March 2015 COGR Meeting Report

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COUNCIL ON GOVERNMENTAL RELATIONS

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March 5 and 6, 2015 Meeting Report

[National Science Foundation – Public Access]

GENERAL DEVELOPMENTS

Regulatory Reform

Administrative Conference of the United States Study

At the March COGR meeting, the Chairman of the Administrative Conference of the United States (ACUS), Paul Verkuil, provided an overview of ACUS; recent recommendations aimed at improving government processes; and ACUS work that is relevant to higher education regulation reform including retrospective review, interagency coordination, and negotiated rulemaking. AAU and COGR staff met with the Chairman and ACUS staff in December to discuss a possible ACUS study aimed at achieving greater regulatory efficiency in higher education and research. ACUS is integrating higher education regulation reform into its on-going projects on interagency coordination and retrospective review and plans to work with agency officials and nongovernmental organizations to organize a roundtable discussion in April to bring together key players, identify key issues, and discuss possible solutions. COGR and AAU will meet with ACUS staff on March 25 to discuss the study and roundtable discussions.

Meeting to Discuss Common Rule with the Office of Information and Regulatory Affairs

COGR staff and representatives from member institutions will meet with staff from the OMB Office of Information and Regulatory Affairs (OIRA), the Office of Science and Technology Policy, and the HHS Office for Human Research Protections on March 27 to highlight COGR concerns about the Common Rule ANPRM and the pending NPRM currently under review with OMB/OIRA. OMB/OIRA received the proposed revisions on February 24. OIRA has 90 days to review the proposed rule and provide feedback prior to its release for public comment and may recommend changes to a proposed rule during both informal and formal review periods.

COGR will highlight concerns specific to proposed mandatory standards for data security and information protection based on standards of identifiability under the HIPAA privacy rule; retaining exempt categories; the proposal to consider all biospecimens to be inherently identifiable; use of one IRB of record for multi-site studies; and, the proposal to extend Common Rule protections to all research studies (including those not funded by the Federal Government) conducted at domestic institutions that receive some federal funding from a Common Rule agency for research with human subjects.

GAO Review of Research Regulations and Reporting Requirements

In October 2012, Representative Mo Brooks, former Chairman of the House Science, Space and Technology Committee's Subcommittee on Research Education, sent a letter to the GAO comptroller requesting GAO review the current regulations and reporting requirements imposed on research universities; in particular those related to effort reporting, sub-recipient monitoring and the paper record maintenance required for contractors under FAR. There are indications that GAO may have recently initiated a study. COGR and AAU will meet with GAO staff on March 25.

Research and Development Efficiency Act

H.R. 5056, the R&D Efficiency Act was passed by the house on July 10, 2014 in a previous session of congress but was not passed by the senate. A new version of the Act, H.R. 1119, including an amendment introduced by Representative Daniel Lipinski, was approved by the House Science, Space, and Technology Committee on March 4, 2015. The bill would direct OSTP to establish a working group to review federal regulations affecting research and research universities and to make recommendations on how to harmonize, streamline and eliminate duplicate requirements and minimize regulatory burden on IHEs performing federally funded research.

Survey to Assess Research Regulatory Burden

AAU, COGR, and APLU, together with Yale University, have engaged in a joint effort to assess research regulatory burden among member institutions and to recommend specific changes to reduce compliance effort and expense. Surveys were distributed to COGR member institutions on February 23. Responses are requested by March 23.

Digital Accountability and Transparency Act (DATA Act)

We received the following information about a DATA Act Section 5 Pilot Webinar: The Chief Acquisition Officers Council, General Services Administration, and the Department of Health and Human Services are sponsoring a dialogue and pilot to identify clear recommendations for (1) standardizing grant and contractor awardee reporting, (2) eliminating duplicative and/or unnecessary reporting, and (3) reducing awardee compliance costs.

The open dialogue, which will launch in spring of 2015, is iterative and will first ask interested parties to weigh in on these ideas, then we will apply those ideas in a pilot, and finally we will ask participants to again weigh in on the next iteration of ideas. Participation in the dialogue will provide federal contract and grant recipient organizations a unique opportunity to guide the future of the government-wide implementation of the DATA Act.

Attendees will learn the background and goals of the DATA Act Section 5 Pilot, expected outcomes, and participant opportunities and requirements. The event also will address commonly asked questions about the pilot.

The event will be held on April 1, 2015 from 1:00PM to 2:00PM ET. Interested parties can register online.

COGR is paying attention to activity around the DATA Act and the upcoming pilots. We are participating in a coalition of associations that is providing input to OMB, Treasury and HHS. We encourage your institutions to follow developments and to keep us posted on questions and concerns you may have.

COSTING POLICIES

Committee: James Luther, Chair, Duke University; Sara Bible, Stanford University; Kelvin Droegemeier, University of Oklahoma; Joseph Gindhart, Washington University in St. Louis; Cynthia Hope, University of Alabama; Lynn McGinley, University of Maryland, Baltimore; Kim Moreland, University of Wisconsin – Madison; Mary Lee Brown, University of Pennsylvania, ACUA Liaison; Michael Daniels, Northwestern University; Dan Evon, Michigan State University; Michael LeGrand, University of California, Davis; Cathy Snyder, Vanderbilt University

March COGR Meeting Sessions on Uniform Guidance Implementation

The March COGR Meeting included two sessions on the Uniform Guidance Implementation. The PPT presentations for both are available at www.cogr.edu (see Meetings | March 2015 Meeting Presentations).

The Thursday morning session was a Costing Policies breakout session with a panel that included: Lynn McGinley - University of Maryland, Baltimore, Mike Legrand - University of California, Davis, Naomi Schrag - Columbia University, and Joe Gindhart - Washington University in St. Louis. The panel discussion focused on Uniform Guidance implementation issues specific to costing-related aspects of the Uniform Guidance. Compensation & Documentation (formerly effort reporting) and F&A related issues were the primary focus.

