



Council On Governmental Relations

An Association of Research Institutions

DECEMBER 2019 UPDATE

[Registration is Now Open for COGR's February 27-28, 2020 Meeting](#)

[Section 117 Proposed Reporting Requirements – UPDATE](#)

[COGR Releases Commentary on Disclosure of Other Support to NIH – UPDATE](#)

[Framework for Reviewing Researcher's Global Engagements – UPDATE](#)

[JASON Fundamental Research Security Report – NEW](#)

[Resources Available – REMINDER](#)

[NIH Regulatory Reform: Subrecipient Monitoring and Financial Reporting – NEW](#)

[Reports of Individual Conflicts of Interests in NIH-Funded Research Made Public – NEW](#)

[OHRP Exceptions to Single IRB Review – REMINDER](#)

[New NIH Advisory Committee on Rigor in Animal Research – NEW](#)

[Save the Date! Fostering Rigorous Research: Lessons Learned from NHP Models and Charting the Path Forward – February 18-19, 2020 - NEW](#)

[F&A White Paper and PPT Sliddeck: Now Available – NEW](#)

[NIFA Challenges – UPDATE](#)

[HHS/NIH G-Accounts and Reconciliation – STATUS QUO](#)

[NSF and HHS OIG Audit Workplans for FY2020 – REMINDER](#)

[Cloud Computing, MTDC, and F&A Application – NEW](#)

[F&A Rate Negotiations – MEMBER FEEDBACK REQUESTED](#)

[NIH Issues Annual Revision of the Grants Policy Statement - NEW](#)

[NIH Data Management and Sharing Policy: COGR to Provide Public Comment – UPDATE](#)

[COGR Submits Letter to SAMHSA Regarding Attestation Requirement – NEW](#)

[USDA Request for Comments to Establish a Domestic Hemp Program - UPDATE](#)

[Final Report from NIH Advisory Committee to the Director on Sexual Harassment – NEW](#)

[Department of Education Investigatory Letters to Institutions – UPDATE](#)

[Senate Report on China's Talent Recruitment Plans – UPDATE](#)

[FY '20 NDAA Addresses Science and Security Issues – NEW](#)

["Partnering with DOD" – UPDATE](#)

[DOE Revises Order 142.3A on Foreign National Approval Requirements – NEW](#)

[Drug Pricing Legislation Status – UPDATE](#)

[Possible DOD Change to Contractor IP Rights – NEW](#)

[NIST Issues iEdison RFI – NEW](#)

[Patent Eligibility Legislative Discussions Stall – UPDATE](#)

[Bayh-Dole 40th Anniversary – REMINDER](#)

Registration is Now Open for COGR's February 27-28, 2020 Meeting

[Register today](#) for COGR's February 27-28, 2020 Meeting in Washington D.C and reserve your [hotel room](#) by February 11 for special COGR pricing. Please note, any meeting cancellations must be received by February 21 for a refund. Please contact Toni Russo at trusso@cogr.edu if you have any questions.

Section 117 Proposed Reporting Requirements – UPDATE

The [October Meeting Report](#) discussed the COGR comments on the Department of Education's (ED) proposed information collection request to "modernize" HEA Sec. 117 reporting (84 FR 46943). On December 9, we sent COGR members a [letter](#) from the Department of Education (ED) to Senator Portman, Chair of the Senate Permanent Subcommittee on Investigations, regarding Section 117 reporting issues. This followed a Senate [hearing](#) on *Securing the U.S. Research Enterprise from China's Talent Recruitment Plans*.

The American Council on Education (ACE) responded to the ED letter in a [December 6 letter](#) to Sen. Portman that we also sent to the COGR membership. The ACE letter stated that the ED letter "is rife with inaccuracies and distortions." The letter further stated, "Instead of clarifying the current requirements so that they are clear and unambiguous, the Department has proposed an expanded information collection process that imposes a vast array of new requirements far exceeding the language of the statute."

On December 13 ED published a notice of a request for OMB approval of the proposed Sec. 117 reporting requirements under emergency procedures which would shorten the comment period to ten days. On December 17 ED published an [updated notice](#) and supporting materials [available here](#) and in the docket folder (Docket No.: ED-2019-ICCD-0154).

We alerted the membership of these developments. The requested use of emergency procedures in this situation seems inappropriate and a questionable attempt to rush the process, especially with the timing right before the holidays. On December 18, COGR [sent a letter](#) to OMB objecting to the process. AAU, ACE and other associations also have sent letters of objection to OMB and/or ED. ***We urge COGR institutions also to strongly consider objecting to OMB.*** ED has made some fairly significant changes to the reporting requirements in response to the public comments. Nevertheless, some serious problems remain. ACE held a conference call on December 19 to discuss the comments and other developments, and COGR has joined with ACE and other associations in substantive comments to OMB. (Note, also see "Department of Education Investigatory Letters to Institutions" further down in the COGR Update).

