

COUNCIL ON GOVERNMENTAL RELATIONS

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TO: COGR Membership

FROM: COGR Staff

SUBJECT: Fall 2012 Update

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Grants Reform and OMB Circular A-21 Update – OMB PROPOSES NEW CIRCULAR

After a relatively quiet summer on the topic of “Grants Reform”, COGR expects that the Office of Management and Budget (OMB) will release a proposed new Circular soon after the Labor Day weekend. COGR understands the proposed new Circular will be published in the Federal Register in the form of a “Consolidated Circular” that combines eight existing circulars into a single OMB guidance document.

As of the writing of this section of the COGR Update, the proposed new Circular has not been released by OMB. However, upon its release, COGR will provide regular updates to the COGR membership via the COGR ListServe.

At this moment, we can only speculate what the format will be for the proposed new Circular. It may be reasonable to assume that it will be presented as a single document, with three distinct sections: Administrative Requirements (A-110 and A-102), Audit (A-133 and A-50) and Cost Principles (A-21, A-122, A-87, and Hospital). Within each distinct section, the consolidation would vary – for example, A-133 (Single Audit) and A-50 (Audit Follow-up) would seem to have little overlap. On the other hand, and as we have heard from OMB on several occasions, consolidation of the Cost Principles would be a more significant update to the Circular and would include special carve-outs/exceptions for each type of performer (i.e., definitions for organized research, application of the 1.3% UCA and the 26% administrative cap, etc. still would be applicable to colleges and universities only). Other more generic cost treatments would be captured in a section applicable to all entities.

COGR is poised to take a lead role in crafting a response to the proposed new Circular. Below are preliminary observations and game plan for the next steps.

Public Comment Period for the Proposed New Circular

There will be a 60-day Public Comment period to make comments to the proposed new Circular. COGR will engage immediately to complete a detailed and thorough review that will require a side-by-side analysis of the proposed new Circular compared with the existing circulars that currently apply to our community. This will be an intense project with the greatest risk possibly being the unintended consequence where an “under the radar” change via consolidation results in change that has significant repercussions.

The Council on Financial Assistance Reform (COFAR), officially, is the important government-wide entity responsible for the oversight of the grants reform process. An October 27, 2011 OMB Memorandum M-12-01, *Creation of the Council on Financial Assistance Reform*, established the COFAR. The COFAR is comprised of OMB’s Office of Federal Financial Management, the Chief Financial Officers from the eight largest grant-making agencies, and one additional rotating member which for the first two-year term is NSF. The COFAR is co-chaired by OMB and the Department of Health and Human Services. COGR’s primary correspondence continues to be with OMB, though we will engage with the COFAR, as appropriate.

We believe OMB may sponsor a Webinar later in September to serve as a public forum for the research community to ask questions specific to the proposed new Circular. If the Webinar is scheduled to take place, COGR expects to communicate with OMB prior to the Webinar, and as appropriate, provide OMB with preliminary comments and questions.

The COGR Costing Committee has scheduled a two-day meeting in mid-September to review the proposed new Circular. This meeting will serve as a formal venue to do the side-by-side analysis between the proposed new Circular and the current circulars, to develop strong responses to those items that may be problematic, and to advance any ideas that we believe were not appropriately addressed in the proposed new Circular. While we will welcome input from the COGR membership throughout the 60-day Public Comment period, feedback that you can provide prior to the mid-September meeting will be timely and appreciated.

We plan to employ a similar strategy to the one we used to respond to both the June 28, 2011 – Request for Information: *Input on Reduction of Cost and Burden Associated with Federal Cost Principles (OMB Circular A-21)* and the February 28, 2012 – Federal Register, Advance Notice

of Proposed Guidance (ANPG): *Reform of Federal Policies Relating to Grants and Cooperative Agreements: Cost Principles and Administrative Requirements (including Single Audit Act)*. In both instances, COGR shared talking points and draft responses with the membership via postings on the COGR ListServe.

Finally, a post-Labor Day weekend release date would target the 60-day Public Comment period to result in a due date in early November. Consequently, one of the morning sessions at the October 25th COGR Meeting likely will be a session that addresses the COGR Response to the proposed new Circular. It will be a major community effort to develop the response – and in addition to the COGR Response, your institutions also will submit responses to OMB. The formal COGR game plan, in combination with the vast wealth of expertise that many of you have, will be crucial to an effective response – we also will rely on the informal network and sharing of your observations as you independently read through the proposed new Circular. We are paying close attention to all developments and will keep the membership posted.

