COGR
Council On Governmental Relations
An Association of Research Institutions

FEBRUARY 2019 UPDATE

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The COGR F&A White Paper Release Schedule

The COGR F&A White Paper will be made available at www.cogr.edu before the COGR meeting. It will be in FINAL DRAFT form and for internal review only. When it is available, we will make an announcement to the COGR Membership, and members will be welcome to download and review. At the COGR Meeting on Friday, March 1, we will answer any questions you may have from the FINAL DRAFT version. Soon after the COGR Meeting in March, we then will post the FINAL VERSION to the COGR website.

The paper will be a memorial to a wide variety of F&A issues; with the hope that it will be a longstanding resource to the research community, as well as an advocacy-piece that can be used when F&A (inevitably) comes under scrutiny (again) in the future.

Blockchain Technology

The COGR Costing Committee will be meeting with federal representatives on Wednesday, February 27th, to learn more about initiatives around blockchain technology. While COGR still is acquiring details about the practical application of this technology, in its simplest form it is sometimes described as the "next internet." The promise of blockchain technology is in its facilitation of financial transactions, plus the enhanced security behind these transactions, via a peer-to-peer paradigm that effectively eliminates the third-party. In fact, practical applications already exist in fields such as the music industry, which introduces a stronger model of intellectual property protection. We will share results of this meeting and other thoughts on blockchain technology on Friday morning at the COGR meeting.

Cloud Computing and F&A

In 2015, COGR for the first time reported that the treatment of cloud computing costs and application of F&A to these costs was of concern to select federal agencies, as well as to investigators at our institutions. At the time, it seemed an isolated discussion. Rather than opening the discussion to a broader discussion around the definition of Modified Total Direct Costs (MTDC) and the corresponding applicability of F&A, COGR leadership concluded the best strategy was to "pay attention." The issue recently was raised again, this time in the form of an NSF Program solicitation, NSF 19-510, which prohibits the application of F&A to cloud computing costs. As these costs normally are included in our MTDC research bases, prohibiting the application of F&A to these costs prompts the concern. We encourage the Membership to share any experience or concerns related to this topic, and as appropriate, COGR will engage further.

OMB Compliance Supplement for 2019

The 2018 Compliance Supplement (CS) was released as a "skinny" CS (251 pages) and included only significant updates to applicable sections. OMB has started to share parts of the 2019 CS (which will be a "full version" update) with COGR, and we will review, accordingly. We will keep the Membership posted on all developments.

Procurement Thresholds (MPT, SAT) and Single Audit

While COGR celebrated the favorable resolution to implementation of the Procurement Standards (2 CFR 200.317-326 of the Uniform Guidance) in the summer of 2018, some auditors now have questioned how research

institutions have implemented the Micro purchase Threshold (MPT) and the Simplified Acquisition Threshold (SAT). A preliminary auditor position in selected cases has been that because a FAR rule has yet to be implemented regarding both the MPT and the SAT, the thresholds referenced in the current version of the Uniform Guidance ($3,000 for the MPT, see 200.67, and $150,000 for the SAT, see 200.88) should be considered the applicable thresholds.

COGR disagrees with this interpretation, and further, single audit representatives seem to have a nuanced view based on conflicting information they have received from OMB. As this issue has been raised by some in the single audit community, COGR is paying attention.

The fact that the higher MPT and SAT thresholds were addressed in the National Defense Authorization Act of 2017 (MPT of $10,000) and the National Defense Authorization Act of 2018 (MPT of $10,000 and SAT of $250,000) has suggested to some that both the MPT and SAT need to be implemented via the FAR before they are "official." However, even though the FAR typically is used to implement provisions from the NDAA, because the MPT and SAT provisions of the NDAA apply to grants, implementation in the FAR may not be the decisive requirement. In effect, this has created a tension between the authority of grants guidance (i.e., Uniform Guidance and OMB memos) versus contracts guidance (i.e., FAR). COGR understands the tension, but we are strong in our positions: 1) "the law is the law" and the NDAA of 2017 and the NDAA of 2018 are the law, and 2) institutions have definitive cover under OMB Memo M-18-18 (also see NIH Notice NOT-OD-18-219). Per OMB M-18-18:

> "In order to allow maximum flexibility for grant recipients in light of the changes to the NOAA for FY2018, OMB is granting an exception allowing recipients to use the higher threshold of $10,000 for micro-purchases and $250,000 for simplified acquisitions in advance of revisions to the FAR at 48 C.F.R."

Below are 4 scenarios that could be applicable to your institution. COGR has discussed these with audit leaders, and you should be absolutely "safe" on the first 3. Scenario 4, where your threshold increase is based on the OMB Memo alone, could have minor risk according to audit leaders. But again, COGR's position is that the OMB Memo is loud and clear, and in COGR's opinion, it is reasonable to rely on OMB Memo M-18-18.