The Thursday afternoon session was a general session with a Federal panel that included: Jean Feldman - Head, Policy Office, NSF, Cynthia Montgomery - Deputy Director, Office of Grants and Financial Management, National Institute of Food and Agriculture, USDA, Michelle Bulls - Director, Office of Policy for Extramural Research Administration, NIH, and Victoria Collin - Office of Federal Financial Management, OMB. The Thursday winter storm in the Washington DC-metro area prevented our guests from traveling to the COGR Meeting. However, we were able to establish a speaker phone / call-in alternative and all four participated.

Both sessions informed "Next Steps" that COGR will undertake in terms of issue engagement applicable to the Uniform Guidance implementation. While COGR knows at one level the Uniform Guidance is final and that the chance for significant update is minimal, at another level COGR recognizes agency implementation is fluid and the opportunity for engagement is natural to COGR's broad goal of reducing regulatory burden. And because OMB is an inseparable partner in the Uniform Guidance implementation, we believe it is appropriate to regularly reach out to OMB and expect dialogue, assessment, and consideration of opportunities to clarify and improve the Uniform Guidance. Several of our "Next Steps" are described in the sections below.

Meeting with OMB to Review February 13th COGR Response Letter

Despite the fact that the Uniform Guidance is final and that the chance for significant update is minimal, COGR maintains there are open issues that still must be addressed. ***We are scheduled to meet with OMB to review these issues.***

The interim joint final rule implementing the Uniform Guidance was published in the Federal Register (Vol. 79, No. 244, Friday, December 19, 2014 - *Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*) in December. Title 2, Part 200 of the Code of Federal Regulations (2 CFR, Part 200) was updated to show the complete Uniform Guidance, with the technical corrections/amendments incorporated. COGR submitted its comments to the December 19, 2014 Federal Register Notice on February 13th. The COGR letter is available at www.cogr.edu on the homepage (see Latest News, February 13, 2015). In the letter, we addressed the following 8 topics:

1) Conflict of Interest, § 200.112 – Confirm that this section is only about conflicts in procurement actions.
2) Requirements for pass-through entities, § 200.331 – Allow for an Audit/Management Decision "Safe Harbor" when the subrecipient is a peer-institution with a current Single Audit report, and not currently debarred or suspended.
3) Procurement Standards, § 200.317 - § 200.326 – Make policy calibrations to codify "research/scientific reasons" as a basis for a sole source procurement and update the micro-purchase threshold from $3,000 to $10,000. Also consider exempting research institutions from all of the procurement standards.
4) Closeout, § 200.343 – Establish a uniform 120-day closeout model for all agencies, which applies to financial closeout, performance, and other reports.
5) DS-2 Requirement, § 200.419 – Update this section to further clarify and facilitate the DS-2 approval process. Also consider eliminating the DS-2 requirement, which is unfairly applicable to higher education only.
6) Compensation - fringe benefits, § 200.431 – Make a technical correction to confirm that tuition reimbursement for employees is allowable for undergraduate and graduate education, and further, it is allowable when the tuition reimbursement is applicable to other institutions as institutional policy permits.
7) Utility Cost Adjustment (UCA), Appendix III to Part 200 – Issue a policy clarification that makes implementation of the UCA more fair and equitable.
8) OMB Leadership and Advancing the Partnership – Provide strong OMB leadership, going forward, so that OMB engages in an assertive agenda that regularly assesses, clarifies, calibrates, and reforms Federal grants policy.

In our meeting with OMB, we expect to address these topics. COGR believes each issue should be advanced through either an OMB clarification or a commitment by OMB to further engage. We will provide an update to the Membership after our meeting with OMB.

Federal Agency Perspectives on the Uniform Guidance Implementation

The Thursday afternoon Federal panel covered both the Federal Agency and the OMB perspective on the Uniform Guidance implementation. Victoria Collin from OMB addressed the OMB-specific items; some of these are addressed in the previous section. Jean Feldman from NSF, Cynthia Montgomery from NIFA, and Michelle Bulls from NIH provided the Federal Agency perspective. Several of the significant items discussed included:

1) Administrative and Clerical salaries – Direct charging is allowable as specified in 2 CFR 200.413. However, prior approval requirements may vary on an agency-by-agency basis.
2) 120-day Financial Closeout – This will be included in the Research Terms and Conditions. Making the 120 days retroactive to all awards is being reviewed on an agency-by-agency basis.
3) New funding increments and Carryover funds associated with the new funding increments – Most agencies are covering these under the Uniform Guidance, though there may be agency variation (e.g., DOD).
4) Conflict of Interest (2 CFR 200.112) – COGR is monitoring and responding, as appropriate. To-date, EPA and NEA have published new policies and NIFA is developing their policy.
5) Agency Guidance and FAQs – These continue to be developed on an agency-by-agency basis. NIH has published Interim Grant General Conditions, corresponding FAQs, and soon will release their updated Grants Policy Statement. NSF and NIFA plan to release FAQs soon.
6) Research Terms and Conditions – These are coming, but are at least a few months away. NSF, NIH, and NIFA are participating.

Jean, Cynthia, and Michelle each acknowledged the intra-agency challenge to ensure all grants and program managers are fully up-to-date on agency policy and the many nuances associated with the agency implementation of the Uniform Guidance. When there are inconsistencies within an agency, all three want to be made aware and will address the issue, accordingly.

COGR also is prepared to engage when there are intra-agency inconsistencies, but at the same time, is confident the policy leaders at each agency will aggressively address these issues when they occur. COGR is more focused on inconsistencies across different agencies. We are developing several strategies to elevate the topic of "uniformity" across agencies in those situations when "uniformity" would be rational and reduce burden.

We encourage the Membership to share with COGR any situation that represents an intra-agency inconsistency, an agency deviation from the Uniform Guidance, or any observation that may affect administrative burden. Contact David Kennedy at dkennedy@cogr.edu. COGR is compiling these cases and will share data and anecdotes, as appropriate, with Federal policymakers and other committees and entities engaged in studying the impact of Federal regulation.

