COGR
Council On Governmental Relations
An Association of Research Institutions

October 22, 2018

TO: COGR Membership

FROM: COGR Staff

SUBJECT: October 2018 Update

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F&A Update and the COGR White Paper: THURSDAY MORNING SESSION

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

Also, and as we reported at the June Meeting, the COGR Costing Committee, with assistance from the RCA Committee, has organized around the development of an F&A White Paper to address many of the themes related to transparency, alternative models, education and myths. ***The paper will be a memorial to a wide variety of F&A issues; the hope is that paper will be a longstanding resource to the research community, as well as an advocacy-piece that can be used when F&A (inevitably) comes under scrutiny (again) in the future.***

A thorough DRAFT of the paper has been completed and we will present an update to the Membership on key topics and discussions from the paper. Feedback from the audience will be encouraged! We expect to complete the paper and make it available in late 2018.

2018 Compliance Supplement and Audit Related Issues

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

Below are audit issues we continue to follow:

Payment and Reimbursement under 2 CFR 200.305. This was not addressed in the 2018 CS and remains a concern. According to some in the audit community, the IG position is that "recipients will be reimbursed without ever paying their invoices" if reimbursement requests are made before issuing payments. In response to a request for Public Comments to the 2017 Compliance Supplement, last year COGR sent a Comment Letter (dated October 20, 2017) to OMB, Gilbert Tran. Some of your institutions also sent letters, either documenting your unique circumstances or simply supporting the COGR letter. COGR views this as an open item and will continue to track it.

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

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

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

In addition, we direct you to recently released audits / settlement.

NSF OIG: Incurred Cost Audit

https://www.nsf.gov/oig/_pdf/18-1-006_MIT.pdf

NSF OIG: Incurred Cost Audit

https://www.nsf.gov/oig/_pdf/18-1-004_University_of_New_Mexico.pdf

DOJ Settlement (note, DOJ settlements normally do not include the specific details, as would be included in an audit report)

https://www.justice.gov/usao-sdtx/pr/texas-am-research-foundation-pays-750000-settle-claims-alleging-improper-charges

University of Montana https://www.nsf.gov/oig/_pdf/18-1-007_University_of_Montana.pdf

Tufts University https://www.nsf.gov/oig/_pdf/18-1-007_University_of_Montana.pdf

If you have audit related issues that you would like to raise, contact David Kennedy at dkennedy@cogr.edu.

Sexual Harassment in Science: THURSDAY AFTERNOON SESSION

As we reported at the June Meeting, representatives from the Office of Diversity and Inclusion (ODI), Bob Cosgrove and Rhonda Davis, along with Jean Feldman gave a presentation on the background and context of a proposed term and condition regarding sexual harassment. Of significant importance during the presentation was NSF's willingness to host COGR and other associations for a small round table discussion on July 24th prior to implementation of the proposed new requirements. During the roundtable discussion, COGR and other associations had the opportunity to provide feedback to a revised draft term and condition based on comments received from the Federal register notice. As result of the collective feedback, NSF released in final form September 21, a new term and regarding sexual harassment, other forms of harassment, and sexual assault.

The panel session Thursday afternoon will include the Chief Operating Officer, Dr. Fleming Crim of the National Science Foundation who will address the new NSF term and condition. Other panelist include Sarah Spreitzer, Director, Government and Public Affairs for the American Council on Education, Dr. Frazier Benya, Senior Program Officer with the Committee on Women in Science, Engineering, and Medicine (CWSEM) at the National Academies of Sciences, Engineering, and Medicine and Study Director of the recent National Academies Report, *Sexual Harassment of Women: Climate, Culture, and Consequences in Academic Sciences, Engineering, and Medicine,* and Theresa J. Colecchia, Senior Associate General Counsel, Johns Hopkins University. We look forward to hearing their respective presentations on this important topic. Look ahead for an upcoming session on Sexual Harassment on November 9th at the National Academies.

Please contact Jackie Bendall at jbendall@cogr.edu for questions or additional information on this topic.