1. If you have approval from HHS or ONR to be above an MPT of $10,000, you are fine.
2. If you were at an MPT of $5,000 or $10,000 (for example) prior to implementation of the Uniform Guidance, and have remained at that same level, you are fine.
3. If you increased (for example) the MPT from $5,000 to $10,000 based on the NDAA of 2017, you are fine. In this scenario, you should have "NDAA 2017" clearly documented in your internal records as the rationale for increasing.
4. If you increased the MPT to $10,000 or the SAT to $250,000 based on OMB Memo M-18-18, you should note that even though the Memo header is addressed to Federal Agencies, the Memo also is talking directly to recipients and the instructions are clear. Per COGR, precedent and decades of practice has said we can rely on crystal clear federal guidance, and in this situation, the guidance is crystal clear!

As to working with your auditors if your thresholds are questioned, COGR recommends you go through your scenario and be clear on your basis for supporting your current policy. If your auditors are not in agreement, then ask your auditors to consult their senior partner and to reference the COGR analysis as shown above.

If there are questions or concerns, contact David Kennedy at dkennedy@cogr.edu.

COGR Comments on Emerging Technologies ANPRM

We reported in the December Update on the Commerce/BIS ANPRM *Controls on Emerging Technologies*. Comments were sought on several subjects. The ANPRM itself did not propose any new controls but was more in the nature of a Request for Information about considerations related to controls on emerging technologies. BIS extended the comment period until January 10, 2019.

On January 10 COGR joined with four other higher ed. associations (AAU, APLU, AAMC and ACE) in submitting comments. We stressed the importance of maintaining the fundamental research exemption from export controls, particularly with regard to emerging technologies. We strongly encouraged the use of the Emerging Technologies Technical Advisory Committee (ETTAC; formerly ETRAC) to identify emerging technologies that may warrant controls. We proposed a definition of "emerging technologies" using many of the current definitions and concepts in the Export Administration Regulations (EAR). Finally, we suggested criteria that should be met before any new emerging technology controls are imposed.

Several individual universities and other associations including the Association of University Export Control Officers (AUECO) and industry groups also submitted comments. Many of these comments proposed a similar definition for "emerging technologies." Some of the industry comments were very sector-specific. The comment letter is posted on the COGR website. BIS plans to follow with another ANPRM on "foundational technologies." The timing is uncertain.

Treasury Pilot for Reporting Foreign Investments in Critical Technologies

Last fall the Treasury Department, which chairs the Committee on Foreign Investment in the United States (CFIUS), established a pilot program (83 FR 51322, 10/11/18) implementing the Foreign Investment Risk Review Modernization Act (FIRRMA). That Act expanded CFIUS jurisdiction to cover additional transactions, including minority investments by foreign persons in U.S. businesses that develop critical technologies. It requires notifications ("declarations") to CFIUS of transactions that involve substantial investments in U.S. businesses involved in critical technologies by foreign persons who are directed by a foreign government.

The pilot program involves critical technologies in 27 designated industries. Critical technologies are defined as those covered by export controls including emerging technologies that will be defined pursuant to the Commerce ANPRM discussed above. Covered investments are those made by a foreign person that do not result in control of a U.S. business but result in access to nonpublic technical information, participation in boards of directors, or involvement in substantive decision-making related to critical technology. In such cases, declarations are required. CFIUS will review the declarations for national security concerns and may clear the transaction ("safe harbor") or impose conditions to mitigate national security risks.

CFIUS has been in existence for approximately 10 years (73 FR 74567; 12/8/08). Previously it was focused on review of transactions that resulted in foreign control of U.S. businesses that might pose national security risks.

The expansion of CFIUS and the pilot program may have a more direct impact on university technology commercialization activities, particularly investments in startups. The designated industries include those involved in nanotechnology and biotechnology R&D, among others. Technology commercialization offices at

COGR member institutions need to be aware of the CFIUS/FIRRMA pilot program and may need to seek appropriate legal advice.

DOD Policy Change on Fundamental Research in SBIR/STTR Contracts

COGR has been advised by several member institutions that DOD agencies no longer are approving fundamental research waivers for the DFARS 7000 clause in SBIR/STTR contracts. The DFARS 7000 clause provides for fundamental research determinations by contracting officers when contracts involve no covered defense information and are scoped as fundamental research by mutual agreement (this process was developed after extensive discussions between COGR and DOD some years ago—see February 2014 COGR Meeting Report).

This change has not been formally announced and is not reflected in the DFARS. It appears to apply only to SBIR/STTR awards, including flow down subcontracts to universities from SBIR/STTR award recipients. The instances we are aware of all involve such situations.

