COGR
Council On Governmental Relations
An Association of Research Institutions

September 5, 2018

TO: COGR Membership

FROM: COGR Staff

SUBJECT: September 2018 Update

TABLE OF CONTENTS

F&A Update and the COGR White Paper
2018 Compliance Supplement and Audit Related Issues
- Payment and Reimbursement under 2 CFR 200.305
- Securing Student Information, Department of Education (ED)
- Annual Compliance Audit, Student Financial Aid (SFA) Cluster
- Revenue Recognition of Grants and Contracts by Not-for-Profit Entities

NDAA (H.R. 5515) Includes Significant Provisions Related to Science and Security
Other Non-Security Related Provisions of Interest in the NDAA
Other National Security-Related Legislative Activities
New Export Controls Reform Act Included in NDAA
Additional Chinese Entities Added to Restricted List for Exports
Higher Ed. Associations Submit Comments on NIST ROI/RFI
Federal Appeals Court Rules Against Tribal Sovereign Immunity
COGR Joins Other Associations in Supporting USPTO's Proposed Claim Construction Standard
Associations Support SUCCESS Act
Updates
- Controlled Unclassified Information
- Drug Pricing

Research Regulatory Reform
- Statement of Administration Policy on DOD and LHHS FY19 Appropriations – Impact on Research Policy Board
- COGR Article on the Current State of Research Regulatory Reform

Research Involving Human Participants
- NIH Notice and RFI on Basic Science Research Involving Human Participants
- National Academies Report on Returning Individual Research Results
- SACHRP July 2018 Meeting and OHRP Resources
- NIH Proposal to Streamline Oversight of Human Gene Therapy Trials
- Federal Websites That Satisfy the Requirement to Post Clinical Trial Consent Forms
- NIH Workshop on Single IRB Resource and Infrastructure Development
- NIH Seeks Comment on a Draft Behavioral and Social Sciences Clinical Trial Template

Senate Hearing on Science and Stewardship at NIH and Discussions on National Security
Congress Writes to Education Secretary on University Partnerships with Huawei
Dr. Kelvin Droegemeier Nominated for OSTP Director
Nonprofit Funder - Research Institution Working Group Meeting and Website
Audit

NSF OIG Audit Reports
HHS and NIH OIG June COGR Session on Payroll Certification
DEA Call for Comments
Stevens Amendment
NIH to Release New Guidance Distinguishing Fixed Amount Subawards from Fixed-Rate Agreements

F&A Update and the COGR White Paper

F&A currently is not under heavy scrutiny, as it was at this time last year. Still, COGR continues its participation in the Associations F&A Working Group, comprised of COGR, the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), the Association of Public Land-grant Universities (APLU), the Association of Independent Research Institutes (AIRI), the American Council on Education (ACE), the National Association of College and University Business Officers (NACUBO).

Also, and as we reported at the June Meeting, the COGR Costing Committee, with assistance from the RCA Committee, has organized around the development of an F&A White Paper to address many of the themes related to transparency, alternative models, education and myths. We expect to complete the paper and make it available in late 2018. In addition, we hope to preview the paper at a session during the October COGR Meeting to be held October 25-26.

2018 Compliance Supplement and Audit Related Issues

OMB released the 2018 Compliance Supplement (CS) earlier this summer. This year's edition was published as a "skinny" CS (251 pages) and includes only significant updates to applicable sections. In effect, auditors will use the 2017 CS and the 2018 CS together to guide their audits.

Below are audit issues we continue to follow:

Payment and Reimbursement under 2 CFR 200.305. This is not addressed and remains a concern. According to some in the audit community, the IG position is that "recipients will be reimbursed without ever paying their invoices" if reimbursement requests are made before issuing payments. In response to a request for Public Comments to the 2017 Compliance Supplement, COGR sent a Comment Letter (dated October 20, 2017) to OMB, Gilbert Tran. Some of your institutions also sent letters, either documenting your unique circumstances or simply supporting the COGR letter. COGR views this as an open item and hopes to pursue it further at a Single Audit Roundtable meeting later this year.

Securing Student Information, Department of Education (ED). COGR has worked with several of our Association partners to raise concerns as to how ED has proposed audit objectives related to safeguarding data specific to an institution's information security program (i.e., Safeguards Rule). ED withdrew their initial inclusion of overly-complex audit guidance from the 2017 CS. COGR's position has been that the CS is not the correct vehicle for this guidance. This issue was not addressed in the 2018 CS, but will be revisited in the 2019 CS. We will continue to track this issue.

Annual Compliance Audit, Student Financial Aid (SFA) Cluster. Throughout 2017, we regularly reported on a 2016 Department of Education *Dear Colleague Letter* that formed the basis for an ED position that an annual compliance audit of the SFA is required. Our understanding is that the Department of Education, at least for now, has backed off of this position.

Revenue Recognition of Grants and Contracts by Not-for-Profit Entities. This new FASB rule will impact how private institutions account for revenue and expense. A summary of the new FASB revenue recognition rule is available at the FASB website.

In the course of reviewing the 2018 CS and other audit related issues, please contact David Kennedy at dkennedy@cogr.edu if you identify any issues of concern.

