

An Association of Research Institutions

SEPTEMBER 2019 UPDATE

Membership Survey: PLEASE COMPLETE BY FRIDAY, SEPTEMBER 6

Foreign Influence and Research Security

University Guidance and Resources on Foreign Influence & Research Security – New

NIH Other Support – New Issue

NSF PAPPG Comments from COGR - New Issue

DOE Implementation of Foreign Talent Recruitment Program Prohibition - Update

Sen. Grassley Requests GAO Review of Implementation of COI Policies to Protect Against Undue

<u>Foreign Influence in Research – New Issue</u>

Department of Education Declines to Issue Formal Guidance on Section 117 Reporting

Requirements - Update

COGR Comments on NIST Enhanced Security Requirements for CUI - Update

FAR CUI Rule Close to Publication - Update

Prohibition on Procuring "Covered" Telecommunications Equipment Published in FAR - Update

Additional Huawei Affiliates Added to Commerce "Entity List" - Update

Discussions Continue on Patent Act Section 101 Reform - Update

COGR Joins in Again Supporting STRONGER Patents Act - Update

Delays in Reporting Basic Research in Clinical Trials.gov for Basic Research Studies – Update

Fetal Tissue Research – Update

Animal Care

Reducing Administrative Burden Under the 21th Century Cures Act – Update

Several Personnel Changes in APHIS Leadership - New

Research Misconduct

Communicating Research Misconduct to NIH – Final Resolution

Confidentiality Scenarios Related to Responding to Allegations of Research Misconduct - Final

OMB Compliance Supplement (CS) for 2019: CS Released & COGR Comments - Update

HHS/NIH G-Accounts and Reconciliation - Update

2018 Farm Bill, Impact on Research, and the NIFA Move - Ongoing & Important Update

The COGR F&A White Paper is Available, and Slide Deck to Follow - Reminder

COGR F&A White Paper "Excellence in Research" Available for Purchase at October COGR

Meeting

New OSTP Committees on Science and Technology

NASA Releases Proposed Sexual Harassment Policy - New

HHS OIG Grant Self-Disclosure Program - New

Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of

Marihuana – New Development



Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development Awards Beginning in FY 2020 - New

NIH Releases Notice of Special Interest for Public Health Research on Cannabis - New

NIH Data Sharing Policies on the Rise - New

Notice of Data Sharing Policy for the National Institute of Mental Health

Notice of NIAAA Data-Sharing Policy for Human Subjects Grants Research Funded by the National

Institute on Alcohol Abuse and Alcoholism (NIAAA) [2nd Revision]

Upcoming Meetings

Nonprofit Funders – Research Institution Partnership Meeting - September 24

National Science Board Meeting July 2019 – Update

Council on Governmental Relations Meeting – October 24-25



Membership Survey: PLEASE COMPLETE BY FRIDAY, SEPTEMBER 6

COGR released a Membership Survey in August (see the email sent to the COGR Listserv on August 8th). The survey addresses topics such as general membership demographics, meeting logistics, communication & resources, membership engagement, and more.

The survey can be accessed via our website at: https://www.cogr.edu/cogrSurvey

We will present a summary of the results at the October 2019 COGR Meeting. The action items that come out of the survey will be determined by the COGR Board and Leadership. We encourage all to participate! If you have questions, contact Toni Russo (<u>trusso@cogr.edu</u>) or David Kennedy@cogr.edu).

Foreign Influence and Research Security

University Guidance and Resources on Foreign Influence & Research Security - New

Many institutions are developing 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. COGR is collecting these from institutions that wish to share their resources with others and making them available here. Please send any additional postings to mchristy@COGR.,edu and your contributions will be added to the shared site. Thanks for sharing.

NIH Other Support – New Issue

NIH issued directive NOT-OD-19-114, "Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components", on July 10, 2019, reminding the extramural research community about its disclosure obligations under NIH policy. The Notice and the accompanying FAQs add significant additional disclosure requirements to grant applications and Just-In-Time reporting beyond what institutions have historically reported. For example, NIH Notice states that investigators must disclose the following information as Other Support: 1) non-financial research resources available to the investigator's lab secured such as high value materials that are not freely available, regardless of whether the resources will be used for the NIH-funded project; 2) all outside professional activities that support the investigator's research endeavors; 3) all of the investigator's scientific appointments; and 4) certain visitors (and maybe students) in the investigator's lab. COGR and other associations are working with NIH to determine how, when, and what specific information should be disclosed to NIH to enable it to make a responsible assessment of overlap with any outside activities. COGR is emphasizing the need to rely on local conflict of interest and conflict of commitments policies and practices where possible.