Human Subjects and Animal Research

HHS SACHRP October 2018 Meeting

The HHS Secretary's Advisory Committee on Human Research Protections met October 16-17. The agenda included issues surrounding informed consent under HHS or FDA jurisdiction with the transition to the revised Common Rule; "key information" in informed consent; and interpretation of the revised Common Rule exemptions 46.101 (b)(1) and (2). Archived webcasts of the meeting can be found here.

Letter to DOT on Airlines' Refusal to Carry Animals for Biomedical Research

In a September 20 letter to the Department of Transportation, COGR joined the National Association for Biomedical Research and other organizations and institutions in calling for the department to require all airlines to eliminate policies which discriminate against carriage of laboratory animals used for biomedical research. COGR will keep members updated on the status of this effort.

FDA Guidance on Certain Provisions of the Revised Common Rule

On October 12 the FDA issued guidance on the *Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations*. The notice indicates that FDA intends to undertake notice and comment rulemaking to harmonize the agency's regulations with the revised Common Rule. In the interim, FDA is issuing this guidance "to reduce confusion and burden associated with complying with two different sets of human subject protection regulations."

Regarding informed consent, the guidance indicates that "the provisions of the 2018 [Common Rule] Requirements related to the content, organization, and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent *are not inconsistent* with FDA's current policies and guidance." Regarding expedited review, the guidance indicates that "Because FDA has not revised its regulations, IRBs must continue to comply with FDA's regulation at 21 CFR 56.110(b) and use the 1998 list for FDA-regulated clinical investigations, including those that are subject to both HHS and FDA regulations." Regarding continuing review, the guidance indicates that "Because FDA has not revised its regulations, IRBs must continue to comply with our current requirements for IRB continuing review at 21 CFR 56.109(f), including for clinical investigations that are subject to both HHS and FDA jurisdiction. IRBs are required to conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year (21 CFR 56.109(f))." The notice indicates that comments on the guidance can be submitted to the agency at any time.

NIH RFI on Registration and Reporting Standards for Certain Basic Science Studies

NIH released a request for information, Registration and Results Reporting Standards for Prospective Basic Science Studies Involving Human Participants, on August 10. The RFI, seeks information on standards and potential alternative platforms (e.g., the Open Science Framework) for registering and reporting basic science studies involving human participants and related areas. The July 20, 2018 NIH notice and this RFI, propose a category of research "prospective basic science studies involving human participants" that "meet the definition

of clinical trials" under the revised case studies. COGR and other organizations have suggested that these basic science studies are not clinical trials and should not be subject to NIH policies specific to clinical trials and asked that NIH consider how basic science studies involving human participants as a whole should be registered and reported in a way that is informative for the public and research community but not unnecessarily burdensome.

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

NIH Training in Human and Clinical Research

In an October 10 blog post, the NIH Office of Extramural Research reminded institutions that as of Sept. 26, NIH will no longer offer the Protecting Human Research Participants course as indicated in NOT-OD-18-221. New courses are being offered on the Principles and Practice of Clinical Research and Principles of Clinical Pharmacology.

Associations Comment on Proposed Changes to the NIH Guidelines

COGR, AAMC, AAU, and APLU submitted joint comments on Proposed Changes to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules on October 10. Recommendations included:

- Adapting Appendix M-1-A (4; a-f) as guidance for Human Gene Transfer [HGT] Risk Assessments rather than eliminating the appendix as proposed;
- A comprehensive review of the NIH Guidelines by a task force that includes scientists with the appropriate expertise from the regulated community to appropriately address relevant newly emerged and emerging technologies;
- The creation of a formal pathway to obtain feedback and guidance from the NIH Office of Science Policy on all inquiries regarding recombinant or synthetic nucleic acid molecule activities; and,
- A mechanism such as a web portal for information sharing during Institutional Biosafety Committee review among sites engaged in multisite trials.

On October 17, 2018, NIH indicated that, due to issues with their electronic comment form, "some comments submitted in response to this proposal may not have been received by NIH." NIH has therefore re-opened the comment period. Comments will now be accepted through October 25, 2018 and can be sent to SciencePolicy@od.nih.gov.