NDAA (H.R. 5515) Includes Significant Provisions Related to Science and Security

The FY '19 National Defense Authorization Act (NDAA) contains a number of provisions of relevance to science and security issues, in addition to other significant provisions discussed below in this Update. Sec. 871 prohibits acquisition by DOD and DOD contractors of specific materials from certain foreign nations. Sec. 885 requires DOD to develop procedures to limit foreign access to technologies through grants, contracts, cooperative agreements or other transactions based on national security interests. A report with assessments and recommendations for penalties for violations "including intellectual property forfeiture" is due Sept. 1 of next year. Sec. 889 prohibits contracts involving telecommunications equipment produced by certain named entities, including Huawei Technologies and ZTE Corp. Other entities may be added by DOD, which presumably will provide appropriate notification to contractors. The prohibitions are effective in two years.

Sec. 1049 requires DOD to develop a list of critical technologies to maintain U.S. national security advantage. The list is to be used for export licensing purposes among other things as well as to inform development of government research investment strategies. It is not clear how this list relates to the interagency process for identification of critical technologies called for by the new Export Control Reform Act (see #4 below)..

Sec. 1091 prohibits DOD funding for Confucius Institutes, or for Chinese language programs at institutions that host Confucius Institutes. A waiver procedure is included that requires certain certifications to the Congressional defense committees. Also it requires that all agreements between the institution and the Confucius Institute or other organizations affiliated with the Chinese government be made available to DOD.

Sec. 1286 establishes an initiative for DOD to work with academic institutions on protection of intellectual property (broadly construed) and information about critical technologies, to limit undue influences of countries through foreign talent programs in exploiting U.S. defense technologies, and to develop more domestic talent in science and engineering. Academic institutions and educational organizations are to participate to the maximum extent practicable in this initiative. An information exchange forum is to be established, along with training for academic institutions to promote security and limit undue influence as well as opportunities for collaboration with defense researchers. **Regulations and procedures are to be developed that both support the goals of protecting intellectual property and critical information while also protecting open scientific exchange in fundamental research.** Policies to limit DOD funding for institutions or researchers who knowingly violate regulations including those related to foreign talent programs also are part of the initiative. Congressional defense committees are to be briefed within 120 days on the implementation, with a report with findings and recommendations due in a year, including a description of compliance by institutions with best practices and guidelines. (**Note that the focus on intellectual property in the NDAA and discussed elsewhere in a security context in this Update refers more to knowledge and ideas than traditional forms of IP.** This will be a challenge in seeking to develop appropriate regulations and procedures).

We are discussing with the other associations ways to move forward working with DOD on this initiative. It was included in the NDAA in lieu of other proposals that would have required greater immediate restrictions (e.g. requiring applicants for DOD funding to certify their non-participation in certain foreign talent programs). We thus have a mutual interest in seeking to assure expeditious and effective implementation of the initiative.

Other Non-Security Related Provisions of Interest in the NDAA

The increase in micro-purchase threshold for DOD (Sec. 821) was covered in previous COGR updates and reports (previous NDAA's also included this increase). There are a number of other provisions of interest. Sec. 854 establishes a new pilot program to expedite SBIR/STTR awards, and requires annual reports and assessments by GAO. Sec. 860 establishes a new commercialization assistance pilot program for SBIR Phase II awards that applies to all SBIR funding agencies. Elsewhere in the NDAA is a requirement (Sec. 1110) for DOD to develop a report on activities to increase engagement with historically black and minority-serving institutions to increase their participation in the technical workforce.

Of particular interest is Sec. 873, which requires data collection and assessments of the use of Other Transactions authority by DOD agencies. Annual reports are required on the use of the authority, with examples of successes and challenges. COGR long has been concerned with use of this authority, which is outside the normal requirements of federal procurement and assistance awards. Anecdotal information from COGR members suggests the use of this authority by federal agencies including DOD may be increasing. We look forward to reviewing the annual reports.

Other National Security-Related Legislative Activities

There is other pending legislation and report language that address security concerns. However none has yet been enacted.

On the House side, report language for the HHS appropriations encourages institutions to disclose to the Dept. of Ed. any contract with a foreign source that does not respect free expression and openness. It appears compliance would be difficult given the lack of clarity. House report language for NSF's appropriation directs NSF to work with the academic community to identify best practices for data security including intellectual property protection in NSF-funded facilities. A report on implementation plans is due within 180 days. We summarized Rep. Wilson's Foreign Influence Transparency Act (H.R. 5336) in the May Update.

Sen. Rubio has a companion bill (S. 2583) to the Wilson bill on the Senate side. On August 21, Sen. Rubio introduced another bill (S. 3361) primarily focused on restricting trade with China. It includes prohibiting exports to China of "any national security sensitive technology or intellectual property." Definitions are included in the bill. "Intellectual property" is defined in this bill as including "patents, copyrights, trademarks, or trade secrets." Several categories of "national sensitive security" IP are set forth. The bill also prohibits contracts involving use of telecommunications equipment similar to the NDAA but applicable to all agencies.

Also on the Senate side, Sen. Cruz has introduced a bill (S. 2903) which maintains the existing $250,000 disclosure requirement for gifts or contracts from a foreign source, but lowers it to $50,000 for gifts or contracts from foreign actors identified as foreign intelligence threats to higher education, with expanded disclosure requirements. Report language in the Senate HHS appropriations bill addresses Confucius Institutes, requiring disclosure of any that have received NIH funding (to our knowledge none have), the security of intellectual property derived from NIH-funded research, and identification of funding to foreign applicants. It also would require Ed. to report on Confucius Institute gifts specifically in foreign gift disclosure reports.