Note that following our initial discussion, NIH removed an FAQ that requires disclosure of start-up funding through Other support, indicating that they did not intend to require reporting of start-up funding provided by the home institution, and were only concerned about start-up funding provided by (and usually at) another institution. They later removed a second FAQ stating that all consulting



activities must be disclosed in Other Support, recognizing that much of this is redundant with current COI requirements. It is likely that one or both of these will be revised to be clearer and added back in. We are monitoring these issues closely and will update the membership as new information becomes available.

NSF PAPPG Comments from COGR - New Issue

On July 29th, <u>COGR responded</u> to a <u>NSF Federal Register Notice</u> proposing changes to the Proposal and Policies Procedures Guide (PAPPG) and noted significant changes to Current and Pending Support (Page II-23 of the PAPPG). Though not a policy change in the eyes of NSF, the language to include reporting from *all sources of support regardless whether salary support is requested* represents a significant departure from current institutional interpretation and practice, particularly in areas such as outside professional activities and in-kind support. What this means in terms of how effort over and above institutional base salary and in-kind support will be determined (i.e. quantified cost-sharing?) going forward, including how the reported information will be used, and kept confidential where necessary, by NSF are just a few of the complexities from this non-policy change. Stay tuned for additional updates. Please contact Jackie Bendall for comments or questions at <u>ibendall@cogr.edu</u>

DOE Implementation of Foreign Talent Recruitment Program Prohibition - Update

The <u>June Meeting Report</u> discussed a number of questions raised by the DOE Order (DOE O 486.1) implementing a prohibition on DOE and contractor employee participation in talent recruitment programs sponsored by countries deemed sensitive by DOE. Subsequently COGR raised these questions directly with DOE. A summary of the responses follows.

Briefly, DOE's approach is to manage this process mostly through the disclosure requirements at the DOE lab level. Joint employees will have to disclose any participation in a talent recruitment program with any of the designated countries of risk to the lab, who will evaluate it. There will be no publicly shared list of talent programs; the situation is too dynamic. Labs will evaluate disclosures case-by-case. Each will be reported to the DOE Counterintelligence office, which will maintain a (non-public) list.

DOE will be amending existing contracts to include the prohibition and the Contractor Requirements Document. The disclosure and reporting requirements in the CRD only apply to contractor employees working within the scope of DOE contracts. DOE is nowhere close on grantee implementation. Their approach is to have the labs manage the process, which they realize won't work for grantees. A workshop will be scheduled this fall where these issues will be further discussed.

The DOE labs now appear to be proceeding with development of forms for reporting by subcontractors. A form received by several COGR members from a DOE prime lab contractor cites the need to report if any subcontractor employee participates in a "foreign government talent recruitment program"(FGTRP), where the subcontracted work in question is performed on or at a DOE/ site or facility including space/facility leased by a contractor. The subcontractor agrees to



make an affirmative disclosure of its compliance with DOE Order 486.1 and must either certify that no employee participates in a FGTRP or disclose the details of any such participation with a copy of the employee's agreement with the FGTRP. The prime contractor may direct the subcontractor to remove the employee from performing work under the subcontract unless the employee agrees to discontinue his/her participation in the FGTRP.

While questions may remain about the implementation of the DOE Order, clearly implementation is proceeding operationally.

Sen. Grassley Requests GAO Review of Implementation of COI Policies to Protect Against Undue Foreign Influence in Research – New Issue

Sen. Chuck Grassley (R-Iowa) sent a <u>letter</u> to U.S. Comptroller General, Gene L. Dodaro, requesting that the Government Accountability Office (GAO) perform a review of how the federal government is implementing conflict of interest policies in taxpayer-supported research. In the letter, Grassley says that "Conflict-of-interest policies and requirements agencies have in place for their own researchers as well as nonfederal researchers that receive federal support are a critical tool in identifying and mitigating potential foreign threats to federally-funded research." Sen. Grassley goes on to state that, "taxpayer money supports billions of dollars in federal research grants every year. However, a number of recent reports, articles and congressional hearings have raised concerns about whether the U.S. public is realizing the full benefit of taxpayer-funded research given the implications of foreign-researcher engagement in federally-funded research." COGR will follow this and provide updates as they become available.

<u>Department of Education Declines to Issue Formal Guidance on Section 117 Reporting Requirements - Update</u>

Recent COGR Updates and Meeting Reports have discussed efforts by the higher education associations, led by ACE, to obtain clearer guidance from the Department of Education on the HEA Section 117 foreign gift reporting requirements. A further request for clarification was sent by the associations on July 12. Copies were provided to the COGR membership.

