

FEBRUARY 2020 UPDATE

An Association of Research Institutions

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Announcements

Council on Governmental Relations Meeting – February 27-28, 2020

Registration is <u>still open</u> for COGR's February meeting. Individuals from member institutions can register <u>online</u> or via <u>paper form</u>. The <u>February agenda</u> has been released and is posted to the COGR website. All meeting registration cancellation requests must be received by Friday, February 21. For any questions or to submit questions for Committees in advance of the meeting, please contact Toni Russo at <u>trusso@cogr.edu</u>.

<u>Live Polling Debuts at February 27-28 COGR Meeting – Download the App in Advance</u>

We will be incorporating a live polling feature during the Thursday morning session at the upcoming February COGR meeting in order to gauge and share membership feedback in real time. Though you will be able to connect via your laptop or your phone, <u>please consider downloading the app on your mobile device in advance for the most streamlined experience.</u> To download, visit https://www.polleverywhere.com/mobile or search for "Poll Everywhere" in your App Store. If you have any questions, please contact Toni Russo at trusso@cogr.edu.

Cross Cutting Issues: Science and Security

COGR Releases Framework for Reviewing Global Engagements (NEW)

On January 14, 2020, COGR released the Framework for Review of Individual Global Engagements in Academic Research to provide an underlying structure to support the institution's analysis of outside engagements, assess potential risks, and develop strategies for risk 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 points addressed in the Framework. We note that this Framework could be applied to domestic activities as well.

This is Version 1 of the Framework with the understanding that the environment is changing quickly and that updates may be needed once federal stakeholders issue additional policies and guidance. A panel of experts will review the goals and structure of the Framework at the February COGR meeting and will discuss case studies, including opportunities for audience participation.



<u>Update on Disclosure of Other Resources for NIH and NSF Proposals (UDPATE)</u>

On December 5, COGR released a "Commentary on Disclosure of Other Support to NIH" to provide Members with COGR's interpretation of the NIH proposal disclosure requirements based on public statements by and open discussions with the NIH. The document summarized our best guess at the time. In late December, NIH issued its revised Grants Policy Statement (GPS), which applies retroactively to October 1, 2019. The new GPS confirmed some of COGRs interpretations of the disclosure requirements. For example, the NIH revised its definition of Other Support to expressly exclude gift funding and start-up funding from "the US-based institution," so investigators are not required to report these as Other Support. The new GPS was also consistent with our focus on disclosure of materials (e.g., biologics, chemical, model systems, technology, etc.) that are considered "high-value" (COGR used the term "uniquely available"). This GPS policy statement may be helpful when program officers appear to be seeking overly detailed information.

While the GPS remains somewhat vague in other sections that COGR addressed in the Commentary, we did not see any policy language that conflicts with our assessment or would cause us to revise our understanding of the disclosure requirements.

Meanwhile, on January 24, the revised NSF Proposal & Award Policies & Procedures Guide 20-1 (PAPPG) was released, with an effective date of June 1, 2020. The revised Current and Pending Support language is broader than what had been published in the draft revisions in May 2019. The new language says: "Current and pending support includes all resources made available to an individual in support of and/or related to all of his/her research efforts, regardless of whether or not they have monetary value." This language is similar to the NIH disclosure language in the updated GPS.

NSF held a webinar on February 6, 2020, which included several new clarifications and exceptions to reporting Current and Pending Support. For example, NSF stated that Current and Pending Support does not include start-up funding from the applicant institution. Current and Pending also excludes gifts where the gift meets a federal-wide definition (e.g., no specific obligations and no time commitment on behalf of the senior personnel.). The NSF PAPPG includes new language about the reporting of in-kind support: "Current and pending support also includes in-kind contributions (such as office/laboratory space, equipment, supplies, employees, students)²⁶. In-kind contributions not intended for use on the project/proposal being proposed also must be reported²⁷." NSF clarified that key personnel must report in-kind support in the Facilities, Equipment & Other Resources section if the support is related to the project. If the support will not be used in the grant proposal, it should be reported in the Current and Pending Support section. NSF stated during the webinar that only in-kind support that requires a time commitment must be reported in the grant proposal. These are helpful statements and are not reflected in the current version of the PAPPG – 20-1. NSF plans to release an FAQ including these clarifications soon. Additional questions may be sent to NSF using the address policy@nsf.gov.



NSF and NIH have been talking publicly since last summer about their coordinated efforts to revised proposal disclosure forms, so it is not a surprise that the two agencies are converging. Jean Feldman and Rebecca Keiser from the NSF and Michelle Bulls from the NIH are scheduled to discuss their agency disclosure requirements at the February COGR meeting.

