COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 460, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)

July 1, 2016

June 9-10, 2016 COGR Meeting Report Summary

RESEARCH & REGULATORY REFORM

Audit

NSF and HHS OIG Semiannual Reports to Congress and Interim Work Plan

The NSF OIG issued its Semiannual Report to Congress in May. The OIG suggests that additional measures can be taken to reduce costs associated with the Intergovernmental Personnel Act and reports questioned costs for senior personnel salary exceeding two-months. A review of single audit reports found "material weaknesses and/or significant deficiencies in internal control over compliance" for 19 of 25 awardees with findings including untimely, inaccurate reporting of time and effort and financial reports and inadequate monitoring of subrecipients. The latter finding may have prompted an amendment to legislation introduced on June 29 that would require the NSF OIG to audit NSF's oversight of pass-through entities compliance and controls for subrecipient monitoring. The report highlights changes to the Fastlane system that will prevent investigators with past-due project reports from receiving another NSF award. NSF issued its response focused mainly on large facilities findings. The HHS Semiannual Report largely focused on Medicare, Medicaid and health services.

The HHS OIG Work Plan – Mid-Year Update reports NIH-specific evaluations underway or planned including: assessing universities' controls over the subcontracting of grant and contract work; universities' compliance with selected cost principles; and, "the extent, scope, and trends of OHRPs' responses to allegations of noncompliance."

Regulatory Reform

National Academy's Releases *Optimizing the Nation's Investment in Academic Research* Part 2

The full report, released June 29, is now available online. The report addresses export control regulations, select agents/dual use research, intellectual property and technology transfer reporting, and the Common Rule NPRM. The committee recommends the executive branch

withdraw the NPRM and "that Congress authorize, and the President appoint, an independent, free-standing national commission." COGR, AAU and APLU have released a joint statement.

Administrative Burden Checklist

COGR has distributed a checklist to assist institutions in reducing the administrative work associated with sponsored awards. Completed checklists can be returned to Lisa Nichols.

Department of Energy (DOE) Retrospective Review

DOE issued a Federal Register Notice seeking comments on how the agency's regulations could be modified, streamlined, expanded, or repealed to minimize burden. Comments are due July 11.

Legislation on Reducing Regulatory Burden for Federally Funded Research

Congressman Dan Lipinski (IL-3) introduced the *University Regulations Streamlining and Harmonization Act of 2016* on June 24. The bill would implement a number of recommendations put forward in the National Academies report *Optimizing the Nation's Investment in Academic Research*, Part 1. Like the Senate's *Promoting Biomedical Research and Public Health for Patients Act*, this bill would create a research policy board. A hearing on the bill could occur in early fall. Disagreement over mandatory funding for NIH may be holding up the Senate bill. The *American Innovation and Competitiveness Act* approved by the Senate Commerce Committee on June 29 includes an interagency working group aimed at regulatory burden reduction.

Human Subjects and Animal Research

NIH Office of Science Policy (OSP) and the Precision Medicine Initiative (PMI)

Carrie Wolinetz, Director, NIH OSP, joined RRR and Costing and Intellectual Property (CIP) committee members to discuss the PMI. CIP members expressed concern about use of Other Transactions Authority (OTA) in making its initial awards and NIH's stated intent in RFA's to use Determinations of Exceptional Circumstances to ensure that patents directed to inventions made under the award cannot be used to block access to the resource and associated technology. Carrie indicated that NIH supports Bayh-Dole and had not yet worked through the allocation of IP rights for PMI. NIH is using OTA's to implement the PMI quickly. NIH and White House staff are working to overcome the current policy conflict between HIPAA and CLIA with respect to returning test results from non-CLIA-certified labs. Carrie indicated that the outcome of proposed changes to the Common Rule will not impact the PMI.

NIH Single IRB Policy

The Final NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research takes effect May 25, 2017. The policy applies to domestic NIH-funded multi-site studies carried out at more than one site "where each site will conduct the same protocol." Guidance on the use of direct and indirect costs for sIRB review and general FAQs are available. Additional guidance is forthcoming and will be posted to the NIH OSP Website. A blog post highlights the NCATS SMART IRB Reliance Platform and an email from NCATS suggests the

platform will serve as a "roadmap" for the NIH single IRB policy. COGR is assessing means of monitoring the cost and impact of implementing the policy among member institutions.

National Science Foundation .118 Determination Letter

COGR has been working with NSF staff to develop a letter that universities can submit for proposals lacking definite plans for involvement of human subjects and a revised determination letter was distributed on June 27. The provisions of the letter will be reflected in the next version of the *NSF Proposal and Award Policies and Procedures Guide* scheduled for release in October and a link to the letter provided. We appreciate the work of member institutions that contributed to this effort and that of NSF staff. Please contact Lisa Nichols with questions.

