



November 15, 2019

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## **COGR Committee Portfolio Update**

Over the past several months, President Streitz, the COGR Directors, and the Board have been reviewing Committee portfolios to ensure that they are clear and make sense. This resulted in some minor shifts in subject area responsibility and new Committee names that more accurately reflect the Committee portfolios. The name changes are as follows:

Contracts & Intellectual Property is now Research Security & Intellectual Property  
Costing Policies is now Costing & Financial Compliance  
Research Compliance & Administration is now Contracts & Grants Administration  
Research Regulatory Reform is now Research Ethics & Compliance

The portfolios of each Committee can be found [here](#). Importantly, each Committee will address regulatory reform and deal with emerging issues in their areas of expertise and will continue to work together on issues that cut across multiple Committees.

## **Cross-Cutting Areas**

### **COGR Comments on Proposed HEA Section 117 Reporting Requirements - Update**

Sec. 117 of the 1965 Higher Education Act requires colleges and universities to file reports twice a year with the Department of Education (ED) disclosing all gifts from or contracts entered into with a foreign government or non-governmental foreign source (i.e. citizens of foreign countries, foreign corporations) with an aggregated value of at least \$250,000. On September 6, the Department issued a [proposed information collection request](#) to “modernize” Sec. 117 reporting (84 FR 46943). The proposed information collection greatly expands the information that is required to be reported. On October 22, COGR sent an update to its members on responses by the higher education associations together with talking points. A draft comment letter was sent on November 1.

COGR chose not to join in comments from a number of higher ed. associations led by the American Council on Education (ACE). Instead on November 4 we submitted a separate COGR comment letter. While sharing many of the concerns expressed in the ACE comments, our comment letter focused mainly on the potential chilling effect of the proposed new disclosure requirements on the commercialization of federal R&D as well as the ability to protect information on critical U.S. technologies. We also cited the greatly increased administrative burdens on our member institutions. We noted that each of these consequences appear counter to stated U.S. government policy goals. We suggested that ED defer the proposed information collection and consult more widely with the stakeholder community, perhaps including the Federal Demonstration Partnership. Copies of the [COGR](#) and the [ACE](#) comment letters are posted on the COGR website.

Should ED continue with the proposed information collection, the next stage of the process will be submission to OMB/OIRA. Comments also may be submitted to OMB at that stage. Additional

quantitative data on the burdens might be particularly helpful for this purpose. We will work with member institutions to seek to develop such data and other relevant information.

### **Government Panel Discusses Science and Security Issues - Recap**

Representatives of the Departments of Justice, State and Defense discussed perspectives on issues pertaining to foreign influence and threats at U.S. institutions of higher education. Adam Hickey, Assistant Attorney General in the National Security Division of the Justice Department, discussed the *Made in China 2025* Initiative, which he described as a “roadmap” for theft and economic espionage benefitting the Chinese state. 80% of Federal economic espionage prosecutions and 60% of trade secret theft cases have been related to China. He discussed a variety of techniques used by China to exploit the openness of the U.S. academic enterprise. He described several recent Justice prosecutions that involved these types of activities. He also discussed efforts by the Chinese government to pressure Chinese students at U.S. universities. He stressed that the government expects U.S. universities to know what their faculty are doing. Universities need to adopt best security practices and focus on suspicious behavior. He closed by contrasting the post—World War II Order with the World Order favored by China.

Andrew Hebbeler of the Department of State Office of Science and Technology Cooperation discussed the vital importance to the U.S. of international S&T cooperation. He cited the importance of protecting our core values and the integrity of the system. These values currently are under assault. State is seeking to minimize risks to the system, in cooperation with our international partners who are experiencing similar challenges. He noted the importance of exchanging information and best practices. U.S. universities play a very important role in this process.

Jason Day, of the DOD Office of Basic Research, discussed the importance of a measured approach in establishing new “rules of the road.” DOD was mandated by Sect. 1286 of last year’s NDAA to work with universities on protecting intellectual property and to limit undue foreign influence. DOD must report back to Congress. The pilot project to collect detailed information on DOD-funded personnel is unable to proceed due to insufficient authority (see COGR [February 2019 Meeting Report](#)). Mr. Day reminded the audience of the March 20 DOD memo requiring submission of information on key personnel in all non-procurement proposals (see COGR [May 2019 Update](#)). DOD plans to follow whatever recommendations JCORE may make on conflicts of interest and commitment (though we understand they may add DOD-specific requirements).