A response from Ed. was received on July 30. It asserts that contrary to the associations' view, Section 117 "clearly puts institutions of higher education on notice of their duty to report." The reporting "must include gifts from, or contracts entered into, with any campus or affiliated association, foundation, or entity that operates substantially for the benefit or support of, or under the auspices of, any institution covered by this statute. Specifically, this includes all aligned associations, foundations, or other entities whose purpose is to assist, aid or support any institution covered by section 117."

Ed. has sent letters to at least four COGR member institutions requesting further information. The letters imply that the Department is expecting institutions to report in-kind gifts in the totals (although that requirement is not spelled out in the existing statute). Another COGR member institution recently was advised by Ed. that tuition payments from foreign governments also should be included in the reports and perhaps outgoing funds as well, though neither of these are supported



by the statute. Despite Ed.'s assertions that the reporting requirements are clear, obviously many questions remain. The associations continue to consider further steps.

COGR Comments on NIST Enhanced Security Requirements for CUI - Update

On August 2, COGR, joined by four other higher education associations, submitted comments to NIST on the draft NIST SP 800-171B, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations: Enhanced Security Requirements for Critical Programs and High Value Assets. Our main concerns are implementing the draft requirements on an agreement-by-agreement basis without advance notification to funding recipients, and how agencies will designate "critical programs" or "high value assets" subject to these requirements. The NIST draft provides very little guidance on that point. The cost and burden implications are potentially substantial. Adopting the enhanced controls would require significant institutional planning and investment. Our members need a consistent basis to know when to anticipate that the enhanced security requirements will be applied and the degree of flexibility in responding. Some of the requirements involve costly tactics and counterintelligence activities (e.g. penetration testing by "red teams"), which may raise serious issues in a university context. The comments are posted on the COGR website.

On August 16 <u>NIST announced</u> that the enhanced security requirements of SP 800-171B are on hold, pending OMB review of the NIST standards for protecting the security of government data overall (NIST SP 800-53; Revision 5 has been pending for two years). Hopefully this will give NIST more time to consider our concerns.

FAR CUI Rule Close to Publication - Update

The long-awaited Federal Acquisition Regulations Rule on Controlled Unclassified Information is now listed in the Unified Regulation Agenda (RIN 9000—AN56). According to the Agenda, the proposed rule (FAR Case 2017—016) will be published for public comment in October. This is two years past the original due date.

Prohibition on Procuring "Covered" Telecommunications Equipment Published in FAR - Update

On August 13 the prohibition on procuring telecommunication equipment from certain providers was published in the Federal Acquisition Regulations (84 FR 40224; FAR Case 2018-017). The FAR clause (52.204—25) implements the FY 19 NDAA (see COGR <u>September 2018 Update</u>). It applies to telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation, and a number of subsidiaries and affiliates. A companion clause (52.204—24) requires that offerors represent that they will not provide such equipment in the performance of a government contract.

Additional Huawei Affiliates Added to Commerce "Entity List" - Undate

On August 19 the Commerce Bureau of Industry and Security added an additional 46 Huawei affiliates to the export controls Entity List with a 90-day transition period. Additional license requirements and limits apply to entities on the list, which is found in Supplement No. 4 to Part 774 of the Export Administration Regulations (EAR). Huawei and certain affiliates were originally added to the Entity List in May (84 FR 22961).



Discussions Continue on Patent Act Section 101 Reform - Update

The <u>June COGR Meeting Report</u> discussed in some detail the discussions with Congressional staff (Sens. Tillis and Coons) on the issues associated with patent eligibility. These discussions continued over the summer.

One new aspect raised by Congressional staff is the possibility of a new statutory research use exemption. The joint association working group responded cautiously to this suggestion. It may be a solution in search of a problem. In our view, "First, do no harm" should be the guiding principle of any proposal. The end goal of this effort should be to encourage true research and experimental uses without compromising the rights of patentees. We suggested that rather than codifying an exemption, Congress instead consider creating a new, narrow defense to infringement for bona fide academic research and experimentation. The difference between redefining what infringement means and providing a defense is significant in terms of litigation practice. Α "Defense to Infringement Based on Academic Purposes and/or Experimental Activities" could be provided in the statute (Sec. 273). We did provide some additional suggestions for a limited research and experimental use exemption if Congress opts for an exemption approach.

We understand that Sens. Tillis and Coons are planning to introduce their bill in September. We will keep the membership informed.

COGR Joins in Again Supporting STRONGER Patents Act - Update

On July 10 COGR joined four other higher ed. associations in supporting the STRONGER Patents Act which was reintroduced in both the House and Senate. A ceremony marking the introduction was held in the Capitol at which Jessica Sebeok of AAU made remarks on behalf of the associations. The bill seeks to limit abuses of the post-grant patent challenge process in the USPTO, particularly with regard to *inter partes* review proceedings. It also addresses abusive patent demand letters and clarifies that universities qualify as micro-entities under the *America Invents Act*.