We plan to raise this issue with DOD. There appears no clear reason for a blanket determination that SBIR/STTR contracts cannot involve fundamental research. Absent an approved waiver, award recipients and subrecipients are subject to the prior approval requirements of the 7000 clause for any information disclosure.

COGR Submits Comments on NIST ROI "Green Paper"

The December Update described the NIST Return on Investment (ROI) Initiative "Green Paper." It noted that the Intended Actions outlined in the Green Paper included many that were recommended in our comments and recommendations. However, we also noted several concerns.

On January 9 COGR joined five other associations (AAU, APLU, AAMC, ACE and AUTM) in submitting comments to NIST. The comments were highly supportive of most of the Intended Actions in the Paper (see discussion in December Update), but discussed a number of concerns. Our primary concern is the recommendation related to Intended Action 9 (New Partnership Mechanisms) to establish a new Research Transaction Authority modeled after Other Transaction Authority (OTA). A footnote also recommended that OTA authority be expanded to all agencies. We expressed concern about the lack of empirical evidence as to the claimed benefits of OTA agreements. Our institutions have found them troublesome and often requiring extensive negotiation. We also noted that agencies have used and continue to use OTs to circumvent normal Bayh-Dole rights (for example, the recent (November 2018) revision to the DOD *Other Transactions Guide* explicitly states (p. 17) that the Bayh-Dole Act does not apply and that "IP rights are fully negotiable under all types of OTs"). We urged that NIST reconsider this recommendation.

AUTM joined in our comments but also expressed some additional concerns. One of these was a recommendation under Intended Action 3 (Strengthening the U.S. Manufacturing Requirement for Federally Funded Inventions) to expand the U.S. manufacturing preference to non-exclusive licenses rather than the current limitation to exclusive licenses. While the purpose to strengthen the U.S. manufacturing base is laudable, AUTM pointed out

this would add time and expense and discourage more private sector engagement. (It should be noted that recently DOE has required domestic manufacturing for all licenses in certain ARPA-E programs pursuant to an exceptional circumstance determination.) AUTM's other primary additional concern involved Intended Action 8, which calls for establishing consistent government-wide licensing policies and practices for federally funded IP. As worded, this recommendation appears to apply to extramural as well as intramural IP and raises the specter of government micro management.

These concerns should not obscure the many positive aspects of the Paper. These include plans to clarify the scope of the government use license and march-in rights under Bayh-Dole, to streamline the U.S. manufacturing requirement waiver process, to allow limited use of federal research funds for IP protection, to implement harmonized government-wide requirements for managing conflicts of interest, and to establish modernized IP reporting requirements. These all correspond to recommendations we had made to NIST. NIST also plans to refer recommendations beyond NIST's scope (e.g. I-Corps expansion, America Invents Act issues, greater flexibility in the use of SBIR/STTR funds) to other appropriate agencies.

The association comments are posted on the COGR website. We plan to work closely with NIST as it moves into the implementation phase of the Initiative.

Drug Pricing Issues Receive Much Congressional Attention

As we have previously reported several bills were introduced in the last Congress to address drug pricing concerns. These issues are likely to receive even more attention in the new Congress. On January 29 hearings were held both in the House (House Oversight Committee) and Senate (Finance Committee) on these issues. The chances for bipartisan legislation appear to be increasing. In both hearings concerns about the patent system were raised. Several members spoke in favor of reducing the exclusivity period for drugs. The hearings did not touch on Bayh-Dole Act issues. The Senate Finance Committee has scheduled another hearing for February 26.

Sen. Sanders has reintroduced legislation (S. 102) that would require compulsory licensing of any drug that the HHS Secretary determines is excessively priced. The bill has four other co-sponsors. Similar legislation (H.R. 465) has been introduced in the House by Rep. Khanna (D—CA). A flurry of other legislation has been introduced involving Medicare drug price negotiation. On February7 Rep. Doggett (D—TX) announced that he was reintroducing the legislation discussed in the December Update. Sen. Brown (D—OH) will introduce similar legislation in the Senate. We expect to see much additional legislative activity in this space and will keep the Membership posted.

Updates

Controlled Unclassified Information. DOD has been assigned responsibility for drafting the proposed FAR clause. The draft originally was due in June 2017. No new due date has been provided (for a reference point see *Jarndyce v. Jarndyce*, Dickens, *Bleak House*, 1852-3).

Innovation to Entrepreneurs Act Reintroduced. Rep. Lipinski D—IL) has reintroduced this bill (H.R. 539), which he also introduced in the last Congress. It would expand the I-Corps program originated by NSF to allow any SBIR/STTR grantee from any federal agency to apply to participate and to use their grant funds to cover expenses. Companion legislation has been introduced in the Senate (S. 118) by Sen. Coons. COGR joined other higher ed.

associations in supporting this legislation last year (see February 2018 Update and Meeting Report), which passed the House.