NIH Workshop on Use of Non-human Primates

NIH has announced a September 7 workshop to discuss the oversight framework governing the use of non-human primates. The workshop will be broadcast live and archived.

COSTING POLICIES

Procurement Standards (2 CFR 200.317-326): UPDATE

In the May 2016 COGR Update (dated May 24, 2016) and at the June COGR Meeting we provided updates on recent developments and the implementation status of the Procurement Standards (2 CFR 200.317-326). At the time of this writing, we know that OMB and the COFAR have reviewed the COGR/AIRI Letter (*Administrative and Cost Impact of the $3,500 Micro-purchase Threshold*) and the corresponding Procurement Survey (not posted on the COGR website) that were submitted on June 1, 2016. We are cautiously optimistic the next steps we discussed in the May Update will be implemented and that OMB will confirm this plan by July. We will keep the membership updated of any significant developments.

Uniform Guidance: Open Items beyond Procurement

In the May 2016 COGR Update (dated May 24, 2016) and at the June COGR Meeting we provided updates on other UG-related items that COGR continues to pursue. COGR addressed the other open items in a letter to David Mader, OMB Controller, dated March 16, 2016 ("*Open Items per 2 CFR Part 200*"), and OMB responded to the COGR letter on May 16, 2016. Both Letters are available on the COGR website. In addition, in a May 17th meeting, COGR staff met with OMB staff to review next steps on open items, which helped to inform COGR's strategy on how to approach each.

The COGR RCA and Costing Committees are coordinating action plans on each of the above and we will keep the Membership posted on all developments.

HHS Office of Grants Policy and Closeouts: Thursday Morning Session on June 9th

Jeffrey Johnson, Associate Deputy Assistant Secretary for Grants, Department of Health and Human Services (HHS), presented an update on the roles and responsibilities of the HHS Office of Grants Policy and how his office works with all of the HHS Operating Divisions. See the February Meeting Report (dated March 14, 2016) for the latest updated on the ongoing and intertwined topics of HHS, many of which Mr. Johnson discussed during his presentation. He invited COGR members to provide feedback on HHS closeouts and related issues. Please contact Toni Russo form the COGR staff at trusso@cogr.edu if you have an issue with any HHS Operating Division that you believe should be shared directly with Mr. Johnson and his staff. COGR will remain actively engaged on these topics and we will keep the Membership posted on important developments.

2016 COGR F&A Survey to Go Live: Thursday Morning Session on June 9th

After the presentation by Mr. Johnson, we transitioned into a separate session on the revival of the COGR F&A Survey. We last initiated a survey in 2011. The session covered the survey format, logistics and timeline, and input from those in attendance. **We will go live with the 2016 COGR F&A Survey this Summer,** first with a pilot group and then the membership. Stay tuned for additional updates.

Single Audit Update: Student Financial Aid and the Compliance Supplement

In the May 2016 COGR Update (dated May 24, 2016) we reported on a new development related to the scope of the single audit, raised by the Department of Education. At issue is whether the Student Financial Aid (SFA) program is required to be audited on an annual basis, or if it can be rotated with the Research and Development cluster. The Department of Education position is that SFA should be audited on an annual basis. This relates specifically to 2 CFR 200.518, Major program determination, and more broadly to the implementation of 2 CFR Part 200, Subpart F – Audit Requirements. COGR's understanding is, if determined to be low-risk, a Type A program (such as SFA) can be rotated and is not required to be audited on an annual basis.

Also note, OMB continues its work on completion and release of the 2016 Compliance Supplement. We believe the release of the 2016 Compliance Supplement is imminent. We will keep the Membership updated on all developments.

Affordable Care Act (ACA) Compliance and Graduate Students

The American Council on Education (ACE) and the College and University Professional Association for Human Resources (CUPA-HR) are the lead Higher Ed associations and are working closely with the IRS and the Department of Treasury to advocate for a fair and reasonable implementation of the ACA as it relates to higher education institutions.

In a Letter sent to the Obama administration by Sen. Charles Schumer (D-NY) and a group of 16 Democratic senators emphasizes the need to develop a permanent solution to allow graduate students to receive subsidized student health insurance coverage under the Affordable Care Act. An ACE Summary of the letter is available on the ACE website.

ACE and CUPA-HR will continue to pursue issues related to ACA compliance. If you have questions, COGR can connect you with contacts at ACE and/or CUPA-HR.

