July 2, 2014

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Committee: James Luther, Chair, Duke University; James Barbret, Wayne State University; Sara Bible, Stanford University; Kelvin Droegemeier, University of Oklahoma; Cynthia Hope, University of Alabama; James R. Maples, University of Tennessee; Kim Moreland, University of Wisconsin – Madison; Mary Lee Brown, University of Pennsylvania, ACUA Liaison; Michael Daniels, Northwestern University; Dan Evon, Michigan State University; Terry Johnson, University of Iowa; Cathy Snyder, Vanderbilt University

HHS/NIH Subaccounting and Closeouts: NEW DEVELOPMENTS

COGR has been notified that the Department of Health and Human Services (HHS), Office of Grants Policy, has granted NIH an extension for implementing subaccounts (i.e., P accounts). Effectively, this would represent a continuation of the current policy where new awards only are transitioned to P accounts. We expect that this extension will be for one more year and that all awards will be required to be transitioned to P accounts beginning October 1, 2015.

NIH staff is finalizing the NIH Grant Notice that will formalize this policy. Upon finalization of the policy, it will be available at the link below:


COGR extends a special thanks to leaders and advocates at NIH and the NIH Office of Policy for Extramural Research Administration (OPERA). NIH has been a huge champion for the extension and this would not have happened without relentless NIH support. In addition, the HHS Office of Grants Policy, which ultimately is responsible for approving NIH policy implementation, has been receptive and helpful, despite the pressure they are under to implement subaccounting across all HHS Operating Divisions. Finally, COGR and the FDP have worked in partnership throughout the past six months to engage representatives from NIH and HHS, and the efforts made by FDP members have been instrumental in securing this outcome.

Despite the positive development, Subaccounting, and in particular, Closeouts, will be ongoing issues for the remainder of the year, and beyond. Issues were discussed during a special session at the Friday, June 13th COGR Meeting and the PPT presentation is available at www.cogr.edu (see Meetings | June 2014 Meeting Presentations). Also see the NSF PAPPG: COGR Comment Letter (described below) and COGR’s comments on Grant Closeouts. We will keep the membership updated on all developments.

OMB Uniform Guidance Update

Below is the most up-to-date list of important developments and dates applicable to implementation of the OMB Uniform Guidance (UG). The first three referenced documents can be accessed under Latest News!, July 1, 2014 on the COGR homepage at www.cogr.edu. We
will provide timely and periodic updates throughout the summer and leading to the December 26th implementation date.

1) **NSF PAPPG: COGR Comment Letter (sent July 1, 2014).** On May 9, 2014, the National Science Foundation (NSF) published a DRAFT revision of their Proposal and Award Policies and Procedures Guide (PAPPG) for comment. This revision of the PAPPG is NSF’s implementation plan for the UG. In the COGR letter, we provided comments on NSF’s proposed implementation of the UG, as well as comments on other policy changes that were included in the DRAFT version of the PAPPG. We take a particularly hard swing at Grant Closeouts and Procurement and ask NSF to request UG implementation deviations from OMB. Comments can be made through July 8, 2014; COGR members are welcome to endorse the COGR letter. See the May 9, 2014 Federal Register notice (79FR26778) for instructions on the submission of comments. A copy of the draft revision is available on the NSF website at: http://www.nsf.gov/bfa/dias/policy/

2) **COGR-crafted FAQs (and answers) to OMB/COFAR (sent June 26, 2014).** At the request of OMB/COFAR, we have provided OMB/COFAR with FAQs (and answers) to those items from the UG that we believe can be clarified with an FAQ. We have focused the COGR-crafted FAQs on those items that we consider the most potentially troublesome areas of the UG where an FAQ with a favorable answer can make for a positive implementation.

3) **Procurement and Fringe Benefits: COGR Letter to OMB/COFAR (sent June 17, 2014).** We have requested on behalf of Institutions of Higher Education (IHEs), Nonprofit Research Institutions (NRIs), and all research performers the following: a) IHEs and NRIs should be exempted from Sections 200.317 through 200.326 (Procurement Standards) and that the standards under Circular A-110 should be reinstated, and b) Sections 200.431 (b)(3)(i) and (e)(3) should be updated for technical corrections to eliminate language that suggest certain fringe benefits (e.g., terminal leave) should be treated as indirect costs.