Implementation of New Bayh-Dole Regulations. In last year's May Update we summarized the revised Bayh-Dole Act implementing regulations issued by NIST last April. We discussed the requirement for employees to assign by written agreement invention rights to the contractor. This amendment was likely a response, in part, to the Supreme Court's *Stanford v. Roche* decision several years ago. We understand several COGR member institutions may not yet have implemented this requirement. We suggest that institutions who have not yet done so review their practices and policies to assure compliance.

Announcements

UIDP Contract Webinar Series. UIDP is hosting a ten-webinar series on contemporary issues and opportunities for effective negotiation of industry-sponsored research agreements (ISRAs), beginning February 27, 2019. Topics include contracting basics, background and foreground IP, confidentiality and publications, software terms and data use and access issues, new contracting models, and liability, warranty and risk. Academic and industry practitioners will share their perspectives.

University Innovation and Entrepreneurship Showcase. On April 10 from 5:00-7:00 p.m. EDT, AAU and APLU will host on Capitol Hill the second University Innovation and Entrepreneurship (I&E) Showcase, highlighting AAU and APLU university-affiliated startup businesses. The showcase will promote the importance of federally-funded university research and demonstrate how university-led entrepreneurial engagement contributes to the innovation economy. University startups interested in participating in the showcase must apply via **this form** **by Wednesday, February 27.** Universities may submit multiple applications to highlight different startups affiliated with their institutions. Additional information about the showcase can be found in the event flyer. For questions about the event, please contact Jessica Sebeok at AAU.

COGR Responds to OMB on Draft Federal Grants Management Data Standards

The OMB launched the President's Management Agenda (PMA) in March 2018 to identify critical challenges where US Government as a whole operates behind the times. The PMA identified fourteen Cross-Agency Priority (CAP) goals throughout the Agenda. In response to OMB's federal register notice seeking comments on proposed grants management common data standards in support of CAP Goal 8, entitled, ''Results Oriented Accountability for Grants," COGR expressed concern that sensitive information including but not limited to intellectual property, animal and human subjects research, public disclosure of researcher citizenship, and anti-discrimination data are very carefully approached in current data sets to protect the identity and privacy of those involved. Without more clarity on how the data sets and information will be used and in light of concerns about the transparency of the data, COGR recommended that OMB continue to include us as stakeholders in future town halls, meetings, workshops. To read COGR's letter click here.

COGR to Address Notice of Award Data Elements in Response to ReInvent Grants Management (RGM) Initiative at HHS

The RGM has assembled a working group tasked with recommending a standardized first page of the Notice of Award (NOA) package for HHS grant recipients, or Page One of the NOA. The working group has identified a standard set of data elements to be used to communicate NOA information to grant recipients and has also developed several versions of a draft format to use in cases where a physical form is needed. Specifically, information was sought on the following two questions. 1) Are all the significant data elements included on Page one of the NOA; if not, what data elements should be added? 2) Does the layout of the data elements on the physical form make sense; is it intuitive and easy to locate the most important fields. COGR and the Federal Demonstration Partnership have been working together on this initiative and will be submitting responses by February 15, 2019. Stay tuned for additional information.

Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH, NOT-OD-19-020 ("Guide Notice")

As reported in the previous update and pursuant to the October 17 Guide Notice (NOT-OD-19-020), "Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH", COGR, along with the Association of Research Integrity Officers (ARIO) and the American Association of Medical Colleges (AAMC), submitted a response to the Guide notice requirement for institutions to report research misconduct that "might impact the conduct of an NIH-supported project," or "suspects" that falsified, fabricated, or plagiarized information has affected the integrity of NIH supported research. COGR, ARIO and AAMC stressed that assessing "suspicion" absent a definition of suspicion would be particularly difficult, and noted how it differs from a determination that the allegation is sufficiently credible and specific to warrant an inquiry or has sufficient substance to warrant an investigation – determinations that institutions already routinely make under the PHS Regulations. To read about this and other important concerns expressed in the joint association letter, click here.

During the Friday, March 1st session, COGR will be hosting Dr. Patricia Valdez, NIH Research Integrity Officer, to discuss the Guide Notice and address questions and concerns noted in the joint association letter.

Sexual Harassment in Science

At the Thursday, February 28th afternoon session, there will be a discussion on Sexual Harassment in Science. Sara Barber, Legislative staff of Ranking Member Eddie Bernice Johnson (D-TX) and Chairwoman of the House Science, Space, and Technology Committee will discuss Rep. Johnson's bill H.R. 36 entitled "Combatting Sexual Harassment in Science Act of 2019." This session will present an opportunity for COGR members to ask questions about the reporting requirements of the bill including publishing on publicly available internet websites the aggregate results of assessments regarding findings or determinations of sexual harassment, the requirement to make public on an annual basis the number of reports of sexual harassment, etc. Joanne Carney, Director, Office of Government Relations, the American Association for the Advancement of Science (AAAS) will discuss sexual harassment from the scientific community perspective. This will include a discussion of a new multi society project along with the specific actions/policies undertaken at AAAS.