Compensation and Documentation, Uniform Guidance Compliance and the Matrix

A portion of the Costing Policies breakout session on Thursday morning was focused on the Compensation and Documentation requirements of the Uniform Guidance (2 CFR 200.430). Naomi Schrag from Columbia University and Joe Gindhart from Washington University in St. Louis led the discussion.

Much of the discussion centered on the importance of reviewing your institution's current written policies and procedures and how they line-up with 2 CFR 200.430. For example, Appointment Letters, Institutional Base Salary, Incidental Pay, Extra Service Pay, Reasonableness, Level of Precision, Budget Estimates, Significant Changes, and After-the-fact Confirmation, among others, each should be considered within the context of your institution's current written policies and procedures. However, the message presented was not about making knee-jerk, major changes to written policies and procedures, but rather to take the opportunity to review your current written policies and procedures and assess their alignment with 2 CFR 200.430.

Most important at this stage may be an internal assessment of your current written policies and procedures, which includes both a review to ensure policy requirements in 2 CFR 200.430 are met and a review of the internal controls that are in place to provide assurance that your written policies and procedures are working as they are described.

Another important consideration may be for your institution to assess whether selected policies and procedures need to be updated, and if so, what will be the "effective date" for implementing new policies and procedures. Whereas it is clear that the effective date of the Uniform Guidance was December 26, 2014, OMB, the COFAR, and the Agencies have regularly defined caveats. For example, at the award level, most agencies have specified the UG is applicable to new awards and new funding increments only, so a cohort of awards remains covered by Circulars A-110/A-21. At the same time, at least one agency (i.e., DOD) has taken the stand that even the new funding increments will remain covered by A-110/A-21.

This creates the dilemma: Inevitably, an institution will have some awards covered by the UG and others by A-110/A-21. In the case of 2 CFR 200.430, ***COGR is formulating a position that an "institution-defined effective date", applicable to those selected policies and procedures that need to be updated, is the most practical and compliant manner to transition from A-21, J.10 to 2 CFR 200.430.*** Under this model, it may be appropriate to coordinate the "institution-defined effective date" with the new fiscal year or with some other benchmark date at your institution.

OMB and the COFAR have acknowledged the challenge that UG implementation will have in selected situations, such as in the case of implementing 2 CFR 200.430. COGR has raised the "institution-defined effective date" model to OMB as an effective approach for transitioning to full compliance with 2 CFR 200.430. This also would be helpful to the Single Audit community and would establish a reasonable audit standard that does not unfairly place institutions in a position of non-compliance. We are asking OMB to approve this approach through either an FAQ or an OMB Clarification memo. Also, we are reaching out to the Single Audit community to get feedback on this approach.

COGR's commitment is to be an active voice in shaping guidance and effective practices as your institutions implement 2 CFR 200.430. To assist you with possible changes in your written policies and procedures, ***COGR is developing a Matrix that will include excerpts from A-21, J.10; 2 CFR 200.430; and COGR observations, examples, and preliminary interpretations***. We expect the Matrix to be a living document that we will update, periodically, throughout 2015, and as needed, into 2016. We are targeting Version 1 to be available later this Spring. We will keep the Membership updated on all activities related to Compensation and Documentation.

F&A and the Uniform Guidance

The other portion of the Costing Policies breakout session on Thursday morning was focused on the F&A requirements of the Uniform Guidance. Lynn McGinley from the University of Maryland, Baltimore, and Mike Legrand from the University of California, led the discussion. The discussion focused on those F&A topics located in various sections of the Uniform Guidance. Several of the significant items addressed included:

1) Direct charging of administrative and clerical salaries (2 CFR 200.413) and the potential impact on the Department Administration (DA) component of the F&A rate.
2) Implementation of the 1.3% Utility Cost Allowance (2 CFR Appendix III, B.4.c to Part 200) and an update on COGR's position in the February 13th response letter to OMB.
3) Treatment of salaries over the NIH salary cap and the interpretation that they should be excluded from the research base (2 CFR Appendix III, A.1.a.(3) to Part 200).
4) Clarifying the DS-2 approval process (2 CFR 200.419) and an update on COGR's position in the February 13th response letter to OMB.
5) Advocating to OMB that tuition reimbursement for employees (2 CFR 200.431) should remain allowable for undergraduate and graduate education, as well as when the tuition reimbursement is applicable to other institutions.

As we suggested in the previous section on Compensation and Documentation, COGR's commitment is to be an active voice in shaping guidance and effective practices as your institutions implement new rules applicable to developing your F&A rate proposals and the corresponding DS-2. We are engaging in each of the issues described above and will update the Membership as we learn more. Also, we encourage you to keep COGR updated on issues raised in your F&A rate negotiations. While we may not intervene is a specific negotiation, if the issue in question may affect the broader COGR membership, it may be appropriate for COGR to elevate the issue.

Grant Closeouts and Related Issues – IMPORTANT UPDATES

This topic has been on the forefront for two years and we have included regular summaries in our COGR Updates. A number of important updates have taken place since the COGR Update on February 20th and these are described below.

120-day Grant Closeout Model

In the NIH Interim Grant General Conditions, Section 10 states: *Recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 120 calendar days of the end of grant support. The reports become overdue the day after the 120 day period ends.* We are thankful for the new NIH closeout model.

At the same time, Federal agency leaders are addressing a 120-day closeout model within the context of updating Research Terms and Conditions (RTCs), though the 120-days will be specific to financial closeout only. Also, DOD currently is finalizing DOD-specific Terms and Conditions for the Uniform Guidance, and our understanding is that they are establishing a 120-day closeout model, again, specific to financial closeout only.