In Q and A, questions were raised about the need to protect prepublication data. The real issue is the need to protect “intellectual capital” more broadly. We must reconcile the need to protect our academic openness with the fact that it is being exploited by bad actors. Other points that were raised include better identification of high-risk foreign entities, the need for a more “surgical” approach to international research collaborations, and the costs and burdens of greater protection.

### **DOD “Dear Academic Colleague” Letter and “Partnering” - New**

In the panel discussion summarized above, Jason Day also mentioned the “Dear Academic Colleague” letter of October 10 from Michael Griffin, DOD Undersecretary of Defense for Research and Engineering. The letter discusses the challenges of protecting the U.S. research enterprise. It mentions DOD’s active participation in JCORE and requests assistance in identifying and taking action against threatening activities, in partnership with DOD. It notes the importance of open international collaborations and protecting against those who seek to exploit this openness. A copy was sent to the COGR membership on October 11.

In early October, [COGR joined other higher ed. associations](#) in meeting with representatives of the DOD Protecting Critical Technologies Task Force established last year. DOD is very interested in partnering with universities on outreach, training, best practices development, and discussions of issues. A draft of the Griffin letter was distributed at that meeting. We will continue discussions with DOD, in coordination with the other associations.

### **Research Security and Regulatory Reform Update from OSTP October COGR Meeting - Recap**

Chloe Kontos, Executive Director of the National Science & Technology Council and Aaron Miles, Principal Assistant Director, National Security and International Affairs, presented to the COGR membership. Both are from the Office of Science and Technology Policy (OSTP) and came to update the membership on the new JCORE initiative. JCORE, the Joint Committee on the Research Environment, was formed in May of this year “to address the most pressing challenges facing America’s research and scientific community”.

Mr. Miles discussed the activities of the JCORE Subcommittee on Research Security, stating that other countries are exploiting the openness and other features of the US system. The subcommittee has been exploring the details of this but is also committed to the sustaining the values of the US research enterprise – openness, transparency and inclusivity. About twenty agencies are participating in the subcommittee, which is focusing on: risk assessment; outreach and engagement, ensuring coordinated messaging; the development of guidance for agencies regarding disclosure requirements; and existing best practices among institutions.

Chloe Kontos described the [JCORE initiative](#) overall, and the work of the other three Subcommittees. The Subcommittee on Research Integrity, Rigor, and Reproducibility is focusing more on the latter two issues than integrity and activities include creating a baseline of current agency approaches, and consideration of relevant culture issues. The Subcommittee on Safe and Inclusive Research Environments is looking at all forms of harassment and the importance of research environments that are safe and inclusive for all participants. Activities of this subcommittee include the creation of a policy inventory of participating and a promising practices summary. Finally, the Subcommittee on Collaborating on Administrative Research Requirements is looking at opportunities to harmonize administrative requirements, focusing on “low-

hanging fruit”. They are also discussing the use of perpetual digital identifiers, such as ORCID iDs and other means of transparency.

### **Other Science and Security Related Developments**

Senator Warner on China. On September 23, Sen. Mark Warner (D—VA) [addressed](#) the U.S. Institute of Peace on U.S.—China competition. He cited a wide range of Chinese threats and the need for a strategic shift to deal with them on the part of all U.S. sectors. In his prepared remarks he stated, “We need to do a better job *protecting our research and development*... especially the critical work that goes on at U.S. universities and research labs. Universities should double-down on security and compliance requirements--things like disclosing additional sources of income...or affiliations with foreign military and intelligence organizations.”

Controlled Unclassified Information (CUI). The timing of the long-delayed FAR clause remains uncertain. At one point the regulations.gov Regulatory Docket indicated a [release in October](#), but it seems to have disappeared from the Docket. The current FAR Open Cases report indicates no action since the drafting was assigned to DOD in February. The proposed enhanced NIST Security Requirements (NIST SP800-171B) that COGR commented on in August remain on hold pending OMB’s government-wide review (see COGR [September 2019 Update](#)).