COGR Releases Commentary on Disclosure of Other Support to NIH – UPDATE

The NIH Notice [NOT-OD-19-114](#), Reminders of NIH Policies on Other Support and Policies related to Financial Conflicts of Interest and Foreign Components, and the [accompanying FAQs](#), raised several questions in the community about what and how investigators must disclose other support in grant applications. Since then, there have been many discussions about the requirements, and public

statements clarifying the requirements. It appears that NIH is unlikely to issue formal clarification in the short term, but institutions still need to submit proposals and reports. In the interim COGR has [summarized our current understanding](#) of the NIH requirements based on what COGR and its members understand from various NIH representatives in public meetings and other open discussions since the publication of the Notice. The commentary represents COGR's best assessment of these statements. This document has not been endorsed by NIH.

Framework for Reviewing Researcher's Global Engagements – UPDATE

As we mentioned at the October meeting, the Research Ethics & Compliance Committee (REC) is working on developing a Framework to assist institutions in the review of individual disclosures of relationships with international organizations. The purpose of the Framework is to provide an underlying structure to support the institution's analysis of such engagements, assess potential risks, and develop strategies for mitigation. Because each institution has different policies, approaches, levels of foreign involvement, and risk tolerance, this Framework does not present a prescriptive approach. Instead, it is a tool to help institutions identify and resolve potential issues relating to global engagements. The recently published [JASON](#) report urges institutions to consider several points before engaging in new international activities (page 34), including many of the same topics addressed in the Framework.

We expect to release Version 1 of the Framework in early January with the understanding that the environment is changing quickly and that updates may be needed once federal stakeholders release additional policies and guidance.

JASON Fundamental Research Security Report – NEW

We reported in the COGR [May 2019 Update](#) that NSF had asked the JASON group of distinguished, mostly academic, scientists to study issues pertaining to research security. NSF released the [JASON group report](#) on December 11. According to the [NSF News Release](#), four main themes emerged from the JASON study: 1) the value of, and need for, foreign scientific talent in the U.S.; 2) the significant negative impacts of placing new restrictions on access to fundamental research; 3) the need to extend our notion of research integrity to include disclosures of commitments and potential conflicts of interest (likely to be somewhat controversial; see the [December 11 article](#) from Science); and 4) the need for a common understanding between academia and U.S. government agencies about how to best protect U.S. interests in fundamental research while maintaining openness and successfully competing in the global marketplace for STEM talent.

Key principles/findings outlined in the report for promoting research security and integrity include: upholding scientific ethics protects research integrity and promotes international collaboration; openness of fundamental scientific research is critical to advancing U.S. scientific research; NSDD 189 and the principles underlying it should be maintained and reaffirmed; international students and researchers in the U.S. as well as international scientific collaborations are crucial to the vitality of fundamental research;

breaches of research integrity that originate in the actions of some foreign governments are a serious challenge to the U.S., its partners and the entire research enterprise; addressing these challenges requires transparency, communication, and collaboration among all stakeholders; and foreign-born scientists and engineers training and working in the United States are essential contributors to U.S. preeminence in science, engineering, and technology. Maintaining that leading position requires that the United States continues to attract and retain the best science talent globally.

An [NSF Fact Sheet](#) notes additionally that the Report found that actions of the Chinese government and its institutions that are not in accord with U.S. values of science ethics have raised concerns about foreign influence in the U.S. academic sector. According to the Report, the scale and scope of the problem remain poorly defined. Academic leadership, faculty and front-line government agencies lack a common understanding of foreign influence in U.S. fundamental research, possible risks and the possible detrimental effects of restrictions that might be enacted in response. Conflicts of interest and commitment in the research enterprise can be broader than those that are strictly financial. There are many stakeholders with responsibility for the integrity of fundamental research, from U.S. government agencies to individual scholars. Universities and research funding agencies have policies and guidelines regarding some of these responsibilities, but these are often insufficient for individuals to assess risk and take appropriate actions. NSDD 189 establishes a clear distinction between fundamental research and classified research. It remains a cornerstone to the fundamental research enterprise. Universities have mechanisms to handle Controlled Unclassified Information (CUI) under existing categories, such as HIPAA, FERPA, export control, and Title XIII, but CUI is ill-suited to the protection of fundamental research areas.