National Science Foundation HERD Survey

The Research Compliance and Administration (RCA) Committee will host NSF's Michael Gibbons, Project Officer at the National Center for Science and Engineering Statistics, during its February 27 Committee meeting. Michael will address his role with the HERD survey and will look for the Committee to discuss any suggestions for improving the current survey. During the Friday morning Committee reports we will brief members on the discussion. We are inviting questions to be sent prior to the meeting so these can be addressed during the Wednesday RCA Committee meeting with Gibbons. Please send your questions to Jackie Bendall at jbendall@cogr.edu

Confidentiality in Research Misconduct Ad Hoc Committee Update

The COGR ad hoc Confidentiality Committee has finalized its confidentiality scenarios and sent them for further review and comment to the RCA Committee. Once the RCA Committee reviews and approves, the document will be sent to both the COGR board and ARIO boards for approval to publish. We anticipate that these scenarios will be available in time for the June meeting. Stay tuned for further updates.

Cannabis Working Group Update

On December 20, 2018, the 2018 Farm Bill was signed into law. Among many things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as cannabis (*Cannabis sativa L.*) and derivatives of cannabis with extremely low (less than 0.3 percent on a dry weight basis) concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC). One very important change for COGR

institutions are that the law removed hemp from the Controlled Substances Act (CSA), which means that it will no longer be an illegal substance under federal law. What does this mean for our researchers? It allows hemp cultivation broadly as opposed to operating under the previous model of USDA pilot programs. The transfer of hemp-derived products across state lines for commercial or other purposes is now permissible as is the sale, transport, or possession of hemp-derived products, as long as the products are produced in a manner consistent with the law.

Although the Farm Bill made progress and opened the door for researchers to obtain access to the product, there are many other questions requiring clarification from the USDA, the FDA and DEA. The Working Group will continue to explore answers to these questions and provide updates to the Frequently Asked Questions (FAQs) in the coming months. In addition, the Working Group will be closely following new and re-introduced bills in this 116th Congress. For additional information, please contact Jackie Bendall at jbendall@cogr.edu.

Human Subjects Research

Removal of the Requirement for IRB Review of NIH Grant Applications and Contract Proposals

NIH issued a notice on the agency's implementation of the revised Common Rule on January 2, 2019. In accordance with provisions of the revised rule: "NIH will no longer require IRB review and approval of the entire grant application or contract proposal." Other areas were also addressed. NIH provided further clarification

specific to this topic in NOT-OD-19-055, Removal of the Requirement for Institutional Review Board Review of NIH Grant Applications and Contract Proposals Related to Research.

FDA Proposed Rule to Allow Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

On January 14, 2019, COGR submitted comments to the FDA in support of the proposed rule to allow IRBs to "approve an informed consent procedure that waives or alters certain informed consent elements or that waives the requirement to obtain informed consent for certain minimal risk clinical investigations" consistent with the Common Rule, recommendations from the Secretary's Advisory Committee for Human Research Protections, and section 3024 of the 21st Century Cures Act. Comments on the proposed rule may be submitted at regulations.gov (Docket No. FDA-2018-N-2727). The comment period has been extended to February 13, 2019.

Updates to the NIH Clinical Trial Case Studies

COGR has previously reported on ongoing changes to NIH's Clinical Trial Case Studies which now capture some basic research involving human participants, most recently in the September 2018 COGR update. On January 7, 2019, the case studies were updated again to indicate which cases involve basic research that is also considered

by NIH to meet its definition of a clinical trial. These cases, including existing cases 9 and 14 and new cases 40 and 41, have been designated "Basic Experimental Studies Involving Humans" (BESH – rather than clinical trials) which "use an intervention to understand fundamental aspects of a phenomena without specific application towards processes or products in mind." Cases 40 and 41 involve types of fMRI studies. These studies "are subject to NIH stewardship policies including Good Clinical Practice Training and the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" but also to Delayed Enforcement and Short-Term Flexibilities for Some Requirements.