In the meantime DOD has announced a [Cybersecurity Maturity Model Certification](#) program to enhance the protection of CUI. The model includes FAQs. FAQ 20 indicates that even if an organization does not handle CUI, it still must be certified (including subcontractors, FAQ 21). COGR informally has expressed concerns to DOD about the implications for universities that conduct only fundamental DOD-funded research. As with the DFARS 7012 Safeguarding clause, DOD appears to be far out in front on this issue, without government-wide coordination. We will continue to pursue this.

### **University Guidance and Resources on Foreign Influence & Research Security – Reminder**

As a resource for our members, COGR has collected member institutions’ websites of educational resources for their faculty and research community on new and existing federal and institutional requirements, especially as they relate to engaging with international partners. Please visit the COGR website [here](#) for links to member pages.

### **Points of Consideration on Outside Professional Activities (OPA) at Foreign Institutions – New**

As disclosures of foreign activities are arriving on the desks of our members for review, the REC has been discussing the need for internal guidance for the evaluation of OPA activities. The REC committee discussed the kinds of information universities and academic hospitals need to assess the risks involved in outside activities and engagement with non-US entities. They considered the data elements, existing pathways for collecting the information, and how to evaluate whether the risks are high, medium, or low. The goal is to share a draft checklist with the COGR membership for use in making determinations when

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faculty come forward with questions about potential activities and want to know whether such activities are permitted and/or under what circumstances. The institution's current policies and practices will mainly drive the allowability of such activities. The REC will continue to refine the checklist over their next few phone calls.

If anyone has thoughts about this project, please let Sue Rivera or Naomi Schrag know. We will send an announcement to the membership when the information becomes available.

### **Federal Agency Update in Reporting Outside Professional Activities and Additional Other Grant Reporting Requirements Around "Undue Foreign Influence" – Update**

COGR has led or participated in several meetings with federal officials regarding recently expanded disclosure requirements, all aimed at more transparency into the outside relationships of key personnel and potential risks to national security. There have been some gains and slowdowns in new regulations/guidance. Still, questions remain about current NIH guidance, and we have been working with NIH in an attempt to refine and, where possible, reduce the burden of disclosures while looking at new and creative ways of disclosing key relationships that assist in the decision-making process. Still, there have been no formal changes to agency's written requirements as of this writing, so the work that COGR has invested in this effort is not yet reflected. In the meantime, COGR is developing a summary of our current understanding based on public comments that NIH has made regarding the July Notice and FAQs, which will be made available to members.

On the positive side, as reported above, several federal agencies and the security community are cooperating with the OSTP JCORE effort to develop cross-agency principles around the desire to safeguard federal funding and protect it from undue influence. That work continues, and while there is no specific expected date for the results, we are told it could be out in the next couple of months.

## **Committee Reports**

### **COSTING & FINANCIAL COMPLIANCE**

Committee: Joseph Gindhart – Chair (Washington University-St. Louis), Robert Andresen (University of Wisconsin-Madison), Cindy Hope - (Georgia Tech University), Lynn McGinley (University of Texas Medical Branch), Jeffrey Silber (Cornell University), Cathy Snyder (Vanderbilt University), Michael Daniels (Northwestern University), Michael Legrand (University of California-Davis), Sarah Axelrod (Harvard University), Nate Martinez-Wayman (Duke University), Marcia Smith (University of California – Los Angeles), Vivian Holmes (Boston University)

### **Thursday Morning Session: An “Effort Reporting” Check-In – The UG Five Years Later - Recap**

This first Thursday morning session of the October COGR Meeting was timely for two reasons: 1) As we near the 5-year anniversary of the Uniform Guidance, it's helpful to take stock of how reform initiatives

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around effort reporting are unfolding at COGR institutions, and 2) in the context of foreign influence, we are looking at documenting commitments, other support, total professional effort, and federal agency expectations and need to better understand commitments in relation to after-the-fact review requirements for payroll charges – this is becoming an increasingly important discussion at our institutions.

