COUNCIL ON GOVERNMENTAL RELATIONS

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CLICK HERE FOR THE JUNE 2016 MEETING REPORT SUMMARY

July 1, 2016

June 9-10, 2016 COGR Meeting Report

RESEARCH & REGULATORY REFORM

Committee: Sara Bible, Chair, Stanford University, Cindy Kiel, University of California-Davis, Kerry Peluso, Emory University, Lois Brako, University of Michigan, John Ritter, Princeton University, Suzanne Rivera, Case Western Reserve University, Ara Tahmassian, Harvard University, Daniel Shapiro, University of Southern California, Robin Cyr, University of North Carolina-Chapel Hill, Lynette Arias, University of Washington, Naomi Schrag, Columbia University, Martha Dunne, New York University

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Audit

National Science Foundation (NSF) Office of Inspector General Semiannual Report to Congress

The NSF OIG issued its Semiannual Report to Congress in May. The OIG acknowledges that cost sharing related to the Intergovernmental Personnel Act (IPA) has increased, but suggests that additional opportunities for reducing the cost of the program have not been implemented. The report includes a university audit with $1.8 million in questioned costs for senior personnel salary exceeding two-months. The OIG suggests that the FAQ document the university relied on to support the costs is “non-authoritative and contradicts the NSF requirement per the award administration guide which was in effect during the audit period.”

The OIG reports reviewing 79 single audit reports and indicates that for 19 of the 25 awardees with findings, auditors reported “material weaknesses and/or significant deficiencies in internal control over compliance” 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 the American Innovation and Competitiveness Act (S. 3084) that would require the NSF OIG to audit NSF’s policies and procedures for overseeing pass-through entities compliance and controls with respect to sub-recipient monitoring. On the Federal Demonstration Partnership’s “Labor Efforts Pilot” the report notes that the universities audited by NSF “took steps to strengthen information technology controls to protect payroll information.” Regarding project reports, the report indicates that in response to OIG recommendations, NSF has taken action to ensure reports are submitted on time. Changes to the

Fastlane system will prevent investigators with past-due reports from receiving another NSF award under a different identification number. NSF issued its response to the OIG semiannual report. The response largely focuses on audit findings related to large facility cooperative agreements.

HHS OIG Semiannual Report to Congress

The HHS OIG issued its Semiannual Report to Congress. The report is largely focused on Medicare, Medicaid and health services, but highlights a recent university settlement as a "case example related to misuse of grant funds."

HHS OIG Work Plan – Mid-Year Update

The HHS OIG released the mid-year update to its annual work plan. Among the evaluations underway or planned with respect to NIH are: assessing universities' controls over the subcontracting of NIH grant and contract work, expected to issue in FY17; colleges' and universities' compliance with selected cost principles, (FY16); and, "the extent, scope, and trends of OHRPs' responses to allegations of noncompliance from 2000 to 2014", (FY17).

Regulatory Reform

National Academy's Report on Reducing Research Regulatory Burden

The National Academies Committee on Federal Research Regulations and Reporting Requirements released Part 2 of its report, *Optimizing the Nation's Investment in Academic Research; A New Regulatory Framework for the 21st Century* on June 29. The full report is now available online. Appendix B of the report includes a table of recommendations.

The report addresses regulations relating to export controls, select agents/dual use research, intellectual property and technology transfer reporting and the Common Rule Notice of Proposed Rulemaking (NPRM). The committee suggests that 'the NPRM does not adequately or effectively address the breadth, depth, and import of unanswered questions' and that the current complexity of issues requires thorough consideration from a broad range of disciplines. The report recommends that the executive branch withdraw the Common Rule NPRM and 'that Congress authorize, and the President appoint, an independent, free-standing national commission modeled on the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research,' a successor to the commission that created the Belmont Report, the foundation for the current Common Rule.

Other recommendations include transferring the responsibility for iEdison, the invention report system, to the Department of Commerce; that the President assign the responsibility for regulating select agents and toxins to a single agency; that the Federal Select Agent Program develop an inventory management system for select agents and toxins; and that Congress and the Administration "support a robust continuation and renewal of the Export Control Reform Initiative" which should work closely with stakeholders and "vigorously support the spirit and letter of the fundamental research exclusion."

The report includes a chapter on operationalizing the proposed regulatory framework and Research Policy Board recommended in Part 1 of the report. This includes the potential participants, how the board might serve an anticipatory function with respect to concerns that arise and advances in research, and how the framework might work with respect to the issuance of new regulations. This would include review of proposed rules and guidance documents and the development of metrics to assess the impact of regulations on the conduct of research.