The above are positive developments, though the following still needs addressed:

1) How do we encourage all Federal sponsors to adopt a uniform 120-day financial closeout model? In the case of HHS, only NIH has adopted the 120-day model.
2) Will the 120-day financial closeout model be applied retroactively to all awards and not just those issued under the UG? In the case of NIH, it will be retroactive.
3) How can we be assured that the corresponding payment systems (e.g., PMS for NIH, ACM$ for NSF, etc.) are programmed to accept the 120-day financial closeout model?
4) Will we be able to request an extension beyond 120 days? Even though compliance and timely closeouts will increase dramatically, extensions still may be necessary.
5) If extensions are allowed for cash draws beyond 120 days, will there be a threshold that requires special documentation? For example, the NSF threshold is $10,000 and above.
6) If we have submitted the FFR and complied with the 120 days, but then determine a revised FFR is necessary, will we be able to request additional funds?
7) Will Federal agencies, besides NIH, consider incorporating programmatic reports into an "across-the-board" 120-day closeout model?

We will keep the Membership posted on the progress of implementing a 120-day closeout model and the other issues that may need to be addressed.

NIH Subaccounting and Final Transition on October 1, 2015

While we were successful in securing a delay of the full transition to NIH subaccounting until October 1, 2015, this date will quickly approach. The final version of the NIH subaccounting policy can be found in NIH Notice Number: NOT-OD-14-103 (July 11, 2014); *Revised Timeline for Administrative Changes to NIH Domestic Awards to Transition to Payment Management System Subaccounts*. NIH non-competing continuation awards that have not yet been transitioned to PMS subaccounts need not be transitioned until the fiscal year beginning October 1, 2015. The Notice is clear that there will be no additional implementation delays and no exceptions will be granted after October 1, 2015. While the transition has been delayed, grantees are encouraged to continue to revamp systems and business processes during this time to make for a smooth transition.

We will follow up on any issues and/or institutional concerns related to the transition to NIH subaccounts at the June Meeting, or as necessary, prior to the June Meeting.

Payment Management System (PMS) and "Budget Period"

In response to the April 2012 GAO report on *Action Needed to Improve the Timeliness of Grant Closeouts by Federal Agencies*, the Division of Payment Management (DPM) initiated a change to the PMS that would have tied access to PMS to the end of the budget period rather than the end of the project period. In effect, cash requests from PMS could have been denied if funds were not expended by the end of the budget period. COGR wrote to the Director of the Program Support Center at HHS (the entity responsible for PMS oversight) last September and expressed concern. NIH raised similar concerns. COGR's understanding is that this issue has been resolved and that cash requests from PMS will remain tied to the end of the project period. However, we encourage the COGR Membership to remain on the alert for unusual experiences you encounter when using the PMS to request cash payments from NIH or any HHS Operating Division.

NSF Higher Education R&D (HERD) Survey for FY2013 is Available

The InfoBrief for the FY2013 HERD Survey includes a summary of the results for the annual NSF survey. Some interesting notes from the InfoBrief include (emphasis added by underline):

- *Including ARRA funding, the total federal funding for higher education R&D declined from $40.2 billion in FY 2012 to $39.5 billion in FY 2013, continuing a decline in the proportion of academic R&D funded by the federal government …*
- *Since FY 2011, federally funded expenditures have dropped from 62.5% to 58.9% of total R&D expenditures, …*
- *Institution-funded R&D continued its rapid growth and rose 9.8% to nearly $15 billion in FY 2013 (table 2). Institution funds now constitute 22.3% of total R&D, rising from 19.5% in FY 2010 …*
- *There are three components to institution funds: direct funding of R&D ($8.9 billion), cost sharing on externally sponsored projects ($1.4 billion), and indirect costs on external projects that are not reimbursed by the sponsors ($4.7 billion).*

The results of the FY2013 HERD Survey reinforce the following point (emphasis added in underline) made in the Executive Summary of the June 2014 COGR paper, Finances of Research Universities. The Full Version of the June 2014 COGR paper provides additional analysis on research funding trends and the corresponding financial implications to research universities.

> *The future of the federal government contribution to the research enterprise is highly uncertain in light of deep discretionary spending cuts. According to the National Science Foundation 2012 Higher Education Research and Development (HERD) survey, for the first time since the 1950s, the federal government contribution to the research enterprise dipped below 60%. As the percentage of total research expenditures funded by federal sources trends downward, research universities bear the additional expense. The university contribution exceeds $13 billion, according to the 2012 HERD survey, and continues to grow.*

Finally note, the underlying Data Tables that support the FY2013 HERD Survey provide institutional specific results. Table 18 from the Data Tables page is the table that shows, by institution, total R&D expenditures by federal, state, institutional, business, nonprofit, and all other funding sources. We encourage you to read the NSF InfoBrief and to be intimate with the numbers that are displayed in the annual NSF HERD Survey. As COGR regularly focuses on the topic of research funding trends and the corresponding financial implications to research universities, the annual NSF HERD Survey is a helpful tool that quantifies our concerns.

Audit Update

2015 Single Audit Compliance Supplement

OMB distributed a draft version of the 2015 Single Audit Compliance Supplement to selected associations for comment. COGR is on the distribution list and we provided several comments specific to Part 5, Research and Development Programs. If you are interested in what was included in the draft version, contact David Kennedy at dkennedy@cogr.edu. We expect the final version of the 2015 Single Audit Compliance Supplement to be available in March 2015, or soon after.

FDP Payroll Certification Pilots

We mentioned in the December COGR update that a report by the Health and Human Services Office of Inspector General indicated that the OIG could not assess the University of California at Irvine's piloted payroll certification program, expressing concern that Federal Financial Reports did not match accounting records. UCI indicated that they reconcile FFRs to the general ledger quarterly using "inception-to-date" amounts and therefore the ledger may include current expenditures not yet available to report and previous expenditures now appropriate to report. It is our understanding that pilots at three remaining institutions have been assessed and this issue remains a concern. Reports from the Inspector General are anticipated soon.