The Panel Discussion was led by (in order of presenting):

- Mike Legrand, University of California, Davis
- Joe Gindhart, Washington University, St. Louis
- David Ngo, The New School
- Lisa Mosley, Yale University
- Jeremy Forsberg, University of Texas, Arlington

Several take-aways from the panel discussion included:

- Internal control framework must be solid.
- Legacy effort reporting still is in play at many institutions ...
- However, Payroll Confirmation may be trending as the new standard? Payroll Confirmation aligns with the Uniform Guidance focus, it is more intuitive for faculty, and it results in fewer reports (and less burden.)
- IG concerns and/or audits? Since the FDP pilots, IG concerns have been NA, though we should continue to be diligent.
- Single audit? To date, Payroll Confirmation has been well-received.
- Approval to change? Changes could be documented via a revised DS-2, and if approval is deemed to be required, it should be done through the HHS Policy Office (CAS cognizance) or ONR.
- Institutional Base Salary (IBS) remains the key principle ...
- Still, as other professional effort and commitments come under scrutiny, institutions should take time to better understanding the relationship between these commitments and the after-the-fact review requirements for payroll charges.

After [2 CFR Part 200](#) (the Uniform Guidance) was released in December 2014, multiple approaches to performing the after-the-fact review for compensation have emerged as alternatives to traditional “effort reporting.” Whereas OMB Circular A-21 had become focused on “Examples” for documentation (i.e., a de-facto system premised on effort reporting), section 200.430(i) of the Uniform Guidance (Compensation-personal services) established “Standards for Documentation.” In effect, by eliminating the old A-21 examples, implementation of the Uniform Guidance and section 200.430(i) opened the door for IHEs (institutions of higher education) to develop new systems for documenting payroll charges associated with federal awards.

The work of the [Cohort for Efficiencies in Research Administration](#) (an organization that has become a leader in advocating for alternatives to effort reporting) was highlighted during the panel discussion by David Ngo, Lisa Mosley, and Jeremy Forsberg. The Cohort seeks to establish industry standards for



institutions to effectively and efficiently implement and comply with the regulations that govern sponsored research. The standards are developed to achieve, but not exceed, compliance. The standards are built through the development of model policies, procedures, and practices designed to reduce administrative burden for both faculty and the institution, minimize audit risk, and most importantly, facilitate research within an ethical and appropriate compliance framework. The standards are validated by their promulgation among institutions and tested or reviewed by members of the audit community. The Cohort has developed a strong library of documents and resources, and there has been significant expertise developed in the Cohort on this topic.

In addition, COGR has been a leader on advocating for and facilitating issues around effort reporting (and related issues) for decades. The 2007 COGR paper, [Policies and Practices: Compensation, Effort Commitments, and Certification](#), still is a relevant document, even after the implementation of the Uniform Guidance. Also, in 2015, COGR released the [Guide to the OMB Uniform Guidance, Section 200.430 Compensation – Personal Services](#) and it is a helpful resource.

The [Slidedeck](#) for this session is available on the COGR Website.

### **HHS/NIH G-Accounts and Reconciliation - Update**

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. Dan Long, Director of PMS, was on the call, and was joined by several of his PMS colleagues. The primary request was to ensure that 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. Mr. Long acknowledged that part of the PMS “rush” to close the G-accounts was prompted by the [2016 GONE Act](#), which requires federal agencies to close expired accounts and to better account for unused federal funds. Some of the institutions affected indicated deficit amounts in question of over \$500,000, and even approaching \$1 million.

Mr. Long 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. Also worth noting is that some institutions may have surplus balances that

are at issue. While COGR has not emphasized the same sense of urgency, our position is that these situations, too, should be resolved with PMS.

If your institution is impacted in any way, contact David Kennedy at [dkennedy@cogr.edu](mailto: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.

### **NIFA Challenges - Update**

As we have reported in the past several COGR Updates, we have described the impacts the 2018 Farm Bill ([Agriculture Improvement Act of 2018](#) – signed into law, December 20, 2018) will have on the administration of research awards from the National Institute of Food and Agriculture (NIFA). We encourage you to review the most recent [September 2019 Update](#) (pages 12-13) for details on the specific issues we are following.