COGR Analysis: Equitable Treatment of Off-Campus Research Centers in RFAs

COGR, with significant help from several COGR member institutions, completed an analysis and forwarded it to NIH representatives. The analysis currently is being reviewed by the NIH Office of Policy for Extramural Research Administration (OPERA). The analysis gleaned important information in how space/lease costs and other facility-related costs are considered direct costs in the case of an off campus research center, and some of the challenging surrounding that.

Several options to restore equity that have been discussed are: 1) Allow the off-campus research center to exclude space and facility-related costs when the RFA includes a maximum Direct Cost limitation, or 2) Allow the off-campus research center to state maximum costs in terms of Total Cost instead of Direct Cost when the RFA includes a maximum Direct Cost limitation. We will keep the Membership updated on all developments.

General Inquiry: Contracts Issued by NIAID?

COGR has learned of what seems to be an isolated situation where contracts issued by the National Institute of Allergy and Infectious Diseases (NIAID) have contained expectations and clauses that are problematic and inconsistent with contracting practices at other NIH Institutes and Centers. For example, vendor relationships are being inappropriately characterized as subrecipient agreements, hourly reporting rather than effort reporting is being imposed, and detailed expense and receipt documentation is excessive. If your institution has had a similar experience with contracts issued by NIAID, please contact David Kennedy at dkennedy@cogr.edu and Toni Russo at trusso@cogr.edu.

CONTRACTS AND INTELLECTUAL PROPERTY

Revised Export Control Definitions Issued

On June 3 the Commerce Department/Bureau of Industry and Security (BIS) issued a final rule containing revised definitions for the Export Administration Regulations (EAR). On the same day the Department of State /Directorate of Defense Trade Controls (DDTC) issued an interim final rule containing certain revised definitions for the International Traffic in Arms Regulations (ITAR). See COGR May 2016 Update for additional background. The June 3 ITAR interim rule doesn't address any of the items of concern with the proposed ITAR rule issued last year – but does add a (potentially) helpful definition of "release" for deemed export purposes similar to the EAR. The final EAR rule responds positively to our two biggest concerns - software is treated the same as other technology resulting from fundamental research (734.8 (a)), and the original wording of the educational exemption from the EAR also is retained (734.3(b)) (see COGR Listserv Message 6/3 for additional detail). Ongoing concerns with the EAR rule include

not retaining the presumption that university research is fundamental research (Commerce/BIS states this presumption still exists, but will be stated in an FAQ on its website rather than stated in the rule.

Possible New OFAC General License for Scientists to Attend Conferences in Iran

The Iranian Transaction and Sanctions Regulations (ITSR, 31 CFR pt. 560) permit individual travel to Iran; however, many activities undertaken while in Iran must be licensed by the U.S. Treasury Office of Foreign Assets Control (OFAC), which is responsible for administering and enforcing the ITSR. After hearing concerns from the university community at a recent AUECO conference, a senior OFAC official seemed willing to consider arguments for issuing or amending a general license to authorize attendance at conferences in Iran. COGR will be participating in developing a whitepaper on this topic for possible presentation to OFAC.

New DFARs Safeguarding Clauses Raises Compliance Cost Concerns

The February Meeting Report discussed the COGR comments on the new DFARS requirement for *Safeguarding Covered Defense Information* (DFARS Clauses 252.204—7008 and 7012) and the panel discussion at the meeting. Institutions are expressing concern about the potential compliance costs, and some have indicated a willingness to walk away from DOD contracts/subcontracts containing the new clauses (though some have already employed a number of 'work arounds'.)

NARA has expressed a desire to work with appropriate university groups in developing the FAR clause, but subsequently has raised concerns about possible Federal Advisory Committee Act (FACA) implications. COGR is reviewing potential avenues to address the potential FACA issues and continue to pursue with DOD the possibility of providing a clear exemption for fundamental research in the safeguarding clauses. However, institutions may need to make hard choices in terms of their willingness to accept sponsor requirements containing these types of safeguarding requirements.

Changes to DFARS Clauses on Rights in Technical Data Issued

On June 16 DOD issued a number of proposed changes to the DFARS provisions dealing with Rights in Technical Data (DFARS Case 2012—D022. The changes are mostly technical and best understood by those familiar with these DFARS provisions (COGR has a brochure available on its website under "Intellectual Property" that explains the relevant FAR and DFARS provisions). Comments on the proposed rule are due September 14. At this time we have not determined if COGR will provide comments.

On a related matter, on June 21 the DOD Government—Industry Advisory Panel issued a request for information on the DOD rights in technical data provisions. The request responds to a requirement in the FY '16 NDAA. It includes eleven questions on which comments are sought. We currently are analyzing the questions to determine if we will provide a response. Comments are due July 21.