New Audit Activity

COGR regularly checks the HHS (NIH) and NSF OIG websites, which provide access to published audit reports. As of the writing of this COGR Update, there are no recent audit reports to convey to the membership. In addition to HHS (NIH) and NSF OIG initiatives, we are interested in activity related to the OIGs at other agencies, as well as other internal and external audit activities. Please do not hesitate to contact us on audit issues or developments at your institution. We keep all informational confidential, unless you specifically request that we share it with selected COGR leaders and/or committees.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: David Winwood, Chair, Louisiana State University; Cindy Kiel, University of California, Davis; Alexandra McKeown, The Johns Hopkins University; Cordell Overby, University of Delaware; Patrick Schlesinger, University of California, Berkeley; Kevin Wozniak, Georgia Institute of Technology; Catherine Innes, North Carolina State University; Fred Reinhart, University of Massachusetts; John Ritter, Princeton University; Wendy Streitz, University of California

Associations Submit Comments on USPTO Subject Matter Eligibility Guidance

The COGR February Update discussed the COGR testimony at the January 21 Public Forum on the revised *Interim Guidance on Patent Subject Matter Eligibility* published by USPTO on December 16 (79FR74618). It included a summary of the testimony provided by Robert Hardy of COGR on behalf of COGR as well as AAU, APLU, AAMC, and AUTM.

On March 13 we submitted a followup comment letter to USPTO also on behalf of the five associations. The letter made many of the same points as the oral testimony, but with a more focused recommendation. We suggested that USPTO give more emphasis in the guidance to the concept of preemption. We expressed the view that the primary concern should be whether claims involving natural phenomena, laws of nature or abstract ideas tie up these areas such that others cannot practice or make use of them. This approach looks back to a line of older Supreme Court cases and seems less subjective than tests for "markedly different characteristics" or "inventive concepts" set forth in the revised *Guidance*, based on more recent cases. We also offered to work with USPTO and other patent stakeholders to seek to bring more clarity to this area, as discussed at the Forum.

A copy of the comment letter is posted on the COGR website.

Senate Holds Hearings On Patent Reform

The Senate held two hearings on patent reform the week of March 16.

> Judiciary Committee The first one was held by the Senate Judiciary Committee on March 18. The theme was "The Impact of Abusive Patent Litigation Practices on the American Economy." Dr. Michael Crum, VP for Economic Development and Business Engagement, Iowa State University, represented the higher ed. associations at the hearing. Dr. Crum's testimony discussed the importance of patents to university tech transfer, the crucial importance of a strong patent system, the need for balanced legislation in an evolving patent landscape, and concerns about provisions that would provide for mandatory fee shifting ('loser pays") and joinder. All other witnesses were attorneys representing companies (e.g. a hamburger chain) or industry groups (i.e. BIO).

14 Senators attended the hearing. All asked questions. The need for balance in addressing abusive practices while preserving a strong patent system was mentioned by many ("clubbing patent trolls while doing no harm" in the words of Sen. Schumer). The two sided nature of the problem also was discussed, with small companies and startups particularly vulnerable to trolls while at the same time needing the protection of the patent system. This makes reform activities something of a "Rubik's Cube" (Schumer).

A partisan split emerged, with Democratic Senators worried about over-reaching and unintended consequences while strong support for fee shifting was expressed by a number of the Republicans. The AAU/APLU letters (see COGR February Update) specifically were cited by two of the Democrats. However, Senators from both parties expressed the need to address the "demand letter scandal" (Sen. Whitehead). Sen. Coons summarized his proposed STRONG Patents Act (S. 632), which is aimed at this issue as well as making changes in the USPTO post-grant review proceedings (see http://www.coons.senate.gov/newsroom/releases/release/senator-coons-statement-on-patent-reform for more information).

With both sides expressing need for balanced legislation it appears some compromise might be possible. In addition to demand letters, some changes in discovery and pleading practices and new customer stay provisions to protect consumer end users are other areas of potential agreement. Several Senators noted that this could be a rare area of bipartisan agreement. The hearing record is available at http://www.judiciary.senate.gov/meetings/the-impact-of-abusive-patent-litigation-practices-on-the-american-economy . For another take on the hearing, see http://www.ipwatchdog.com/2015/03/18/senate-judiciary-committee-seeks-balance-on-patent-troll-legislation/id=55854/

Small Business Committee. On March 19, the Senate Committee on Small Business and Entrepreneurship held a hearing on "Patent Reform: Protecting Innovation and Entrepreneurship." Dr. David Winwood, Chief Business Development Officer of Louisiana State's Pennington Biomedical Research Center and President-Elect, AUTM and Chair, COGR CIP Committee was among the witnesses. His testimony discussed the critical importance of intellectual property protection for startup companies based on university technologies, the serious concerns for the ability of universities and licensees to enforce patents arising from the fee shifting and joinder provisions in H.R. 9 (see February Update) , and the potential chilling effects on university tech transfer.

The hearing covered much of the same ground as the Judiciary Committee hearing the day before. However, the emphasis was more on the potential harm to small business from efforts to weaken the patent system. It also was well-attended, with 10 Senators present all or part of the time. There was more discussion of issues involving USPTO, including the patent application backlog, need for additional resources, and fee diversion. Another issue discussed was abuse of the new AIA post-grant Inter Partes Review system (also discussed the day before). Concerns were expressed about the procedural fairness of the system, with the very high rate of patent invalidations. There also was a call for tightened standing requirements to initiate infringement litigation or Inter Partes review.

The witness from the Small Business Technology Council was particularly critical of H.R. 9, calling it the counterfactual "Ending the American Dream Act."

Sen. Coons also attended this hearing and discussed his proposed STRONG Patents Act, which all witnesses supported. That Act also includes provisions addressing some of the problems that have arisen with Inter Partes review as well as ending USPTO fee diversion. Dr. Winwood made it clear that the university associations strongly support Sen. Coons' bill.

The hearing was chaired by Sen. Vitters (R—LA), who in his opening statement noted the importance of maintaining a level playing field between large companies and other inventors including small business and universities. This was a constant theme throughout the hearing. More information can be found at http://www.sbc.senate.gov/public/index.cfm?p=Hearings&ContentRecord_id=6b38e456-9bff-44f0-a636-4a0d37b21f41

Given all this attention, it appears there is some prospect of bipartisan Senate legislation.. It also appears that the two sided nature of the problem and the need for balance is better understood at least on the part of many Senators than may have been the case in the last Congressional session. COGR will continue to closely follow and report on developments.