Audit

NSF OIG Audit Reports

The NSF OIG published three audit reports of incurred costs at institutions in the month of September. In the first report, auditors questioned $331,114 of $256 million costs claimed across 811 NSF awards over a three-year period. Questioned costs included $255,745 in indirect costs; $52,524 in travel expenses that the OIG

suggested did not benefit the award; $17,266 in equipment expenses charged at the end of the award period; $4,254 of unsupported expenses; and $1,325 in foreign airfare expenses that were not in compliance with the Fly America Act. The institution agreed with the findings. Regarding indirect costs, the report notes that per the Uniform Guidance IHEs must use the negotiated rates in effect at the time of the grant award throughout the life of the award. The report indicates that the institution "did not have sufficient policies and procedures to ensure that it set up its cost collectors to apply indirect costs using the negotiated indirect cost rate agreement rates that were in effect as of the effective date of the grant award, rather than the rates that were in effect when [the institution] submitted its grant proposal or established its cost collector."

In a second report auditors questioned $20,461 of $41 million of costs claimed on 193 awards over a three year period, including $15,426 in travel and related charges; $2,386 in participant support costs; and $2,649 in meal and visa costs. The institution agreed to pay the charges but suggested that "adequate evidence of allocability, accountability and reasonableness was provided" for $11,959 of the $15,426 in questioned travel costs. The institution generally agreed with the remaining findings but indicated that $1,672 of expedited visa processing fees were "reasonable and necessary" "because the delays caused by standard processing would have affected the start date of the postdoctoral associate and would have negatively impacted the project."

Auditors questions $367,779 in costs in a third report. Questioned costs included $342,020 of expenses related to the use of research-based salaries, and other expenses, charged on $22 million of costs claimed to NSF awards over a three-year period. The report indicates that the institution "established a second salary rate for externally funded research to enable faculty to charge sponsored projects at a rate higher than their regular salary rate" and cites the following language in the Uniform Guidance "Charges for work performed on sponsored agreements during all or any portion of such period are allowable at the base salary rate. In no event will charges to sponsored agreements, irrespective of the basis of computation, exceed the proportionate share of the base salary for that period." The institution did not concur that its use of research base salary was unallowable and did not agree to repay the $342,020 in questioned costs. Other questioned expenses included equipment purchased on the last day of an award and a day after an award expired, tuition for a student no longer working on an award, as well as fundraising, dental, lodging and shipping costs. The institution agreed to pay these questioned costs.

The NSF OIG also issued a report on an audit of incurred costs at the National Academy of Sciences, including questioned costs of $90,902 on $43.2 million in costs claimed on 163 NSF awards over a three-year period. Questioned costs included $54,725 in costs drawn down from NSF's Award Cash Management $ervice on 18 NSF awards that were not supported by actual expenses; $12,447 of airfare, fellowship, meeting and lodging expenses that were not budgeted or thought to not benefit the award; $12,046 of meal expenses that exceeded the maximum allowable cost per person; $11,684 of travel expenses; and expense reports on travel that were not submitted within NAS-required time frames. The National Academies agreed with all of the findings.

National Science Board (NSB) Midscale Research Report

On October 16, 2018, the National Science Board released a report on NSF's investments in mid-scale research infrastructure, Bridging the Gap: Building a Sustained Approach to Mid-scale Research Infrastructure and Cyberinfrastructure at NSF. The report recommends that NSF:

- Affirm and sustain its mid-scale Big Idea with a long-term agency-level commitment to mid-scale research infrastructure.
- Investigate the feasibility of using the Major Research Equipment and Facilities Construction account as one possible funding mechanism.
- With the NSB, review existing infrastructure oversight and management structures to ensure they are compatible with mid-scale range investments.
- In cooperation with the NSB, determine the full scope of the demand for mid-scale research infrastructure and ensure the agency's programs and processes address that demand by developing an evaluation and assessment program.