Revised Education Department Section 117 Reporting Requirements Withdrawn; New Reporting Requirements Issued (UPDATE)

On February 4, <u>OMB announced</u> that the revised HEA Section 117 reporting requirements that the Department of Education (ED) sent to OMB for emergency review had been withdrawn. According to the announcement, ED was to resubmit the request as a standard non-emergency Information Collection Request (ICR) "in short order." Upon resubmitting the ICR for OMB approval, ED would provide public notice in the Federal Register and provide 30 days for the public to comment. The supporting statement in the resubmitted ICR would address concerns raised by OMB to date. Lastly, OMB and the Department agreed that ED will pursue rulemaking to address the Department's desire to collect "true copies" of contracts from covered institutions.

The new ICR <u>was released</u> on February 10. Perhaps COGR's biggest concern with the previous ICR was the requirement that "true copies" of contracts or gifts be submitted. This requirement has been eliminated in the revised ICR. In response to the comments received, ED indicates that it "continues to believe it has authority under Section 117 to collect this information for enforcement purposes. The Department has decided to use notice and comment rulemaking to propose the requirement and further engage with the public on this issue. Thus, we will not include true copies of gifts and contracts on the disclosure instrument in this package."

The revised ICR clarifies that institutions must report only gifts from and contracts with a foreign source the value of which is \$250,000 or more (either alone or aggregate from that foreign source). With regard to other concerns raised by COGR members, the revised disclosure form no longer require institutions to list all legal entities (including foundations) that operate substantially for the benefit of the institution, However, language has been added to specify that an institution must report gifts or contracts when the benefit is received by an institution through an intermediary. ED also has removed the language in the previous ICR requiring information about a U.S. reporting party's relationship with a foreign source, and the previous certification requirements related to compliance with various laws and regulations beyond ED's authority. Finally, ED indicates in the revised ICR that "intellectual property license fees from a foreign licensee of a University patent and data or materials...would generally be included in the statutory definition of contract."

On December 23 ED <u>announced</u> a new reporting system for the Section 117 reports. According to the ED announcement, institutions had the option of using the current or new system for the reports. Submission of the proposed required additional information in the current system was voluntary. However since the ICR had not yet been approved by OMB, we understand that most institutions used the current <u>E-App system</u> for the required January 2020 reports without providing the "voluntary" additional information. We will further engage with ED when the "true copies" rulemaking is released and will likely comment further on the revised ICR.



Follow Up to Senate Hearing on Chinese Threats to U.S. R&D and CIS Conference (NEW)

The COGR <u>December Update</u> mentioned the recent Senate hearing on <u>Securing the U.S. Research Enterprise from China's Talent Recruitment Plans</u>. As one follow-up, three U.S. Senators (Sens. Scott, Rubio and Cotton) recently <u>sent a letter</u> to the American Hospital Association asking a series of questions. The questions included information about COI disclosures, vetting of individuals, researcher disclosure of participation in foreign talent recruitment programs, and changes made since the NIH notifications on foreign influences. Sen. Scott sent a <u>similar letter</u> in December to Florida university presidents. The Florida legislature also recently <u>began an investigation</u> of foreign ties of researchers at state universities.

There continue to be myriad articles, reports and conferences about these issues. Among the more noteworthy was the CSIS DOJ China Initiative Conference on Feb. 6. Speakers included Attorney General Barr (who spoke mainly about 5G), FBI Director Wray, and other DOJ and FBI representatives. Speakers repeatedly cited the need for a "whole of society" U.S. response to the Chinese threat. Some recent well-publicized cases involving arrests of U.S. and Chinese researchers were discussed. A panel of U.S. attorneys from around the U.S. was particularly interesting. They stressed that foreign collaborations were fine but lying about them to U.S. agencies or officials was not. Suggestions were made that more legislative guidelines for collaborations might be helpful, and that U.S. institutions need to pay more attention to disclosures in grant applications, particularly involving financial interests. One suggestion was that failure to verify financial information might even be considered to be "administrative misconduct." Another suggestion was that the Foreign Agents Registration Act (FARA) be expanded to include researchers (Rep. Moulton (D—MA) has introduced a bill (H.R. 5733) that would expand FARA beyond the current restriction to political activities on behalf of foreign principals, but that bill was not specifically mentioned). A summary of the views of one of the participating U.S. attorneys currently prosecuting these cases can be found here.

There also were industry and academic experience panels. Interestingly no individual company was represented in the industry panel. The academic panel included two university presidents, AAU President Coleman, and Mike Lauer of NIH. Difficulties for universities in dealing with these issues due to their openness and decentralized nature were emphasized. Steps that universities have been taking were summarized. Dr. Lauer noted several times that the misbehavior of some investigators that NIH has found was "egregious." Overall the discussion by the law enforcement and security agency representatives was mostly positive on university responses to the concerns.

Transportation of Research Materials (UPDATE)

On December 20, COGR informed the membership that the FBI and other federal law enforcement agencies had increased their surveillance efforts to identify transport of research materials and verify that those exports comply with federal laws.