This is the <u>third version</u> of the bill that Sen. Coons has introduced (see <u>COGR June 2017 Meeting Report</u>). It was introduced in the House last year by Rep. Stivers (R—OH), who again introduced the bill in this session. We and the other associations have supported the bill each time, and both the House and Senate bills have bipartisan support. The AAU Press Release for the current version is available here.

Delays in Reporting Basic Research in ClinicalTrials.gov for Basic Research Studies - Update

On July 24, NIH <u>issued a notice</u> delaying the requirement for institutions to report the results of basic research on human studies in <u>ClinicalTrials.gov</u> until September 2021. The delay applies only to basic experimental studies with humans (BESH), which are studies submitted to funding opportunities designated as "basic experimental studies with humans" in the title. Applicants must identify alternative platforms for reporting the research results and include the information in the Dissemination Plan attachment of the application.

In a November 2018 <u>letter</u>, COGR, many other organizations, and many of our member institutions strongly urged the NIH to separate the reporting of clinical trial studies from basic research and consider a more



appropriate reporting mechanism for basic research studies.

Fetal Tissue Research – Update

As reported at the June meeting, HHS published a <u>news release</u> on June 5th announcing that it would terminate certain studies using human fetal tissue. COGR and other associations responded through a July 11, 2019, <u>Coalition letter</u> with several specific concerns about NIH's new position and citing research advances in HIV, Alzheimer's and Parkinson's diseases due to human fetal tissue research. Two weeks later, HHS published Notice <u>NOT-OD-19-128</u> – "Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research," announcing several new proposal review and approval requirements when requesting NIH funding for studies involving human fetal tissue from elective abortions. NIH published clarification Notice <u>NOT-OD-19-137</u> on August 23, 2019 including detailed instructions for grant applicants. A new FAQ on the Notice and Clarification has also been published, and is posted here.

The new grant application requirements include the following: 1) all grant applications and renewals must include a detailed justification of the need for human fetal tissue and documentation that alternatives methods do not exist (justifications are subject to the application page limits); 2) applications must include a sample IRB-approved consent form to be used in the event of award, and a compliance assurance signed by the PI assuring that the donating agency complies with informed consent; 3) applications must undergo a separate review by an NIH ethics advisory panel yet to be formed; 4) costs and procurement for human fetal tissue must be separately documented and justified, even if there is no cost to the grant for the material; 5) investigators may not use the NIH modular budgets for human fetal tissue research. See the Notice, the Notice Clarification and FAQs for further details and additional requirements.

The new requirements apply to competitive applications for grants and cooperative agreements submitted for due dates on or after September 25, 2019, and R&D contract proposals submitted to solicitations issued after September 25, 2019. COGR will continue to work with AAMC and other organizations on these issues. Contact mchristy@COGR.edu if you would like to be involved in these efforts.

Animal Care

Reducing Administrative Burden under the 21th Century Cures Act – Update

On August 28, a Working Group of experts from NIH, the USDA and the FDA released their final report "*Reducing Administrative Burden for Researchers: Animal Care and Use in Research*" on their planned activities to reduce administrative burden in animal research. This report is in response to the language in the 21st Century Cures Act requiring a review of animal research regulations.

The Working Group looked at inconsistent, overlapping, and unnecessarily duplicative regulations and policies and identified areas to reduce burden in semiannual IACUC inspections, protocol reviews and institutional reporting. In addition, the Working Group identified opportunities to improve coordination on federal standards and training and resources.



COGR led the formation of a <u>workshop</u> of university and other experts in the field aimed at providing ideas and specific areas where burden could be reduced, and that workshop is acknowledged in the report. In addition, <u>COGR provided comments</u> to the Working Group's <u>draft report</u> (issued November 2018). We are reviewing the final report in detail to assess the impact to administrative burden and will follow up with the Working Group as appropriate.

The report states that over the next two years, NIH, USDA and FDA intend to make progress on the steps and actions described in this final report and will identify additional ways to protect animal welfare while reducing unnecessary administrative burden on researchers.

Several Personnel Changes in APHIS Leadership

We have been made aware of several changes in important APHIS leadership positions.

Dr. Mark Davidson is a new Associate Administrator, filling the position previously held by Mike Gregoire, who retired earlier this year. Dr. Jack Shere is a new Associate Administrator, filling the position previously held by Dr. Mary Bohman, who left the Agency earlier this year. Ms. Bernadette Juarez a new Deputy Administrator for Biotechnology Regulatory Services, succeeding Dr. Mike Firko, who is retiring at the end of the August. Doug Nash is new Deputy Administrator for Marketing and Regulatory Business Services.

See the APHIS Leadership site for more information.