National Research Council (NRC) Report on Research Universities Now Available

As COGR reported in the June 2012 Meeting Report (June 28, 2012), the NRC Committee on Research Universities released the report: *Research Universities and the Future of America: Ten Breakthrough Actions Vital to Our Nation's Prosperity and Security*. The report was made available to the public on June 14th. The Full Report and the Summary version are available at: <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=13396>

In the report (see Summary version, page 3), the committee makes ten major recommendations, including a strong call for Revitalizing the Partnership: *“It is essential that we as a nation reaffirm, revitalize, and strengthen substantially the unique partnership that has long existed among the nation’s research universities, the federal government, the states, and philanthropy by enhancing their individual roles and the links among them and also by providing incentives for stronger partnership with business and industry. In doing so, we will encourage the ideas and innovations that will lead to more high-end jobs, increased incomes, and the national security, health, and prosperity we expect.”*

Of the ten recommendations (also see Summary version), four (note, we initially reported on only three) are of particular interest and two of these (Recommendations 6 and 7) are ones that COGR advocated to the NRC Committee. Recommendations 6 and 7 also are related to recent COGR interactions with OMB on grants reform and could provide leverage in that arena:

- **Recommendation 3. Strengthening Partnerships with Business.** Strengthening the business role in the research partnership, facilitating the transfer of knowledge, ideas, and technology to society, and accelerate “time-to-innovation” in order to achieve our national goals.
- **Recommendation 4. Improving University Productivity.** Increase university cost-effectiveness and productivity in order to provide a greater return on investment for taxpayers, philanthropists, corporations, foundations, and other research sponsors.
- **Recommendation 6. Full Federal Funding of Research.** The federal government and other research sponsors should strive to cover the full costs of research projects and other activities they procure from research universities in a consistent and transparent manner.

- **Recommendation 7. Reducing Regulatory Burdens.** Reduce or eliminate regulations that increase administrative costs, impede research productivity, and deflect creative energy without substantially improving the research environment.

Over the course of then next year, NRC Committee members will be meeting with stakeholders across the country to seek further input and advocate for implementation of the recommendations. NRC Committee members have been invited to the October COGR meeting to discuss concrete actions needed to achieve the goals outlined in the NRC report.

SWAP Agreements and Similar Financing Arrangements are Determined by OMB and ONR to be Allowable

The OMB ANPG on Grants Reform included the following “reform idea”: *Specifying that gains and/or losses due to speculative financing arrangements are unallowable.* While the gains and/or losses normally would be unallowable, additional language in the ANPG related to this “reform idea” further suggested the interest expense associated with any financing arrangement deemed “speculative” would be unallowable in an institution’s F&A rate.

COGR did not support this “reform idea” and maintained in the COGR response that thoughtful and effective use of all available debt financing arrangements can result in significant cost savings. The Office of Naval Research (ONR) and the Defense Contracting and Audit Agency (DCAA) over the past several months, however, disallowed interest expense for at least three institutions based on what they considered inappropriate debt financing arrangements. While COGR does not engage in specific F&A rate negotiations on behalf of an institution, we do engage on an issue if OMB policy guidelines are not being followed and there could be significant repercussions to the entire research community. The fact that the financing arrangements in question are legitimate, result in significant cost savings, and are not disallowed according to current OMB policy compelled us to engage further on this issue.

After providing documentation to OMB and ONR specific to SWAP agreements and participating in a conference call that included four COGR member institutions, COGR, and representatives from OMB, the Department of the Treasury, and ONR, ONR reconsidered its position concerning SWAP agreements. OMB concurred and interest expense associated with SWAP agreements has been determined to be allowable.

In the aftermath, it seems as though there were a number of issues and rationalizations that resulted in ONR and DCAA to initially rule that interest associated with SWAP agreements was unallowable, including: SWAP agreements are “contingencies” and per Circular A-21, contingencies are unallowable; interest expense, in some cases, is reported as a non-operating expense and therefore is unallowable; and the OMB “reform idea” that would make similar financing arrangements unallowable necessitated that the interest expense be treated as unallowable. And not to be underestimated as a cause for concern was the general misunderstanding as to the mechanics behind a SWAP agreement.