Also note the following:

4) **OMB/COFAR Outreach this Summer.** While dates have not been set, OMB/COFAR has shared that we should expect the following this summer: a) Stakeholders Meeting- COFAR-led meeting with representatives from higher ed, nonprofit research institutions, state, local, and tribal governments, and other nonprofits to update all stakeholder on new developments, b) Webcast- COFAR-sponsored webcast, possibly including a panel of stakeholders, and c) Updated FAQs- an update to the currently available FAQs at: https://cfo.gov/wp-content/uploads/2013/01/2-C.F.R.-200-FAQs-2-12-2014.pdf

5) **Agency Implementation Plans and an Interim Final Rule.** Draft agency implementation plans were due to OMB/COFAR on June 26th. The NSF plan (see 1) above) may be the only one in which we have an opportunity to provide formal comments. In addition, DOD has received clearance from OMB to share parts of their implementation plan with COGR and other DOD stakeholders. Though this does not constitute a formal comment process, we appreciate DOD’s outreach to address a number
of key parts of the DOD implementation plan. OMB has indicated they expect one single issuance of an interim final rule to include all Federal agency implementing regulations, unless there is an exception approved by OMB. The exact date that the issuance will be published is unknown, though it could be as late as December. OMB intends to take a close look at the timeline based on issues that have been raised and they hope to be able to provide more information later this summer.

Finally, COGR Resources and Publications are available at [www.cogr.edu](http://www.cogr.edu) (see the homepage, Latest News!, June 11, 2014 and the Meetings tab for PPT presentations).

6) **COFAR-COGR Review (June 11, 2014).** A status report on those topics COGR has raised to the COFAR as the most important issues. This document has been used as the basis for two meetings between the COFAR and COGR. The Requested Action was up-to-date on June 11th, however, the more recent documents and correspondences described above now supersede parts of this document.

7) **FDP/COGR Whitepapers on the Uniform Guidance (June 4, 2014).** On April 14, 2014, COGR participated in an FDP-sponsored meeting where university representatives presented "University Perspectives" to federal agency representatives on key issues from the UG. These detailed analyses on specific issues were completed after the meeting and were made available on the COGR website in June.

8) **PPTs from COGR Meetings (February and June, 2014).** The PPT presentations are available at the COGR website (see Meetings | February 2014 Meeting Presentations and Meetings | June 2014 Meeting Presentations, respectively).

9) **COGR Guide to the OMB Uniform Guidance (April 17, 2014).** A detailed assessment on key sections from the UG. This document was up-to-date on April 17th, however, the more recent documents and correspondences described above now supersede parts of this document.

10) **An Implementation Plan for a Major Research University (March 10, 2014).** Parts of this paper are based on an article written by Sara Bible, Associate Vice Provost for Research at Stanford University, which was published in the March/April 2014 issue of the NCURA Magazine. Sara is on the COGR Board and a member of the Costing Policies Committee. Other parts of this article are based on COGR Updates and other COGR insights to the UG. We expect to address updated implementation strategies later in the Summer / early Fall.

11) **COGR Preliminary Assessment of the OMB Uniform Guidance (January 14, 2014).** The COGR “first look” of selected items. The preliminary assessment was written less than a month after the UG was released and is now superseded by the more recent documents and correspondences described above.

Implementation of the OMB Uniform Guidance continues to be a fast-moving and fluid process; OMB and the COFAR remain committed to the December 26, 2014 implementation date. We will keep the membership abreast on all developments.
**June COGR Meeting Session Summary: OMB Uniform Guidance**

The June COGR Meeting, like the February Meeting, was heavily infused with sessions related to the OMB Uniform Guidance (UG). Two sessions specific to the implementation of the UG, and a third session that addressed the “internal control” aspects of the UG, were covered in the June Meeting. The PPT presentations for all three are available at [www.cogr.edu](http://www.cogr.edu) (see Meetings | June 2014 Meeting Presentations).

**OMB Uniform Guidance Hot Topics & Implementation (combined Costing and RCA session).** Representatives from the Costing and RCA Committees led a panel discussion to provide a status update on the hottest topics related to the UG, followed by four institutional perspectives on how these institutions are preparing for the implementation. This was a “members only” session. The four presenters, from the Costing and RCA committees, were: Sara Bible - Stanford University, Pamela Webb - University of Minnesota, Kim Moreland - University of Wisconsin, and Dan Evon - Michigan State University. A list of action items and implementation strategies from the session is included in the next section.

**Internal Controls and Mitigating Institutional Risk.** Mandy Nelson, a Partner at KPMG LLP, and Andrew Rudczynski and Alice Tangredi-Hannon from Yale University, addressed internal controls from an audit/implementation of the UG perspective (Nelson) and from a research compliance/institutional risk perspective (Rudczynski and Tangredi-Hannon). Both perspectives emphasized the importance of reevaluating existing programs of internal controls, especially in the context of the soon-to-be-implemented UG.

**NSF Proposed Implementation of the UG and Other Changes to the PAPPG.** Jean Feldman, the NSF Policy Head, summarized the NSF proposed UG implementation plan and other proposed policy changes, both of which are included in the DRAFT version of the NSF PAPPG. Comments are due by July 8th (see previous section).

Follow-up sessions to the themes and topics addressed in these sessions will be scheduled, accordingly, for the October COGR Meeting (October 23-24, 2014).

**Action Items and Implementation Strategies of the OMB Uniform Guidance: What Next?**

The Thursday morning session summarized above, OMB Uniform Guidance Hot Topics & Implementation, provided action items and implementation strategies from the participants on the panel. Key points are listed below.