COGR has been made aware of continuing surveillance actions by the FBI and other security officials at airports, including screening individuals traveling with research materials, computers, and data (for example, see



<u>here</u>). Travelers may benefit from additional documentation about materials leaving the country, including a description of the materials, the status of the materials (e.g., are they proprietary, do they pose a security risk), and an indication that the institution is aware of and has approved their export. Security agencies appear to be focusing on areas where many researchers are traveling abroad, for example, Boston, Massachusetts; the bay area in California; and Research Triangle Park, North Carolina.

We urge institutions to remind researchers that prior institutional approvals may be required before research materials and/or data are exported abroad. In some cases, it may be appropriate for the individual to have an export license exemption ("bag letter") or other institutional approval for the materials. Contact your export controls office, materials transfer office, or EH&S office for more information.

Research Security and Intellectual Property

DOD Releases CMMC Framework (NEW)

On January 31, DOD publicly released its <u>Cybersecurity Maturity Model Certification 1.0</u> draft Framework. The intent is to develop uniform standards for future DOD acquisitions. The framework includes 5 levels of cyber "hygiene," each with several associated cybersecurity practices. The basic hygiene Level 1 consists of 17 practices equivalent to the FAR Basic Safeguarding Requirements (FAR 52.204—21). The most advanced Level 5 consists

of 171 practices, including the FAR, NIST SP 800-171, a subset of 4 practices from the draft NIST 800-171B, and an additional 11 practices consistent with an advanced cybersecurity program. The intermediate levels consist of an escalating number of practices up to Level 5 (i.e. Level 2 "Intermediate Cyber Hygiene" includes FAR compliance plus a subset of 48 800-171 practices plus an additional 7; Level 3 "Good Cyber Hygiene" includes the FAR plus all of NIST 800-171 plus an additional 20 practices, etc.). Key to the framework is a requirement for third party certification verifying the implementation of the practices associated with a cybersecurity level. Contractors can implement levels either for their entire enterprise or enclaves, depending on the information to be protected.

DOD plans to phase in the model over the next 5 years starting later this year, eventually applying to all DOD contracts. An obvious issue is the application of the requirements to DOD contracted fundamental research at universities. The description indicates that the model is intended to protect unclassified Federal Contract Information (information provided by or generated for the government not intended for public release) or Controlled Unclassified Information (CUI). Since fundamental research, by definition, does not involve either, it should be excluded from the requirements. We understand that DOD plans to incorporate the requirements into the DFARS 252.204-7012 clause. COGR has contacted DOD to express concerns about the implications for fundamental research. We expect to continue discussions, especially regarding possible changes in the DFARS, and the possibility of waivers or carveouts for fundamental research at universities. (The 7012 clause should not apply if a university has received a fundamental research determination under a DOD contract.)



All DOD contractors apparently will be expected to achieve Level 1 certification, at a minimum, to receive awards. There has been some discussion of extending the requirements to grants. Most COGR institutions already are in compliance with many but not necessarily all FAR Basic Safeguarding requirements. In any event it appears those institutions that handle CUI now will be expected to achieve the Good Cyber Hygiene level, which includes a total of 130 practices. The costs and resources needed to achieve these practices may be significant. As an example, currently the 7012 clause only provides for self-certifications, but CMMC requires certifications by third parties. This has obvious cost implications.

House Science Committee Hearing on U.S. Competitiveness in Critical Technologies (NEW)

On January 29, the House Science, Space and Technology Committee <u>held a hearing</u> on U.S. competitiveness in critical technologies. Witnesses included Dr. Diane Souvaine, Chair of the National Science Board, Dr. Eric Schmidt, Founder of Schmidt Futures and former CEO of Google, and Dr. Chaouki Abdallah, Executive Vice President for Research at Georgia Tech. Questions and the follow on discussions were mostly positive – many made the case for why increased research funding, primarily at NSF, would help keep the U.S. competitive. Questions were also raised about exploring ways to address the competition for foreign talent.

Republican House Minority Introduces SALSTA Bill (NEW)

Rep. Lucas (R-OK), Committee Ranking Member, along with 11 Republican <u>co-sponsors</u>, took the opportunity of the Critical Technologies hearing to introduce H.R. 5685, the Securing American Leadership in Science and Technology Act (<u>SALSTA</u>). The legislation aims to create a national science and technology strategy, prioritize investments in federal basic research, invest in U.S. research facilities, develop a STEM workforce, and reform current regulations. The legislation would authorize a doubling of basic research funding over the next 10 years at DOE, NSF, NIST and NOAA. According to Rep. Lucas, it aims to address two fundamental challenges facing the U.S: Chinese threats to American science and technology leadership and a changing climate.