The Report makes 9 recommendations that track these findings. Most are directed to NSF, but some also are directed to universities and other government agencies. Among the latter is that education and training in scientific ethics at universities and other institutions performing fundamental research should be expanded beyond traditional research integrity issues to include information and examples covering conflicts of interest and commitment. For additional commentary see <https://www.nature.com/articles/d41586-019-03818-4>

Both the [House and Senate Armed Services Committee \(HSAG\)](#) JASON reports were discussed at the meeting of the NSF Advisory Committee for International Science and Engineering on December 13. The reaction to the JASON report was positive, however there were concerns expressed about overemphasis on distinctions between basic and applied research and possible overreaction by universities.

Resources Available – REMINDER

Educating researchers about disclosures of international engagements – Many institutions have shared their [resources](#) for educating their faculty and the research community on new and existing federal and institutional requirements, especially as they relate to engaging with international partners.

Conflict of commitment policies from peer institutions – Many institutions are reviewing their policies

and procedures in response to recent cases of non-disclosure of outside relationships. To help with this effort, some COGR members have provided [links](#) to their conflict of commitment policies.

NIH Regulatory Reform: Subrecipient Monitoring and Financial Reporting – NEW

The [21st Century Cures Act](#), signed into law on December 13, 2016, included several regulatory reform initiatives to be implemented by the National Institutes of Health (NIH). Two of those initiatives, which COGR has tracked closely over the past three years, are subrecipient monitoring and financial reporting. In a recent call with Michelle Bulls from NIH, we received the following update:

Subrecipient Monitoring – The expectation is that new language, which will address administrative burden associated with the monitoring requirements for a subrecipient already subject to the single audit, could be available soon. The vehicle for implementing this change would be through [2 CFR, Part 200](#) (i.e., Uniform Guidance). Our understanding is that OMB expects to publish proposed changes to the Uniform Guidance, including language related to Subrecipient Monitoring, and that HHS/NIH will implement these changes through [45 CFR, Part 75](#).

Federal Cash Transactions Report (OMB Standard Form 272) – COGR’s position is that the Federal Cash Transactions Report (FCTR) has been redundant and obsolete since 2015 after HHS/NIH implemented “sub accounting” (i.e., cash balances by award maintained in “real-time”). Reconciling the FCTR to the NIH financial close-out report is a low-value, burdensome activity, which would be eliminated if the FCTR were to be eliminated. Our understanding is elimination of the FCTR could happen in two phases: 1) single portal submission of the NIH close-out report through the HHS Payment Management System, and 2) Certification Statement by the institution indicating the institution has a) completed an appropriate internal reconciliation, and b) has met all Terms and Conditions related to cash draws.

Timing for Award Closeout – [2 CFR, 200.343\(g\), Closeout](#) states: “*The Federal awarding agency or pass-through entity should complete all closeout actions for Federal awards no later than one year after receipt and acceptance of all required final reports.*” The HHS/NIH implementation under [75 CFR, 75.381\(g\), Closeout](#) states: “*The HHS awarding agency or pass-through entity should complete all closeout actions for Federal awards no later than 180 calendar days after receipt and acceptance of all required final reports.*” Our understanding is that when HHS/NIH implements the changes to the Uniform Guidance, “*no later than 180 calendar days*” will be changed to “*no later than one year.*”

While the exact timing for these reforms is unclear, our understanding is that OMB/NIH hope to initiate these administrative flexibilities after going through the appropriate rulemaking process. COGR appreciates the dedicated efforts of Michelle Bulls and other leaders from the research community to keep these items front in center during a time when lots of other activities are consuming NIH resources. We will keep you posted as we learn more details in 2020.

Reports of Individual Conflicts of Interests in NIH-Funded Research Made Public – NEW

ProPublica [has published](#) the NIH database of financial conflict of interest disclosures as part of a series of articles regarding investigators not fully disclosing their outside professional activities. The [database](#) appears to include disclosures dating back to the implementation of the PHS COI policy in 2012.

OHRP Exceptions to Single IRB Review – REMINDER

OHRP recently announced an exception for two categories of research included in the single IRB (sIRB) review requirement under the 2018 Requirements of the Common Rule. The change is due, in part, to the [letter that COGR and other associations sent to OHRP](#) highlighting the increased administrative burden and costs associated with complying with the sIRB review requirement for studies approved before the sIRB compliance date of January 20, 2020.

COGR Members are reminded to consider the additional costs of sIRB reviews and to budget accordingly for multi-site studies. The full text of the exceptions is [here](#).

New NIH Advisory Committee on Rigor in Animal Research – NEW

The NIH has formed a new ACD Working Group on Enhancing Reproducibility and Rigor in Animal Research. An [interim report](#) was given at the NIH ACD meeting in early December. The charge to the groups is to identify gaps and opportunities to: 1) improve the rigor, reproducibility, translational validity, and transparency of animal models studies; 2) assess the current state of science for validating alternative models to animal research; 3) model the financial implications of potential changes in the average costs of grants using animal models, the number of studies funded, or the need to develop consortia to achieve appropriate statistical power; and 4) consider how rigor in animal research is incorporated into training. The Working Group expects to issue its final report late fall 2020.