Strengthening Research Rigor and Reproducibility

Federal agencies and nonprofit organizations and societies continue to introduce resources to enhance research rigor and reproducibility in an effort to address concerns regarding both preclinical and clinical research results. At the October 25-26 2018 meeting, COGR will hold a panel discussion on reproducibility. Shai Silberberg, Director of Research Quality at the National Institute of Neurological Disorders and Stroke (NINDS), will discuss the outcomes of the October 22-23 NINDS workshop "A Visionary Resource for Instilling Fundamental Principles of Rigorous Neuroscience Research" and the role institutions can serve to facilitate rigor and reproducibility. Brian Nosek, Co-founder and Executive Director of the Center for Open Science (COS) that operates the Open Science Framework, will discuss how COS is enabling open and reproducible research practices, as well as outcomes of the October 15 Philadelphia Symposium on Research Credibility and Excellence. COGR Research and Regulatory Reform committee members Naomi Schrag, Vice President for Research Compliance, Training, and Policy, Columbia University, and JR Haywood, Assistant Vice President, Office of Regulatory Affairs and Professor, Michigan State University, will discuss the results of the COGR survey on rigor and reproducibility and next steps.

SciLine – Scientific Expertise and Content on Deadline

SciLine is a AAAS-hosted initiative that provides journalists with quick, free, access to knowledgeable, articulate scientists. One year after its launch, Rick Weiss, Director, and Meredith Drosback, Associate Director for Science, will provide an overview at the October COGR meeting of the organization's mission and services and an update on its various approaches to enriching the news stream with research-based evidence.

National Security

COGR Session on Addressing Foreign Threats to U.S. Research and National Security

Concern among members of Congress, the administration, the national intelligence community, and federal agencies that fund research regarding efforts on the part of China to become an international leader in science and technology through both competitive and more questionable means has escalated significantly. As one response to this concern, Federal officials have in recent months communicated the need for greater transparency and reporting with respect to research collaborations with foreign institutions, companies, and governments. At the October 25-26 COGR meeting Rebecca Keiser, Head of the Office of International Science and Engineering, NSF; and Bindu Nair, Acting Director, DOD Basic Research Office, will join us to discuss federal concerns and expectations. The DOD Office of Basic Research will take the lead on establishing a forum for DOD to work with academic institutions on protection of intellectual property (knowledge and ideas)

and information about critical technologies, to limit undue influences of countries through foreign talent programs, and to develop more domestic talent in science and engineering as directed in section 1286 of the National Defense Authorization Act. Robert Daly, Director of the Wilson Center's Kissinger Institute on China and the United States, will also join us. In September the Wilson Center published the report A Preliminary Study of PRC (People's Republic of China) Political Influence and Interference Activities in American Higher Education.

Discussions Continue on Science and Security Issues

Over the past month discussions have continued between higher ed. association representatives and other groups including security agencies, Congressional staff, and research funding agencies. This included a Roundtable held on Sept. 5 with members of the House Science Committee and a "Summit" with university leadership hosted by the FBI on Sept. 20. COGR participated in both meetings. While recognizing the serious concerns, we have expressed the need for more specifics as to actual threats. Materials that have been provided by security agencies tend to conflate universities with companies in the focus on protecting trade secrets (e.g. see October RRC Report; Vol. 15, No. 10) or in the emphasis on export controls ("Project Shield America"), with which universities already are very familiar. The concerns about foreign "IP thefts" appear to involve behavior that may raise ethical issues or perhaps scientific misconduct more so than actual IP theft. More recently concerns have arisen about Chinese origin microchips placed in equipment sold to major U.S. tech companies. AAU plans to send a survey form out shortly to its member institutions asking for examples of effective practices, policies, tools and resources used by campuses to protect against foreign security threats (note: this should **not** be confused with the self-assessment security questionnaire distributed by AAU federal relations representatives in August).

NIST Holds Workshop on Controlled Unclassified Information (CUI)

On October 18 NIST hosted an all-day workshop on CUI. The biggest news was a report from NARA on the status of the long delayed FAR clause. It now is close to a final draft. We may expect to see it in the December—February timeframe. While based on the DFARS 7012 clause it will be more "complicated" in providing more specific requirements for marking the CUI. The CUI will need to be specifically identified and the contract will state why the information needs to be protected as CUI. In response to an audience question, the FAR clause may provide for separating out certain information included in CUI registry categories as non-CUI for purposes of the contract (e.g. EAR 99 from the export controls category).