Research Involving Animals

Federal Draft Report on Reducing Administrative Burden in Animal Care and Use

We provided details on the NIH OLAW, USDA, and FDA draft report on reducing administrative burden in animal care and use in our December 2018 COGR update. The report was posted in a Federal Register Notice dated December 7, 2018. The comment period has been extended to February 20, 2019. Agencies were only allowing for a 900-word response; however, the word count has been increased to 2,700 words following an association request. Comments must be submitted electronically here and cannot be uploaded. COGR is submitting comments and will distribute them to members prior to the deadline. Dr. Pat Brown, Director, NIH OLAW, Bernadette Juarez, Deputy Administrator, USDA Animal Care Program, and Dr. Brianna Skinner, Senior Regulatory Veterinarian, FDA, will join us at the February COGR meeting to discuss the report and next steps in reform efforts.

COGR Survey Report on Institutional Administrative Requirements for Animal Research

In 2016, COGR developed a checklist of actions that institutions have taken to reduce administrative burden, while maintaining oversight and ensuring the stewardship of sponsored research funds. The actions adhere to federal regulations and policy without adopting or extending additional requirements, or otherwise offer the

potential to reduce administrative work in a number of areas, including those researchers have identified as being particularly burdensome.

In 2018, we surveyed COGR members on actions included in the checklist specific to animal research and institutional animal care and use committees (IACUCs), adding several additional items. Ninety-four of COGR's 188 members responded to our survey on whether institutions have or are planning to take actions to reduce possible institutional administrative burden in this area.

We found that institutions are more likely to take action to reduce administrative burden when federal agencies provide clear directives and address uncertainty. Agencies could provide significant assistance to institutions by distinguishing between requirements and best practices. A contributing factor may be the complexity of multiple sets of regulations, policies, and guidelines that often create confusion. Steps to align agency requirements will help this situation. The full report can be found here.

Foreign Influence on NIH Funded Research

On December 21, 2018, NIH responded to an October 24, 2018 letter sent to Dr. Francis Collins, NIH Director, by Senator Chuck Grassley. In the letter, the Senator had inquired about the agency's vetting process for foreign researchers and grants. The letter suggested that it is not clear that financial conflict of interest disclosure requirements "adequately address the significant and pervasive threats posed by foreign entities to our research institutions and the integrity of taxpayer funded studies" and posed a series of questions, regarding background checks of researchers and institutions, reviews or audits for potential violations concerning foreign affiliations and financial contributions; and "a list of all entities currently under investigation for employing individuals that failed to disclose contributions from foreign governments."

In its December 2018 response the agency noted that NIH employees, including intramural researchers, are subject to background checks and that foreign nationals undergo screening, while extramural researchers would be subject to the requirements and policies of their institution. The agency also noted that it consults SAM, FAPIIS, and audit reports, and addresses compliance with applicable requirements through its award terms and conditions. The agency declined to provide a list of individuals excluded from peer-review as they might be on the list for reasons other than violating NIH policies and procedures (e.g., extended leave). In response to the Senator's request for "a list of all entities currently under investigation for employing individuals that failed to disclose contributions from foreign governments" NIH declined, indicating that the agency is not in a position to comment on "reviews under way within the HHS OIG, Department of Justice, or institutions…" but noted that it works and fully cooperates with its federal partners to address "foreign influence on the U.S. biomedical enterprise." NIH suggested that the Senator reach out to the HHS OIG and the DOJ for information on violations referred to these entities.

Senator Grassley subsequently sent letters to the HHS OIG, DOJ and FBI. The letter to the former asks how many times in the last five years institutions were referred by NIH to the OIG for "failure to take corrective action after learning researchers received contributions from foreign governments and did not disclose it, and referrals for institutions that failed to adequately perform background checks on researchers involved in taxpayer-funded research" as well as investigations conducted of researchers for nondisclosure, diversion of IP, or acting as an agent of a foreign government. The letter also asks about referrals to DOJ for prosecution. The letter to the latter

seeks additional information on how DOJ and FBI assist institutions and the NIH with background checks, identifying foreign threats, and investigating and prosecuting nondisclosure of foreign funding, diversion of IP, or those acting as an agent of a foreign government.

A response dated January 31, 2019, and signed by Inspector General Daniel Levinson, notes that the HHS OIG "recently initiated evaluations to assess NIH's vetting and oversight of its peer reviewers, including its efforts to prevent or detect inappropriate sharing of information by peer reviewers, and an evaluation of how NIH monitors the financial conflicts of interest (including foreign financial interests) reported by grantee institutions" and is "initiating audits that will assess NIH's Institutes and Centers to review their (1) pre-award process for assessing risk of potential recipients of Federal funds; (2) policies, procedures, and controls in place for ensuring that both foreign and domestic grantees disclose all relevant affiliations, sources of support, and financial interests, including intellectual property interests; (3) internal controls for identifying and addressing potentially duplicative grant funding and overlap; (4) testing of select cybersecurity controls within the NIH Electronic Health Records system; and (5) controls to ensure that NIH has an accurate inventory of hardware, software, and Internet Protocol (IP) resources."