In related news, [PETA](#) recently publicized a plan to modernize animal research by decreasing federal funding for animal research to fund non-animal studies aimed at accomplishing the same goals.

Save the Date! Fostering Rigorous Research: Lessons Learned from NHP Models and Charting the Path Forward – February 18-19, 2020 - NEW

NIH has announced new dates for this workshop which was previously scheduled for Fall 2019. This workshop is aimed at addressing some of the unique challenges and important generalizable lessons [in terms of science, welfare, and ethics](#). NIH will work with the research community to convene a workshop to:

- Identify emergent challenges facing the conduct, reproducibility, and translation of rigorous research when working with NHP models; and
- Discuss strategies for addressing these challenges, including building on or augmenting current best practices.

For more information, see <https://osp.od.nih.gov/2019/12/05/fostering-rigorous-research-nhp-models-chartering-the-path/>

F&A White Paper and PPT Slidedeck: Now Available – NEW

Released in April 2019, the COGR F&A White Paper, “[Excellence in Research: The Funding Model, F&A Reimbursement, and Why the System Works](#),” is available at www.cogr.edu.

As a complement to the paper, COGR is pleased to announce a slide deck presentation version (as a PDF) is [now available here](#). The PDF version, which is for viewing only, is complete with graphics and exceptional formatting and design. The PDF version also is available in a PPT format (100 slides, in total), which can be edited and tailored to your institution. The PPT version can be obtained by contacting Toni Russo at trusso@cogr.edu. You can request with a PPT version with all the graphics and design, or you can request the “plain” version without the graphics and design.

A special thank you to the team who developed what we hope will be a valuable resource for the COGR Membership:

Barbara Cole (University of Miami)
Dawn Boatman (Portland State University)
Tommy Coggins (University of South Carolina)
Louise Griffin (University of New Hampshire)
Jason Guilbeault (Augusta University)
Vivian Holmes (Boston University)
Cindy Hope (Georgia Institute of Technology)

David Kennedy (COGR)
Nazam Mohammed (Rutgers University)
Dennis Paffrath (University of Maryland)
Toni Russo (COGR)
Judith Ryan (Harvard University)
Jill Frazier Tincher (University of Georgia)

The slide deck is complimentary for COGR Members. Also note, bound copies of the April 2019 report, “Excellence in Research,” are available for purchase. The cost is \$15 per book. Please contact Toni Russo at trusso@cogr.edu to request copies for purchase.

NIFA Challenges – UPDATE

As we have reported throughout 2019, awards from the National Institute of Food and Agriculture (NIFA) have presented administrative and cost reimbursement challenges. Two factors have contributed: 1) changes to the 2018 Farm Bill ([Agriculture Improvement Act of 2018](#) – signed into law, December 20, 2018), and 2) the recent and controversial move of NIFA Headquarters from Washington D.C. to Kansas City. Changes to the 2018 Farm Bill adversely impacted institutional matching requirements on selected NIFA programs, as well as F&A reimbursement on subrecipient agreements. The move to Kansas City created a drain of experienced NIFA leaders and grant administrators who decided not to move to Kansas City (see the [September 2019 Update](#) – pages 12-13 – for details on these issues).

COGR met with [Dr. J. Scott Angle, Director of NIFA](#), on Thursday, December 19th to discuss concerns, priorities, and how the Higher Education Associations can be helpful as NIFA works through its transition. COGR is partnering with the Association of Public and Land Grant Universities (APLU) and the Association of American Universities (AAU) on this effort.

The meeting was designed as an informal “meet and greet” with Dr. Angle, with the goal of establishing a plan to address specific issues, with solutions, in 2020. We will keep the membership updated on all developments.

HHS/NIH G-Accounts and Reconciliation – STATUS QUO

As we have reported in the past several COGR Updates, COGR and 9 member institutions conferenced with representatives from HHS/Payment Management System (PMS) in June 2019. The primary request was to ensure a collaborative reconciliation process would take place, allowing institutions to work with PMS to determine a fair, documented deficit/surplus amount associated with those G-accounts (pooled cash draw accounts) being closed. Dan Long, Director of PMS, committed: 1) to a slow-down of the process, 2) to work with institutions, collaboratively, to determine the fair deficit/surplus amount, and 3) to provide a letter to institutions that have been affected that ensures deficit amounts will not be sent to collections. Institutions were invited to contact Mr. Long and his colleagues at PMS, directly, to establish a process for the institution to address its unique situation.

