan, Pat Ward - University of Michigan.

Communicating Research Misconduct

In February we wrote about the joint association letter submitted to Dr. Patricia Valdez, Research Integrity Officer at NIH, pursuant to the October 17, 2018 Guide Notice (NOT-OD-19-020), "Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH." As of the writing of the February update, no response to the joint letter had been received. The associations recommended that NIH revise the guidance rather than issue a set of frequently asked questions. Due to the time constraints of getting policy changes through the NIH bureaucracy and other urgent priorities, we have been told to expect additional information in the form of frequently asked questions. We hope to see those before the June meeting and will keep the membership informed as we receive more information.

Food and Drug Administration Notice of Public Hearing and Public Comments

The COGR Cannabis Working Group will respond to the federal register notice published April 3, 2019 entitled, "Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments." A public hearing will be held May 31, 2019, and comments are due July 2, 2019. Stay tuned for additional updates.

New NIFA Guidance on Determining the Maximum Indirect Costs Allowed

On March 14, 2019, the National Institute of Food and Agriculture (NIFA-USDA) revised how grant applicants calculate facilities and administrative costs (F&A), also known as indirect costs, in proposal budgets. The amended guidance was released by NIFA in response to new statutory language in the 2018 Farm Bill under Section 1462(c), Treatment of Subgrants, National Agriculture Research, Extension, and Teaching Policy Act of 1977 (NAREPTA). The new language has sparked many concerns from the research community in terms of the complexities of calculating F&A costs along with concerns of potential reductions in the F&A recovery. NIFA's new indirect cost rate guidelines state:

> "Section 1462(a) and (c) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (NARETPA) limits indirect costs for the overall award to 30 percent of Total Federal Funds Awarded (TFFA)

> under a research, education, or extension grant. The maximum indirect cost rate allowed under the award is determined by calculating the amount of indirect costs using: 1) the sum of an institution's negotiated indirect cost rate and the indirect cost rate charged by sub-awardees, if any; or 2) 30 percent of TFFA. In summary, the total F&A requested by grant applicants plus all subawards must be less than 30% of total funds requested."

Although management of the NIFA-USDA F&A restriction never has been ideal, prior to the 2018 passage of the Farm Bill, prime recipients and subrecipients established processes that made management of the F&A restriction manageable. Under the new guidance, burden is significantly increased and COGR has questioned whether NIFA's implementation of the language is consistent with the intent of the new statutory language.

Click here to read COGR's letter to NIFA asking for a retraction of the revised guidance.

Costing and Audit Update: Thursday Morning Session

The COGR Costing Policies Committee will lead a panel discussion on costing and audit related issues at the June COGR meeting. Topics that could be covered in the session include recent audit reports related to subrecipient monitoring; treatment of procurement rebates as addressed in a recent DOJ settlement; procurement standards implementation under 2 CFR.200 317-326; status of the 2019 Compliance Supplement and single audit issues (e.g., procurement / micropurchase threshold / simplified acquisition threshold and payment / reimbursement request / documentation); and other issues of interest. If you have issues you would like to have addressed in this session, please forward them to David Kennedy at dkennedy@cogr.edu by May 30th, at the latest.

The COGR F&A White Paper is Available

The COGR F&A White Paper, "Excellence in Research: The Funding Model, F&A Reimbursement, and Why the System Works," is available at www.cogr.edu. Also, we are publishing a limited number of bound, hard copies and will provide a complimentary edition to each COGR institution. If more copies are desired, we will take orders and ask that you pay for the copies ordered, at cost.

The paper is a memorial to a wide variety of F&A issues, with the hope that it will be a longstanding educational resource to the research community, as well as an advocacy piece that can be used when F&A (inevitably) comes under scrutiny in the future (see next section below). The paper was completed through the active and dedicated efforts of COGR leadership and staff, the COGR Board, the COGR Costing Policies Committee, volunteers from the COGR Research Compliance and Administration (RCA) Committee, and at-large volunteers from throughout the research community. A special "THANK YOU!" goes out to all of those who were involved in this project. We have tried to recognize all of you in the first two pages of the paper, and if we made an oversight, please accept our apologies and we will make sure you are included.