However, after the thoughtful and productive correspondences between all parties, all of the objections by ONR and DCAA were successfully refuted. Using the simplest explanation, a SWAP agreement allows an institution to take advantage of lower interest rates, while

minimizing the volatility and risk associated with those rates. Below is a simplified example of an interest rate SWAP agreement:

- The institution issues variable rate bonds (e.g., at 1%) rather than higher priced fixed rate bonds (e.g., 5%) and pays the bondholders, accordingly.
- Concurrently, the institution enters into a SWAP agreement with a 3rd party (e.g., an investment firm).
- The SWAP agreement with the 3rd party establishes a fixed rate (e.g., 3.5%) that the institution pays to the 3rd party.
- The SWAP agreement also establishes that the 3rd party will make a payment to the institution at a rate that correlates to the variable rate payment (1%) that the institution made to the bondholders.
- In effect, the variable rate payment to the bondholders is netted to zero (it may be plus or minus depending on market conditions), and the university outlay, consequently, is approximately the 3.5% payment to the 3rd party.
- All stakeholders (i.e., the institution and its students, the Federal Government) benefit in that the net interest expense is approximately 3.5% rather than the higher priced fixed rate bonds at 5%.

The four COGR member institutions that were involved in this process did incredible work to provide documentation, simplify the discussion, and answer all questions and concerns in a straightforward and convincing manner. Documentation that COGR provided to the Federal officials in response to their initial questions is available upon request. And if you have additional questions, contact David Kennedy at dkennedy@cogr.edu.

Audit Update: Administrative and Clerical Audit, \$2.9 Million Finding

COGR has followed developments on the audit program entitled, *College and University Indirect Costs Claimed as Direct Costs*, being conducted by the Department of Health and Human Services (HHS), Office of Inspector General (OIG). We have commonly referenced to this audit initiative as the “Administrative and Clerical” audit program. Eight institutions were selected from across the country, and over the past year three audits have been completed and the audit reports have been posted to HHS OIG website (see links below and in following section).

The three audit reports that were posted through the end of 2011 included minor cost disallowances and did not indicate any systematic or serious issues. However, the most recent report, posted by the HHS OIG on July 19, 2012, included these recommendations:

We [HHS OIG] recommend that the University:

- *refund \$2,977,548 to the Federal Government and*
- *enhance oversight of charges to Federal awards to ensure consistent compliance with Federal regulations.*

The HHS OIG sampled 100 salary transactions and 100 non-salary transactions associated with costs claimed on HHS awards (mostly NIH awards, though also awards from other HHS components) for the period October 1, 2008 through September 30, 2010. The University took exception to and provided additional documentation for most of the transactions that the HHS

OIG deemed as unallowable. The HHS OIG reduced the number of unallowable transactions, and consequently, reduced the recommended refund amount from \$5.8 million to \$2.9 million.

The University also took exception to the HHS OIG methodology for extrapolating the results of the 100 salary transactions and 100 non-salary transactions, as well as taking exception to the HHS OIG conclusion that the University has weaknesses in its internal controls.

The HHS OIG recommendations are not final. An official from the HHS Division of Audit Resolution, Office of Grant and Acquisition Management, is responsible for making final determination on the HHS OIG recommendations. The HHS OIG audit report is available at: <http://oig.hhs.gov/oas/reports/region4/41101095.asp>

The issues raised in the audit report are broad. The audit report opens up discussions on the use of job titles and the actual duties and activities associated with a job title; allowable activities for direct charging; consistency of effort reporting with what has been directly charged; the functional use of space in a lab and its correlation to which awards are charged; composition of recharge and specialized service facility rates; graduate student compensation and compliance with NIH limitations; allocability and reasonableness decisions and methodologies utilized by the institution; and the appropriate level of central oversight and review of direct charging practices and the corresponding documentation required.

For several years, COGR has closely paid attention to the findings and issues associated with this HHS OIG audit initiative. In fact, the HHS OIG conducted a pilot covering 4 institutions prior to the 8 under the current initiative. In the pilot of 4, audit reports were posted in 2007, 2008, and 2009 – two audit reports included no findings, one resulted in more significant recommended disallowances, and one remains unconcluded. The one that remains unconcluded has been cloaked in some mystery and the extent of the potential findings remains unknown.

As is the case with many audit pilot programs, extending it to cover more institutions often is determined by the results of the pilot. Most likely, the HHS OIG findings from the pilot of 4 prompted them to pursue a continuation of the audit program to the 8 additional institutions. One observation by COGR is that the significant cost disallowances and recommended refunds, covering both the pilot of 4 and the 8 subsequent institutions, have been associated with HHS Region 4 – this region covers Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee. Interestingly, we were contacted by a COGR member institution last month and were told they were just selected for a new “Administrative and Clerical” audit – not surprisingly, this institution is located in Region 4.