- **CAS Disclosure Statement (DS-2).** Review institution’s DS-2 to identify intersections with new requirements in the UG. Institutions should communicate with their cognizant agency regarding when to make changes to their DS-2. Consider changes applicable to administrative and clerical salaries, computing devices, fringe benefits, and documentation of payroll charges.

- **Proposal Submissions.** Evaluate what your institution will do in regard to proposals that will be submitted in the coming weeks/months, and will be funded after implementation
of the UG. For example, consider including administrative and clerical salaries, computing devices, and 10% F&A on subawards.

- **Compensation/Effort Reporting.** Continue to use current systems, for now. Consider options for replacement of traditional effort reporting system/processes including FDP Project Certification pilot, including considerations of internal controls environment, faculty input, and input/approval from cognizant agency. Also consider “minor changes” that may reduce burden, such as frequency of reporting.

- **Fringe Benefits.** Initiate planning for a new fringe component for unused terminal leave, but pay close attention to the status of COGR request to the COFAR.

- **Closeouts.** Be aware of ongoing changes at HHS, NIH, and NSF, as well as current COGR advocacy, as it relates to closeout policies. Note, this applies to financial, performance, and other reports and the liquidation date.

- **Purchasing & Property.** Analyze the UG and institutional systems. Perform a fit-gap analysis. Engage your Procurement and Property Directors. And pay close attention to the status of COGR requests to the COFAR.

- **Subawards.**
  - Wait for agency implementations to determine if documentation requirements are imposed for vendor vs. subaward classifications. Watch for a sample documentation template from FDP should agencies add this optional requirement.
  - Watch for updated subaward templates from FDP that incorporate the additional data elements required in 200.331. Review your local business processes/systems and decide whether you also need these data elements.
  - Notify campus about new requirement for agency prior approval of fixed price subawards. Determine local business process to acquire these approvals via proposal or after-award. Watch for guidance on how to handle fixed price subawards over the simplified acquisition threshold ($150K).
  - Review your risk assessment tool and subaward monitoring processes to see if they meet the new standards in 200.331 and work with the updated Federal Audit Clearinghouse. Decide how review of subrecipient progress reports/invoices will be documented. Watch for FDP announcements on sample risk assessment tools and monitoring procedures.
  - Put business processes in place to make sure you can incorporate subrecipient’s negotiated F&A rate or give them 10% MTDC de minimus rate/negotiate an F&A rate with them. Wait for guidance on how to handle ongoing subawards priced under the old rules.

- **Lead Time.** For all of the above, evaluate the lead time to make changes, the impact on internal system and IT requirements, and other business processes.

As is the case with many COGR sessions, the information gleaned from the presentations serves as a fact-finding opportunity and the identification of good institutional practices and important next steps. The action items and implementation strategies gathered from the Thursday morning
session serve as a starting point for specific recommendations and approaches on how institutions may contemplate preparing for their implementation of the UG.

While we recognize that there still will be uncertainty, by late Summer and early Fall institutions should expect to be further along in their implementation plans, including their approach to faculty and staff training. Over the course of the summer and leading into the fall, COGR will consider formalizing the recommendations and approaches listed above. We have been committed to providing resources to the COGR membership, and will continue to do so as we get closer to December 26th and the official implementation of the UG.

**A-133 Compliance Supplement for FY2014 is Available**

The May 22, 2014 issue of the *Federal Register* (see link below) announced the availability of the A-133 Compliance Supplement (CS) for FY2014. The CS will apply to audits of fiscal years beginning after June 30, 2013.


The *Federal Register* announcement includes:

- List of changes to the FY2014 CS, which can be found in Appendix V.
- Audit alert concerning deletion of American Recovery and Reinvestment Act programs from clusters, which can be found in Appendix VII.
- Preview of types of revisions that will be applicable to the FY2015 CS based on the OMB Uniform Guidance.
- Notification that comments on the FY2014 CS must be in writing and received by October 31, 2014.

The 2014 CS can be found at the link below:

http://www.whitehouse.gov/omb/circulars/a133_compliance_supplement_2014

As we addressed in the April COGR Update (published April 24, 2014), the concern regarding Suspension and Debarment has been resolved. At issue was the language in the FY2013 CS that required the status of principals (e.g., board members, corporate officers) of a vendor to be verified. A clarification was issued in February and removed the pressure on auditors to issue adverse audit opinions “based solely on the tests for suspended and debarred principals.” The 2014 CS has eliminated the problematic language and this should no longer be an issue.

Also, Part 5 includes guidance specific to the Research and Development Cluster. Per Appendix V, there are two changes to Part 5: an updated reference regarding the NIH salary limitation and information specific to Hurricane Sandy Relief programs.