COGR, AAU and APLU have released a joint statement on the report. COGR will issue a full analysis in the coming weeks.

Administrative Burden Checklist

COGR has distributed a checklist to assist institutions in reducing the administrative work associated with sponsored awards. The checklist contains a list of actions that a number of institutions have initiated to reduce administrative burden. Chris Newcomer, Executive Director of the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), joined the Research and Regulatory Reform (RRR) committee at the June COGR meeting and provided helpful feedback on the section on animal research and IACUCs.

We are interested in hearing about actions your institution has implemented or may implement; actions that might be added to the list; and, how your institution incentivizes burden reduction. If your institution plans to participate, completed checklists can be returned to Lisa Nichols. There is no deadline for returning the checklists. We anticipate receiving completed checklists in late summer or early fall.

Department of Energy (DOE) Retrospective Review

DOE issued a Federal Register Notice on May 10 seeking comments on how the agency's regulations could be modified, streamlined, expanded, or repealed to better achieve regulatory objectives and 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. The bill proposes that the board be composed of federal officials from research funding agencies, administrators from research institutions, non-profit associations representing research institutions and stakeholders from the scientific and engineering research community. The board would be charged with reviewing existing and proposed federal regulations, policies and guidance with the goal of reducing regulatory burden associated with federally funded research. The bill would also create the position of an Associate Administrator for the Academic Research Enterprise within OIRA to oversee these efforts; exempt prime grant-receiving institutions from monitoring subrecipients subject to single audit; set the micropurchase threshold to $10,000 or greater; create a shared database of researcher information; require inspector general reports of audits on research institutions to publish only disallowed costs sustained by the head of the agency; require periodic

OMB reviews of Paperwork Reduction (burden) estimates; and, address administrative burden associated with federal public access policies. A hearing on the bill could occur in early fall. Disagreement over mandatory funding for NIH may be holding up the Senate's 21st Century Cures legislative package which includes the *Promoting Biomedical Research and Public Health for Patients Act*. Senator Alexander, Chairman of the Senate Health, Education, Labor and Pensions Committee, underscored his dedication to the passage of the bills in a recent discussion at the Bipartisan Policy Center and op-ed.

The *American Innovation and Competitiveness Act* approved by the Senate Commerce, Science, and Transportation Committee on June 29 includes an interagency working group on research regulation and other measures aimed at administrative and regulatory burden reduction. The working group, in consultation with stakeholder groups, would be charged with reviewing, and eliminating and streamlining as necessary, regulations imposed on federally funded researchers; creating a simplified, uniform grant format that takes into consideration preliminary proposals, greater use of just-in-time, and simplified initial budget proposals; creating a centralized researcher profile database for investigator biosketches, curriculum vitae, licenses, publications, and other relevant documents that might incorporate existing databases and be utilized for all grant proposals; creating a central repository for all of the assurances required for Federal research grants; and, developing a strategy to simplify investigator progress reports. The proposed working group would seem to have some overlapping responsibilities with that of the Research Business Models subcommittee under the NSTC.

Human Subjects and Animal Research

Precision Medicine Initiative

Carrie Wolinetz, Director of the NIH Office of Science Policy (OSP), joined RRR and Costing and Intellectual Property (CIP) committee members to discuss the Precision Medicine Initiative (PMI). Initial awards are being made, including awards to create an enrollment process and portal (Google Verily and Vanderbilt University); to establish 5-8 health provider organizations which will enroll the majority of the one million or more participants; a coordinating center; a mobile technology center; and a central biobank (Mayo Clinic). Interestingly, we learned that the OSP has established and is administering the central IRB for the PMI. A PMI Office has been established within the NIH Office of the Director. Eric Dishman, a social scientist from Intel, will lead that office. Carrie indicated that the project is moving quickly and evolving every day.

CIP members expressed concern about NIH's use of Other Transactions Authority (OTA) rather than cooperative agreements in making its initial awards. OTA's can be used to circumvent the Bayh-Dole Act. CIP members also expressed concern about NIH's stated intent in initial RFA's to use Determinations of Exceptional Circumstances, or DECS, 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 indicated NIH had not yet worked through the allocation of IP rights for PMI. NIH is using OTA's to implement the PMI quickly.

Other policy issues were discussed. 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. Regarding the Common Rule, Carrie suggested that the outcome of proposed changes to the Common Rule will not impact the Precision Medicine Initiative.

There was brief discussion on how the PMI data would be used. Researchers could design experiments and NIH could potentially run them and provide data. The details, in terms of how the PMI biospecimens and data will be used, have not yet been worked out.