COGR will continue to follow the status of those Administrative and Clerical audits not completed, as well as any follow-up or repercussions associated with the most recent audit report.

Audit Update: General

COGR regularly checks the HHS (NIH) and NSF Office of Inspectors General (OIG) websites (see links below).

<http://oig.hhs.gov/reports-and-publications/oas/nih.asp>

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

There are now eight audits of NIH ARRA awards that are posted on the HHS (NIH) OIG website. The first seven audits posted were audits of NIH ARRA awards for colleges and universities – in each case, there were no findings, no cost disallowances, and no recommendations.

The eighth and most recent audit of an NIH ARRA award included a complete disallowance of all expenditures on the award. Syntrix Biosystems, Inc. (Syntrix) is a private, Washington State-based biotechnology company dedicated to developing and commercializing therapeutic compounds and research platforms for the pharmaceutical, biotechnology, and research markets. The complete disallowance of \$200,000 of expenditures (direct and indirect) was based on the HHS OIG position that Syntrix did not adhere to its policies for recording and distributing employees' time and attendance. Private industry is not subject to the same OMB Circular A-21 payroll distribution and effort reporting rules as colleges and universities, so there is not likely to be any repercussion to the higher education community. However, the Syntrix audit can be a helpful reminder of the importance of supporting salary charges made to federal awards.

Two other notes as COGR follows other audit developments:

- The 2012 A-133 Compliance Supplement was released in July. Several issues, including a clause that would have required all NSF awards to be reported in the R&D cluster (also see update in next section), delayed the release. The 2012 A-133 Compliance Supplement is posted at:
http://www.whitehouse.gov/omb/circulars/a133_compliance_supplement_2012
- We have been informed by a COGR member institution that they have been selected by the NSF OIG for an open-ended audit that is premised on a new audit approach that the NSF OIG describes as “data analytics.” COGR shared this with the membership in COGR Updates late last year after we met with NSF OIG staff. Under this approach, the NSF OIG asks institutions for an electronic version of the General Ledger, specifically, NSF funds and accounts. Based on various analytical techniques, NSF OIG staff looks for indicators that suggest audit risk or need for additional information. Our initial understanding was that between 10 and 20 institutions would be audited in FY2012 using the new methodology. To date, we are aware of the one institution that contacted us.

Also of interest may be the NSF OIG approach as described on pages 8 and 9 of the 2012 NSF OIG Workplan (see <http://www.nsf.gov/oig/FY12auditworkplan.pdf>): *“[The Office of Audit] also identifies risk by analyzing multiple NSF databases using data analytics, which increases the probability of identifying risk because it enables the examination of 100 percent of transactions. Data analytics is useful in identifying risk at all stages of grants ... at the preaward stage, risks would include inflated budgets and conflicts of interest among proposal reviewers. At the active award stage risks would include unusual burn rates (e.g., expenditures for equipment at the end of an award), excess cash on hand ... or inadequate project reports. Red flags at the end of an award include multiple post-closeout financial adjustments.”*

COGR always is 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 OIG 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.

Other Costing Developments and Discussions

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

2012 A-133 Compliance Supplement and NSF Awards. Normally, the A-133 Compliance Supplement is available in March. There were a number of reasons for the delay; one item that was applicable to research institutions. For our community, at issue was a “last second” insertion of guidance that would have required all NSF awards to be reported on the SEFA as part of the R&D Cluster, and consequently, to be treated as “organized research” for F&A rate development purposes. Upon raising our concerns with OMB, the “organized research” treatment language was eliminated. Still, we objected to the requirement where all NSF awards be reported on the SEFA as part of the R&D Cluster (in short, some NSF awards are not R&D). After discussions with OMB, NSF, and NSF OIG personnel, OMB agreed to remove the entire insertion from the A-133 Compliance Supplement. The 2012 A-133 Compliance Supplement was released in July and is now available (see previous section).