Since then, a new concern has arisen as it relates to new language in NIFA Award Notices:

*All funds for this award are withheld from payment pending a full administrative review by NIFA. The awardee may be required to provide NIFA with additional budget or organizational information for this administrative review. This award may be rescinded or reduced as deemed necessary pending the full administrative review of the proposal and budget; the grantee organization's Institutional Information, including financial status; and the award matching requirements, if applicable. Should the award be reduced or rescinded, NIFA will not be responsible for any costs incurred prior to funds being released.*

***As NIFA challenges for the COGR Membership compile, COGR is partnering with the Association of Public and Land Grant Universities (APLU) to meet with and raise concerns directly to the Director of NIFA. We are cautiously optimistic that concerns will be heard and there will be a pathway to some resolution.***

However, we are working within the context of significant upheaval at NIFA. As we reported in the September 2019 Update, the reality is the controversial move of NIFA Headquarters from Washington D.C. to Kansas City is official. An [August 12 article in FedSmith](#) provides insight. Key COGR contacts, including Melanie Krizmanich (Senior Policy Specialist) and Maggie Ewell (Senior Policy Advisor) have left NIFA (also see [Washington Post, July 18, 'The brain drain we all feared'](#) and [Washington Post, October 21, 'The White House didn't like my agency's research'](#)). Recently, we were informed that another key contact, Cynthia Montgomery (Deputy Director, Office of Grants and Fiscal Management), has left NIFA.

COGR will continue to participate on these NIFA issues and will work closely with APLU to advance solutions. We will keep the membership updated on all developments.

### **Other CFC (Costing) Issues & Developments**

**Revised 2019 Compliance Supplement is Available - Update** A corrected version of the 2019 Compliance Supplement (CS) was released in August (see “Errata” pages 1 through 4, immediately after Table of Contents) – it is available on the [OMB, Office of Federal Financial Management home page](#) (see 3<sup>rd</sup> link down under “Resources and Other Information”). When the initial version of the 2019 CS was released in June, included in the release was a request for comment. COGR responded in a [July 26<sup>th</sup> letter](#) to OMB. While our issues were not addressed in the revised version, we will follow these issues in the draft version of the 2020 CS (anticipated to be released in early 2020).

**NSF and HHS OIG Audit Workplans for FY2020 - New** 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 White Paper and Slide Deck to Follow - Update** 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](#). We have ordered a limited number of bound, hard copies and are providing one complimentary edition to each COGR institution. If your institution has not received a copy, contact Toni Russo at [trusso@cogr.edu](mailto:trusso@cogr.edu). If you are interested in additional copies, we will take orders and ask that you pay for the additional copies ordered, at cost. Also, we organized a Workgroup, comprised of volunteers from the COGR Membership, to develop a PowerPoint slide deck. We have been working on this product the past three months and we will notify the Membership when it is available.

**F&A Rate Negotiations - New** 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; if you are experiencing something similar, please contact COGR.

We encourage your feedback and input on issues addressed in this report, as well as issues not addressed that you believe should be on the CFC radar. Please contact David Kennedy at [dkennedy@cogr.edu](mailto:dkennedy@cogr.edu).

## **RESEARCH ETHICS & COMPLIANCE**

Committee: Suzanne Rivera – Chair (Case Western Reserve University), Kerry Peluso (Florida State University), Ara Tahmassian (Harvard University), Lynette Arias (University of Washington), Karen Hartman (Mayo Clinic), Naomi Schrag (Columbia University), Martha Jones (Washington University – St. Louis), Mary Mitchell (Partners), J.R. Haywood (Michigan State University), Brian Smith (University of California, SF), Debra Thurley (Pennsylvania State University)

### **Panel on Conflict of Commitment - Recap**

Four COGR members [presented details](#) of their institution’s policies on managing outside professional activities including the kinds of activities that require disclosure and how institutions review activities. Institutional policy approaches range from stand-alone conflict of commitment policies to covering this topic through statements in various other polices. Several institutions combine conflict of commitment policies with conflict of interest policies, for example. The panel also discussed new challenges they are facing as these policies become integral to the grant application process. NIH stated in reminder Notice [NOT-OD-19-114](#) that Key Personnel must disclose all outside professional activities that are research endeavors in grant applications. The NSF PAPPG 2020 issued in draft form this past May included a reminder that all Senior Personnel must disclose funding for activities that require a time commitment, whether funded through their home institution or paid to them directly. COGR and other organizations have taken the position that some of these are new requirements, not previously required by the agencies.

As a follow-up and a resource for our members, COGR will host a list of member institutions’ conflict of commitment policies. See below.

### **Policies on Conflict of Commitment – New**

As a follow up to the October meeting session on Conflict of Commitment, COGR sent a notice to the membership asking for links to public Conflict of Commitment policies to make it easier for institutions to locate each other’s policies. The latest page can be seen [here](#). Please send any additional submissions to Michelle Christy at [mchristy@COGR.edu](mailto:mchristy@COGR.edu).