Since then, the HHS Grants Policy Office has reached out to COGR to further support Mr. Long’s approach – specifically, the policy of the HHS Grants Policy Office is that G account deficit balances will not move to collections. The practice should be to continue to work with Mr. Long’s office at PMS to resolve any differences, with the hope that “soon” your institution will be able to fully resolve any discrepancies. Granted, this may be a time-consuming process, but we have been assured your accounts will not go to debt collection. If your institution is impacted in any way, contact David Kennedy at dkennedy@cogr.edu and he will provide contact information for both PMS and the HHS Grants Policy Office, as well as answer other related questions.

NSF and HHS OIG Audit Workplans for FY2020 – REMINDER

The [NSF OIG Workplan](#) is now available on the NSF OIG website. The HHS OIG approach has moved to a more real time, dynamic version of their workplan where the plan is updated regularly. If you go the [HHS OIG Workplan](#) website and click on “Active Work Plan Items” link (and then search on NIH), you can see the status of workplan items. We will follow NSF and HHS OIG activity and encourage you to contact COGR when relevant issues affect your institution.

Cloud Computing, MTDC, and F&A Application – NEW

We have deliberated the treatment of cloud computing for F&A purposes over the past five years. COGR’s position has been to not take a position, partly because to advance a policy position might be inconsistent with how some COGR member institutions view this issue. What COGR has committed to do is to craft a short “Considerations” paper – we will share this with the Membership in 2020.

F&A Rate Negotiations – MEMBER FEEDBACK REQUESTED

COGR has heard concerns related to timing of negotiations (e.g., 2+ year timeframe between submission and negotiation), as well as concerns related to CAS policy positions. We are interested in learning more about these issues, and if applicable, please contact COGR. Please contact David Kennedy at dkennedy@cogr.edu.

NIH Issues Annual Revision of the Grants Policy Statement - NEW

The National Institutes of Health (NIH) [announces the publication](#) of the revised NIH Grants Policy Statement (NIHGPS, rev. December 2019). This revision is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2019. This revision supersedes, in its entirety, the NIH Grants Policy Statement (October 2018) as a standard term and condition of award. Previous versions of the NIHGPS remain applicable as a standard term and condition for all NIH grants and cooperative agreements with budget periods that began prior to October 1, 2019.

NIH states that while this revision does not introduce any new material for the first time, it is part of an annual process that incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes since the previous version of the NIHGPS dated October 2018. The Other Support section of the revised GPS includes statements from [NOT OD-19-114](#) (not included in the [Summary of Significant Changes](#)). Also note the revisions to Section 4.1.27 regarding additional notifications to NIH regarding misconduct investigations

Prior versions of the NIHGPS are accessible at <http://grants.nih.gov/grants/policy/policy.htm#gps>.

NIH will continue to publish interim grants policy changes through the issuance of [NIH Guide Notices](#). Each change will be described, including its applicability and effective date; and the necessary language to implement it as a term or condition of award provided.

NIH Data Management and Sharing Policy: COGR to Provide Public Comment – UPDATE

In COGR’s [November 2019 Meeting Report](#), we indicated the National Institutes of Health (NIH) released their [Data Management and Sharing Policy](#) and Supplemental Draft Guidance for public comment. COGR anticipates submitting a joint response with the Association of Public Land Grant Institutions (APLU) and the Association of American Universities (AAU). Due to a number of agency actions requiring comments

before year-end, coupled with holiday leave, the CGA Committee took the lead to draft a letter and circulate for comment amongst all COGR Committees. COGR anticipates submitting its response and posting to the COGR listserv no later than January 3rd in the event member institutions find it helpful in drafting their own letters.

On December 16th, NIH hosted an [informational public webinar](#) on the Draft Policy and Supplemental Draft Guidance to provide information on the draft policy and answer any clarifying questions about the public comment process.

Please contact Jackie Bendall at jbendall@cogr.edu for additional information.

COGR Submits Letter to SAMHSA Regarding Attestation Requirement – NEW

On December 18, 2019, COGR [submitted a letter](#) to SAMHSA (Substance Abuse and Mental Health Services Administration) expressing concerns about a separate attestation that SAMHSA now requires as part of the acceptance process for receiving an award. This required attestation is not only duplicative of existing requirements of federal law, but extends beyond such requirements, creating additional burdens on research institutions without regulatory authority. Contact Jackie Bendall at jbendall@cogr.edu for questions or comments.