BIO Updates 2012 Report on Economic Impact of U.S. Academic Licensing

On March 17 the Biotechnology Industry Organization (BIO) issued an update to its previous (2012) report on *The Economic Contribution of University/Nonprofit Inventions in the United States: 1996—2013*. The report estimates that, during this 18-year time period, academic-industry patent licensing bolstered U.S. gross industry output by up to *$1.18 trillion*, U.S. gross domestic product (GDP) by up to *$518 billion,* and supported up to *3,824,000 U.S. jobs*. This is an impressive increase since the previous report. Due to growth in academic-industry licensing activity, the newly-released numbers show about a 20% increase in the licensing contribution to U.S. gross industry output and GDP, with an 11% increase in jobs supported.

The economic impact estimates draw on AUTM licensing surveys. The AUTM annual numbers for 2013 show 818 startup companies formed around academic patents (up 16% from 2012); 4200 startups in operation, mostly located in the same state as the parent research institution; $22.8B in product sales from commercialized academic inventions; and 719 new products introduced into the market (up 22%).

These are important findings, and can be used to refute other recent studies and reports which purport to downplay the importance of patent licensing to innovation (e.g. see http://www.ipwatchdog.com/2015/03/17/in-defense-of-patents-and-licensing-why-the-newest-attack-is-bogus/id=55831/ . The report also was available in time to be cited in university testimony at the Senate hearings discussed above.

For a copy of the report see https://www.bio.org/articles/Value-of-Academic-Industry-Patents

HHS Publishes Proposed Revision to HHS Acquisition Regulations (HHSAR)

On March 2 HHS proposed a revision to the HHS Acquisition Regulations (HHSAR; 80 FR 11266). This is the first full revision of the HHSAR since 2009, although some correcting amendments were made in 2010.

The revision updates the HHSAR to reflect changes in the FAR over this period. It also incorporates new requirements included in appropriations acts, and removes what HHS considers to be internal procedures from the HHSAR.

Our review of the revision does not indicate particular problems or concerns. There is new material on patent and data rights in Subpart 327 and the related clauses in 352.227. These all appear consistent with the FAR. Of note is an addition in 352.227-70 that explicitly provides that contractors may publish the results of their work under the contract. This has been a concern with other agencies, and occasionally with HHS, so it's refreshing to see explicit recognition of the right to publish in the HHSAR.

While not of particular concern, Subpart 335 on Cost Sharing is worth mentioning. The approach is based on the FAR, but exactly opposite to that of the Uniform Guidance for federal assistance. Under the FAR, cost sharing is encouraged, and there are guidelines as to the amount, based on the expected benefits to the contractor. COGR is getting increasing questions about inconsistencies between the Uniform Guidance and FAR. It is important to keep in mind that the FAR governs procurement contracts, and takes precedence over the Uniform Guidance for contracts except where the FAR specifically incorporates provisions in the Uniform Guidance (i.e. Cost Principles).

Comments are due May 1. At this time COGR does not anticipate submitting comments. However, COGR members are encouraged to contact us (Robert Hardy or Jacquelyn Bendall) with any concerns about the revision.

DOE Publishes Final Rule on Nuclear Export Regulations

On February 23 DOE/NNSA published a final 10 CFR Part 810 rule on nuclear export controls. This is the first comprehensive update to Part 810 since 1986. COGR/AAU submitted comments in November 2011 when the 810 revision was first proposed (see COGR October 2011 Meeting Report). Our principal concern was that the definitions in the 810 rule should be consistent with the definitions used in other export control regulations, particularly as to fundamental research and "U.S. persons."

The final rule responds to these concerns. It defines "fundamental research" consistent with other export control regulations and NSDD 189. It also excludes lawful U.S. permanent residents and certain other protected individuals from the definition of "foreign nationals," consistent with other export control regulations. Unfortunately the regulatory preamble contains an unhelpful statement (p. 9367) that when "[a]pplied research crosses the boundary from theoretical scientific inquiry to potential reactor specific applications of new technologies," such research will not be generally authorized (although it could be specifically authorized) because it can be applied to a facility that could be involved in the production of special nuclear material.

Also DOE did not completely respond to comments submitted by other university groups as to the definitions of "publicly available information" and "publicly available technology."

However, as a bottom line DOE's final definition of fundamental research still covers basic and most applied research, which is not subject to 810 controls. Applied research that covers specific reactor applications may require further consultation with DOE.

USPTO Announces Patent Quality Summit

USPTO has asked us to alert COGR members to the Patent Quality Summit, to be held March 25—26 at USPTO headquarters. The purpose is to collect public feedback and to guide the agency in developing and implementing improved quality standards and practices. The Summit will be webcast at www.uspto.gov/patents/initiatives/patent-quality-summit

While the USPTO statement indicates registration closed March 18, USPTO has advised us they are anxious for university participation, so late registration for the webcast may be possible. We also understand AUTM is planning to participate.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Michael Ludwig, Chair, University of Chicago; Lois Brako, University of Michigan; Pamela Caudill, Harvard University; Kerry Peluso, Emory University; Suzanne Rivera, Case Western Reserve University; James Tracy, University of Kentucky; Pamela Webb, University of Minnesota; Walter Goldschmidts, Cold Spring Harbor Laboratory; Jennifer Lassner, University of Iowa; Steve Martin, Indiana University; Lisa Mosley, Arizona State University

NIH Genomic Data Sharing Policy

Now that the Genomic Data Sharing Policy ("Policy") is in full force as of this past January, many of the comments voiced at the recent COGR meeting still highlight the need to go on record about the investigator and administrative burden the Policy has created along with the concerns many had in terms of how genomic data stripped of identifiers nonetheless falls into the human subjects bucket, thus requiring informed consent.