### **Posting Human Subjects Consent Forms – Reminder**

OHRP sent out information about posting human subjects study consent forms on websites as required by the Common Rule. OHRP has posted guidance regarding posting informed consent forms, see [NOT-HS-19-23](#).

OHRP says that [posting of informed consent forms](#) can be accomplished in one of two ways - either through [ClinicalTrials.gov](#) or through new docket on [Regulations.gov](#). OHRP goes on to say that new federal websites (e.g. from other sponsoring agencies) may be forthcoming in the future.

### **Non-profit Funders and Research Institution Partnership (NFRI) – Update**

The Non-profit Funders and Research Institution Partnership (NFRI) is a partnership of made up of volunteers from the funding community and research institutions, which is jointly sponsored by COGR and the Health Research Alliance (HRA). See this [link](#) for history and more information about the organization. At this stage, volunteers from the partnership are developing resources for the community around the three work streams – management of intellectual property, streamlining the application & award reporting processes, and research support costs. Resources are being refined over the next few months, with a plan to release the guidance and best practices in the Spring of 2020.

### **RESEARCH SECURITY & INTELLECTUAL PROPERTY**

Committee: Patrick Schlesinger - Chair (University of California-Berkeley), Alexandra Albinak (The Johns Hopkins University), Elizabeth Peloso (University of Pennsylvania), Kevin Wozniak (Georgia Tech Research Corporation), David Winwood (Louisiana State University), Fred Reinhart (University of Massachusetts), John Ritter (Princeton University), Jennifer Ponting (University of Chicago), Dan Nordquist (Washington State University), Cindy Kiel (University of California, Davis), Michael Moore (Northwestern University), Janna Tom (University of California)

### **IP and Tech Transfer Developments and Updates**

**Section 101 Reform.** Recent COGR Updates and Meeting Reports have discussed Congressional activities pertaining to Sec. 101 patent eligibility in the Patent Act (see [September 2019 Update](#)). Congressional staff has met with many stakeholders, including higher ed. association representatives. However, there has been little progress in reaching consensus, and it appears less likely that legislation will be introduced in this session of Congress. A particular concern for some university patent counsels has been the implications for the Sec. 112(f) combination claim description requirement. Concerns also have been expressed about gene patenting.

A group led by former USPTO Director Kappos and former CAFC Chief Judge Michel now is trying to salvage the reform effort and seek consensus on these and other issues raised by stakeholders. COGR has followed but has not been an active participant in this process. Given the great diversity in views it is not clear that the group will be able to achieve sufficient consensus. We will continue to report on this matter.

**PTO Seeks Comments on AI Protection.** On October 30 [PTO issued a RFI](#) requesting comments on the impact of artificial intelligence on patent and other IP law. The RFI lists 13 questions on which PTO would like input. Examples include whether a work produced by AI without a natural person's involvement

qualifies for copyright, whether fair use applies to AI, AI liability for copyright infringement, the impact of AI on trade secret and trademark law, etc. While these questions are fascinating, they are not issues on which COGR can provide much input. However, we encourage member institutions to consider providing comments. The due date is December 16.

**Sovereign Immunity Developments.** The [September 2018 Update](#) discussed the Federal Circuit's ruling that tribal sovereign immunity does not apply to *inter partes* review (IPR) proceedings since they are not judicial but rather federal administrative proceedings. Last June the Federal Circuit ruled similarly that state sovereign immunity does not apply in a case involving IPR petitions filed against a number of University of Minnesota patents.

Minnesota now has appealed that decision to the Supreme Court. A number of state universities and APLU have filed [amici briefs](#) in support of Minnesota's petition for *certiorari*. The APLU brief cites the potential adverse effect on technology transfer and innovation since the need to defend against IPRs would raise patent costs.

COGR was not asked and did not join in the APLU brief. State sovereign immunity long has been a difficult issue for COGR and other higher ed. associations with both public and private institution members, since private institutions cannot assert sovereign immunity. However, that inability does not appear to have had any clear adverse effects on their ability to patent and commercialize inventions.