Among the more notable provisions are **Section 503**, which directs NSF to develop a policy requiring all proposals include a plan for managing the risk of any potential ethical or security implications resulting from the research; **Section 506** which directs NSF to coordinate with heads of other federal science agencies to develop a set of criteria for trusted open repositories to be used by the scientific community in order to facilitate the transparent sharing and availability of data and code for federally funded research studies; and **Section 509** which provides for the development of a pilot program at three universities to ensure the security of federally supported research data and assist regional institutions and their researchers in compliance with regulations regarding the safeguarding of sensitive information and other relevant regulations and federal guidelines.

The bill also includes provisions to reform technology transfer regulations through updating the Stevenson-Wydler Act, updating federal laboratory IP reporting requirements, improving industry access to the DOE national labs, and allowing set asides of some SBIR funds for proof of concept programs. These provisions basically would implement



recommendations in the <u>NIST ROI Green Paper</u>. (NIST informally has advised us it is taking no position on the SALSTA bill).

As minority legislation, the prospects for SALSTA are unclear. It remains to be seen whether the House Science Committee majority will support the SALSTA provisions.

Removal of IHE Exemption to DOE Order 142.3A Confirmed (UPDATE)

We noted in the <u>December Update</u> that COGR member institutions had advised that the <u>142.3A exemption</u> for institutions of higher education had been eliminated. COGR and a couple of COGR institutions negotiated this exemption with DOE several years ago. It had exempted grant-funded research at institutions of higher education from the requirement for DOE approval for foreign national access to DOE information, technologies or equipment, provided the research was to be published. A Limited Change to DOE Order 142.3A recently <u>removed this exemption</u>. Informal discussions with the DOE Office of Science indicate that this change will be cancelled, and the exemption will continue to apply (unless the research involves access to DOE sites). However, the exemption always applied only to research funded by program offices that report to the DOE Undersecretary for Science and not to other DOE program offices that fund research at universities (e.g., Office of Energy Efficiency & Renewable Energy (EERE)). Even if the 142.3A change is cancelled it will not completely resolve the issue. We will continue to pursue this matter with the DOE Office of Science. If foreign national approval is required, the fundamental research exclusion (FRE) from export controls may no longer apply. In that case there could be implications for the willingness of some institutions to continue to perform DOE-funded research.

COGR Submits iEdison Comments (UPDATE)

On January 24, COGR <u>submitted comments</u> to NIST in response to the <u>iEdison RFI</u> (see COGR <u>December Update</u>). AAU, APLU and AAMC joined in the COGR comments.

In our comments we summarized some common themes in the feedback from COGR members: lack of agency uniformity both in iEdison participation and reporting rules and standards; inability of the system to identify the applicable Bayh-Dole regulations; challenges with the government support clause; problems with responding to error messages; and the requirement to upload confirmatory licenses and government support clauses for old abandoned cases. Several sets of detailed comments from COGR member institutions were attached to the COGR letter.

NIST received 47 sets of comments in response to the RFI. Many were highly technical in nature. NIST currently is in the process of selecting an outside vendor to assist in the system redesign. One concern is the need for both NIST and its support contractor to understand the scale and complexity of the issues with iEdison especially since NIST plans to expand its use for certain actions required by Bayh-Dole (e.g. U.S. manufacturing waivers).



NIH should be commended for its efforts to improve iEdison and providing additional staffing and resources in recent years (a point made in several university comment letters). We suggested that NIST consider establishing a stakeholder user group as it proceeds with the system redesign. COGR would be happy to assist in establishing such a group.

House R&D Caucus Hosts Panel on NIST ROI Green Paper (UPDATE)

On February 5, the House R&D and Entrepreneurship Caucuses hosted a panel on the NIST ROI Green Paper findings. In addition to Courtney Silverthorn of NIST, panelists included Kathy Ku, formerly of Stanford, Lesley-Millar Nicholson of MIT, Julie Lenzer of the University of Maryland, and Marc Singer of Osage University Partners. It was moderated by Orin Herskowitz of Columbia. Reps. Foster (D—IL) and Baird (R—IN), R&D Caucus Co-Chairs, made introductory remarks.

Much of the discussion focused on the difficulties with technology transfer at the federal labs, which was a main topic in the NIST report. One study showed that the invention rate at the labs is only 10% that of universities. The need to foster a more entrepreneurial culture at the labs and revise current regulations governing federal agency tech transfer was emphasized. The need for exclusive rights to obtain necessary investments in early stage inventions also was highlighted, particularly by Mr. Singer.

In response to an audience question about Bayh-Dole march-in rights, Dr. Silverthorn mentioned that both Bayh-Dole and the Stevenson Wydler Act contained certain "guard rails" that need to be reexamined after 40 years of experience. March-in is one such guard rail. The Administration has taken no position on the use of march-in for price control purposes. However, Dr. Silverthorn pointed out that while the discussion tends to focus on therapeutics, march-in applies to all Bayh-Dole subject inventions.