Under the current OHRP guidelines, pathology specimens may qualify for exemption from consideration as human subjects research if they: (a) have not been obtained specifically for the current research project through an interaction or intervention with a living person; and (b) preclude the investigator from ascertaining the identity of the donor in any manner. Human genomic data submitted to NIH-designated data repositories should be de-identified pursuant to HHS regulations for the Protection of Human Subject's and HIPAA. Under the NIH GDS **Policy,** although de-identified, NIH is obtaining Certificates of Confidentiality as an additional precaution and ***encourages*** investigators and institutions submitting datasets to NIH-designated data repositories to follows suit as ***an additional safeguard***. According to the current definition of "human subject" in the Common Rule informed consent for use of de-identified samples and data (such as those that are often stored in bio banks and data repositories for unspecified future research use), or for stored samples and data from people who are deceased ***is not required***. For some research, while informed consent is not required by federal regulation as we currently interpret, NIH now expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified. Furthermore, the Policy goes on to state that if there are compelling scientific reasons that necessitate the use of genomic data from cell lines or clinical specimens that were created or collected after the effective date of the Policy and that lack consent for research use and data sharing, ***investigators should provide a justification*** in the funding request for their use. So, while we're all collectively looking at ways to reduce burden, we must now grapple with conflicting guidance and jurisdictional authority (e.g., OHRP or NIH). Encouraging the collection of obtaining certificates of confidentiality as an extra safeguard, and the burden this Policy places on the institutional IRB's to conduct reviews ***beyond the Common Rule*** is a real deterrent to advancing scientific endeavors and yet another unfunded mandate to fix a problem

that wasn't broken in the first place. How does this correlate with Obama's Executive Order 13563, Reducing Regulatory Burden?

The Policy notes that research on information from deceased individuals who did not provide consent before death is legally permissible under HIPAA and the Common Rule. … but then goes onto say, "it is important to consider whether prior consent or consent from surrogates can and should be sought, even if not explicitly required by regulations, and how the interests of participants and surviving relatives will be protected if informed consent cannot be obtained." How will IRBs evaluate samples from deceased individuals since the currently regulation specifically exclude such materials? If the NIH has determined that these samples will not be truly de-identified by the very fact that genomic data cannot be de-identifiable, are HIPPA waivers also required?

Research investigators must agree to follow a Code of Conduct and abide by the terms as Approved Users of data received through the database of Genotypes and Phenotypes (dbGaP). Failure to abide by the terms may result in revocation of approved access to any or all datasets obtained through dbGaP. Investigator(s) will make no attempt to identify or contact individual participants from whom these data were collected **without appropriate approvals from the relevant IRBs**; and finally Investigator(s) will not distribute these data to any entity or individual beyond those specified in the approved Data Access Request. Again, what was broken in the first place to have changed what we all thought was exempt from human subject's regulations? Who's in charge now? ? Any advances in policy prior to regulation will only add burden, will costs more time and money for institutions and the federal government and will deter critical scientific advances from moving forward.

COGR will be voicing these concerns with the NIH and will provide updates to the membership as necessary. http://gds.nih.gov/PDF/NIH_GDS_Policy.pdf

Clinical Trials Registration and Results NPRM and the NIH Draft Policy

COGR informed you in our December update of the DHHS Notice of Proposed Rulemaking (NPRM) issued on November 21, 2014 proposing regulations to implement reporting requirements for clinical trials that are subject to Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). http://www.gpo.gov/fdsys/pkg/FR-2014-11-21/pdf/2014-26197.pdf . The one hundred plus page NPRM set out to provide definitions, simplify what is determined to fall into the "applicable clinical trial" category, added and refined database elements and added new deadlines and penalties that have brought forth enormous concerns in the member community in terms of being able to comply with another unfunded mandate in an already difficult to navigate clunky system called clinicaltrials.gov. The NPRM requires actual protocols and lay summaries, adverse event reporting, and other reporting timeframes that will be difficult to monitor. As is, with other recent draft policies/guidance, ANPRMs and NPRMs the common theme prevails, more work, more time, no funding or resources, and less efficiency.

Further adding to the burden above, the NIH followed with a Request for Public Comments on the Draft NIH Policy on Dissemination of NIH Funded Clinical Trial Information (NOT-OD-15-019) designed to complement the statutory mandate under Title VIII of the FDAAA of 2007. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-019.html The difference being, that

they further intend to apply this to **all funded NIH Clinical Studies**. Comments to draft policy are also due on March 23rd. We thank you for your feedback, the COGR response can be found on COGR's website for more information. http://www.cogr.edu

Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

On January 29, 2015 COGR responded to the NIH draft policy to promote the use of a single IRB of record for domestic sites of multi-site studies funded by the NIH. The draft Policy proposes that NIH funded institutions will be expected to use a single IRB of record for domestic sites of multi-site studies *unless there is justification for an exception.* This Policy is one of many of the proposed changes being considered to the Common Rule. For more information, the COGR letter can be found on COGR's website.

NSF OIG and Responsible Conduct in Research (RCR)

Many of you have expressed concerns to COGR about the letters you've received from the NSF OIG regarding Responsible Conduct in Research (RCR) Training and whether we had additional information about this matter. We have heard feedback that the visits are intended to be reviews initially, not audits and that a report will be issued making recommendations in the aggregate. We understand, although this could change, that the team consists of approximately two individuals deeming themselves "Investigative Scientists". The team has asked for materials related to the implementation of the RCR Program (curriculum, procedures, etc.), and a list of the number of trainees who've completed the program, broken out by discipline and year. We understand that interviews are being conducted with the highest institutional official involved with RCR, the person who directs the RCR program and approximately three students (undergrad, grad and postdoc). The investigative team is asking for permission to tape the interviews. While we have no crystal ball as to what may come of these site visits, we and other members are interested in hearing your feedback, in full confidence of course.