Regarding "referrals for the institution's failure to take corrective action after learning researchers received contributions from foreign governments and did not disclose it" the IG indicated that their office "recently received 12 referrals from NIH with such allegations." Per the letter, OIG is "conducting a review of these referrals to determine whether the allegations warrant the opening of investigations." The OIG has conducted one investigation involving failure to disclose foreign government funding in the past five years, none involving "researchers who were allegedly foreign government agents" which have "historically been review by the FBI", and one investigation involving allegedly stolen IP. The letter indicates that the OIG "has made two referrals to

DOJ for potential prosecution in the past 5 years" one for failure to disclose and one for allegedly stolen IP, neither of which were pursued by DOJ.

Dr. Mike Lauer, Deputy Director for Extramural Research, NIH, will join us at the February COGR meeting to discuss the topic of foreign influence, including the NIH Advisory Committee to the Director foreign influence working group's December 2018 report (see December 2018 COGR update) and steps NIH is taking to address the report's recommendations and foreign influence generally.

Other Science and Security Developments

Huawei Technologies. The September Update discussed the prohibition in the FY'19 NDAA on telecommunications equipment produced by companies including Huawei Technologies in DOD contracts. On January 28, the Justice Department announced the filing of criminal charges against Huawei for bank fraud and violation of U.S. economic sanctions on Iran. A large number of COGR member institutions have announced that they will no longer accept any research funding or gifts from Huawei.

DOE Foreign Talent Program Prohibition. On February 1 DOE announced a new policy prohibiting DOE federal and contractor personnel from participating in talent recruitment programs sponsored by countries determined by DOE to be seeking to exploit U.S. scientific and technological expertise. Participation would have to be disclosed and if necessary terminated. While not specifically targeted, the policy seems to be aimed primarily at China's

talent programs. It is not clear from the announcement how contractor personnel are defined. However, COGR's understanding is that the policy also includes grant recipients. The announcement is a policy statement that leaves many unanswered questions where we will seek clarification as DOE moves forward with implementation. For more information click here.

Senate Worldwide Threat Assessment Hearing. On January 29 the Senate Intelligence Community held its annual Worldwide Threat Assessment Hearing. The hearing received considerable press attention. Of particular interest were statements from the FBI Director concerning China, including that China was the most significant counterintelligence threat to the U.S. and noting that China was using strategies such as providing financial aid to U.S. universities and stealing U.S. intellectual property. He also noted that China has adopted a policy that seeks to gain economic advantage by "hook or by crook" especially in technologies such as artificial intelligence, biotechnology, 5G, and advanced surveillance.

Rubio/Warner Bill. Sens. Rubio and Warner have co-sponsored legislation (S. 29) that would establish in the Executive Office of the President a new Office of Critical Technology and Security. The Office would be responsible for coordinating activities aimed at stopping the transfer of critical technologies posing national security risks and maintaining U.S. technological leadership. The Office also would seek to educate the public about threats to national security from transfers of critical technologies to countries that pose a national security risk and act as chief government policy spokesperson on security and critical technology issues. Other responsibilities include formulating a long-term strategic plan to enhance the process for identifying critical technologies, protect and enforce IP rights, and maintain U.S. technological leadership. An annual report to Congress is required. An interagency Council on Critical Technologies and Security also would be established.

Updates to the NIH Policy on Early Stage Investigator (ESI) Application Status

NIH published a notice on February 12, 2019, indicating that the agency will automatically update the ESI status of an application within eRA Commons. Circumstances include "if a PD/PI updates his/her degree or residency information after submission of an R01 or R01-equivalent application, or if an investigator requests and/or receives an extension of ESI status after submitting an R01 or R01-equivalent application. Details can be found here.

COGR Survey Report on Institutional Resources for Promoting Research Quality

On February 7, 2019 COGR released a survey report on institutional resources for promoting research quality. COGR developed the survey in support of efforts on the part of federal agencies and the research community to improve rigor and reproducibility. The report includes detailed information on resources provided and associated references and links.

The results of our survey indicate that universities are providing resources to help ensure research rigor and reproducibility but that the depth and breadth of resources provided varies considerably both between and within institutions and is often not tracked centrally. Additionally, responses suggest that researchers may not be aware of the institutional resources available to them.

COGR will continue to work with federal and other stakeholders on this issue. The National Academies Committee on Reproducibility and Replicability in Science is expected to present its pending report at the June COGR meeting.

Proposed Efforts and Initiatives of the Non-Profit Funder - Research Institution Partnership

At the October 2017 COGR meeting a panel of non-profit funder and research institution representatives discussed an ongoing and growing partnership aimed at facilitating academic research funded by nonprofit organizations. As the Nonprofit Funder – Research Institution (NFRI) Partnership plans its third major meeting, university representatives leading efforts in the areas of intellectual property and technology transfer, research project support costs, and streamlining administrative processes (e.g., application processes, financial reporting, and contracting language) will discuss current initiatives at the February COGR meeting. This session will provide an opportunity for COGR members to delve into these issues and to provide input to those leading the initiatives of the NFRI on behalf of research institutions.