Research Misconduct

Communicating Research Misconduct to NIH – Final Resolution

COGR previously informed the membership the October 17, 2018 NIH Guide Notice NOT-OD-19-020, reminding award recipients of the need to inform ORI as institutions are investigating the potential for research misconduct. The notice also reminds institutions of the need to inform the NIH grants office of situations that could impact the performance of the grant, including misconduct investigations. The Notice included vague new statements about the timing of reports to the NIH grants office, which triggered COGR and other associations to submit a joint association letter seeking clarifications from Dr. Mike Lauer and Dr. Patricia Valdez, Research Integrity Officer at NIH. On July 23, 2019, the NIH responded with a new misconduct FAQ. Unfortunately, while the new misconduct FAQ provides some clarification, the concerns discussed in the letter have not been fully addressed, and the problematic statements and vague language in the Notice remain. Until further clarifications are provided by the NIH, COGR urges members to refer to the Section 8.1 of Grant Policy Guide, Changes in Project and Budget, which states "Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation." Institutions may also refer to



42CFR §93.318, "special circumstances" for reporting to the NIH grants office, including, when the health or safety of the public is at risk, including an immediate need to protect human or animal subjects; HHS resources or interests are threatened; research activities should be suspended; there is a reasonable indication of possible violations of civil or criminal law; federal action is required to protect the interests of those involved in the research misconduct proceeding; the research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights.

Finally, the membership is reminded that NIH prior approval from the NIH grants office is always required for a change in PI or when the institution wishes to transfer a grant to another institution.

Confidentiality Scenarios Related to Responding to Allegations of Research Misconduct - Final

The COGR ad hoc working group on Confidentiality Issues in Research Misconduct is pleased to announce the release of "Confidentiality Issues Related to Responding to Allegations of Research Misconduct". The document is posted to the COGR website and will be shared with the COGR membership via the listserv. COGR would like to especially thank the Association of Research Integrity Officers (ARIO) and the following members of the work group for their dedication and support of the work product: Ann Pollack - UCLA (Chair), Grace-Fisher Adams - UCLA, Sheila Garrity - George Washington University, Lauran Qualkenbush - Northwestern University, Emily Sobiecki - Partners, Gretchen Brodnicki - Harvard, Naomi Schrag - Columbia, Gerri Sands - Fred Hutchinson Cancer Research Center, Dave King - University of Kentucky, Kristen West - Emory University, Eric Everett - UNC, Lois Brako - University of Michigan, Ray Hutchinson - University of Michigan, Pat Ward - University of Michigan.

OMB Compliance Supplement (CS) for 2019- CS Released & COGR Comments: Update

The 2019 Compliance Supplement (CS) was released on June 28th and is available on the <u>OMB</u>, <u>Office of Federal Financial Management home page</u> (see 3rd link down under "Resources and Other Information"). Included in the release was a request for comment, and COGR responded in a <u>July 26th Comment Letter</u> to OMB. We remarked on the following three items:

• Part 3 - Compliance Requirements, C. Cash Management. As we raised in 2017, COGR believes better language around what is meant by "paid" will be helpful to auditors and grantees and, importantly, will not place federal dollars at risk. COGR recommended the following definition: "Paid" is defined as the placement of the costs into the nonfederal entity's accounts payable system, which then disburses cash in the normal course of business using the non-federal entity's payment policies and procedures. This definition would support a longstanding and accepted practice where federal reimbursement is requested after costs are entered into an institution's account payable system.



- Part 3 Compliance Requirements, I. Procurement and Suspension and Debarment. As we wrote to OMB in April, COGR suggests OMB modify the current version of the 2019 CS and insert simpler, clarifying language to confirm the allowability of research institutions using the \$10,000 micropurchase threshold (MPT) and the \$250,000 simplified acquisition threshold (SAT). In short, an authoritative reference to OMB Memo M-18-18 seems to be all that is needed, which would then take away any ambiguity in using the \$10,000 MPT and the \$250,000 SAT.
- Part 5 Research and Development Cluster. COGR has asked OMB for an explanation as to why 8 compliance requirements, rather than 6, have been included under the 2019 CS, OMB initiated a new methodology where auditors should review only 6 of the 12 compliance requirements.

We will keep the membership posted on all developments.

HHS/NIH G-Accounts and Reconciliation: Update

As we reported in June Meeting Report, on June 20, COGR organized a call with representatives from HHS/Payment Management System (PMS). Dan Long, Director of PMS, was on the call, including several of his PMS colleagues. In addition, nine member institutions from COGR, each of which has been struggling with the G- account reconciliation process, participated on the call.