NOTE ON NSF PAPPG (2012 DRAFT VERSION): The draft version of the 2012 NSF Proposal & Award Policies & Procedures Guide (PAPPG) includes the same insertion that NSF awards should be part of the R&D Cluster on the institution's SEFA (see page 3, Chapter II.F. Records Retention and Audit, per the link to the PAPPG below). COGR comments on the draft version of the PAPPG were sent to NSF and we requested that this language not be included in the final version of the PAPPG. We are waiting to see how NSF responds to our objection.

http://www.nsf.gov/bfa/dias/policy/papp/pappg2012_draft.pdf

NSF Survey Results on R&D Expenditures, FY2010. The National Science Foundation, National Center for Science and Engineering Statistics (NCSES), recently released results from the FY2010 Higher Education Research and Development (HERD) Survey. The FY2010 report represents the first year of the new survey format and includes new data points such as expenditures funded by Nonprofit organizations and a more detailed breakdown on Institutional funded expenditures (i.e., unrecovered indirect costs, cost sharing, and internal research projects). The report can be found at:

<http://www.nsf.gov/statistics/infbrief/nsf12313/>

NOTE ON “INSTITUTIONAL FUNDS” EXPENDED AS R&D: The section on “Institutional Funds” expended as R&D highlights differences between how research institutions report this amount and it raises questions that may be pursued further by the COGR Costing Committee. As the differences in reporting get raised in a number of forums, it may behoove COGR to better understand who at your institution collects and reports this data, what is included, and why some institutions report unusually low numbers in comparison to other institutions.

NIH Salary Limitation and an NHLBI Contract Clause – RESOLUTION. We have reported on an issue regarding contracts issued by the National Heart, Lung, and Blood

Institute (NHLBI) over the past several months – NHLBI initially implemented the new NIH Executive Level II Salary Limitation in a manner inconsistent with prior NIH guidance. In the past two COGR Updates, we reported on a favorable resolution. After corresponding with staff from the NIH Office of Acquisition Management and Policy (OAMP) and the NIH Division of Acquisition Policy and Evaluation (DAPE), the Directors of OAMP and DAPE confirmed that NIH Acquisition and Contracts policy was meant to be consistent with the January 2012 NIH Notice (NOT-OD-12-035) and subsequent FAQs – i.e., the Executive Level I salary limitation should be used for the FY2012 contracts in question. While there was at least one NHLBI Contracting Officer that delayed implementation of the correct treatment, COGR understands that the correct policy now is being uniformly implemented at NHLBI. However, if your institution has not resolved this situation with NHLBI, please contact COGR staff.

Final FAR Rule on FFATA Reporting Requirements Published

The COGR Late Summer 2010 Update summarized the interim FAR rule (*75FedReg39414*) requiring prime contractors to report first tier subcontracts of \$25,000 or more to a public website (Federal Funding and Accountability and Transparency Act Subaward Reporting System (FSRS--www.fsrs.gov). In addition, contractors must report to a different website (www.ccr.gov) the names and total compensation of the contractor's five most highly compensated executives as part of the annual Central Contractor Registration (CCR) requirement. Comparable compensation information for first tier subcontractors reported in the FSRS must be reported to FSRS. Entities with gross income under \$300,000 are exempted from reporting the first tier subcontract information, and the compensation information is not required unless the contractor or subcontractor receives 80% or more and \$25M or more of its gross revenue from Federal awards and the public does not otherwise have access to the compensation information through SEC or IRS reports. These requirements, while similar to (but less detailed than) ARRA reporting, implement the '06 Federal Funding Accountability and Transparency Act (FFATA) which required OMB to establish a public website containing full disclosure of Federal award information, to deter "wasteful and unnecessary spending." Similar but not completely identical requirements apply to federal financial assistance (see COGR Fall 2010 Update; the main difference is that the financial assistance requirements cover only subawards and exempt contracts with vendors for supplies or services).

COGR commented on the interim FAR rule on September 7, 2010. In the comments we pointed out our repeated expressions of concern to the FAR Councils on inconsistencies among similar requirements such as FFATA between federal assistance awards and procurement contracts. We urged that the FAR rule incorporate the federal assistance definition of "subaward," and the reporting requirements be consistent. We also pointed out potential compliance issues for contracts subject to disclosure restrictions such as DFARS 252.204-7000, and urged the FAR Councils to consider developing an alternative clause for research contracts with educational and non-profit organizations.

On July 26, 2012 the final FAR rule on FFATA reporting was published (*77FedReg44047*). There are relatively few changes from the interim rule. The two most significant changes are to remove the exemption for classified contracts since the statute exempts only "classified information," and to delete the exception for contracts with individuals, since that is not included in the statute. The notice repeatedly cites the need for consistency in implementation of FFATA. Removing the exemption for classified contracts does not appear to much impact universities

since relatively few perform classified contracts. On the other hand, removing the exemption for individuals may have a more significant impact, since most universities engage a substantial number of independent contractors (although presumably in such cases the executive compensation reporting requirement would apply only to the individual).