The session was well-attended, including by Congressional staff. Dr. Silverthorn indicated that the regulatory package implementing the ROI is now expected to be released in April, considerably later than initially planned. The COGR RSIP Committee plans to meet with NIST representatives at its meeting this month to further discuss both the ROI status and iEdison.

Costing and Financial Compliance

<u>Proposed Revisions to the Uniform Guidance – 2 CFR Part 200 (NEW)</u>

On January 22, 2020, the Office of Management and Budget (OMB) released <u>Proposed Revisions to 2 CFR Part 200</u> (i.e., the Uniform Guidance). This represents an update to the <u>current version of 2 CFR Part 200</u>, which was made effective on December 26, 2014. Comments are due Monday, March 23, 2020 and can be submitted by accessing the first link above.



Note the following:

- A COGR Workgroup of 15 individuals has begun developing a COGR response.
- Gilbert Tran, OMB Office of Federal Financial Management, is an invited guest to the February COGR meeting. He is scheduled to present from 4:30 to 5:30 p.m. on Thursday, February 27, 2020, and will provide additional insights to the Proposed Revisions.
- In the introduction to the Proposed Revisions, OMB has framed the revisions to align with OMB's <u>Results-Oriented Accountability for Grants</u>, as specified in the President's Management Agenda (March 20, 2018).
- To be consistent with the goals of the President's Management Agenda, COGR believes this may be an opportunity to suggest additional ideas that will reduce administrative burden, without compromising accountability.
- COGR's approach will be to comment on the specific topics addressed in the Proposed Revisions, as well as additional topics that will support the President's Management Agenda to reduce burden.

In the <u>December 2019 Update</u>, we included a section titled "NIH Regulatory Reform: Subrecipient Monitoring and Financial Reporting." In effect, this NIH update was a precursor to the release of the OMB Proposed Revisions. In addition to several of the topics we covered in the NIH update, topics such as Procurement, the DS-2, and many other topics are addressed in the OMB Proposed Revisions.

Also, <u>COGR's website</u>, under Policy Issues: Financial Management, we have created a new page titled "<u>2 CFR</u> <u>200 (Uniform Guidance)</u>." On that page we provide the "track changes" version of the Proposed Revisions, as well as documents tracing the history of and issues covered in COGR's engagement with OMB on the Uniform Guidance over the past decade. As appropriate, we will provide regular updates.

COGR's plan is to keep the membership updated as we develop the COGR Response. This will include sharing substantive drafts that your institutions can use to craft your responses to OMB. We will provide a complete status report at the February COGR meeting.

HHS/NIH G-Accounts and Reconciliation (UPDATE)

We have reported on this topic since <u>June 2019</u>. COGR's core priorities have been to protect institutions at risk of having non-reconciled G-accounts unilaterally closed and in the case where there are alleged deficits, ensure these deficit amounts are not sent to collections. COGR and nine member institutions conferenced with Dan Long,

Director of the Payment Management System (PMS), last June, and Mr. Long committed to: 1) slowing down the collection process, 2) working with institutions collaboratively to determine the fair deficit/surplus amount, and 3) providing 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 provide support and work to address their unique situations.



In the fall 2019, COGR conferenced with representatives from the HHS Grants Policy Office. In that call, HHS representatives assured COGR that G-account deficit balances at the pooled account level would <u>not</u> move to collections. We agreed that that the reconciliation process may be a time-consuming process, and we were assured that institution accounts at the pooled account level would not go to debt collection.

In a follow-up call in January 2020, COGR spoke with HHS representatives Alice Bettencourt (the new Deputy Assistant Secretary, HHS Office of Grants) and Richard Brundage (Acting Director, Division of Grants Policy, Oversight, and Evaluation) for a status update. *Ms. Bettencourt and Mr. Brundage shared with COGR that HHS/PMS are undertaking an initiative to close all pooled G-accounts.* Over the next couple of months, HHS/PMS will close pooled G-accounts and may move grants for which funds still remain available in the pool, for payment, into subaccounts. HHS awarding agencies will reach out to recipients should there be any required action on the part of the institution. Consequently, we encourage institutions to proactively reach out to HHS Policy Office, PMS, and the HHS awarding agencies if you are uncertain on the status of your institution.

We appreciate that closing the G-accounts is a complex process for all parties, especially when there are legacy projects that date back more than a decade (and in some cases, even further!). In the context of that complexity, COGR's commitment to its members is to continue to facilitate and advocate for a fair process. Please contact David Kennedy at COGR at dkennedy@cogr.edu if your institution has concerns.

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 <u>Dr. J. Scott Angle, Director of NIFA</u>, on Thursday, December 19th to discuss concerns, priorities, and how the higher education associations can be helpful as NIFA works through its transition. Dr. Angle asked COGR to respond to a "Reimagining NIFA" Initiative, and COGR <u>submitted a response</u> on January 23, 2019. We will keep the membership posted on any developments.