NFRI Partnership: F&A Developments

The F&A working group (now referred to as the Research Project Support Costs working group) aims to draw a sharper distinction on costs that are normally indirect on federal awards, but could in fact, be direct on foundation awards (e.g., IRB, hazardous waste removal, data and storage, etc.).

Historically, and today, F&A and infrastructure support has been understood primarily to be the role of the federal government. Whereas the federal government, as well as research supported by private industry, normally reimburses the full F&A rate, many foundations, nonprofit funders, and charitable organizations limit grantee F&A cost reimbursement according to their organization's internal policies. Many of these organizations recognize F&A costs as essential to research. However, these policies may be set by the organization's Board with the premise that donors desire their contributions to fund the direct costs of research only. Expanding the definition of direct costs to recognize Research Project Support Costs may result in an opportunity to provide more equity in those research costs paid for by foundations. Also note, we know there are situations where foundation awards function more like an NIH R01 award. In these cases, COGR supports application of the full F&A cost rate.

National Science Board February 2019 Meeting

The National Science Board met on February 12, 2019. Links to the agenda and webcast can be found here.

Audit

NSF OIG Audit Reports

The NSF OIG recently published two audit reports of incurred costs at research institutions. The audits covered costs claimed to NSF awards over a period of three years from October 1, 2011 to September 30, 2014 and July 1, 2013 to June 30, 2016 respectively.

The first report questioned $441,719 of costs claimed to NSF awards. The NSF OIG "analyzed the data contained in the University's general ledger and supporting detailed ledgers to identify anomalies, outliers, and aberrant

transactions" and provided auditors with a list of 248 transactions for testing. Questioned costs included $44,330 due to lack of supporting documentation for payroll costs and expenditure costs with no supporting documentation that the expenditures supported the award, $15,581 in questioned relocation costs, questioned costs of $381,808 for inadequate documentation for costs transferred from one award to another (and specific to the award) both within and outside the period of performance, and costs incurred near the end of an award period. The institution agreed to repay $206,279 but disagreed with some questioned costs related to cost transfers. The audit period chosen, 2011-2014, is interesting since the institution strengthened its policies and procedures related to cost transfers in 2014.

The second report questioned $51,461 of costs claimed on NSF awards. Per the report, the NSF OIG "assessed the risk and approach for the audit by conducting planning, data mining, and analytical procedures over the universe of data provided by the University. Based on procedures performed by NSF OIG, 250 transactions (i.e., 220 General Ledger and 30 Payroll), totaling $5,570,158, were judgmentally selected for testing." Questioned costs included $21,937 in expenses near award expiration, $17,517 of indirect costs "inappropriately applied to capital equipment," $7,174 in general expense charges (tuition and direct charged operational costs), $3,589 in travel costs, and $1,244 in participant support charges used for employee travel. The institution agreed with the findings and to repay all questioned costs.

NSF OIG 2019 Audit Work Plan

The NSF OIG published its audit work plan for fiscal year 2019. The plan includes audits to assess NSF's controls for ensuring that awardees comply with criteria for government-owned equipment, including tracking, reporting, and disposition requirements; ensure awardees are complying with requirements in the administration of the Established Program to Stimulate Competitive Research (EPSCoR) awards; and determine if NSF is ensuring that awardees are complying with the agency's use and reporting requirements for program income.

The report indicates that the NSF OIG will "continue to audit NSF awardees at various universities, non-profits, and for-profit entities to detect improper spending or noncompliance with Federal and NSF requirements" and that "in FY 2019, we plan to broaden the scope of work our contractors perform to include projects such as surveys and accounting system reviews. In addition, we plan to increase the number of awardee audits OIG staff perform and initiate more limited desk reviews."

The OIG will also continue to review the quality of Single Audits of NSF awardees for which it is the cognizant agency as well as "NSF-related information" for other awardees. In FY19 the OIG plans to "conduct desk reviews of approximately 100–120 single audit report packages and conduct quality control reviews of 2 single audits."

The OIG will also "continue to monitor NSF's compliance with the American Innovation and Competitiveness Act of 2017."

HHS OIG

The HHS OIG has reported that a research institution paid $2,396,769.76 to resolve allegations that it misappropriated NIH grant funds. The institution is alleged to have placed an order for a large quantity of materials just prior to the end of a grant, then stopped shipment of that material and had the company establish a credit that the Center/institution then used to purchase goods and services after the close-out of the grant.