We encourage your institutions to review the key sections of the FY2014 CS, and if you have questions or comments, contact COGR staff. As appropriate, we will develop a formal comment letter to OMB prior to October 31, 2014.
New Audit Report from the HHS OIG

A recent audit report from the Department of Health and Human Services, Office of Inspector General (HHS OIG) is available at:

https://oig.hhs.gov/oas/reports/region4/41201016.asp

The University disagreed with the overall findings of the audit. The report states:

… (the University) did not always claim selected costs charged directly to HHS awards in accordance with Federal regulations and National Institutes of Health guidelines. In our sample of 112 salary transactions, 78 were allowable but 34 were not, and in our sample of 110 nonsalary transactions, 70 were allowable but 40 were not. On the basis of our sample results, we estimated that, of approximately $24.8 million in transactions, the University charged at least $6.4 million in unallowable transactions and related facilities and administrative costs to HHS awards during fiscal years 2010 and 2011.

These unallowable transactions occurred because the University did not provide adequate oversight to ensure consistent compliance with Federal regulations.

We recommended that the University:

(1) Refund $6.4 million to the Federal Government and

(2) Enhance oversight of charges to Federal awards to ensure consistent compliance with Federal regulations.

University officials disagreed with our overall findings.

We continue to monitor audit activity and implementation of the annual Audit Workplans for the HHS and NSF Offices of Inspectors General (OIG). In addition, we encourage you to regularly check the HHS (NIH) and NSF OIG websites (see links below). These sites provide access to published audit reports.

http://www.nsf.gov/oig/auditpubs.jsp

We always are interested in audit experiences at your institution so that we can update the general landscape for the membership – do not hesitate to contact us. We have the most access to HHS and NSF OIG initiatives, but also are interested in activity related to the OIGs at other agencies, as well as other internal and external audit activities.

NSF Inspector General Audit Findings at the University of California-Santa Barbara Reversed

After 3.5 years, the audit and audit resolution process at UC-Santa Barbara pertaining to costs incurred under NSF awards for the period January 1, 2008 to December 31, 2010, has finally
come to a conclusion. NSF management has upheld the findings of the Cost Analysis and Audit Resolution Branch (CAAR) after they did a complete analysis of the OIG audit. CAAR found that 99.3% of the expenses questioned in the OIG audit report were allowable, reducing the disallowance from $6,325,483 to $43,551. The decision is posted on the website of the NSF Office of Budget, Finance, and Award Management.

http://www.nsf.gov/bfa/responses.jsp

**We encourage everyone to read this report.** NSF management and the Audit Resolution staff provide detailed explanations for why the costs questioned by the OIG are, in fact, allowable costs, in important areas such as salary charges, cost sharing, cost transfers, and F&A costs, among others. This result highlights what COGR has advised its member institutions for some time – that although it can be time-consuming, it is worth challenging audit findings if you believe you can support the actions, policies, and costs questioned in an audit report.

**Other Costing Developments and Discussions**

Below are topics that are either new developments or items we have reported on in the past and continue to follow. If there are cost, financial, or audit related topics that you would like to discuss with COGR, please contact David Kennedy at dkenney@cogr.edu.

**NSF Dear Colleague Letter – ITRAK Conversion and ACM$ Payments.** A June 18, 2014 Dear Colleague Letter from NSF (NSF 14-083) announces that NSF will be implementing a new financial accounting system during October 2014. Leading up to the implementation, ACM$ will be temporarily unavailable beginning September 18th at 8:00 p.m. EDT through October 13, 2014. The letter goes on to describe the process for requesting funds by 8:00 p.m. EDT on September 18th. Throughout the upcoming summer months, the NSF Grantee Cash Management Section will be conducting multiple webinars and distributing additional guidance. Further information can be found in the link to Frequently Asked Questions (FAQs) on the ACM$ FAQ's. A copy of the letter can be found by googling “NSF 14-083”.

**Department of Energy (DOE), Office of High Energy Physics (OHEP).** In the May 23, 2012 COGR Update, we reported on effort and salary policies implemented by OHEP. This continues to be a concern, as OHEP limits salary support to $15,000/month. An additional concern was raised in OHEP’s budget guidance that appeared to restrict funding from other federal sources: i.e., *PIs [can] receive no more than 2 months summer salary from all federal sources*. COGR contacted OHEP and received the favorable response shown below. If this issue remains a concern for your institution, please contact COGR staff.

We have reviewed the budget guidance and *found that the sentence you referred to concerning funding from all federal sources was inadvertently included in the guidance letter and should be disregarded as it is not HEP policy [emphasis added]*. We note that HEP tries to optimize the number of research personnel supported by its financial assistance awards. As such, HEP may recommend downward adjustments to the budgets contained in the applications based on funds available. HEP may reduce support for Principal Investigators (PIs), co-PIs, and/or co-Investigators prior to considering any
reduction in support for postdocs or graduate students. Any recommended reduction in support will be made through a reduction in the supported level of effort with an attendant reduction in cost.