The primary request by those institutions on the call was to ensure there is a collaborative reconciliation process in place, which allows an institution to work with PMS to determine a fair, documented deficit/surplus amount associated with those G-accounts (pooled cash draw accounts) that are being closed. Mr. Long acknowledged that part of the PMS "rush" to close the G-accounts has been prompted by pressure under the 2016 GONE Act, which requires federal agencies to close expired accounts and to better account for unused federal funds. Consequently, some PMS representatives have been overly enthusiastic in requiring institutions to quickly resolve alleged deficit balances.

From the COGR membership standpoint, a "rushed" process to closing G-accounts could lead to unilateral action by PMS and result in deficit amounts being sent to collections, with no recourse for the institutions to dispute the amount. Some of the institutions that participated in the call indicated amounts in question of over \$500,000, and even approaching \$1 million.

The call was productive. 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 each institution to address its unique situation.

Those that participated on the June 9 call, plus several others who have since contacted COGR, have indicated that PMS representatives have handled their unique situations well, i.e., assuring each institution that their situation will be handled on a case-by-case approach, and providing more time to



each institution to submit documentation. COGR will continue to work with the affected institutions and reach out to PMS, as appropriate. If your institution is impacted, contact David Kennedy at dkennedy@cogr.edu and he will provide contact information for Mr. Long and answer other related questions.

2018 Farm Bill, Impact on Research, and the NIFA Move: Ongoing & Important Update

We reported in detail in the <u>June Meeting Report</u> on the impacts of the 2018 Farm Bill (<u>Agriculture Improvement Act of 2018</u> – signed into law, December 20, 2018) on the administration of research awards from the National Institute of Food and Agriculture (NIFA). At a Wednesday afternoon Committee Meeting (held prior to the start of the June COGR Meeting), the RCA and Costing committees met with NIFA representatives; Cynthia Montgomery (Deputy Director, Office of Grants and Fiscal Management) and Melanie Krizmanich (Senior Policy Specialist). Since those meetings, COGR has engaged with Maggie Ewell (Senior Policy Advisor) at NIFA.

The primary impacts of revised statutory language in the 2018 Farm Bill will be new matching requirements on selected NIFA programs (e.g., Specialty Crops Research Initiative), less F&A recovery under a new methodology necessary to comply with the 30% F&A for total federal funds awarded (TFFA) restriction, and possible changes to effort reporting requirements specific to federal formula funds (i.e., Hatch, Smith-Lever).

In a recent discussion with Ms. Ewell, we raised the following items (note, some of these items also were raised with Ms. Montgomery and Ms. Krizmanich at the Wednesday afternoon Committee Meeting):

- 1) Address regulatory changes to matching requirements, where possible. For example, per <u>Matching</u> Requirement FAQs, "fix" FAQ #9 that disallows F&A to be used for cost sharing.
- 2) Ensure post-award compliance is done with maximum flexibility. NIFA indicated that F&A cap compliance will be monitored at the end of each budget period, and not on each funding draw. This is positive. We'd also like to explore the possibility of being able to rebudget costs to F&A at the end of the budget period and/or project period, if the 30 percent TFFA was not reached. Guidance can be incorporated into the Farm Bill Indirect Cost Provision Guidance.
- 3) Explore using the NSF model of "linked / collaborative" proposals. In effect, awards would be issued directly to each collaborator, which would eliminate the messy subaward / F&A management issue.
- 4) Confirm "grandfathering" awards issued prior to the 2018 Farm Bill is the uniformly implemented at NIFA to ensure that the provisions of the 2014 Farm Bill are applicable.
- 5) Consider use of fixed award / subawards, when appropriate.



- 6) Ensure that any new time effort reporting requirements, especially as they relate to Hatch funds and Smith-Lever funds, are consistent with all NIFA programs and consistent with <u>2 CFR 200.430</u>, <u>Compensation Personal Services</u>.
- 7) We are available to provide data and other support to NIFA, including review of FAQs, implementation guidance, etc., which minimizes administrative burden and is user-friendly.

While conversations with NIFA have been positive, the reality is the controversial move of NIFA Headquarters from Washington D.C. to Kansas City seems to be official. An August 12 article in FedSmith provides insight. Further, COGR conversations with NIFA representatives confirm the move is underway. And most concerning is that key COGR contacts, including Ms. Ewell and Krizmanich, will be leaving NIFA (also see Washington Post, July 18, 'The brain drain we all feared'). The loss of NIFA talent will be significant and will make engagement a challenge. However, COGR will continue to participate on these NIFA issues, and will work closely with the Association of Public and Land-grant Universities (APLU) to advance solutions. We will keep the membership updated on all developments.

The COGR F&A White Paper is Available, and Slide Deck to Follow: Reminder

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 published 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. If you are interested in additional copies, we will take orders and ask that you pay for the additional copies ordered, at cost.