NIH Single IRB Policy

The Final NIH Policy on the Use of a Single Institutional Review Board (sIRB) for Multi-Site Research was published in the Federal Register on June 21. 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* (emphasis added) involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards." The policy will take effect May 25, 2017. Ongoing, non-competing awards will not be expected to comply until the grantee submits a competing renewal application.

The document contains a long narrative of the comments provided, however, the section on implementation indicates that the agency "found no compelling reason to narrow the essential scope of the final policy." Details of note begin on page 40329, at the top of the third paragraph, in the section "Implementation of the Policy" and the actual policy begins on page 40330. Of note, the policy lacks the necessary details required for implementation which will be included in guidance. The policy indicates that guidance materials will be issued prior to the policy's effective date. Per the notice, the guidance will address:

- How costs associated with sIRBs may be charged as direct versus indirect costs;
- Considerations in the selection of the sIRB;
- The content of the sIRB plan that must be submitted with applications and proposals;
- Process for applicants/offerors to submit a request for an exception and process for NIH review of the request for exception;
- Roles and responsibilities of the sIRB and participating sites;
- Model authorization agreement that lays out the roles and responsibilities of each signatory;
- Models for gathering and evaluating information from all the reliant sites about community attitudes and the acceptability of proposed research;
- A model communication plan that identifies when and which documents are to be completed and shared with those involved so each may fulfill their responsibilities.

Guidance on the use of direct and indirect costs for single IRB review under the policy and general FAQs were also published on June 21. Additional guidance is forthcoming and will be posted to the NIH Office of Science Policy Website. A blog posted on June 21 highlights the NCATS SMART IRB Reliance Platform and an email from NCATS suggested that the platform would serve as a "roadmap" for the NIH single IRB policy.

Per the notice, applicants will be required to submit a plan identifying the sIRB that will serve as the IRB of record and to ensure that the designated sIRB is qualified to serve. The plan will not be evaluated as part of peer-review. The policy indicates that awardees are responsible for ensuring that authorization agreements are in place, ensuring that a mechanism for communication between the sIRB and participating sites exists and notes that tasks associated with these responsibilities can be delegated. The sIRB will conduct the review and may also serve as the Privacy Board. Participating sites are responsible "for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved

protocol, and reporting unanticipated problems and study progress to the sIRB" and "must communicate relevant information necessary for the sIRB to consider local context issues and state/local regulatory requirements during its deliberations." The policy does not prohibit any participating site from duplicating the sIRB provided NIH funds are not used to pay for the cost of the duplicate review.

The notice also indicates that NIH anticipates that the challenges associated with implementation will be "short-lived," that benefits will outweigh any costs and that burden to the "research process" will be reduced, but also that NIH will "closely monitor the implementation of the policy, consider its impact on research such as improvements in time to initiation of research and reduction of unnecessary burden, and be vigilant about any diminution in the protection of human subjects." COGR is assessing means of monitoring the cost and impact of implementing the policy among member institutions. Questions on the policy can be directed to SingleIRBpolicy@mail.nih.gov.

Prior to the release of the policy, Lois Brako and Judy Birk from the University of Michigan and David Wynes from Emory University discussed the possible benefits and challenges of several options for implementing the policy during a Thursday AM session of the June COGR meeting. Options included ceding to a commercial IRB; utilizing existing IRB infrastructure; creating a virtual IRB infrastructure; and possible options for direct charging the full cost of an institutional IRB review. The presentation is available on the COGR website.

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 letter indicates that the grant or protocol meets the requirements of 45 CFR 46.118 and stipulates that "one year from the date identified above, the Authorized Organizational Representative is required to either verify that the project continues to lack immediate plans for the involvement of human subjects, their data, or their specimens; or provide documentation to the cognizant NSF Program Officer to demonstrate that IRB approval has been obtained." Universities that utilize this notification letter will therefore track the expiration through their financial or IRB systems (or other mechanisms). These changes will be reflected in the next version of the *NSF Proposal and Award Policies and Procedures Guide* that is scheduled for release in October and a link provided to the letter which will be available on the NSF website.

We appreciate the work of member institutions that contributed to this effort to identify a more versatile option and that of NSF staff and hope that you find this notification letter helpful. Please contact Lisa Nichols if you have questions about the use of this letter.

NIH Workshop on Use of Non-human Primates

NIH has announced a workshop scheduled for September 7 that will convene experts in science, policy, ethics, and animal welfare to discuss the oversight framework governing the use of non-human primates in NIH-funded biomedical and behavioral research. The workshop will be broadcast live and archived for future viewing. Additional details are forthcoming.