Ongoing F&A Advocacy: FY2020 Budget and the F&A Associations Work Group

In March 2017, the President's Budget Request (PBR) for FY2018 included drastic cuts to NIH, mostly in the form of imposing a 10 percent capped F&A rate. Soon after, several leading Associations from the higher

education and research community organized to create the F&A Associations Work Group (FAAWG). Through education, outreach to policymakers on the Hill, and other activities, we successfully rebuffed the proposed cap. The FAAWG includes:

- Association of Public Land-grant Universities (APLU)
- Association of American Universities (AAU)
- Association of American Medical Colleges (AAMC)
- Association of Independent Research Institutes (AIRI)
- American Council on Education (ACE)
- National Association of College and University Business Officers (NACUBO)
- Council on Governmental Relations (COGR)

We remain organized and active. As we reported in the February Meeting Report, the President's Budget Request for FY2020 suggested that we have to remain vigilant around F&A and related issues. The FY 2020 White House Budget, presented by OMB, contains the full overview and detail of the proposed budget. An HHS appendix includes the "small print" for NIH starting on page 19 (435). The most user-friendly read can be found on page

55 (43) of the Major Savings & Reforms document. Below are excerpts from that document {***emphasis added in bold***}:

> The Budget proposes to reduce funding for the National Institutes of Health (NIH) to better target funding to support the highest priority and most critical biomedical research {2019 Enacted - $38.0 million; 2020 Request - $33.5 million; ***2020 Change - ($4.5) million***}
>
> In addition, NIH would take other steps to increase the impact of its resources. For example, the Budget proposes to decrease the cost of research by capping the percentage of investigator salary that can be paid with grant funds, ***and by reducing the limit for salaries paid with grant funds from $189,600 to $154,300***.
>
> … For the past two years, NIH has been prohibited by law from reducing grantee administrative costs and shifting these resources to support direct research on high impact areas, such as cancer, Alzheimer's disease, and heart disease. The Congress imposed this prohibition, which limits NIH's ability to maximize its support of direct biomedical research. ***The Budget proposes to eliminate the current prohibition,*** which would give NIH the flexibility to support more direct research while encouraging research institutions to improve the efficiency of operations.

The "current prohibition" referred to above is language that was successfully inserted, through efforts by the FAAWG, into the FY2019 Labor, Health, and Human Services (LHHS) House Appropriations bill. **That same language is part of the FY2020 LHHS draft bill:**

> SEC. 224. In making Federal financial assistance, the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such

> provisions were applied in the third quarter of fiscal year 2017. None of the funds appropriated in this or prior Acts or otherwise made available to the Department of Health and Human Services or to any department or agency may be used to develop or implement a modified approach to such provisions, or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter.

In addition to this language, the LHHS draft bill ignores both the proposed change to reduce NIH funding and the call for a reduction of the NIH salary cap from the Executive II level (now at $192,300) – though note, there may be some momentum around a 90% time and effort limit that an investigator and key personnel could charge to an award. We will further track this issue.

In summary, the FAAWG will continue to meet regularly and work strategically around F&A issues. We are confident the efforts of the FAAWG continue to provide the foundation for effective F&A advocacy – we will stay focused on all developments and will keep the membership updated.

NIH Salary Limitation for 2019

NIH published NIH Notice Number: NOT-OD-19-099 on April 17, 2019 to implement the new salary limitation for grants and cooperative agreements. Per the Notice: "*The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, restricts the amount of direct salary to Executive Level II of the Federal Executive pay scale. The Office of Personnel Management has recently released new salary levels for the Executive Pay Scale. Effective January 6, 2019, the salary limitation for Executive Level II is $192,300*." As NIH policy permits, institutions are allowed to rebudget funds to accommodate the new Executive Level II salary level.

OMB Compliance Supplement for 2019

COGR has responded to OMB with comments on the draft version of the 2019 Compliance Supplement. We have commented on Part 5, Research & Development Cluster. The most notable change seems to be that the 12 compliance requirements will be rotated on an annual basis. In other words, only 6 of the 12 will be flagged for testing in the 2019 CS – we are asking OMB to confirm that a rotational approach is their intention going forward.

We also have provided comments related to implementation of the micropurchase threshold (MPT) and simplified acquisition threshold (SAT) as they relate to the Procurement Standards in 2 CFR 200.317-326, and as addressed in OMB Memo M-18-18 (June 20, 2018). We specifically commented on draft language concerning the $10K MPT and $250K SAT, emphasizing that the NDAA of 2017 and 2018 are now applicable law, and that institutions have definitive protection under OMB Memo M-18-18 (and further in NIH Notice NOT-OD-18-219) when using thresholds up to these values in their procurement practices.

Finally, we again are disappointed that OMB is not addressing the Payment / Reimbursement Request / Documentation issue that continues to come up in some audits. COGR first raised this issue in regard to the 2017 Compliance Supplement (see COGR Comment Letter, dated October 20, 2017), and we will continue to remind OMB and the audit community that our concerns from 2017 – i.e., creation of reporting burden without any value-added to accountability – still are applicable. We will keep the membership posted on all developments.