New Export Controls Reform Act Included in NDAA

The FY '19 National Defense Authorization Act (NDAA) includes a new Export Control Reform Act (Sec. 1741 et. seq.). It establishes a new Export Controls Act of 2018.

For the most part the new Act codifies previous law and regulations. However, it specifically addresses emerging critical technologies, calling for a process to identify and regulate them. This is addressed in Section 1758. It directs the President to establish an interagency process for this purpose, informed by a number of sources including the Emerging Technology and Research Advisory Committee (ETRAC). It also revises the objectives of the ETRAC to include advising the interagency process through identifying technologies that may emerge over a 5—10 year time frame and to identify trends in foreign ownership and transactions relating to such technologies. It further provides for interagency representation at ETRAC meetings.

COGR has participated and made presentations in a number of ETRAC meetings over the years, most recently in March of last year. However, since then we have not heard much about the activities of the Committee. The new Export Controls Act does not address Committee membership, or specifically provide for academic representation. This is of concern given the enhanced role of the Committee.

Another area of concern is a provision (Sec. 1753(b)(7) that singles out academic institutions for specific enforcement attention. Other potential concerns include lack of definition of certain terms ("critical infrastructure") and language that may be in conflict with the existing Export Administration Regulations (EAR) definition of "use" (Sec. 1754(d)(1)B), although the Act incorporates the existing EAR). There also could be potential implications for foreign licensing of federally-funded inventions from a provision providing for assessments of potentially significant negative impacts on the U.S. defense industrial base from reductions in U.S. production of items resulting from federally-funded research (Sec. 1756(d)(3)(B).

BIS currently is soliciting candidates to serve on the ETRAC. **Given its enhanced role, it is critical that there be strong academic representation.** We will discuss with the other associations ways to encourage academic candidates to apply, and other ways to facilitate effective interactions.

Additional Chinese Entities Added to Restricted List for Exports

On August 1 Commerce/BIS published a rule adding additional Chinese entities to the Entity List for export restrictions. There is a presumption of denial for export licenses to entities on the List for national security reasons. The entities primarily involve the China Aerospace Science and Industry Corporation Second Academy and the China Electronics Technology Group Corporation and their subordinate institutions (including a number of research institutes), for a total of forty-four.

Higher Ed. Associations Submit Comments on NIST ROI/RFI

On July 27 COGR joined AAU, APLU, AAMC and ACE in submitting comments on the NIST RFI on Federal Technology Transfer (83 FR 19054). The RFI and NIST's Return on Investment (ROI) Initiative under the President's Management Agenda were discussed by NIST Director Dr. Walter Copan at the June COGR meeting (see June Meeting Report).

We submitted extensive comments in response to the RFI that we summarized in seven basic points:

1) No changes in the Bayh-Dole Act are necessary. It should be considered a set of core principles that should be protected.
2) Lack of funding for university technology transfer is an ongoing challenge to universities' ability to transfer technologies.
3) We identified a number of bureaucratic hurdles that create disincentives by imposing unjustified cost and compliance burdens.
4) A robust patent system is essential for successful technology transfer. Uncertainty about march-in rights, patent eligibility, enforceability of patents and confusion over the treatment of software have a destabilizing effect.
5) There are opportunities to use the tax code more effectively to stimulate and support technology transfer.
6) There are a number of mechanisms and new or existing programs by which federal agencies could improve university technology transfer.
7) "Return on investment" should not be construed too narrowly, such as by using inappropriate metrics of success.

In each case we made specific related recommendations. We also cited a number of previous reports, including particularly the NAS 2011 report on *Managing University Intellectual Property in the Public Interest* (see COGR Fall 2010 Meeting Report; and recent AAU and APLU reports and statements.

Specific recommendations included changes to the recent revised Bayh-Dole implementing regulations (see May Update for a summary); a number of approaches to provide more funding for technology transfer; a new streamlined government-wide invention reporting system; a uniform government policy towards conflicts of interest that is better aligned with the government's interest in promoting commercialization; more guidance on waiver requests for U.S. manufacturing and rights to inventors; reaffirmation that NIH has appropriately interpreted the scope and use of march-in rights in responses to march-in petitions; improvements to patent law and practice; clarification of rights to software developed with government funding; simplification and improvements in certain tax code provisions; and improvements in a number of current technology transfer practices and programs.

NIST received 104 responses to the RFI. NIST has confirmed that they currently are not publicly available and has not yet made firm plans for their release. However we have seen a number of the comments submitted by other groups. Most are consistent with and supportive of the association comments. We understand NIST plans to summarize the comments and recommendations and issue a draft report for public comment in late fall. The final report is expected in early 2019.

The joint higher education association comments are posted on the COGR website.

Federal Appeals Court Rules Against Tribal Sovereign Immunity

We have reported several times on issues relating to claims of sovereign immunity by Native American tribes from patent challenges in *inter partes* review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB; see October 2017 Meeting Report for more background). In February the PTAB ruled that tribal sovereign immunity does not apply to IPRs since they are federal administrative proceedings.

On July 20 the Federal Circuit affirmed the PTAB decision. The court held that IPR is an agency action to reconsider its previous grant of a patent franchise. Tribal sovereign immunity does not apply to agency reconsideration of previous decisions. IPRs are not judicial proceedings and they do not follow the Federal Rules of Civil Procedure.

Perhaps ominously for state institutions, the court concluded "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."