COSTING POLICIES

Committee: Kim Moreland, Chair, University of Wisconsin, Joseph Gindhart, Washington University-St. Louis, Cindy Hope, University of Alabama, Lynn McGinley, University of Maryland-Baltimore, Jeffrey Silber, Cornell University, Cathy Snyder, Vanderbilt University, Michael Daniels, Northwestern University, Dan Evon, Michigan State University, Charles Hrncir, Texas A&M University, Michael Legrand, University of California-Davis, James Fortner, Georgia Institute of Technology, Vivian Holmes, Broad Institute

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.

As we reported in the May 2016 COGR Update, our understanding of the next steps is summarized below:

1) In June, OMB will review the data submitted by COGR. If the data supports the same conclusions made by the 5 institutions at the March 24th meeting (see May 2016 COGR Update), OMB has indicated that an extension of the grace period to FY 2019 (i.e., July 1, 2018 for most institutions) would be appropriate.

2) Furthermore, if the data supports the same conclusions made by the 5 institutions at the March 24th meeting, OMB would plan to formally reopen the Rulemaking process. As such, we would expect a Federal Register notice in the September/October 2016 timeframe.

3) Over the remainder of 2016 and into the first-half of 2017, the Rulemaking process would unfold. As warranted and as supported by the data, 2 CFR 200.317-326 will be modified. NOTE: Under this timeline and due to an extension of the grace period, our expectation would be that regardless of any modifications, new procurement standards would become effective in FY 2019 (i.e., July 1, 2018 for most institutions).

We are cautiously optimistic that these next steps will be implemented and that OMB will confirm this plan in July. While our primary focus has been on addressing the micro-purchase threshold, our position remains that 2 CFR 200.317 must be addressed in its entirety. While OMB cannot promise the exact outcome, we can state that David Mader, Karen Lee, and the entire staff at the OMB Office of Federal Financial Management and the COFAR are committed to dialoguing with our community in the spirit of good faith and under the auspices of open and transparent communication. We look forward to working closely with OMB and the COFAR to bring positive closure to the implementation of procurement standards.

Also note, as COGR and AIRI work with OMB and the COFAR to address the Procurement Standards, **concurrent legislative efforts are in motion that could create a statutory basis for a $10,000 micro-purchase threshold.** To date, some of these legislative efforts have trended toward an agency-specific micro-purchase threshold (e.g., DOD per the National Defense Authorization Act). And while COGR recognizes that agency-specific thresholds would not be a tenable solution, we believe certain legislative outcomes still could provide productive leverage for OMB to implement a government-wide $10,000 micro-purchase threshold, with the option for an institution to use a higher threshold as warranted by the institution's single audit results.

We appreciate the support and patience of the COGR Membership as we continue to pursue this issue. Also, we reiterate our thanks to the entire COGR community and membership on the response to the COGR Procurement Survey. Our community has pulled together and effectively has advanced this issue. We will update the Membership on all 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.

As we shared at the Friday morning session at the June COGR Meeting, COGR expects to continue its advocacy on the following open items: **Conflict of Interest** (agency consistency/rational policy implementation); **1.3% UCA and the REUI** weighting factor (adjust the REUI, accordingly); **DS-2** (eliminate the 6 month approval process); **Subrecipient Monitoring** (implement/confirm the "Safe Harbor" exists when the subrecipient is a peer institution and is subject to the single audit); **For-Profits/10% Deminimus** (confirm applicability to for-profits or allow budget approval by the agency to constitute rate acceptability, also address small entities that have a provisional rate or have had a rate in the past, but no longer have a negotiated rate); **Foreign Entity Subrecipients** (clarify applicability of the single audit to foreign entities); **Research Terms and Conditions** (encourage government-wide participation); **Cost Share and F&A deviations** (pursue creative solutions such as targeting selected funding announcements and organizing an email outreach to OMB, seek agency compliance via the agency IGs, etc.).

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.

The February Meeting Report (dated March 14,2016) provided an update on the ongoing and intertwined topics of HHS (including NIH) subaccounting (i.e., award-by-award accounting), the 120-day grant closeout model implemented by NIH, reconciliation between the Federal Financial Report (FFR) and the Federal Cash Transaction Report (FCTR) at closeout, and the functionality of the Payment Management System (PMS). This update still represents an accurate account of the issues of most concern to the COGR membership.