**Finance of Research Universities – 2014 Version.** COGR has released the 2014 version of its Finances of Research Universities analysis. The paper was first published in 2003 and updated in 2008. An Executive Summary will be available soon. The paper can be accessed at the COGR website at [www.cogr.edu](http://www.cogr.edu) (see Latest News, June 20, 2014).
CONTRACTS AND INTELLECTUAL PROPERTY

Committee:  David Winwood, Chair, Louisiana State University; Mark Crowell, University of Virginia; 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; Valerie McDevitt, University of South Florida; Fred Reinhart, University of Massachusetts; John Ritter, Princeton University; Wendy Streitz, University of California

NIST Discusses Joint Workshop on Tech Transfer Issues

The CIP Committee met with a number of representatives* from the National Institute of Standards and Technology (NIST), to discuss issues of concern in tech transfer. These included the domestic manufacturing waiver requirement under the Bayh-Dole Act, invention reporting, metrics and conflicts of interest.

The NIST representatives mentioned that agencies have been tasked by the Administration with implementing the Lab to Market initiative, following on the Lab to Market Summit workshop last year (see COGR June 2013 Meeting Report). This primarily involves the federal labs; however, there could be implications for universities, particularly if the result is “bad ideas.” With regard to manufacturing waivers, the NIST representatives conceded there have been problems with obtaining agency approvals; however, there is intense pressure from the Congress with regard to the need to facilitate more U.S. manufacturing. One issue of concern is that domestic manufacturing requirements may violate trade agreements to which the U.S. is a party. There is a lack of a clear process within the government to consider waiver requests.

On invention reporting, NIST recognizes there is some confusion and inconsistencies among agencies. Streamlining existing reporting requirements (and reducing duplicate reporting) would be in our mutual interests. Also the i-Edison system has no dedicated resources. On metrics, NIST and the agencies also face the familiar problems of the need to develop metrics for demonstrating the success of tech transfer and federal R&D (see COGR February 2012 Meeting Report). One option NIST is considering is to find ways to incentivize more economic publications on the impacts of research. They do not want to burden the community with requests for more data.

On conflicts of interest, the NIST representatives indicated that the fed labs have two issues: prior IP of researchers coming into the federal labs, which often requires waivers from the Office of Government Ethics (escrow accounts for any royalties that accrue is one mechanism that has been used); and the lack of mechanisms to facilitate entrepreneurial activities of researchers. Learning about university best practices in these areas might be helpful.
We discussed the possibility of a joint workshop to further discuss and explore these issues. An additional topic that might be discussed is comparative analyses of implementation of Bayh-Dole in other countries. NIST shares our interest in assuring that any changes in Bayh-Dole or the current implementing regulations at 37 CFR 404 be constructive. We plan to pursue the workshop idea with the other higher ed. associations.

*Henry Wixon, Chief Counsel; Paul Zielinski, Director, NIST Technology Partnerships Office (TPO) and Chair, Interagency Working Groups on Technology Transfer and Bayh-Dole; Courtney Silverthorne, Interagency Specialist, TPO.

**TRANSFER Act Advances in Congress**

We previously mentioned in the December 2013 COGR Update that the TRANSFER Act (Technology and Research Accelerating National Security and Future Economic Resiliency) had been approved by the House Science Committee. It was the subject of a hearing held last July by the House Science Subcommittee on Research and Technology (see August 2013 Update). Representatives Kilmer (D-WA) and Collins (R-NY) originally introduced the TRANSFER Act in the House (H.R. 2981), in August 2013.

The National Defense Authorization Act of 2015 (H.R. 4435), passed by the House on June 5, essentially incorporates the TRANSFER Act (Section 829). It amends the Small Business Act (15 U.S.C. 638(jj)) to provide that each of the five federal agencies required to establish an STTR program shall carry out a grant program to support innovative approaches to technology transfer at institutions of higher education to improve or accelerate the commercialization of federally funded research and technology by small business. The grants may include activities aimed at providing early stage proof-of-concept funding for translational research; identifying technologies that have the potential for accelerated commercialization; prototype construction, etc.; technical validations, market research and IP strategy; providing advice, mentoring and entrepreneurial education to innovators; and conducting outreach to small business. Among the proposal requirements is establishment of a program oversight board (COGR was not enthusiastic about this requirement when the TRANSFER Act first was proposed). Grants may be made up to an amount of $3M, to include individual projects of not more than $100k. The agencies are directed to spend .05% of their extramural research budgets on the program the next two fiscal years and 1% for the following two fiscal years. Agencies are required to develop evaluation plans with certain data elements and to submit evaluative reports that will be made public (we also had some concerns about these requirements).

On June 26 companion stand-alone legislation (S. 2551--“Innovative Approaches to Technology Transfer Grant Program”) was introduced in the Senate by Sens. Gillibrand (D--NY) and Coates (R--IN). The bill would allow institutions of higher education, technology transfer organizations, federal laboratories, public or private non-profit entities, or consortia of any of these types of organizations to apply for grants.