Coupled with the Supreme Court's recent *Oil States* decision upholding the constitutionality of IPRs (see COG May Update), there is reason to doubt that a different outcome would be reached in cases involving state sovereign immunity. The Supreme Court also found in that case that IPR is only an agency reconsideration action involving a public franchise.

The Federal Circuit decision is *Saint Regis Mohawk Tribe v. Mylan Pharmaceuticals* (No. 2018—1638; Fed. Cir. 7/20/18.)

On August 21, the Tribe filed a petition for a rehearing by the Federal Circuit *en banc*.

COGR Joins Other Associations in Supporting USPTO's Proposed Claim Construction Standard

On July 9 COGR jointed AAU, APLU and AAMC in a letter to the USPTO supporting USPTO's proposal to harmonize the claim construction standard used in IPRs with that used in federal courts by applying the *Philips* "ordinary meaning" standard rather than the current "broadest reasonable interpretation." The letter cited the asymmetries in the patent system resulting from different standards.

We also had advocated this change in our response to the NIST ROI. The proposed STRONGER Patents Act (see May Update) which we and the other associations supported also included this change.

Associations Support SUCCESS Act

On August 27 COGR joined AAU, APLU, AAMC and AUTM in a statement supporting the SUCCESS Act (Study of Underrepresented Classes Chasing Engineering and Science Success), introduced by Rep. Comstock (R-VA) with seven cosponsors on August 6 (H.R. 6390). The bill requires SBA in consultation with other federal agencies (including USPTO) to conduct a study of patents applied and obtained by small businesses owned by women and socially disadvantaged individuals and to provide legislative recommendations for promoting their participation in entrepreneurship and increasing the number who apply for and obtain patents. The report is due within six months.

Updates

a. Controlled Unclassified Information

In July NIST issued a bulletin containing information on procedures and methodology for conducting assessments of the NIST SP 800-171 security requirements NIST will hold a workshop on the requirements on October 18. Registration for in person attendance closes Oct. 11, but the workshop also will be webcast. The oft-postponed due date for the draft FAR CUI rule was postponed again, until August 29 according to the latest FAR Open Cases Report.

b. Drug Pricing

80 House Democrats signed on last month to a bill (HR 6505) that would give HHS the authority to offer licenses to competitors to make generic versions of patented Medicare Part D drugs when negotiations over the price of a drug are unsuccessful. "Reasonable compensation" would be required. The bill does not involve march-in under the Bayh-Dole Act nor, interestingly, the patent "eminent domain" statute at 28 USC 1498.

Research Regulatory Reform

Statement of Administration Policy on DOD and LHHS FY19 Appropriations – Impact on Research Policy Board

The Office of Management and Budget published a Statement of Administration Policy (SAP) dated August 15, 2018, regarding appropriations for the Departments of Defense, and Labor, Health and Human Services, Education, and related agencies, for FY19. Of note is a statement related to the 21st Century Cures Act Research Policy Board. The SAP indicates that "The Administration is disappointed that the bill does not authorize the use of NIH funding to establish and operate the 21st Century Cures Act Research Policy Board, as requested in the FY 2019 Budget." The 21st Century Cures Act requires that OMB establish and operate the Research Policy Board. The RPB was to be established by December 2017.

The SAP goes on to say that the indirect cost policy provision, "which prohibits changes to the method NIH uses to pay grantee institutions for administrative and facilities costs" "makes it difficult to address regulatory burden in a meaningful way. As a result, the Administration will not be able to establish the Research Policy Board as directed by the Congress." OMB had previously made this argument in private meetings but has only recently publicly asserted that it cannot establish the RPB due to prohibitions on F&A cost reimbursement at NIH. While it is hard to imagine how this prohibition would make it difficult to address conflict of interest or animal research regulatory reform, for example, OMB has seemingly dug in its heels on this issue and the RPB looks unlikely to be established near-term.

COGR Article on the Current State of Research Regulatory Reform

An update on the current state of research regulatory reform was published in *Science* on July 20. A link to the full text article, *Engage research institutions on research regulatory reform*, is available through the COGR website.

Research Involving Human Participants

NIH Notice and RFI on Basic Science Research Involving Human Participants

NIH issued a Guide Notice on July 20, Delayed Enforcement and Short-Term Flexibilities for Some Requirements Affecting Prospective Basic Science Studies Involving Human Participants. COGR and other organizations previously expressed concern that extensive revisions made to the NIH clinical trial case studies in 2017 broadened the agency's interpretation of the definition of "clinical trial" to include basic science studies involving human participants. The new and revised case studies varied substantially from previous cases published at the time of, and subsequent to (April 2015 and September 2016) the October 2014 publication of NIH's revised definition of "clinical trial", thereby retroactively subjecting these basic science studies to agency policies specific to clinical trials.

Ongoing concerns from the research community about the new and revised case studies led to language in the Consolidated Appropriations Act of 2018 directing NIH to "delay enforcement of the new policy published in the Federal Register on September 21, 2017 [2016], including NIH' s more expansive interpretation of 'interventions', in relation to fundamental research projects involving humans" and "consult with the basic research community to determine the reporting standards best suited to this kind of research." In response to this language, NIH has released this notice (NOT-OD-18-212) which delays enforcement of registration and reporting policies for prospective basic science studies involving human participants under NOT-OD-16-149 . Per the notice, "through September 24, 2019, NIH will continue to expect registration and reporting for prospective basic science studies involving human participants, with additional flexibility to allow reporting on existing basic science portals, with the expectation that data will eventually be transported to ClinicalTrials.gov."