Mr. Johnson addressed some of these issues during his presentation, though the critical issues related to Closeouts still are being addressed internally by the HHS Office of Grants Policy and their "Closeout Workgroup". We expect the Closeout Workgroup to provide recommendations this Summer and our understanding is that the recommendations will be shared with COGR and we may be able to provide feedback on these recommendations to the Closeout Workgroup.

Also addressed in the session was the prospect of all HHS Operating Divisions, in addition to NIH, joining the Research Terms and Conditions. While Mr. Johnson could not commit to this as an immediate action, he expressed openness to reviewing this. Note, this point also was raised during the Thursday afternoon session with Jean Feldman from NSF and Michelle Bulls from NIH; both Ms. Feldman and Ms. Bulls supported efforts by COGR and other Federal partners to encourage all non-participating Federal agencies to join the Research Terms and Conditions.

Mr. Johnson stated he wanted to know about all concerns COGR members have with HHS closeouts and related issues. Mr. Johnson and his staff will be responsive to direct emails. 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.** The plan is to do the testing phase with approximately 20 institutions in July and to go live with all COGR member institutions in August. The goal is to reach a significant level of completion before the October COGR Meeting and to provide preliminary results at that meeting. Be on the look-out for further updates this Summer.

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.

NACUBO took the lead on advocacy with the Department of Education and OMB. In an email to the COGR membership on June 14th, COGR reported that NACUBO's advocacy efforts were successful and that Education will not pursue mandating audits of SFA for FY 2016 single audits. However, Education and OMB will be working on detailed guidance for the 2017 Compliance Supplement and it is likely Education will call for mandated audits of SFA in FY 2017. It is possible they also will ask for mandatory retroactive audits of SFA in FY 2016.

We are grateful for NACUBO's work on this issue, though we will need to monitor this situation and engage where appropriate. We recommend working with your Single Audit team to determine further details and issues specific to your institution.

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

COGR continues to stay engaged with developments related to ACA compliance and the treatment of graduate students and subsidized student health insurance plans (SHIPs). 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.

Last year, the IRS raised questions as to whether institutions providing subsidized student health insurance to their graduate students are in violation of the ACA. On February 5, 2016, the IRS and several other agencies issued an IRS Notice which provides temporary transition relief for institutions that provide such subsidies.

However, 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 emphasis of the analysis is to devise a more equitable mechanism for NIH to evaluate proposed costs between on-campus and off-campus research centers. Specifically, at issue is the treatment of "space and facility-related costs" when a Research Funding Announcement (RFA) or policy regarding Investigator initiated proposals limits maximum costs in terms of maximum Direct Cost.

In the case of an off-campus research center, space/lease costs and other facility-related costs are considered a direct cost, which means that the off-campus research center will disproportionately have to propose these types of costs in comparison to an on-campus research center. In effect, the off-campus research center is at a competitive disadvantage because fewer costs can be proposed for research staff and other direct research-related costs. The inequity is compounded when a proposed collaborator is associated with an off-campus research center; in this situation, the potential subrecipient also would include space and facility-related costs in the proposed budget.

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

Committee: Alexandra McKeown, Chair, The Johns Hopkins University, Cindy Kiel, University of California-Davis, Elizabeth Peloso, University of Pennsylvania, Patrick Schlesinger, University of California-Berkeley, Kevin Wozniak, Georgia Tech Research Corporation, David Winwood, Louisiana State University, Cathy Innes, North Carolina State University, Fred Reinhart, University of Massachusetts-Amherst, John Ritter, Princeton University, Wendy Streitz, University of California, Wendy Montgomery, University of Maryland, Melanie Roewe, Washington University – St. Louis

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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).

An addendum to the COGR May 2016 Update indicated that at the Association of University Export Control Officers (AUECO) conference earlier in May, State/DDTC indicated that the revised final ITAR definitions would be issued in two stages. The first would be what was characterized as "easy lift" items. Those definitions were to be issued shortly. The "heavy lift" definitions will not be issued until sometime after the first of the year. The revised fundamental research definition is considered a "heavy lift." There would be another opportunity to comment on both sets of rules.

The June 3 ITAR interim rule is consistent with this understanding. The ITAR interim rule does not address any of the items that were the focus of our concerns with the proposed ITAR rule issued last year (Prepublication Review, Fundamental Research, Defense Services, Public Domain). These are "heavy lift" items for which the revised definitions have been postponed. It adds a potentially helpful definition of "release" for deemed export purposes similar to the EAR. The rule clarifies that for a "release" to occur, technical data must be revealed to a foreign person (120.50). Access to inspect a controlled defense article that does not reveal technical data is not a "release" for these purposes.