COGR did not formally join in the letter of support that was submitted by the other higher ed. associations last August; however, we support the general concept of the legislation. It will provide funding for activities that mostly fall in the gap between fundamental research and present SBIR/STTR funding. The higher ed. associations are discussing legislative strategy,
especially given expected opposition from the small business community and the corresponding Senate committee. We will keep the COGR membership informed.

**PTO Interpretation of Myriad Decision Raises Concerns**


The new procedure requires patent examiners to consider whether a patent claim recites or involves a judicial exception to patent eligibility (abstract ideas, laws of nature/natural principles, natural phenomena, and natural products). If so, the claim must recite something significantly different than the judicial exception (see chart on page 2 of the Guidance), based on an analysis of 12 factors. Claimed subject matter involving natural products includes chemicals derived from natural sources (e.g. antibiotics), metals and metallic compounds that exist in nature, nucleic acids, organisms, proteins, and other substances found in or derived from nature. “Significant differences” must involve features or steps demonstrating that the claimed subject matter is markedly different from what exists in nature. A series of examples are given of applying the factors for and against eligibility. One example is purified “amazonic acid” from the leaves of the Amazonian cherry tree useful for treating cancer. The purified acid is not structurally different from the natural product, and not patentable. However a chemical derivative of the acid created in a laboratory that is both structurally different and results in a functional difference (stimulates the growth of hair) is patentable. Other examples include process claims. One involves a patient with mood disorders exposed to sunlight, synthetic white light, and another claim involving filtering the light and positioning the patient in certain ways. A well-established natural principle is that exposure to light affects a person’s mood, so the first two claims fail. However, the filtering and positioning steps involves a significantly different practical application of the natural principle, and is eligible subject matter.

The reaction to the Guidance from the patent community has been strongly negative. PTO held a public forum on May 9 to receive public feedback. Comments and presentations may be found at [http://www.uspto.gov/patents/announce/myriad-mayo.jsp](http://www.uspto.gov/patents/announce/myriad-mayo.jsp). The thrust of the comments was that the Guidance was overly broad, in contravention of the Supreme Court’s warning in Mayo against overly broad applications that might stifle innovation. There was strong criticism of the emphasis on structure rather than the functional characteristics of a product. PTO was asked why it chose the broadest interpretation of the cases that would invalidate patents on antibiotics or vaccines. There also were suggestions that patent examiners did not understand or believe in the new Guidance (PTO has indicated that it plans to provide additional examiner training).

The BIO statement criticized PTO for assuming a judicial function in reinterpreting Supreme Court caselaw, with no opportunity for public comment. BIO stated “Expanding *Myriad’s* holding to all claims to isolated or purified natural molecules like antibiotics and other medicinal substances, and combinations thereof, and fermentation or distillation products or bacterial...
enzymes, will not only prospectively block inventors from acquiring commercially meaningful protection for products that were ever even mentioned by the Supreme Court. Doing so also casts a shadow over thousands of issued patents that the PTO now says would never be issued if they were examined today and--implicitly-- should never have been issued in the first place.” BIO also stated the belief that “Supreme Court precedent stands in tension with itself. It has split the lower and intermediate courts and has spawned endless legal commentary….There is no unified reading (of the Supreme Court precedents) that is fully coherent…We need the PTO to acknowledge that reality. And we need a dialogue not only over how best to interpret the caselaw … but also whether that caselaw leads us to the right place.”

There also was discussion at the recent NACUA conference of the new Guidance. It appears there are two major issues from a university perspective:

1) To patent a product purified from a natural source such as a drug, the claimed product must be both structurally and functionally different from its natural state. In the past PTO has granted patents on purified natural products with practical utility. PTO’s position is not supported by caselaw, except for Myriad which was limited to isolated segments of DNA. Earlier cases emphasized functionality.

2) Simple diagnostic assays are no longer patentable since they are considered to be natural phenomena that are discovered rather than invented. The claimed diagnostic now must contain significantly more than the correlation between the marker and the condition, but it is not clear what that something more must be, perhaps even to PTO.

PTO has indicated that it will be updating the Guidance, and has extended the period for public comment until July 31, 2014. Submission of comments may be more appropriate for AUTM than COGR, and we have called the matter to AUTM’s attention. However, we may consider joining should AUTM choose to submit comments, depending on the degree of specificity.

“Demand Letter” Federal Legislation May Be Resurrected

One of the most contentious issues in the ongoing debate over patent troll legislation has been the perceived need to address the issue of demand letters. 13 states led originally by Vermont now have enacted legislation aimed at curbing bad faith patent infringement notifications. Most but not all carve out original inventors and institutions of higher education and affiliated tech transfer organizations. 3 more states have passed legislation that is awaiting gubernatorial approval, and legislation is pending in 4 others.