USDA Request for Comments to Establish a Domestic Hemp Program - UPDATE

In COGR's [October 2019 Meeting Report](#), we mentioned that USDA is [seeking comment](#) on an Interim Final Rule (IFR) to establish rules and regulations for a domestic hemp production program and to facilitate the production of hemp, pursuant to the [Agricultural Improvement Act of 2018](#) (i.e., the Farm Bill). COGR is preparing a response to the USDA notice for comments, expressing concerns with several requirements in the IFR including the timeframe USDA specifies for tetrahydrocannabinol concentration (THC) testing. The THC requirement—which specifies only DEA registered laboratories may conduct (THC) testing of hemp and that a testing measurement of 0.5% THC or more should automatically be considered “negligence”—triggers potentially severe penalties. Comments are due December 30th. Contact Jackie Bendall at jbendall@cogr.edu for additional information.

Final Report from NIH Advisory Committee to the Director on Sexual Harassment – NEW

On December 12, 2019, the NIH Advisory Committee to the Director (ACD) working group on “Changing the Culture to End Sexual Harassment” presented its [final report](#) recommendations. The report contains four themes and multiple recommendations within each theme. NIH stated in its [executive summary](#) that the creation of a culture that eliminates sexual harassment demands the concerted efforts of NIH leadership, research institutions, and every individual within the biomedical ecosystem. While NIH has indicated that they recognize that many of these changes will require significant community input, time, and resources, they believe the changes are necessary for ensuring a safe research environment. NIH will continue to post resources including SOPs, flow charts and trainings.

Department of Education Investigatory Letters to Institutions – UPDATE

On November 21, ED published in the [Federal Register](#) two additional investigatory letters to COGR member institutions, bringing the total to six. The ED letter to Sen. Portman discussed the six compliance investigations that now have been opened at COGR member institutions. According to ED, they appear to demonstrate “a problematic lack of transparency and accountability regarding the solicitation and receipt of large amounts of foreign money by at least some of our colleges and universities ... American colleges and universities have provided unprecedented levels of access to foreign governments, corporations, and persons without adequate oversight.” ED suggested further Congressional scrutiny of “whether foreign money might provide the means for access to sensitive U.S. government research and/or create insider threats.”

We understand that at a recent Federal Student Aid Training Conference ED suggested that the proposed new information collection requirements should be final in time for the January 31, 2020 reporting cycle. (This is the primary rationale for the emergency review request discussed at the beginning of this COGR Update). Elsewhere in the conference presentation, ED asserted that a total of 172 Sec. 117 reports were filed over the last 7 years. This suggests that many institutions have not been in compliance with the existing requirements, which unfortunately makes institutions vulnerable to the ED assertions quoted above.

We are not certain whether an additional response to the ED letter to Sen. Portman would be helpful at this point. We will work with the other higher ed. associations on this issue, which may include further discussions with Congressional staff.

Senate Report on China’s Talent Recruitment Plans – UPDATE

We reported to the COGR membership on November 20 that the Senate HSGAC (Homeland Security and Government Affairs) Permanent Subcommittee on Investigations released its official report on threats to the U.S. research enterprise posed by China’s talent recruitment plans. The report contained a series of recommendations, including that the U.S. research community should establish a “Know Your Collaborator” culture, and that the administration should consider updating National Security Decision Directive (NSDD) 189 and implement additional, limited restrictions on U.S. government funded fundamental research, including assessing whether openly sharing some types of fundamental research is in the nation’s interest. Other recommendations addressed harmonizing grant proposal and reporting requirements, and dissemination of more information on foreign talent recruitment programs. The federal agencies represented at the hearing did not push back on the notion that more legislation and regulations may be necessary, which could adversely affect fundamental research.

Report: [Threats to the U.S. Research Enterprise: China’s Talent Recruitment Plans](#)

Appendix A: [China’s Talent Recruitment Plan Contracts](#)

Hearing: [Securing the U.S. Research Enterprise from China’s Talent Recruitment Plan](#)

Appendix A contains (redacted) contract terms. NIH also presented examples of contract terms at a recent higher ed. association meeting, but the NIH examples are not the same. Some of the contract terms that U.S. researchers have signed may be rather surprising (e.g. following all PRC laws and regulations and non-interference in China's internal affairs, intellectual property to be owned by the Chinese institution, non-disclosure of the contract).

FY '20 NDAA Addresses Science and Security Issues – NEW

On December 9 the House and Senate Armed Services Committee (HSAG) completed the FY2020 National Defense Authorization Act (NDAA) [conference report, S. 1790](#). The bill subsequently was passed by the House on Dec. 11 and the Senate on Dec. 17. The President is expected to sign it.