Invention Reporting Issues Continue

In COGR's October 2014 Meeting Report and October 2015 Meeting Report, we discussed concerns about reporting of inventions resulting from federally-funded awards. NIH has issued a series of compliance reminders on Bayh-Dole Act invention reporting. An NIH Grants Notice (NOT-OD-15_119) last July indicated that NIH cannot waive title to inventions until all compliance reporting requirements have been resolved.

Earlier this year NIH issued another reminder (NOT-OD-16-066; 2/ 17/16) that all subject inventions that were made under an applicable funding agreement and reported on the HHS 568 must be reported in iEdison. COGR plans to survey a small number of institutions on their practices, and may plan a session (or sessions) at future COGR meetings on this topic.

NIH Declines March-In Request

The February Update discussed the petition filed by Knowledge Ecology International (KEI) requesting march-in based on pricing grounds on a prostate cancer drug (Xtandi) developed with co-funding by NIH and DOD to UCLA. A petition to march-in on an AIDS drug on similar grounds was filed with NIH by the same group in 2004. The May Update noted that KEI also had suggested that NIH instead use the royalty-free government use license to inventions subject to Bayh-Dole to produce generic versions of Xtandi for Medicare patients.

KEI has stated that it plans to appeal the NIH march-in decision to HHS. KEI also has threatened to refile the petition next year with a new Administration, assuming the appeal is denied. Statements on its website cite NIH's "flawed legal rationale" and that NIH's response is "contrary to the legislative intent". These assertions are questionable, particularly given Sen. Bayh's testimony at the 2004 hearing. However they are attracting some press attention. Given that there also is ongoing Congressional interest in these issues, this matter appears far from settled.

Drug Pricing and IP Rights Remains a Hot Topic

The May Update discussed the recent article and related op-ed in the May 13 Washington Post proposing that the government use its authority under 28 USC 1498 as a mechanism to address high drug prices. We understand the authors have received foundation funding to publish such articles, and expect to see more publications on the subject.

The proposal has been criticized for discouraging biomedical innovation. We may see more criticisms of this nature. COGR will continue to monitor this issue and keep the membership informed of any significant developments.

RESEARCH COMPLIANCE AND ADMINISTRATION

Effective Practices Guide (Available in Print)

COGR reported in the February 2016 Meeting Report that the Effective Practices Guide (March 2016) was complete and the on-line version had been posted publically to the COGR website. Hard copies will be sent out over the next few weeks to each institution's Primary Representative.

HHS, Office of Research Integrity (ORI)

At the February meeting the RCA Committee met with Dr. Kathryn Partin, new Director of ORI to hear about her plans for developing strategic goals for ORI, who asked for written suggestions/recommendations by early May. COGR responded to her request on May 9th with nine recommendations. COGR submitted a follow up letter to address one of the recommendations on self plagiarism, concluding that although such actions represent bad scholarship and bad behavior, it does not rise to the level of research misconduct or any action that merits ORI enforcement.

Department of Labor Overtime Rule

On May 18, DOL released its Final Rule increasing the salary threshold from $23,660 to $47,476 with automatic increases every three years. COGR voiced its concerns in its comment letter, and invited Josh Ulman, Chief Government Relations Officer, CUPA-HR, to its June meeting to discuss the latest developments since the release of the Final Rule. As suspected, the bill introduced by Senate and House of Representatives entitled "Protecting Workplace Advancement and Opportunity Act (S. 2707, H.R. 4773)" will unlikely not come to fruition. COGR continues to advocate its cause however will be focusing its efforts on sponsor outreach for any guidance that may be available as agencies prepare for final implementation on December 1, 2016

Division of Biomedical Research Workforce (DBRW), Office of Extramural Programs, NIH

Drs. Kay Lund, Director, DBRW and Henry Khachaturian, Training Program Policy Officer joined the RCA Committee meeting to discuss the vision for NIH training and career development programs, practices and support as well as the potential impact of the DOL issue on postdocs. Drs. Lund and Khachaturian asked for feedback on the discussion. Click here to see COGR's letter on recommendations to future NIH DBRW guidance to NRSA, RGA and other federal postdoctoral fellow programs.

National Science Foundation (NSF), Proposal and Award Policies and Procedures Guide (PAPPG), Research Terms and Conditions (RTCs)

Dr. Jean Feldman and Michelle Bulls joined COGR Thursday afternoon to present the latest developments regarding the PAPPG and RTCs. At this time, COGR has no further comments to the PAPPG and will submit its response to the Federal Register Notice to thank the NSF for the improvements and clarification made to the Guide. As presented by Dr. Feldman, we are encouraged by the changes to the RTCs at this juncture and will update the membership when the RTCs have been released to the research community. COGR will continue its advocacy to encourage other agencies to join the Federal-wide RTCs.