The notice also provides a period of "leniency for applications submitted to the incorrect funding opportunity announcement (FOA) based on the study type designation" during which time NIH will not "administratively reject any application for submission to an incorrect FOA based on study-type designation." The notice also indicates that the agency "plans to issue FOAs specifically for prospective basic science studies involving human participants."

NIH released a request for information, Registration and Results Reporting Standards for Prospective Basic Science Studies Involving Human Participants, on August 10. The RFI, seeks information on standards and potential alternative platforms (e.g., the Open Science Framework) for registering and reporting basic science studies involving human participants and related areas. The July 20, 2018 NIH notice and this RFI, propose a third category of research involving human participants. The first "clinical trials", the second "prospective basic science studies involving human participants" (studies that meet the NIH definition of "clinical trial" per the revised case studies but also meet the federal definition of basic research), and the third, basic science studies involving human participants that do not "meet the definition of clinical trials" (were not included in the revised case studies) but which we would suggest are in fact "prospective." COGR will suggest, as the organization has previously, that "prospective basic science studies involving human participants" are not clinical trials and should not be subject to NIH policies specific to clinical trials, and that NIH consider how basic science studies involving human participants as a whole should be registered and reported in a way that is informative for the public and research community but not unnecessarily burdensome.

COGR is currently working with other organizations in response to the RFI and will provide a draft or final letter to members well in advance of the November 12 deadline for comments. If you have questions about the RFI, or COGR's response, please contact Lisa Nichols.

National Academies Report on Returning Individual Research Results

The National Academies Committee on the Return of Individual-Specific Research Results Generated in Research Laboratories released its report *Returning Individual Research Results to Participants: Guidance for a New Research Paradigm* on July 10. The report addresses the balance between returning research results and ensuring that poorly validated results are not communicated to participants. The report errs on the side of returning research results while enhancing their quality and with consideration of associated burdens, and includes twelve recommendations.

The committee recommends investigators include plans in study protocols that describe if, when and how results will be returned; that sponsors require that applications address the issue; and that institutions and IRBs develop policies to support the review of plans to return results. With respect to the quality of results, the committee acknowledges that requirements established by the Clinical Laboratory Improvement Amendments of 1988 are not "appropriate or feasible for all research laboratories" but also suggests that there is no viable alternative. The committee therefore recommends that NIH "lead an effort to develop a quality management system (QMS) for research laboratories testing human biospecimens" and that when results are not intended for clinical decision making, IRBs should permit use of the recommended QMS once developed or after determining that analysis is "sufficient to provide confidence in the result," the value outweighs the risks, and appropriate disclaimer information is provided.

The report recommends that results be returned in terms of key takeaway messages "what is known and unknown about the meaning and potential clinical implications of the results, including the level of uncertainty in the results' validity." The committee also recommends that regulators harmonize pertinent regulations, addressing inconsistencies and facilitating return of results. The reports suggests that CMS revise CLIA regulations "to allow for the return of results from non-CLIA certified laboratories when results are requested under the HIPAA access right and also when an IRB process determines it is permissible." It also suggests that the Office for Civil Rights of the Department of Health and Human Services "limit access to individual research results under HIPAA to those generated in a CLIA-certified laboratory or in a research laboratory compliant with the recommended externally accountable QMS for research laboratories."

SACHRP July 2018 Meeting and OHRP Resources

The Secretary's Advisory Committee on Human Research Protections met July 10-11. The agenda and links to the archived webcasts are available on the HHS website. Among the topics discussed were "Key Information in Informed Consent: Interpretation and Application of Section 116 (a)(5)" with a focus on clinical trials. There was some discussion about the language in the preamble with respect to key information. It was suggested that there can be very different implications for participants and also motivations for engaging, and discussion on what the most pertinent information would be. What is the information needed to make a well-informed choice? Why participate? What is the research question that the study is trying to answer and why is it relevant? What is

the impact (or potential impact) on the participant's life and what activities will be conducted and information collected? What are the benefits and risks and possible side-effects?

There was discussion on recommendations from SACHRP including that "OHRP and other agencies confirm that there is compliance flexibility going forward, unless and until such time that there is common agreement on how to select and provide key information, and should specifically state that diverging from the preamble suggestions of key information will not incur a compliance risk. This will encourage the open development of new and potentially better approaches to key information." It was suggested that the elements from the preamble would be sufficient for some studies but not others. The committee discussed making recommendations final in October.

Other topics covered at the meeting included the OIG report "OHRP Generally Conducted its Compliance Activities Independently, but Changes Would Strengthen its Independence" and an update on EU General Data Protection Regulation. OHRP recently announced the availability of a "Compilation of European General Data Protection Directive Guidance" on the OHRP website.

Not discussed at the meeting was OHRP guidance on three burden-reducing provisions in the revised Common Rule which were subsequently released on July 19. The draft guidance includes Scholarly and Journalistic Activities Deemed Not to be Research; When Continuing Review Is Not Required During the 6-Month Delay Period; and Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals.