As discussed in a message to the COGR listserv on June 3, the final EAR rule responds positively to our two biggest concerns with the revised EAR definitions that were proposed last June. Software is treated the same as other technology resulting from fundamental research (734.8(a)). The original wording of the educational exemption from the EAR also is retained (734.3(b)). The final EAR rule also contains a helpful addition to information considered as Published. It now includes submissions to journal editors or reviewers and to open conference organizers (734.7(a)(5)). The rule also contains clarifications to the section on the status of technology or software subject to USG access or dissemination controls, as we had suggested.

Unfortunately the EAR rule does not retain the presumption that university research is fundamental research. Commerce/BIS states that the presumption continues to exist, but will be stated in an FAQ on its website rather than stated in the rule. (Note: the presumption is included in the "Deemed Export FAQs," but is not strongly stated). The EAR rule also contains a revised definition of fundamental research somewhat shortened from the previous (NSDD-189) definition (734.8(c)). We did not object to the revised definition when it was proposed last year.

There are extensive changes in the sections dealing with export of encryption source code and software (734.17) and cloud computing (734.18). While we and others had questioned the requirements to follow NIST standards (FIPS 140-2), the final rule adopts them. Sending controlled technology or software using secured end-to-end encryption or FIPS 140-2 standards is not considered an export (734.18(a) (5)). However, while we suggested that vendor notification be sufficient for cloud storage compliance requirements, the final rule did not adopt this suggestion. It states that encrypted data may not be intentionally stored in Country Group D: 5 countries and Russia without authorization. These may be issues for institutions to consider when contracting with cloud service providers.

The EAR rule is a final rule, although public comments are welcome on a continuing basis. The ITAR rule has a 30-day comment period. We have not identified any concerns with the rule and do not plan to submit comments. However, the ITAR rule contains an interesting justification for the different treatment of deemed exports (120.19(b)) from the EAR. The ITAR continues to treat deemed exports to a foreign person as an export to all countries in which the foreign person

has held citizenship or permanent residency (rather than the most recent country of citizenship or permanent residency as in the EAR). It is justified as an example of "higher walls around fewer items" which was the purpose of export control reform, now that most items have been moved to the Commerce list. We note that a similar justification could be used for treatment of any item differently from the EAR, such as the definition of "fundamental research." We hope this approach is not adopted for the "heavy lift" items that will be the subject of the future ITAR revised definitions.

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. While existing general licenses authorize certain narrow educational activities and transactions directly related to publishing, OFAC views the attendance of a U.S. institution faculty member at a conference in Iran (even if not presenting) as an activity requiring a specific license granted on a case-by-case basis. Such licenses typically take several months to obtain. That delay can inject an element of significant uncertainty into plans to attend academic events in Iran.

After hearing concerns from the university community about this interpretation of the ITSR, at the recent AUECO conference a senior OFAC official indicated a willingness 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 that have received these requirements are expressing concerns about the potential compliance costs. At the recent AUECO conference there were indications that come institutions may be walking away from DOD contracts or subcontracts containing the new clauses because of the cost implications.

The NARA representative at the February meeting panel indicated that the DFARS clauses were interim pending development of a comprehensive government-wide FAR clause that would address controlled unclassified information (CUI). Our Meeting Report also noted that the government representatives had expressed some recognition of the potentially adverse implications for fundamental research. The COGR comments had expressed concerns about this. What we are hearing from institutions reinforces those concerns.

Universities have employed a number of "work arounds' to deal with the CUI requirements. Institutions that heavily engage in defense contracting will need to consider the resource implications. We understand that institutions that are involved in global contracting have received even more stringent requirements for protecting information from European sponsors. The new EU requirements for protection of personal data may reinforce the stringency of these requirements.

The NARA representative had 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. We are looking into ways to address the potential FACA issues. We also will 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). They implement Section 815 of the FY'12 National Defense Authorization Act (NDAA).

The biggest changes involve policies and procedures for deferred ordering of technical data and handling technical data necessary for segregating or reintegrating items and processes with other items and processes. There also are a number of technical changes to the SBIR provisions, although the basic approach to SBIR (and other) data rights has not changed. While Section 815 covers only technical data (which does not include computer software), DOD is treating computer software analogously.

NDAA Section 815 added a new exception to the restriction on sharing outside of DOD technical data relating to items or processes developed exclusively at private expense, to which the government gets only limited rights. It applies to a new purpose or activity when use of the technical data or software is necessary for segregation or reintegration purposes. The proposed DFARS changes distinguish segregation or reintegration data from form, fit and function data to which the government gets unlimited rights. The basic concept is that segregation and reintegration data is more detailed than form, fit and function data. Contractors are more reluctant to share such detailed technical information regarding proprietary technologies if subject to unlimited government rights. A new definition of form, fit and function data is included which clarifies the distinction.