**NIST ROI Status.** The [May Update](#) discussed the final version of the NIST Green Paper on the Return on Investment (ROI) Initiative. It noted that NIST planned to submit implementing legislative and regulatory packages. We understand that the legislative package is still under review in the Commerce Department. The regulatory package needs to be submitted by OMB for interagency review.

## CONTRACT & GRANT ADMINISTRATION

**Committee:** Walter Goldschmidts - Chair (Cold Spring Harbor Laboratory), Jeffrey Friedland (University of Delaware), David Norton (University of Florida), Jennifer Lassner (University of Iowa), Steven Martin (Indiana University – Bloomington), Lisa Mosley (Yale University), Allen DiPalma (University of Pittsburgh); Jeremy Forsberg (University of Texas-Arlington), Stephanie Endy (Case Western Reserve University), Twila Reighley (Michigan State University), Jennifer Rodis (University of Wisconsin – Madison)

## **NIH Releases a Data Management and Sharing Policy and Supplemental Draft Guidance for Public Comment - Update**

In COGR's [November 2018 meeting report](#), we mentioned that the National Institutes of Health (NIH) issued a Request for Information (RFI) in the [NIH Guide to Grants and Contracts](#) to solicit public input on proposed key provisions that could serve as the foundation for a future NIH policy for data management

and sharing. Click [here](#) to read COGR's response. Just over a year later the NIH [draft policy](#) has been released and is available for public comment. Comments are due no later than January 10, 2020.

At the October meeting, COGR's Contracts and Grants Administration Committee hosted members from the Office of Science Policy (OSP), the National Institutes of Mental Health (NIMH) and the National Institutes of Aging (NIA) to discuss the recently released Institutes' policies. CGA submitted questions in advance for consideration, including questions to OSP about their overall strategy for an NIH-wide data sharing policy. Some of our questions included whether standard/common NIH data dictionaries, quality control validations, timing expectations, and data access agreements would be established and harmonized as much as possible across all NIH Institutes and Centers (I/Cs). Other questions involved budgeting for costs in proposals for sharing data (e.g. cleaning, formatting, curating, long-term storage, purging of data), privacy concerns, and cross reference of NIH I/C specific repositories. While NIH did indicate that the I/Cs can come up with their own guidelines, their intent was to provide flexibility amongst scientific disciplines while setting minimum expectations to serve as building blocks for NIH I/Cs.

Complete information about the draft policy and draft supplemental guidance can also be found on the [NIH OSP website](#). COGR anticipates a joint comment letter with the Association of Public Land Grant Institutions and the Association of American Universities (AAU). Please send your comments to [jbendall@coagr.edu](mailto:jbendall@coagr.edu) **no later than January 2<sup>nd</sup>** for consideration in the joint response. NIH will be hosting a webinar on the draft policy in the near future and will be conducting "road shows" for discussions with the stakeholder community. Stay tuned for additional information on this topic.

### **USDA Releases Federal Register Notice on Hemp Regulations Under 2018 Farm Bill - New**

On October 31, the USDA posted a Federal Register Notice, conveying an [interim final rule](#) seeking comments on rules and regulations to establish a domestic hemp production program and to facilitate the production of hemp, pursuant to the Agricultural Improvement Act of 2018 (aka the Farm Bill). Unlike its predecessor, the 2014 Farm Bill, where institutions of higher education were permitted to cultivate hemp for research purposes, the 2018 Farm Bill has expanded access and removed hemp from the Controlled Substances Act (CSA). While wins from the 2018 Farm Bill have been realized, producing hemp requires an approved license from the USDA. This Federal Register notice establishes a USDA plan to regulate hemp production in areas where hemp production is legal but not previously covered by an approved State or Tribal plan. All hemp produced outside of States and Tribes with previously approved plans must meet the requirements of the USDA plan. Comments are due December 30, 2019. USDA has announced that it will accept applications for a producer's license thirty (30) days after the effective date of the interim rule. COGR anticipates commenting. For the 2020 planting season, the 2018 Farm Bill provides that States and institutions of higher education can continue operating under the authorities of the 2014 Farm Bill. The 2018 Farm Bill extension of the 2014 Farm Bill authority expires 12 months after the effective date of the rule. If you have comments, please send them to Jackie Bendall at [jbendall@coagr.edu](mailto:jbendall@coagr.edu) no later than December 16<sup>th</sup> for inclusion in the COGR comment letter.