NIH Proposal to Streamline Oversight of Human Gene Therapy Trials

NIH issued a notice on August 17, 2018 seeking comments on a proposal to amend the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*). The stated goals of the proposed changes are to streamline the oversight of human gene transfer clinical research protocols and reduce duplicative reporting requirements. As indicated in the notice, "NIH proposes amendments to: Delete the NIH protocol registration submission and reporting requirements under Appendix M of the *NIH Guidelines,* and modify the roles and responsibilities of entities that involve human gene transfer or the Recombinant DNA Advisory Committee." Additional information is available in a perspective article authored by Dr. Francis Collins and Dr. Scott Gottlieb, a statement by NIH Director Collins, and a blog post by Dr. Carrie Wolinetz, Associate Director for Science Policy. Comments are due October 16, 2018. COGR anticipates submitting comments in support of the proposed changes and will distribute comments to members prior to the October 16 due date.

Federal Websites That Satisfy the Requirement to Post Clinical Trial Consent Forms

In an email dated August 28, HHS and other Common Rule departments and agencies announced where clinical trial consent forms can be posted, a requirement of the revised Common Rule. The websites include ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021). Per the email, additional federal websites may be identified in the future and additional information including instructions and other materials will be provided at a future date.

NIH Workshop on Single IRB Resource and Infrastructure Development

NIH will hold a public workshop on Single IRB Resource and Infrastructure Development on September 12. NIH previously funded seven administrative supplements to foster development of approaches for modifying and enhancing institutional IRB infrastructure for efficient and effective single IRB review. Awardees will share the strategies they have developed. In-person registration is now closed; however, the workshop will also be webcast.

NIH Seeks Comment on a Draft Behavioral and Social Sciences Clinical Trial Template

NIH issued a request for public comment on August 27 seeking input on a Draft Protocol Template for Behavioral and Social Sciences Clinical Trials. Comments must be submitted by October 11, 2018. Additional perspective on the template can be found in a recent blog post by Dr. Carrie Wolinetz, Associate Director for Science Policy, and Dr. William Riley, Director of the Office of Behavioral and Social Science Research.

Senate Hearing on Science and Stewardship at NIH and Discussions on National Security

The Senate Committee on Health, Education, Labor and Pensions (HELP) held the hearing *Prioritizing Cures: Science and Stewardship at the National Institutes of Health* on August 23. HELP Chairman Lamar Alexander highlighted the $4.8 billion in funding for NIH made available through the 21st Century Cures Act and with respect to appropriations, the $2 billion increase that the Senate was poised to approve for NIH for FY19 and the overall $9 billion increase since 2015. The stated focus of the hearing was to ensure that the increased funding is being spent wisely. Senator Alexander noted that it was difficult to think of major science advancement since World War II that hasn't been supported by federal funding. The Senator took the time to note that spending for research, part of discretionary spending, is not contributing to the budget deficit, and indicated that entitlements will continue to squeeze funding for research.

Senator Alexander highlighted recent NSF data indicating that China has increased its spending for basic science by a factor of four since 2007 and may exceed the U.S. in total R&D spending this year. He mentioned that he and Senator Murray had been informed by NIH about an ongoing investigation into federally funded research "including in some cases research conducted by foreign nationals" and asked that Dr. Collins take a few minutes to brief the committee on this issue during his opening remarks. Senator Alexander noted that it is important to protect the integrity of research funded by the federal government and to identify bad actors but also to recognize the important role that scientists from other countries play in U.S. research. This includes foreign born citizens leading U.S. national labs, foreign nationals working in the U.S. legally on NIH-funded research as graduate students, 33 foreign born U.S. citizens who have won the Nobel Prize in chemistry, medicine, and physics since 2000, and the "great advantage to our country of attracting the brightest people from around the world to our universities and laboratories."

Dr. Collins thanked the Senators for the opportunity to discuss efforts to protect the integrity of U.S. biomedical research from undue foreign influence. He noted that NIH has long understood that there are risks to the security of intellectual property (IP) and the integrity of peer-review in biomedical research and that this has shaped current policies and practices, but also that the magnitude of this risk is increasing. It should be noted that on the subject of foreign influence, members of congress and federal agency staff have been using the term

IP broadly to include knowledge and ideas, not just products and patents. Dr. Collins indicated that NIH recently sent a letter to senior representatives of grantee institutions asking that they review their records for evidence of malfeasance in three areas of concern: 1. Failure on the part of researchers to disclose substantial contributions of resources from other organizations, including resources from foreign governments; 2. The diversion of IP to other entities including other countries; and 3. Failure by some peer reviewers to keep information from peer review confidential, including some disclosures to foreign entities.

In his remarks, Dr. Collins indicated that NIH is creating a new working group of the Advisory Committee to the Director (ACD) to identify "robust" methods to improve accurate reporting of all sources of research support, financial interests, and affiliations; to mitigate risk to IP security; to explore additional steps to support the integrity of peer-review; and to carry out these actions in a way that reflects the "long tradition of partnership between NIH and grantee institutions, and that emphasizes the compelling value of ongoing honorable participation by foreign nationals in the American scientific enterprise." Collins named working group members including: Roy Wilson, President, Wayne State University, and Larry Tabak, Principal Deputy Director, NIH (Co-Chairs); Jeffrey Balser, President, Vanderbilt University Medical Center; Ana Mari Cauce, President, University of Washington; Michael Drake, President, The Ohio State University; Wallace Loh, President, University of Maryland; Samuel Stanley, President, Stoney Brook University; and Maria Zuber, Vice President for Research, Massachusetts Institute of Technology, and former Chair of the National Science Board. The COGR CIP and RRR committees, working with other associations, will continue to follow these issues and to maintain an ongoing dialogue with senior federal agency staff.