Section 815 codified the government's right to order technical data post-contract, and somewhat expanded the previous DFARs coverage. The new DFARS clause on Deferred Ordering (252.227-7029) now is to be included in all solicitations and contracts, with a few exceptions. The data must have been generated or utilized in the performance of the contract, needed to sustain a DOD system, and result from government-funded development activities or be segregation or reintegration data. Importantly, however these criteria do not apply to technical data or computer software resulting from basic or applied research (22.-7029(b)(2)). The government thus apparently will have a deferred ordering right in all basic or applied research contracts. However the right does not create an implied obligation to preserve the data when it would be unreasonable (although contracts can include such a requirement for a specific period). The government's deferred rights follow the applicable rights-allocation clauses in the contract. The clause is a mandatory flow down.

Other changes involve the government's rights to challenge asserted restrictions in data and various technical corrections or clarifications, particularly with regard to SBIR. DOD is proposing to apply the new deferred ordering requirements to contracts below the Simplified Acquisition Threshold, but is seeking public comments on this.

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

We previously have discussed concerns about reporting of inventions resulting from federally-funded awards. These concerns run the gamut from deficiencies in iEdison reporting to NIH to NASA's requirements for New Technology Reporting (see COGR October 2014 Meeting Report and October 2015 Meeting Report).

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. Examples of actions that need to be taken and Compliance Notification Messages that an iEdison user may encounter include no written description of an invention (disclosure) has been uploaded into iEdison; the Government Support Clause is missing (or not accepted) for a non-provisional patent filing; and the submitted Confirmatory License is missing (or not accepted) for a patent filing.

Earlier this year NIH issued another reminder that all subject inventions that were made under an applicable funding agreement and reported on the HHS 568 must be reported in iEdison. Failure to report (on the HHS 568 AND in iEdison) all inventions funded in whole or in part by NIH as required by a funding agreement's terms and conditions, the NIH Grants Policy Statement, and the Bayh-Dole Act may result in an organization's loss of rights in the invention or other actions as appropriate (NOT-OD-16-066; 2/ 17/16). We understand that a number of institutions recently may have received letters from the HHS IG regarding a possible audit of the Bayh-Dole compliance requirements.

We noted in the October 2014 Meeting Report that NIH had concerns about the apparent lack of knowledge of basic Bayh-Dole obligations based on questions they have received from funding recipients as well as concerns about the accuracy and completeness of invention reporting in iEdison. Those concerns continue. In a subsequent webinar, NIH representatives noted that there has been a large increase in government-funded inventions in the 35 years since Bayh-Dole, which has greatly increased the number of *i*Edison submissions. However, 40% more government-funded inventions are reported in the USPTO database than in the NIH RePorter data. More recently, NIH has expressed concerns about the large discrepancies between research expenditures and the number of inventions reported. At the same time institutions have expressed

concerns to COGR about the excessive detail required by NIH often leading to prolonged and unproductive exchanges between NIH and institution staff.

NASA has been asserting that institutions have failed to file invention disclosures for particular grants, based on NASA reviews of final technical reports. NASA has a broad definition of reportable new technology that requires reporting. It includes but extends beyond patentable subject matter requiring reporting under the Bayh-Dole Act. NASA's New Technology Reports are submitted to a separate NASA system accessible only by NASA tech transfer staff, and are not included in iEdison.

AUTM is planning a new Compliance Course in partnership with NIH to be held this October. They also hope to have NASA and NSF representation. The course may be webcast. While improved understanding of the reporting requirements obviously is very important, discussions within the COGR CIP Committee indicate wide variations in institutional practices. These variations include not only differences in processes and staffing for the reporting function but also lack of uniformity as to what constitutes a reportable "invention."

Given what appears to be the wide variety of approaches to and priority given invention reporting among institutions, we plan to survey a small number of institutions as to their practices. Diversity of institutions included in the survey is important, particularly assuring representation of smaller research institutions. This could lead to better understanding and perhaps to development of best practices at some point. We 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

On June 20 NIH formally declined either to exercise march-in or to use the government license. NIH had noted in its previous decisions declining march-in that the failure to achieve practical application necessary for march-in was triggered by its availability to the public. Xtandi is broadly available as a prescription drug. There is no information suggesting that it is in short supply. Earlier this month HHS also declined KEI's request to hold a public hearing. (DOD has taken no formal action to date with regard to the march-in request that KEI also filed with DOD).