Sen. McCaskill (D--MO) had introduced similar legislation at the federal level in February but subsequently withdrew it, after concerns were expressed particularly about giving the Federal Trade Commission (FTC) broad enforcement power in this area (although the FTC has claimed that it may already have such power--see COGR April 2014 Update). The House Energy and Commerce Committee now is discussing draft legislation that would make it an unfair or deceptive practice to assert patent infringement in bad faith. It also would give the FTC specific enforcement authority. Importantly the bill would preempt any state laws on patent demand
letters, although it also would authorize state attorney generals to bring civil actions in federal
district courts for violations.
The draft legislation is more narrowly drawn than the previous McCaskill bill, although concerns
remain about inserting the FTC into patent licensing and enforcement. One issue is what
constitutes ‘bad faith” for these purposes. The higher ed. associations that have worked together
on the troll legislation are continuing to follow developments. From our perspective federal
preemption may be more desirable than a patchwork of state laws in this area.

**AIA “Grace Period” Redux?**

In previous COGR Updates and Meeting Reports we extensively discussed the problems for
scientific publications resulting from the PTO interpretation of the America Invents Act (AIA)
grace period. Under the PTO Examination Guidelines, in order for the one-year grace period for
public disclosures in the AIA to apply under the “first inventor to file” system, the Guidelines
state that the subject matter disclosed must be identical. Insubstantial changes or obvious
variations to the subject matter disclosed are not covered by the grace period (and thus do not fall
within the shield provided by the grace period prior art exception). This essentially guts the
grace period for scientific publications that the higher ed. associations fought hard to maintain
throughout the patent reform process. We strongly objected to PTO when the Guidelines were
proposed, stating that we would not have supported the AIA had this interpretation been
advanced during the patent reform process (see COGR October 2012 Update for a full
discussion).

While recently this has been something of a “back burner” issue, the higher ed. associations
remain determined to address it. It will require an amendment to the AIA. This matter has been
under discussion between the higher ed. associations and Congressional staff. We hope that
legislation may be introduced in this session of Congress in both the House and Senate. While it
is very unlikely that Congress will act this year, such legislation would provide a “marker” for
Congressional action in the next term.
RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: James Tracy, Chair, University of Kentucky; Lois Brako, University of Michigan; Pamela Caudill, Harvard University; Michael Ludwig, Purdue University; Susan Sedwick, University of Texas, Austin; Pamela Webb, University of Minnesota; Kathleen Delehoy, Colorado State University; Walter Goldschmidts, Cold Spring Harbor Laboratory; Suzanne Rivera, Case Western Reserve University

NSF Update

The Research Compliance and Administration (RCA) Committee had an always agreeable and informative meeting with Jean Feldman, head of the National Science Foundation (NSF) Policy Office to talk about anything but the implementation of the Office of Management and Budget (OMB) Uniform Guidance. Feldman alerted us to the now issued (June 14, 2014) Dear Colleague letter announcing the conversion to iTrak and shutdown of the Award Cash Management Service (ACMS) from September 18 through October 14 (see the Costing Policies Committee report for details). This notice reminds institutions to be prepared, in general, for the close of the Federal fiscal year on September 30, 2014 and the need for timely responses to just-in-time requests for approvals as all the agencies seek to make awards before the conclusion of the FY 2014.

Feldman confirmed that the March 28, 2014 Important Notice to Presidents (Notice No. 136) concerning Abstracts and Titles does not signal any change in policy but, rather, serves to highlight the need for the continuing cooperation of investigators as NSF creates and/or modifies titles and prepares abstracts for public posting. NSF finds all investigators to be helpful but institutions should remind investigators to be attentive to requests for help from NSF program officers as the program officers prepare materials for the public.

The discussion of the iTrak conversion and just-in-time requests led to a discussion of the National Science Board’s (NSB) report on Reducing Investigators Administrative Workload and those recommendations directed toward the expansion of the use of the just-in-time mechanism. Feldman noted that discussions are underway at NSF to consider what aspects of the application and award process could be changed to accommodate just-in-time. RCA members urged NSF to pay particular attention to the budget in applications arguing that virtually every budget submitted to NSF is modified before an award is made and that it’s an area ripe for change.

The question of the burden of reporting echoed throughout the responses the NSB received from investigators. NSF hopes that as investigators become more accustomed to using the Research Performance Progress Report (RPFR) and its use expands across the agencies under the Uniform Guidance from OMB, investigators will be able to anticipate what they need for reports and will find the process easier, easing the burden over time. The ease of familiarity will be strengthened
if the proposed extension of the RPPR for final as well as interim or annual reports is implemented.

As we reported in the April 2014 COGR Update, the Research Business Models (RBM) Interagency Working Group of the National Science and Technology Council (NSTC) proposed revisions or updates to RPPR on March 11, 2014. The major goal of the proposed revision is to provide sufficient flexibility in the format to allow it to be used for final reports. COGR submitted comments on the proposed format (see the May 12, 2104 letter on the COGR website under Latest News, www.cogr.edu).