The remainder of the hearing was spent discussing scientific progress and areas of concern including gene therapy, obesity, Alzheimer's disease, and opioid addiction. Senator Alexander inquired about three areas where investigators have suggested that NIH could do a better job, including support for more young scientists; ensuring the quality of peer-review panels; and reducing the bureaucracy associated with grant proposals. Collins noted that NIH is prioritizing funding for early stage investigators (ESI), funding 1100 ESI this year, the largest group ever. Collins indicated that NIH will fund over 11,000 grants this year, more than any other year, and is funding more individual investigators. An ACD working group will provide additional recommendations on the agency's Next Generation Research Initiative in December. Regarding peer-review, Dr. Collins indicated that as a condition of award, investigators receiving NIH funding are required to say yes if asked to serve on a peer-review panel. As a result, approximately 80% of awardees serve as reviewers. Regarding Senator Alexander's inquiry on the bureaucracy associated with grant proposals, Collins mentioned only NIH's use of Pioneer and related awards that have brief applications and longer funding periods.

Senator Warren, expressing concern about conflicts of interest, indicated that the largest contributors to the Foundation for NIH are all pharmaceutical companies and that the agency needs to be careful that funding sources don't have a vested interest in research outcomes. She suggested that funds should instead be made available through taxes.

Congress Writes to Education Secretary on University Partnerships with Huawei

On June 19, Representative Jim Banks and Senator Marco Rubio sent a letter signed by 26 members of Congress to Education Secretary Betsy DeVos. The letter expresses concern about Huawei Technologies partnerships with U.S. research institutions through its Huawei Innovation Research Program. The letter

suggests that "these partnerships may pose a significant threat to national security," that companies like Huawei "cannot be trusted to be free of foreign-state influence," and that these partnerships are "a primary mode of China's toolkit for Foreign Technology Acquisition." The letter ends with a request that the department discuss this matter with the U.S. intelligence community and "request (and require) information from the U.S. universities involved in any partnership with Huawei, especially those receiving any federal research funding (including Department of Defense funding)" to determine whether funding and personnel are involved in a Huawei partnership and/or talent program. The letter also requests a "senior-level working group to understand how the People's Republic of China attempts to gather U.S. technology on U.S. university and college campuses" and to develop recommendations "for protecting the U.S. technology advantage."

A letter dated July 17, 2018, from Diane Auer Jones, Principal Deputy Under Secretary for Education, indicates that the department scheduled a security briefing and will follow-up with "executive branch partners." The letter notes that under section 117 of the Higher Education Act, IHEs that participate in Title IV must file a report with the department when they "receive a gift from or enter into a contract with a foreign source, the value of which is $250,000 or more, considered alone or in combination with all other gifts from or contracts with that foreign source within a calendar year." The letter includes, on the last page, a summary of IHEs that reported Huawei Technologies as a funding source and provides a link to funds reported by all IHEs under section 117. The letter indicates that the Department will "continue to follow-up with our executive branch partners in their respective missions to protect our national security."

Dr. Kelvin Droegemeier Nominated for OSTP Director

The Senate Committee on Commerce, Science, and Transportation held a nominations hearing on August 23. Among the witnesses testifying was Dr. Kelvin Droegemeier to be the Director of the Office of Science and Technology Policy. COGR issued a statement on August 1 endorsing the nomination. Dr. Droegemeier has served as Oklahoma's Secretary for Science and Technology and Vice President for Research at the University of Oklahoma, and is a former member of the National Science Board and of COGR's board.

Nonprofit Funder - Research Institution Working Group Meeting and Website

COGR, the Health Research Alliance, and Faster Cures led a day-long workshop on May 16, 2018 to discuss guiding principles and beneficial practices to build and foster effective relationships between non-profit research-funding organizations and research-performing institutions. The meeting was supported by the National Academies Government University Industry Research Roundtable.

May 16 meeting materials are available on the COGR website. A follow-up meeting has been scheduled for November 7, 2018 at the National Academies Keck Center in Washington, DC. A draft agenda for the meeting has been posted to the COGR website. If you would like to participate in the November 7 meeting in person or via webcast please contact Lisa Nichols for information on how to register.

Audit

NSF OIG Audit Reports

In a performance audit of one institution dated August 22, auditors tested $1.7 million of costs charged to NSF awards over a three year period. Auditors questioned $48,842 of costs claimed, including $28,733 for equipment purchases near the end of an award; $16,775 for various transactions such as reallocated participant support costs, advertising costs near the end of an award, meal costs, and cost transfer; and $3,334 in travel costs. Interestingly the report notes the institution's total funding from grants and contracts in 2016, the percentage of grants and contracts awarded by federal agencies, and a breakdown of the $79 million in costs claimed to 281 NSF awards over the three year audit period by budget category. The institution agreed with $8,017 in questioned costs but disagreed with the remaining questioned costs relating to equipment purchases and reallocated participant support costs.