NIFA and Cost Sharing Under the Specialty Crop Research Initiative (NEW)

In a positive development, NIFA has regained its authority to waive the cost sharing requirement under the Specialty Crop Research Initiative program. Per the above discussion, this authority had been removed under the 2018 Farm Bill. In a <u>January 15 NIFA Update</u>, Dr. Angle wrote: "NIFA informed Specialty Crop Research Initiative (SCRI) applicants that for FY 2020, in accordance with General Provision 762 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94), NIFA will be waiving the match requirement for recipients of grants under SCRI. This provision also applies to the Emergency Citrus Disease Research and Extension (ECDRE) program. This means that no matching funds will be required of FY 2020 applicants or awardees, and applicants will not need to submit a waiver request with their application."

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 generally been to not take a position, partly because to advance a particular policy position might be inconsistent with how some COGR member institutions view this issue. However, as cloud computing use increases, COGR has decided to craft a short "Considerations" paper. We will share an update this with the Membership at the February COGR meeting.

2020 Compliance Supplement – DRAFT VERSION AVAILABLE (NEW)

COGR has been notified that parts of the Draft Version of the 2020 Compliance Supplement (CS) are available. Note, the final version of the 2019 CS was released in August 2019 and is available on the OMB Office of Federal Financial Management home page (see 3rd link under "Resources and Other Information"). When the 2019 CS was released last June, COGR raised several issues in a July 26th Comment Letter to OMB. While our issues were not addressed, we expect to provide comments applicable to the 2020 CS. If you are interested in helping with 2020 CS review process, please contact David Kennedy at dkennedy@cogr.edu.

NSF and HHS OIG Workplans (UPDATE)

The <u>NSF OIG Workplan</u> is now available on the NSF OIG website. In addition, we encourage members to review both the <u>Audit Reports</u> (see External Reports link) released by the NSF OIG <u>and</u> the <u>Management Responses to External Audits and Internal Reviews</u>. this latter page shows the arguably more important NSF audit resolution results, which includes the resolution letter from the NSF Division of Institution & Award Support to the institution.

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.



Reducing Administrative Burden in Federal Research Grants to Universities (NEW)

Lisa Mosley (Yale), Jeremy Forsberg (Texas-Arlington), and David Ngo (The New School)—regular COGR contributors—authored the recently released report, Reducing Administrative Burden in Federal Research Grants to Universities. This report focuses on the financial and programmatic compliance requirements of managing grants at universities, with the understanding that at a foundational level, the ethical conduct and integrity of conducting research is critical to the success of the U.S. research enterprise. However, the focus on procedural accountability is increasingly undermining the ability of academic researchers to focus their attention on conducting the research itself. We encourage COGR members to read the report, and as opportunities present themselves, advance those items of high priority to your institution.

F&A Rate Negotiations (REMINDER)

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. The February COGR meeting may be a good venue to share in a confidential setting. *If there are issues of concern applicable to your institution, we encourage to reach out to members of the Costing and Financial Compliance (CFC) Committee.*

Research Ethics and Compliance

Common Rule Go-Live and Single IRB Reviews (NEW)

The revised <u>Common Rule</u>, including the wide-spread use of Single IRB reviews, went into effect on January 20, 2020. As a result, agencies issued notices reminding institutions of this and providing additional guidance.

- DHHS/AHRQ issued NOT-HS-20-005 reminding applicants to include a Single IRB Plan in proposals.
 The Notice also states that the adequacy of the Single IRB Plan will not factor into the scoring of the application. Institutions may request an exception from the use of a Single IRB of record for a project but should not assume that an exception will be granted. Therefore, applicants should include the full cost of Single IRB compliance in all grant applications.
- NIH issued NOT-OD-20-058, stating that NIH K and F awards, which were previously exempt under the NIH Single IRB policy, are now covered under the Common Rule. NIH also reminded awardees that exceptions granted under their Single IRB Policy are only in effect until the next competing award.



Clinical Trials – Call for Comment (NEW)

The U.S. National Library of Medicine (NLM) issued <u>NOT-LM-20-003</u> seeking feedback on ways to improve <u>ClinicalTrials.gov</u>. <u>The notice</u> asks for information about proposed changes in website functionality and the standards and information that awardees must submit through the portal. Comments are due March 14, 2020. COGR plans to respond to the call.

Meanwhile, <u>Science</u> and other news outlets have recently published articles about the lack of compliance by award recipients in reporting of clinical trial data. Please see the articles below for more information.

- FDA and NIH let clinical trial sponsors keep results secret and break the law -
- Update- NIH extends reporting mandate to more clinical trials, but obscures their policing

Please contact Michelle Christy at mchristy@cogr.edu with any questions or comments.