The bill includes provisions that the higher ed. associations have been actively advocating for including a modified version of the Securing American Science and Technology Act. Sec.1746 that establishes an interagency working group of federal science, intelligence, and security agencies under the direction of OSTP. The working group would be tasked with identifying and assessing existing mechanisms for control of federally funded research, taking inventory of current control definitions, and developing and updating a framework to assist federal agencies and grantees in defending against threats. The legislation also would create a new Science, Technology, and Security Roundtable—convened by the National Academies of Science, Engineering and Medicine—that would bring together key stakeholders from the scientific enterprise, including federal agencies, universities, and industry. We also have advocated for establishment of this group.

Sec. 1281 of the bill (*Protection of National Security Academic Researchers from Undue Influence and Other Security Threats*) contains a number of provisions related to science and security. It requires the Department of Defense to provide training and advice to universities for protecting sensitive national security information including the dissemination of unclassified materials and resources for identifying and protecting against emerging threats to institutions of higher education. Additionally, Sec. 1281 calls on the Secretary of Defense to work with BIS and others to create a list of countries (China and Russia cited) that “have a history of improper technology transfer, intellectual property theft, or cyber or human espionage” and pose a risk. Sec. 1281 also requires the Secretary of Defense to establish enhanced information sharing procedures to collect appropriate information on any personnel participating in defense research and development activities (other than basic research) and to maintain appropriate security controls over research activities, technical information, and intellectual property. The accompanying conference report encourages the Secretary of Defense to establish a memorandum of understanding with the Secretary of Homeland Security in order to coordinate the implementation of this provision, including leveraging existing government information systems and repositories, including the Student Exchange Visitor Information System, to reduce the burden on universities and the Department of Defense. These provisions appear intended to provide authorization for the stalled DOD pilot project to collect more information on DOD-funded personnel (see COGR [February 2019 Meeting Report](#)).

Sec. 5713 (*Oversight of Foreign Influence in Academia*) requires the Director of National Intelligence to submit to congressional intelligence committees an annual report on risks to sensitive research subjects posed by foreign entities. The report is to include (1) a list of sensitive research subjects that could affect national security; 2) a list of foreign entities that the Director determines pose a counterintelligence, espionage, or other national security threat with respect to sensitive research subjects; (3) a list of any known or suspected attempts by foreign entities to exert pressure on institutions of higher education, including attempts to limit freedom of speech, propagate misinformation or disinformation, or to influence professors, researchers, or students; and (4) recommendations for collaboration between institutions of higher education and the intelligence community to mitigate threats to sensitive research subjects associated with foreign influence in academia, including any necessary legislative or administrative action.

Other sections of relevance to COGR members include Sec. 228, establishing a DOD research program on foreign malign influence operations; Section 5322 establishing a Foreign Malign Influence Center within OD/NI; and Section 5323 authorizing OD/NI and DOD to award a grant or contract to establish a Social Media Data and Threat Analysis Center as an independent nonprofit organization.

[Click here](#) for further discussion of the FY'20 NDAA.

“Partnering with DOD” – UPDATE

The [October Meeting Report](#) mentioned DOD’s interest in partnering with universities in activities aimed at protecting the research enterprise from foreign threats. COGR has participated in two meetings with representatives of the DOD Protecting Critical Technologies Task Force, together with other association representatives. At the last meeting, we offered to help organize a workshop with VPRs and DOD representatives. We also are discussing informally with the DOD Basic Research Office possible clarifications to the current DOD Fundamental Research Policy (i.e., [DOD May 24, 2010 Memorandum](#)).

DOE Revises Order 142.3A on Foreign National Approval Requirements – NEW

COGR has been advised by member institutions that DOE is eliminating the exemption in Order 142.3A for institutions of higher education. Several years ago, COGR representatives met with the then DOE Undersecretary for Science and Engineering with regard to this Order. As a result, in January of 2017 DOE issued an amendment exempting DOE funded publishable research at institutions of higher education from the foreign national approval requirement that otherwise applies to any access to DOE sites, information, technologies, equipment, programs or personnel (see COGR [February 2017 Update](#)). This change has not been formally announced. It was received by COGR institutions as a contract amendment. COGR will request a meeting with appropriate DOE representatives to discuss the issue.

Drug Pricing Legislation Status – UPDATE

H.R. 3, the *Lower Drug Costs Now Act* (also known as the *Elijah E. Cummings Lower Drug Costs Act*), was introduced in the House in September (H.R. 3). The bill requires the Centers for Medicare & Medicaid Services (CMS) to negotiate prices for certain drugs (current law prohibits the CMS from doing so). Specifically, the CMS must negotiate maximum prices for (1) insulin products; and (2) at least 25 single source, brand-name drugs that do not have generic competition and that are among the 125 drugs that account for the greatest national spending or the 125 drugs that account for the greatest spending under the Medicare prescription drug benefit and Medicare Advantage. The negotiated maximum price may not exceed (1) 120% of the average price in Australia, Canada, France, Germany, Japan, and the United Kingdom; or (2) if such information is not available, 85% of the U.S. average manufacturer price. Drug manufacturers that fail to comply with the bill's negotiation requirements are subject to civil and tax penalties. The bill also makes a series of additional changes to Medicare prescription drug coverage and pricing. It has 106 co-sponsors, all Democrats. On December 9 House Republicans introduced their proposed drug pricing package, H.R. 19, the *Lower Costs, More Cures Act*.