The paper is a memorial to a wide variety of F&A issues, with the hope that it will be a longstanding educational resource to the research community, as well as an advocacy-piece that can be used when F&A (inevitably) comes under scrutiny in the future (see May 2019 Update, Ongoing F&A Advocacy). The paper was completed through the active and dedicated efforts of COGR leadership and staff, the COGR Board, the COGR Costing Policies Committee, volunteers from the COGR Research Compliance and Administration (RCA) Committee, and at-large volunteers from throughout the research community.

In addition, the COGR Costing Committee has organized a Workgroup, comprised of volunteers from the COGR Membership, to develop a PPT slide deck. The idea is to produce approximately 5 to 10 slides for each chapter from the paper, which then can be available for COGR institutions to present to faculty, staff and other stakeholders. Cindy Hope (University of Alabama) and Vivian Holmes (Boston University) are the university representatives leading this effort, with support from Toni Russo and David Kennedy.

COGR F&A White Paper Publication "Excellence in Research" Available for Purchase at October COGR Meeting

Bound copies of the COGR Publication <u>Excellence in Research</u>: The Funding Model, F&A Reimbursement, and Why the System Works (otherwise known as the F&A Paper) will be available for purchase at the October 24-25, 2019, COGR Meeting for \$15 each. Payments can be made via check or credit card. As



previously reported, each COGR member institution is entitled to a free copy. If you have not received your free copy or are unsure, please contact Toni Russo at trusso@cogr.edu. You can register for the October meeting here.

New OSTP Committees on Science and Technology

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

On July 9, 2019, the NSTC, with management guidance from OSTP, hosted its second meeting of the NSTC Joint Committee on the Research Environment (or NSTC J-CORE), which is comprised of four independent sub-committees each tackling a key issue critical to the future health and well-being of the American R&D ecosystem:

- The Subcommittee on Safe and Inclusive Research Environments
- The Subcommittee on Rigor and Integrity in Research
- The Subcommittee on Research Security
- The Subcommittee on Reducing Administrative Burdens

The meeting summary is available <u>here</u>. Each of the Subcommittees has also had several meetings. We will keep COGR members apprised of any developments.

NASA Releases Proposed Sexual Harassment Policy - New

On August 16th, COGR, The American Council on Education (ACE), Association of American Universities (AAU), and other associations responded with comments to NASA's Federal Register notice entitled, "Reporting Requirements Regarding Findings of Sexual Harassment, Other Forms of Harassment, or Sexual Assault" issued July 10, 2019 (corrected notice issued July 17, 2019). Of particular concern is the requirement to report an administrative action. Consistent with COGR's comment letter submitted to the National Science Foundation (NSF), we point out that "administrative action" captures a vast array of temporary actions which could be and frequently are preliminary to any findings or conclusions, and may have no impact on the performance of the grant. As with NSF, NASA's use of these interim measures could chill or prevent victims from reporting instances of sexual harassment out of concern that NSF may create a record or take action against a PI or co-PI prematurely. We asked that reporting only be required in situations where administrative leave has been imposed and the PI or Co-I has been found responsible but is appealing the adjudication, or when the terms of a pre-adjudication leave would affect performance of the grants. We also urged NASA to rely on existing prior approval processes for substituting a PI or Co-I when absence for more than three months is necessary and questioned how the reported information would be used and kept confidential, including NASA's process to update the information should no finding(s) be made.



The Federal Register also indicates that the recipient will be responsible for ensuring that all reports, including those related to co-investigators who are subrecipients, comply with this term and condition. Due to privacy concerns, we recommend that the primary award recipient's responsibility should be limited to passing through the appropriate terms and conditions from the prime award for inclusion in the subaward and suggest that the subrecipient report directly to NASA. Click here to read the letter, including other comments made by COGR. Please contact Jackie Bendall at jbendall@cogr.edu for questions or comments.

HHS OIG Grant Self-Disclosure Program - New

On July 12, the Office of Inspector General (OIG) announced OIG's new <u>Grant Self-Disclosure Program</u>. <u>According to the OIG</u>, <u>recipients and subrecipients are to investigate potential violations</u>; assess any losses suffered by the Federal programs; take corrective action; and make full disclosure to the appropriate authorities. The HHS OIG Grant Self-Disclosure Program provides a means to meet these obligations. <u>The June 2019 document provides guidance to non-federal entities when disclosing potential violations of Federal criminal, civil, or administrative law relating to their awards or sub-awards.</u>

Bulk Manufacturer of Controlled Substances Applications: Bulk Manufacturers of Marihuana – New Development

The Drug Enforcement Administration under Department of Justice released a <u>Federal Register Notice</u> on August 27, 2019, acknowledging the 33 pending applications received to grow or manufacture cannabis and noting that recent amendments to federal law (e.g. hemp) may no longer require DEA registration. Since DEA's 2016 statement to expand the number of growers in the U.S., DEA states, "they intend to continue the review process with the intent to propose regulations in the near future that would supersede the 2016 policy and govern persons seeking to become registered with DEA to grow marihuana as bulk manufacturers, consistent with applicable law."

Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development Awards Beginning in FY 2020 - New

Since 2017, more than 30,000 eRA Commons Profiles have been linked to ORCID iDs (Open Researcher and Contributor Identifiers) as a means to improve efficiency and link researchers to their contributions over time. The process also simplifies the creation of biosketches for grant applications.

Pursuant to an NIH Notice released on July 10, individuals supported by NIH, AHRQ, and CDC research, training, fellowship, research education, and career development awards will be required to have ORCID iDs. NIH has indicated that applicants for individual fellowship and career development awards are encouraged to follow the ORCID link from their Personal Profiles in the eRA Commons, where they can either link their eRA profiles to existing ORCID accounts or create ORCID profiles and link them back to the eRA Commons. Similarly, PD/PIs of institutional research, training, career development and research education awards are urged to begin alerting potential appointees to do the same.



NIH Releases Notice of Special Interest for Public Health Research on Cannabis - New

With 33 states across the United States with approved medical and recreational cannabis laws, the National Institute of Drug Abuse (NIDA) announced on August 14 that it plans to fund grant applications on the effects of changing cannabis laws and policies in the US and globally on public health. This follows a report from an Advisory Council Workgroup recommending that NIDA work in concert with the CDC, SAMHSA, ONDCP, and others to support a systematic effort to inform and be informed by states addressing cannabis law reform for purposes of delineating challenges, lessons learned, and unintended consequences from their experiences thus far.

NIH Data Sharing Policies on the Rise - New

Following the 21st Century Cures Act provisions for an Information Commons, COGR is seeing a recent uptick in the number of data sharing policies being released from NIH Institutes and Centers. We expect that each I/C will be responsible for its own data sharing policies and the lack of harmonization as a result will likely be challenging. COGR will request a meeting with representatives from NIMH and NIAAA and asks for your feedback on issues and/or recommendations with the proposed policies and others as they evolve. Please send your feedback to Jackie Bendall at jbendall@cogr.edu. A brief synopsis of the mandate for each of these I/Cs is provided below:

Notice of Data Sharing Policy for the National Institute of Mental Health

This <u>notice mandates</u> that the NIMH Data Archive (NDA) serve as the repository for genomic data funded by NIMH unless NIMH agrees to a different data archive during the negotiation of the terms and conditions of the grant award.

Notice of NIAAA Data-Sharing Policy for Human Subjects Grants Research Funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) [2nd Revision]

Released July 31, <u>this notice</u> mandates that the NIAAA serve as the repository for all genomic data funded by NIAAA unless NIAAA agrees to a different data archive during the negotiation of the terms and conditions of the grant award.

Upcoming Meetings

Nonprofit Funders – Research Institution Partnership Meeting - September 24

COGR and the Health Research Alliance (HRA) will hold a day-long workshop of the Nonprofit Funder –Research Institution (NFRI) Partnership on September 24, 2019, following the FDP meeting in Washington, DC. The workshop will facilitate ongoing discussions and efforts around four key elements of foundation-institution relations: (1) Streamlining administrative requirements; (2) Indirect costs/research project support costs; (3) Intellectual property and tech transfer issues; and (4) overall principles for successful partnerships between nonprofit funders and research



institutions. This is the fourth in-person NFRI partnership meeting. The draft agenda for the meeting can be found here. The link to registration can be found here. Details on current and planned partnership initiatives were presented at the February 2019 COGR meeting and included in the meeting report.

National Science Board Meeting July 2019 – Update

At its most recent meeting, the National Science Board (NSB) reviewed a report of the societal benefits of Social and Behavioral Sciences, including projects aimed at combatting terrorism. The meeting also included a plenary session on Research Security, including representatives from AAU, OSTP, Stanford, NSF and MIT. The webcast can be viewed here. The next NSB meeting will be held on November 19 & 20.

Council on Governmental Relations Meeting – October 24-25

Registration is <u>now open</u> for COGR's October meeting. Individuals from member institutions can register <u>online</u> or via <u>paper form</u>. The October agenda will be released a few weeks prior to the meeting and posted to the <u>COGR website</u>. Please be sure to <u>book your hotel room</u> at the Georgetown Marriott by October 8 for special COGR pricing. All meeting registration cancelation requests must be received by Friday, October 18. For any questions, please contact Toni Russo at <u>trusso@cogr.edu</u>.