Nonprofit Funder and Research Institution Partnership (NFRI) (UPDATE)

The Nonprofit Funder and Research Institution Partnership (NFRI) is a partnership of volunteers from the funding community and research institutions that is jointly sponsored by COGR and the Health Research Alliance (HRA). NFRI teams have been focusing on developing streamlined administrative processes and requirements that benefit both research institutions and the funding community. See this <u>link</u> for history and more information about the organization.

Several COGR members are leading or participating in cross-functional teams with nonprofit funders in the three workstreams - management of intellectual property, streamlining the application & award reporting processes, and research support costs. The teams are in the final stages of refining documents and other resources for the community, which will be launched at the next NFRI meeting, to be held on April 23 in Washington, D.C. More information about the meeting can be found here.

Environmental Health and Safety (NEW)

On January 23, COGR provided detailed information regarding a new DOE program to help research institutions decommission cesium irradiators and replace them with equipment that poses less risk to the public.

The <u>Cesium Irradiator Replacement Project</u> (CIRP) supports the Department of Energy's National Nuclear Security Administration (NNSA) Office of Radiological Security (ORS)'s mission to enhance global security by preventing high-activity radioactive materials from being used in acts of terrorism.

CIRP is a voluntary program that provides users of cesium-137 or cobalt-60 irradiators a limited financial incentive toward the purchase price of a replacement non-radioisotopic device (typically an X-ray irradiator). The financial



incentive provided is typically 50% of the purchase price of the new machine, though the incentive can be higher for institutions replacing multiple radioisotopic devices. Through CIRP, ORS will also fully fund the recovery of the original radioisotopic device through the Offsite Source Recovery Program (OSRP).

Several COGR member institutions have taken advantage of this program. For more information on CIRP please contact ORS at orsinfo@nnsa.doe.gov.

Contracts and Grants Administration

OSTP Releases Federal Register Notice Seeking Desirable Characteristics of Repositories (NEW)

Consistent with the 2013 White House Office of Science and Technology Policy (OSTP) memorandum entitled "Increasing Access to the Results of Federally Funded Scientific Research" that called for improved access to data and publications resulting from Federally funded research and development, OSTP has released a Federal Register notice seeking comments on desirable characteristics of repositories for managing and sharing data. OSTP seeks to reduce burden for federally funded investigators, promote equal access and harmonize, when possible, agency policies. In the notice, OSTP sets forth a non-exhaustive list of characteristics as a tool to be used for agencies and federally funded investigators when identifying non-federal agency data repositories. OSTP requires that repositories have features for restricted access, privacy, download control, data retention and breach response. Comments are due to OSTP by March 6, 2020. COGR intends to respond to the request for comments. Please send your comments to Jackie Bendall at jbendall@cogr.edu.

NSF Releases the 2020 Proposal and Procedures Policy Guide (PAPPG) (NEW)

On January 24, NSF released the <u>2020 PAPPG (NSF 20-1)</u> effective for proposals submitted or due, and awards made, on or after June 1, 2020. NSF hosted a <u>webinar</u> on February 6th to review the significant changes and clarifications to the PAPPG Guide. Although not an exhaustive list, several noteworthy changes are listed below:

- Applicants *must certify and re-certify on an annual basis* through the General Services Administration (GSA) System for Award Management. Note: NSF-specific terms and conditions will show up on the screen at the time of proposal submission.
- RAPID and EAGER proposals *now require concurrence letters* to be uploaded as a supplementary document.
- Two formats for the Biosketch are available NSF fillable PDF and SciENcv. NSF encourages institutions to obtain an ORCID ID and to test these formats well before June 1st as a preventative measure for reducing errors. Error messages will show if the NSF-approved formats are not utilized on June 1st both in Fastlane and Research.gov. The fillable format must be saved as a PDF and attached to proposals in Fastlane, Research.gov, or Grants.gov. It will no longer be permissible to use Word starting on June 1st.



- Conference costs secured through a service agreement should be budgeted as other direct cost. This change was made so institutions receive the appropriate amount of indirect costs.
- The Publication, Documentation and Dissemination section of the budget includes the addition of two new allowable costs: Data Deposit Costs a one-time charge you pay at the time you deposit data; and Data Curation Costs expenses associated with preparing data into a form others can use.
- Current and Pending Support is used to assess the capacity to carry out the project as proposed and to assess overlap or duplication with other projects. See the write-up above on "Update on Disclosure of Other Resources..." in the Science and Security section for more details on Current and Pending Support.
- Compliance checking is no longer required for intellectual merit. Broader Impacts is still required.

Jean Feldman and Rebecca Keiser will be participating in a NSF/NIH Disclosure Updates session at the February COGR meeting. Please contact Jackie Bendall at jbendall@cogr.edu if you have any questions.

NIH Draft Policy for Data Sharing and Management (UPDATE)

In COGR's October 2019 meeting report, we mentioned the NIH draft policy had been released and was available for public comment through January 10, 2020.