FDA Draft Guidance on Use of an Electronic Informed Consent in Clinical Investigations

On March 9, 2015, the Food and Drug Administration (FDA) announced in the Federal Register (FR) the availability of a draft guidance for industry, clinical investigators, and institutional review boards entitled "Use of Electronic Informed Consent in Clinical Investigations: Questions and Answers." http://www.gpo.gov/fdsys/pkg/FR-2015-03-09/pdf/2015-05377.pdf The guidance provides recommendations for clinical investigators, sponsors, and institutional review boards on the use of electronic media and processes to obtain informed consent for FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices and combinations thereof. Comments are due May 8, 2015. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf

To enhance human subject protection and reduce regulatory burden, The Office for Human Research Protections (OHRP) in the same issue of the FR published a notice requesting public comment on whether FDA's draft guidance document would be **appropriate for all research regulated under 45 CFR part 46.** OHRP will consider comments received from the public before deciding whether to issue a joint final guidance document with the FDA.

http://www.gpo.gov/fdsys/pkg/FR-2015-03-09/pdf/2015-05301.pdf.

Comments are due May 7, 2015. If you have comments please send them to jbendall@cogr.edu

Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law No: 113-240)

On December 18, 2014 the Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law No: 113-240), an extension of the Newborn Screening Saves Lives Act of 2008 was signed into law. The law went into effect on March 16, 2015 and for many of us, crept up as a big surprise. The bill includes an amendment addressing research uses of newborn dried blood spots, requiring immediate new interpretations of the HHS regulations for the protections of human subjects effective 90 days from the enactment of the law (see below). The amendment also requires HHS to promulgate proposed revisions to Federal Policy for the Protection of Human Subjects within six months and final regulations within two years. ***The two most significant changes: 1) the law requires that all research funded pursuant to the Public Health Service Act using newborn dried spots be considered human subjects research regardless of whether the specimens are identifiable***, ***2) the law eliminates the ability of the IRB to waive informed consent under 45 CFR 46.116(c) and 116(d) for research involving newborn dried blood spots.***

Although the law only applies to HHS-funded research, and not to research funded by other entities being conducted at institutions who have extended their FWA to cover all research, regardless of funding (institutions that have "checked the box.") our antenna's will be up on how this law will impact future revisions to the Common Rule.

HHS Possession, Use and Transfer of Select Agents and Toxins; Biennial Review

http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04169.pdf

HHS has issued an advanced notice of proposed rulemaking (ANPRM) seeking public comments on the appropriateness of the current list of select agents and toxins. The CDC is considering removing six of the current fifteen biological agents and toxins from the list due to the low risk of transmissibility, low mortality rates with proper antibiotic treatment, and vaccine availability. Interested persons are invited to submit comments, research data, and other information that will better inform HHS as to whether: (1) There are any other biological agents or toxins that should be added to the list that have the potential to pose a severe threat to public health and safety; (2) any other biological agents or toxins currently on the list that should be removed because they no longer have the potential to pose a severe threat to public health and safety, and/or (3) the biological agents specifically listed in the ANPRM should be removed or remain on the list. Comments are due on or before April 28, 2015.

Biennial Review and Republication of the Select Agent and Toxin List

http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-04180.pdf

The Department of Agriculture Animal and Plant Health Inspection Service (APHIS) is seeking public comment on the current list of select agents and toxins in agriculture regulations and suggestions regarding any addition or reduction of the animal or plant pathogens currently on the list of select agents. Comments are also due on or before April 28, 2015.

EPA Interim Financial Assistance Conflict of Interest Policy

COGR has received feedback from the member community regarding EPA's recently released Interim Financial Assistance Conflict of Interest Policy to comply with 2 CFR 200.112. EPA issued its policy to ensure that the Agency met the requirement in 2 C.F.R. 200.112 for non-federal entities to provide written COI disclosures. While EPA believes that the disclosure provisions of the policy are fully consistent with Section 200.112, our take is that the interim policy establishes requirements for recipients including but not limited to requiring new disclosures from Faculty and other researchers and personnel, including contractors and subrecipients that goes ***beyond t***he written standards of conduct required in Uniform Guidance part, 2 CFR 200.318 (c) (1) and (2) FAQ 200.112-1 below.

"The conflict of interest policy in 2 CFR 200.112 refers to conflicts that might arise around how a non-Federal entity expends funds under a Federal award. These types of decisions include, for example, selection of a subrecipient or procurements as described in section 200.318."

We have been told that the EPA has initiated the feedback process by sending letters to EPA's non-Tribal recipients asking for comments by March 31, 2015. In addition, EPA is in the process of starting consultation with the Agency's Tribal partners to obtain their feedback.

COGR's two primary concerns requested that EPA remove the requirement to disclose, on a project-by-project basis, contracting and subaward COIs that violate 2 CFR 200.318, instead allowing recipient organizations to manage COIs on an institutional basis. The second request asked that EPA immediately remove the requirement for disclosures relating to COI violations of EPA's Competition Policy. In COGR's view, compliance with that Policy's COI requirements is an EPA, and not a recipient, responsibility.

EPA anticipates receiving comments from the recipient community on the issue raised by COGR's first request and has been told that in order to ensure that all viewpoints are fully and fairly considered, the EPA will address our request as part of the stakeholder comment process noted above, a process to be completed by September 2015.

With regard to the second request, EPA is reviewing that now and anticipates a final decision in April 2015. COGR's letter to the EPA can be found on the website http://www.cogr.edu

We will keep the membership informed on further updates. If you see other policies being implemented that go beyond the requirements in the Uniform Guidance, please contact Jackie Bendall at jbendall@cogr.edu

http://www.epa.gov/ogd/epa_interim_financial_assistance_coi_policy.htm

National Science Foundation - Public Access

In response to the Office of Science and Technology Policy's Feb. 22, 2013, memorandum, "Increasing Access to the Results of Federally Funded Research," The National Science Foundation has developed a plan entitled "Today's Data, Tomorrow's Discoveries," which outlines a framework for activities to increase public access to scientific publications and digital scientific data resulting from NSF funded research.

This NSF requirement will apply to new awards resulting from proposals submitted, or due, on or after the effective date of the *Proposal & Award Policies & Procedures Guide (PAPPG)* that will be issued in **January 2016**.

Look for a notice in the Federal Register for public comment no later than April 2015.
http://www.nsf.gov/news/special_reports/public_access/index.jsp?WT.mc_id=USNSF_51