The NSF OIG recently concluded an audit of NSF's oversight of subrecipient monitoring. The report found that "NSF's processes for monitoring grantees were sufficient to ensure that [pass-through entities] PTEs monitored subrecipients properly" but that "PTEs of major facilities did not always provide subrecipient budgets and budget justifications when required." And that "NSF was not always able to identify subrecipients on major facility budget proposals because the systems and documents PTEs used to request approval for subawards did not always distinguish requests for contract funding from requests for subaward funding." The report suggests that NSF's oversight of subrecipient risk assessments on large and complex awards could be improved and recommends that NSF "take action to ensure that PTEs clearly identify entities that will receive a subaward." The full report, including NSF's process for overseeing pass-through entities subrecipient monitoring and the agency's response to the audit findings can be found here.

In a National Science Board Committee on Oversight meeting on July 17 NSF IG Allison Lerner indicated that the agency agreed with the findings, began implementing recommended changes prior to publication of the report, and continues to make changes. Allison also noted that the IG Act was enacted 40 years ago and that in 2019 the NSF OIG will have been in existence for 30 years. She also noted that the NSF OIG can now be followed on Twitter.

HHS and NIH OIG June COGR Session on Payroll Certification

We previously reported in the June 2018 COGR update on the June COGR meeting session with Laura Rainey, Audit Manager and National Single Audit Coordinator, NSF Office of Inspector General, and Lori Pilcher, Regional Inspector General for Audit Services, Atlanta, HHS OIG. Lisa Mosley, Executive Director, Office of Sponsored Projects, Yale University, and Co-Chair of the University Cohort on Alternatives to Effort Reporting served as moderator. The moderator notes for this session are now available on the COGR website.

DEA Call for Comments

The Drug Enforcement Administration (DEA) seeks comments through the Federal Register Notice, Proposed Year 2019 Aggregate Production Quotas and Assessment of Annual needs for Schedule 1 and II Controlled substances to be manufactured in the U.S.

Of significance to COGR and its Cannabis Working Group is the proposed increase of tetrahydrocannabinols in 2019, which more than quintuples (1,000 pounds in 2018 to more than 5,400 pounds in 2019) the amount of cannabis that can be legally grown in the U.S. for medical, scientific, and research purposes.

Comments to the federal register notice are due September 19, 2018. COGR anticipates sending a response that will address not only the proposed quantity increase but also the need for additional strains. Stay tuned for further updates.

Stevens Amendment

In April 2017 five Republican senators signed and submitted a letter to the Government Accountability Office (GAO) requesting a review of the transparency requirements under the Stevens Amendment for grantees who receive federal funding. Specifically triggering the review were previous reports about institutions who failed to follow certain provisions of the spending bill. The Stevens Amendment states that, "When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds, including but not limited to State and local governments, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

GAO recently requested a meeting with COGR in August to discuss the federal funding disclosure requirements in the context of grants management. Specifically, they were interested in COGR's thoughts regarding grantee compliance with the requirements of the Stevens Amendment (Consolidated Appropriations Act of 2018, Public Law No. 115-141, Division H, Title V, Section 505).

The GAO was asked to re-visit the legislative mandates pursuant to the Consolidated Appropriations Act of 2018, which includes the Stevens Amendment as part of the President's Management Agenda, CAP Goal 8, "Results-Oriented Accountability for Grants." Since the law currently provides no specifics for agency monitoring, GAO will continue to document any cases of existing guidance, and instances of best practices with the amendment. Stay tuned for additional updates.

NIH to Release New Guidance Distinguishing Fixed Amount Subawards from Fixed-Rate Agreements

During COGR's February 2018 meeting, the RCA Committee, along with members from the FDP Subaward Subcommittee leadership hosted Samuel Ashe, Director, Division of Grants Policy at the National Institutes of Health (NIH). The purpose of the meeting was to share concerns member institutions had when applying fixed amount subawards to Clinical Trial Agreements with capitation payments. Concerns included the need to ask for prior approval, whether new awards had to be issued for agreements over the Simplified Acquisition Threshold (SAT), and how best to craft a subaward template to subrecipients using the fixed amount award model that includes capitation payments.

During the discussion, COGR and the FDP Subaward Subcommittee leadership offered to jointly craft language they recommend be included in the NIH Grants Policy Statement. The language drafted would build off language already present on the topic of fixed amount subawards found in 8.1.2.11 of the NIH Grants Policy

Statement and mirrors the approach adopted by the Department of Defense (DOD) in the General Terms and Conditions, which defines clinical trial fixed amount subawards to be "fixed-rate" awards not subject to prior approval requirements or the SAT.

COGR and FDP followed up in August and was told that NIH will issue guidance clarifying the distinction between the two agreement types. NIH will now refer to a fixed rate agreement as an agreement commonly used by Clinical Trial Coordinating Centers to distribute capitation funds. In a fixed amount subaward, the total value of the award is negotiated upfront. This requires the pass-through entity to know both the unit price and the total number of units that will be provided. However, in a fixed-rate agreement, while there is a negotiated cost per unit, e.g., per patient cost in a clinical trial, the total amount of the award may be unknown when the agreement is created. Since this type of agreement is based on a "fixed rate" as opposed to a "fixed amount" as defined by 45 CFR Part 75.201, NIH has indicated that prior approval will not be required to enter into this type of agreement provided there are no other factors that would require NIH prior approval consistent with NIHGPS Chapter 8.1.1.4. In addition, the SAT cap will not apply to these types of agreements since they are not based on "fixed amounts". By issuing this clarification NIH will acknowledge that we have not made any changes to our current clinical trial capitation award funding model.

The guidance is currently working its way through the NIH clearance process and should be published in September. Stay tuned for further updates.