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.

Section 1498 dates from the 1800s. It was originally created to waive the government's sovereign immunity from patent infringement suits. It gives patent owners a way to seek compensation from the government while at the same time assuring government contractors that they can meet contracts without fear of being sued for work they do on behalf of the government. Later, the statute was viewed as important for ensuring that the war effort in World Wars I and II would not be impeded by claims of patent infringement between competing government contractors. Its use always has been predominantly military. It never has been used to regulate product prices, especially in the biomedical sector (although its use was threatened by HHS 15 years ago at the time of the anthrax scare, as discussed in the May Update).

It is not clear the government actually would save money by use of the provision to address drug prices, since patent owners are entitled to "reasonable and entire compensation" under the statute. This could include lost profits, royalties, and other compensation. There also are a myriad of food and drug laws which could make it difficult for the government to find generic drug substitutes. There are other potential complications such as the effect on other drugs needed for individual patients' therapies and questions such as for which particular patient populations the government would provide the drugs. It also is not clear what government agencies might actually have authority to produce and distribute drugs.

The proposal has been criticized for discouraging biomedical innovation. We may see more criticisms of this nature.

On a related matter, the Update also discussed the upcoming Report of the UN Secretary General's High Level Panel on Access to Medicines. A recent draft version of the recommendations included items such as compulsory licensing for all drugs on the World Health Organization list of essential medicines, non-exclusive licensing for all publicly-funded inventions, exemptions from patentability for essential medicines, and a gradual takeover by governments of drug development.

These recommendations also have been subject to increasing criticism.
In response, on June 15 the Panel issued a statement stating "Any commentaries based on improperly obtained, incomplete drafts do not represent the findings of the Panel. The Panel is still actively working on the report and is unable to comment at this point in time."

Nevertheless, from discussions with appropriate USG officials it appears the main thrust of the report will remain the role of patents and IP in preventing access to medicines. Given that the U.S. is the top developer of drugs, many of which originate in university laboratories, we need to be active in defending the critical role that patents perform in drug and medical innovation. We are continuing to consult with government officials and provide materials and information that might be helpful.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Michael Ludwig, Chair, University of Chicago; Jeffrey Friedland, Princeton University, Pamela Caudill, Harvard University, Walter Goldschmidts, Cold Spring Harbor Laboratory, David Norton, University of Florida, James Tracy, University of Kansas, Pamela Webb, University of Minnesota, Jennifer Lassner, University of Iowa, Steven Martin, Indiana University – Bloomington, Lisa Mosely, Arizona State University, Allen DiPalma, University of Pittsburgh

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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. A general overview of the Guide was given at the Thursday a.m. meeting session. Hard copies of the Guide are now available. COGR will be sending out seven spiral bound copies of the Guide to the Primary Representatives of each member institution. The on-line Guide will be updated as necessary as regulations impact its contents. The Guide has been condensed from Twelve (12) Principles to Eight (8). Many of the Principles incorporate changes as a result of the culmination of OMB circulars (A-133, A-110, A-21, etc.,) to 2 CFR 200, The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. A new glossary was added along with live hyperlinks for ease in navigation.

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. During this meeting Dr. Partin asked for written suggestions and recommendations by early May on changes the grantee community would like to see implemented, examples of challenging issues with ORI, and what ORI data we would like to see published. COGR responded to her request on May 9th with nine recommendations. Among them included the recommendation to include self-plagiarism in the definition of plagiarism. After further discussion with the COGR Community, COGR decided to change its position on the issue of 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 regarding significant impacts to postdocs and other research positions, financial resources to fund the increase, and increased administrative burden. The RCA Committee 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. In addition COGR plans to seek your feedback on DOL FLSA Survey focused on post docs in the coming month. Stay tuned for more information.

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. A brief summary of the proposed changes include but aren't limited to: 1) new language to Human and Vertebrate Animal sections, 2) an Organizational Environmental Impacts Checklist and associated instructions that proposers may be requested to submit as part of the environmental requirements, 3) special processing instructions and types of proposals, (e.g., RAPID, EAGER), 4) the addition of two new proposal types Research Advanced by Interdisciplinary Research and Engineering (RAISE) and Grant Opportunities for Academic Liasson with Industry (GOALI), 5) and renames International Travel proposals to Travel proposals to clarify that both domestic and international can be used.

Although the RTCs remain to be released, we were encouraged with the efforts to date and that the FAQ's will be incorporated as part of the RTCs. We 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.