The point also was made that the DFARS clauses do **not** implement the NARA CUI Program (e.g. the marking requirements). It is expected that once the FAR clause is issued the DFARS clause will be substantially modified. However the FAR clause may not cover all of what DOD views as the five principal requirements of the DFARS (information protection, cyber incident reporting, submission of malicious software, in-depth damage assessments in particular instances, and flowdown requirements) so there may continue to be separate DFARS clauses. DOD currently is not requiring third party review of the required NIST SP 800-171 compliance certifications. However, it is possible that DCMA will review certifications in the future.

Much other interesting information was presented at the workshop including the origin of the CUI Program (citing a 2013 Defense Science Board report), the evolution of 800-171 by tailoring the federal system

requirements of 800-53 for the non-federal environment, and related challenges. The "errata" update of the 800-171Revision 1 issued on June 7, 2018 (https://csrc.nist.gov/publications/detail/sp/800-171/rev-1/final) should be considered the current version. It contains a number of minor clarifications as well as helpful footnotes and a discussion of implementing and assessing each of the security requirements (Appendix F). A "2.0" version of 800-171 nay be issued in March of next year.

Slides for most of the workshop sessions are to be posted at https://csrc.nist.gov/Events/2018/Controlled-Unclassified-Information-Security-Requi).

PTO Issues Final Rule on Claim Construction Standard

On October 11 the U.S. Patent and Trademark Office issued a final rule (83 FR 51340) changing the standard for interpreting patent claims in *inter partes* review proceedings before the Patent Trial and Appeal Board (PTAB). The rule adopts the same standard used in the courts giving the words in a claim their ordinary and customary meaning (the so-called *Philips* standard) rather than the "broadest reasonable interpretation" previously used by the PTAB. COGR and the other associations supported this change (see September Update).

SUCCESS Act Passes Congress

On October 11 an amended version of the SUCCESS Act (H.R. 6758) passed the Senate. As noted in the September Update we also supported this legislation. It tasks PTO with providing a report and recommendations on promoting the participation of women, minorities and veterans in entrepreneurship activities and in obtaining patents. The report is due within a year. The scope of the bill as amended is slightly narrower than the original, which also included socially and economically disadvantaged individuals. It also appears to give priority responsibility to PTO rather than SBA.

Bayh-Dole Critics Strike Again

In the Fall 2018 issue of Daedalus two frequent critics of the Bayh-Dole Act, Rebecca Eisenberg of the University of Michigan and Robert Cook—Deegan of Arizona State University, assert that universities prioritize the pursuit of revenue over the commercialization goals of the Bayh-Dole Act. The article cites a number of examples of this alleged behavior. While some of the examples provided may be valid criticism, others appear misleading, such as the discussion of the *Stanford v. Roche* Supreme Court case. The basic issue in that case involved an important policy issue relating to the requirements for effective assignments of invention rights under Bayh-Dole, which the article glosses over. The authors criticize universities for seeking to enforce patents in a number of instances, ignoring the fact that university patents would have no value if they never were enforced. It is hard to see how this would promote commercialization.

Particularly questionable is the discussion of university activities in connection with the America Invents Act. It asserts a high degree of university influence ("universities persuaded Congress") in certain provisions included in the final statute. This glosses over the long complex legislative process leading to the AIA that featured extensive compromises by the myriad stakeholders. (The COGR February 2011 Meeting Report discussed this process as well as the Supreme Court arguments in the *Stanford v. Roche* case; https://www.cogr.edu/COGR/files/ccLibraryFiles/Filename/000000000250/151808.pdf).

The article concludes that universities have lost their "halos" in the pursuit of revenue. This type of criticism is not new, but is a perception that continues to raise challenges for university tech transfer offices. The article may be found at https://www.mitpressjournals.org/doi/pdf/10.1162/daed_a_00521 .