On December 12 H.R. 3 passed the House ([H.R. 3](#)). Meantime the Senate Finance Committee also has introduced drug pricing legislation (S. 2543). It primarily addresses Medicare B and Medicare D benefit payments and drug price “transparency.” It includes a provision for a mandatory rebate drug maker would have to pay when they raise the price of their products beyond inflation. The House Republican version does not include the rebate but otherwise is similar to the Senate version.

The House bill is not expected to advance in the Senate. There is more bipartisan support for the Senate bill, but its future is uncertain. None of these bills appear to directly impact universities. Rep. Sherrill (D: NJ) had introduced legislation in October (*Biomedical Innovation Expansion Act*; H.R. 4667) that would have authorized additional funding for NIH innovation projects under the 21st Century Cures Act. It was incorporated in H.R. 3, with reduced funding levels (Sec. 701). Other provisions include acceleration of clinical trials (Sec. 702) and provisions to enhance commercialization of biomedical innovations (Sec. 703). Other amendments including Rep. Doggett’s compulsory licensing bill (see last December’s [COGR Update](#)) were not accepted.

All the attention being paid to drug pricing in the Congress has led to a flood of articles and reports, many advocating for government price controls and march-in rights (e.g., see “[Do large pharma companies provide drug development innovation? Our analysis says no](#)”).

In addition, most of the leading Democratic Presidential candidates are advocating similar positions (see “[Democrats Tout Federal Patent Take-Backs for Lowering Drug Costs](#)”).

Possible DOD Change to Contractor IP Rights – NEW

According to recent articles, the Air Force is considering changes in procurement policy because “it can ‘no longer afford’ to allow contractors to keep a consistently strong grip on IP amid increasing competition from Russia and China.” The envisioned change would include moving from contractor ownership of inventions and data to a “smart IP” model to create a future system of “open architecture and open IP rights, allowing any company to compete to build or upgrade” parts over time. The Air Force said it would [consider paying more](#) to its contractors whose intellectual property is being taken for this “flexibility.”

Last year the Army published its [first-ever IP policy](#) which emphasized the importance of IP in acquisition planning. It focused particularly on rights to technical data. Earlier this year the DOD established a [new IP group](#) to update its data rights policy. An initial public meeting is scheduled for December 20. It is not clear what the effect of these policy changes may be on DOD funding of research at universities. They seem mostly directed at large defense contractors. COGR will continue to follow and report on developments.

NIST Issues iEdison RFI – NEW

One of the findings in the NIST ROI Green Paper was the need to improve federal invention reporting requirements and systems (see COGR [May 2019 Update](#)). iEdison invention reporting system responsibilities have been transferred from NIH to NIST.

On December 13, NIST [issued an RFI](#) on challenges and improvements to the iEdison system (84 FR 68128). It is aimed at rebuilding the iEdison system as a strategic priority for the Lab-to-Market Cross Agency Priority (CAP) Goal. It also corresponds to a recommendation in the 2016 NAS Report on *Optimizing the Nation’s Investment in Academic Research*.

The RFI lists 3 major topic areas on which NIST seeks information (responses may include other topics if they have implications for a redesigned iEdison). The three listed questions are directed to iEdison users (including e.g. screen shots of user interface screens or error messages). COGR is not in a position to respond directly to these questions. However, we would be happy to collect and coordinate responses from COGR member institutions. Such responses should be sent to Bob Hardy at COGR at rhardy@cogr.edu. The RSIP Committee will be discussing further. AUTM also is planning to submit responses. Comments are due January 27.

Patent Eligibility Legislative Discussions Stall – UPDATE

We’ve reported several times recently on efforts to reform the patent eligibility provisions (Sections 101 and 112) of the Patent Act (see COGR [October Meeting Report](#)). These efforts appear to have stalled for now, given the inability of stakeholders to come to consensus as to needed changes. We expect renewed discussions with Congressional staff next year.

Bayh-Dole 40th Anniversary – REMINDER

Next year marks the 40th anniversary of the Bayh-Dole Act. AUTM is leading efforts to commemorate the occasion, including public events, media op-eds, publications, etc. More detailed plans will be rolled out next month. We encourage our member institutions to consider ways to appropriately mark the anniversary and will keep members informed as the association plans develop.