<u>COGR's response</u> listed several concerns and recommendations. A brief summary of some of the comments are as follows:

- Although pleased to see the proposal to submit data management and sharing plans (DMSP) as part of the "Just-In-Time" (JIT) documentation, that could make it challenging to budget for costs in the application when details are to be finalized with NIH Program Staff at JIT. COGR recommended that NIH allow additional costs for data management to be added to the budget at JIT based on final negotiated DMSP.
- COGR recommended an option that allows grantees to appeal NIH Institute, Center, and Office (ICO) mandated data sharing requirements to the NIH Policy Office should the requirements be considered unreasonable or inappropriate by the grantees, without fear of reprisal.
- COGR recommended NIH harmonize among the 27 ICOs via the use of a consistent format for collecting DMSP information.
- COGR recommends NIH establish a centralized location to host ICO-specific requirements as opposed to individual institute websites.

USDA Releases Interim Final Rule on Domestic Hemp Production Program (UPDATE)

As reported in COGR's <u>December 2019 update</u>, on October 31, 2019, the USDA posted a Federal Register Notice, conveying an <u>interim final rule</u> (IFR) seeking comments on rules and regulations to establish a domestic hemp production program and to facilitate the production of hemp, pursuant to the <u>Agricultural Improvement Act of 2018</u> (aka the Farm Bill). The IFR became effective on October 31, 2019. Although effective October 31, 2019, USDA sought to collect comments from stakeholders by January 30, 2020 (extended from December 30, 2019). COGR expressed many concerns and recommendations <u>in its letter</u>, including the following:



- COGR recommended the USDA regulations address the inherent differences between requirements for forprofit commercial hemp cultivation that is geared toward commercial CBD products and the cultivation of hemp for research purposes.
- COGR recommended the USDA allow states to adopt different rules that better facilitate research by universities or exempt such research from some of the requirements that apply to commercial entities.
- The IFR requires enforcement agency or approved DEA laboratories to collect samples for delta-9 tetrahydrocannabinol concentration (THC) level testing no more than 15 days prior to the anticipated harvest of hemp plants. State agriculture departments have requirements that conflict with this. COGR urged USDA to extend the timeline for pre- and post-harvest testing to more realistic timeframes such as those that State Departments of Agriculture have established.

<u>Substance Abuse and Mental Health Services Administration (SAMHSA) New Attestation Requirement (NEW)</u>

Several COGR members have voiced concerns about a <u>new SAMHSA attestation requirement</u> that is being required as part of the process for receiving an award, stating that the attestation includes restrictions much broader than what the law requires. The special term of the award requires that the grantee organization/recipient, State and all sub-recipients (contractors and sub-awardees) comply with the following:

"Grant funds may not be used, directly or indirectly, to purchase, prescribe, or provide marijuana or treatment using marijuana. Treatment in this context includes the treatment of opioid use disorder. Grant funds also cannot be provided to any individual who or organization that provides or permits marijuana use for the purposes of treating substance use or mental disorders. See, e.g., 45 C.F.R. § 75.300(a) (requiring HHS to "ensure that Federal funding is expended... in full accordance with U.S. statutory... requirements."); 21 U.S.C. §§ 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase or distribution of marijuana). This prohibition does not apply to those providing such treatment in the context of clinical research permitted by the DEA and under an FDA-approved investigational new drug application where the article being evaluated is marijuana or a constituent thereof that is otherwise a banned controlled substance under federal law"

On December 18, 2019, <u>COGR requested</u> that SAMHSA remove the new attestation requirement from all awards as not only is it duplicative of existing law and overreaching, but it also functions in direct contradiction to the increasingly urgent need to reduce barriers to research that may lead to treatments for certain forms of substance abuse. COGR also proposed an alternate term and condition for SAMHSA to consider. COGR will keep the membership informed on any developments with SAMHSA on this issue.

NIH Annual Policy Update

NIH posted its annual Notice announcing implementation of FY2020 policy requirements. These annual Notices coincide with legislative approval of the final HHS/NIH budget and clarify statutory and other policy requirements.



Below are links to the 5 notices posted on February 7th (note the final four represent annual policy updates, and the first one is new and may be of interest):

- Updated Guidance for Videos Submitted as NIH Application Materials (NOT-OD-20-061)
- Guidance on Salary Limitation for Grants and Cooperative Agreements FY 2020 (NOT-OD-20-065)
- Notice of Legislative Mandates in Effect for FY 2020 (NOT-OD-20-066)
- Notice of Fiscal Policies in Effect for FY 2020 (NOT-OD-20-068)
- Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2020 (NOT-OD-20-070)



COGR would like to thank COGR Board Chair Pamela Webb, University of Minnesota, and the COGR Committee members for their time, dedication, and expertise without which the efforts and activities conveyed in these updates would not be possible.

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Research Ethics & Compliance (REC)

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