In our comment, COGR raised its continuing concern with increasing the number of data elements that investigators must provide, expanded in the proposed revision to a “Researcher Identifier” and place of residence. We raised concerns with ambiguous language notably in the request for an indication of changes in “active other support” and the suggested need for prior agency approval. NSF acted as the agent for the RBM in this request for comment.

**NIH Public Access Requirement**

As you know, since 2008 the National Institutes of Health (NIH) has had a Public Access policy that requires the all peer-reviewed manuscripts from research supported in whole or in part by NIH direct costs and accepted for publication be posted to PubMed Central. In November 2012, NIH announced that beginning in the Spring, 2013, it would delay the processing of non-competing continuation grant awards if publications arising from that award are not in compliance with the NIH public access policy. NIH made various enhancements to its systems to assist in the identification and processing of publications in PubMed Central.

We have heard recently of a number of problems confronted by investigators in meeting this requirement with the result that awards have been delayed for several months. Some are attributable to investigator delays and inexperience but an increasing number appear to arise from NIH procedures that fall outside an individual investigators control and others to the relationships NIH has established which have become unreliable. For example, processing through PubMed Central can take more than ten weeks and varying policy interpretations of “compliance” by NIH grant specialists result in different award decisions. Delays and inaccuracies in the Public Access Compliance Monitor result in delayed in awards and the inaction of publishers listed on the roster of journals – a list that is inaccurate – cause further confusion and delays.

COGR is preparing a summary of the problems that we will address to NIH to determine if there are modifications in the design of the system or the procedures that can assist investigators in meeting their obligations. We welcome your comments (cblum@cogr.edu) and will keep the membership informed of the discussions and progress.

**Effective Management Practices**

A working group convened by RCA with representatives from additional COGR members has begun a revision of COGR’s Managing Externally Funded Research Programs: A Guide to Effective Management Practices. First published in 1989, this will be the seventh edition of the
Guide to Effective Practices. The working group anticipates a thorough restructuring of the Guide to reflect the most current management practices. The goal is to issue the revised edition no later than Spring 2015.

Regulatory Burden

The National Research Council (NRC) received $1 million to conduct the Higher Education Opportunity Act of 2008 (HEOA) mandated study of regulatory burden. Section 1106 of HEOA directed the Secretary of the Department of Education to enter into an agreement with the NRC to determine the number and scope of Federal regulations and reporting requirements with which higher education institutions must comply. At the time, Congress failed to appropriate funds to support the study. The Consolidated Appropriations Act of 2014 provides $1 million for the study. In addition to the number and scope of the regulations, NRC is asked to estimate the time and costs to institutions required to comply with the regulations and reporting requirements. Finally, NRC is asked to make recommendations for consolidating, streamlining, and eliminating redundant and burdensome Federal regulations and reporting requirements affecting institutions of higher education. We know that the NRC has begun to organize the study and in anticipation of the inevitable question, RCA has begun (another) examination of the primary or “top ten” regulations we’d recommend for review and consolidation, streamlining, or elimination.

Creating a list of burdensome regulations seems easy but once you get past effort reporting (on the list) identifying those regulations or parts of regulations, quantifying the costs and designing useful alternatives is a challenge. RCA began developing a framework for consideration by the NRC that describes the challenge, offers specific examples, and, eventually, offers changes to reduce the burden.

For example, rather than calling for harmonization of regulations, we want to identify Conflicting or Overlapping Regulations that are different enough to place the institution at risk of non-compliance or result in repetitive oversight of the same activity. Examples include the differences in self-reporting requirements of the PHS/NIH’s Office of Laboratory Animal Welfare (OLAW) and the US Department of Agriculture Animal and Plant Health Inspection Service (APHIS). Differences in the policies and regulations in the management of human subjects research including Federal privacy rules is another area ripe for harmonization. Recently, the constellation of agencies and regulations addressing foreign nationals as students and scholars has created a toxic environment that can create discriminatory practices in access and assignments. All of these regulations deserve review and, at least, modification to ease the burden and ensure the unimpeded conduct of research.

Another area is Poorly or Inadequately Implemented Regulations. The burden is not created by the regulation, per se, but inadequate or failed implementation – either under-resourced efforts like federal FFATA reports on USASPENDING.gov or inadequately trained federal officers. We talked about the area of Enforcement and Oversight. We know that it drives institutional risk adverse behaviors and hope to highlight areas in which agencies can take a more performance-based and global approach to inspections and audits. Finally, we examined the opportunity in shifting requirements from applications to awards. It could be an opportunity to “institutionalize” just-in-time approaches. For example, requiring the disclosure, review, determination and reporting, if necessary, of financial conflicts of interests as a part of
the award process rather than the application process would allow institutions to focus on those investigators and activities that will be funded rather than the universe of applicants.

We will consult with the membership as this process of identifying examples and building the rationales for changes continues and the NRC study gets underway.