As usual, the COGR comments were ignored or dismissed by the FAR Councils. With regard to adding “subaward” to the FAR rule, the Federal Register notice notes that the term is not used in the rule and providing a definition for it “would not be prudent.” With regard to contracts with disclosure restrictions, the notice cites the FFATA and states “there appears to be no conflict with the intent of the statute.” These responses basically ignore the issues raised in the COGR letter.

Most universities will be exempted from reporting compensation under the public availability exception. However, subcontractors including vendors will be covered by the FAR reporting requirements (except for long term supplier contracts that benefit multiple contracts or are covered out of general and administrative or indirect costs). The rule is effective August 27.

Export Control Developments

- a) **Commerce “Deep Dive” Space Industry Survey Raises Concerns** - A large number of COGR member institutions have received a Space Industry “Deep Dive” survey from the Commerce Bureau of Industry and Security (BIS). The survey is divided into 15 sections, with subparts. It requests detailed information about the institution, its involvement in specific space-related product and service “segments,” participation in government space programs, customers, competitors, manufacturing and business operations, sales, export control licenses, R&D expenditures, etc. Many of the survey categories are of limited applicability to universities. Institutions are required to complete the survey within 30 calendar days.

In response to many expressions of concern from COGR members, COGR contacted BIS and arranged a conference call between BIS and approximately two dozen universities (BIS requested that we not open the call to the entire COGR membership). The call was held on July 12. BIS briefly reviewed the history of industrial base assessments and the importance of mapping the space industry supply chain, especially in view of possible budget cuts and sequestration. A number of agencies are funding the survey. Strong university input is needed. BIS recognizes the uniqueness of universities as organizations and sought to tailor the survey template. However, BIS conceded that the survey basically had been designed for industry. In response to a question, BIS indicated that the survey was beta tested with a few universities.

In the discussion COGR member representatives indicated that the 14 hours estimated for response was grossly understated, perhaps by a factor of five. In many cases individual faculty need to be consulted with regard to specific projects. Where the questions seem not applicable to universities BIS will accept the “most relevant input.” Use of comments or narrative is encouraged. However, supporting documents are not wanted. BIS will extend the reporting deadline on request, but only in two week increments. BIS indicated that specific questions should be directed to 202-482-7808 or sent to spacedeepdiveuni@bis.gov. BIS has conducted briefings for agency groups and may consider a similar event for universities.

The balance of the discussion involved specific survey questions. Subsequently one institution shared its responses as a possible template. We also have shared the template with a number of other institutions that contacted us after the conference call.

COGR has heard from a number of institutions that conduct significant space-related research that they have not received the survey. It appears that there was a degree of randomness in choosing the recipients. Also the survey was sent to a variety of offices and officials at different universities. We believe it is in the interests of our members to complete the survey as fully and accurately as possible. However, if your institution has not received the survey (or cannot find any record of having received it), we suggest you may want to wait and see if there is any follow-up contact from BIS.

- b) **Export Control Reform: COGR/AAU Comment on Proposed EAR License Exception Revisions** - The June 2012 Meeting Report noted that on June 21, BIS proposed rules (77FedReg37524) for the transition of control over items transferred from the State Munitions List controlled by the ITAR to the EAR Commerce Control List, pursuant to the President's Export Control Reform Initiative. The Report also noted that last September COGR and AAU jointly submitted comments on the regulatory framework previously proposed by BIS for the transferred items. Our comments generally supported the proposed framework but noted concerns that the proposal did not indicate that existing ITAR license exemptions would continue to apply to the transferred items, particularly the ITAR "bona fide" employee exemption for institutions of higher education. In response to our comments, the proposed rules add the bona fide employee exemption to the EAR License Exception TSU (EAR 740.13(f)), among other changes.

On August 6 COGR/AAU submitted comments to BIS on the proposed rules. We expressed appreciation to BIS for incorporating the bona fide employee exemption in the EAR. Our comments also generally supported the proposed changes. We noted that the proposed General Order No. 5 authorizing continued use of State Department authorizations for transferred items, the extension of validity of EAR licenses from two to four years to harmonize with license terms under the ITAR regulations, and harmonization of EAR license exceptions with those available under the ITAR all appear consistent with the objectives of the Reform Initiative.

However, we expressed two concerns. One is that the proposed 740.13(f) bona fide employee license exception is subject to a large number of restrictions not found in the ITAR exception. We urged BIS to reconsider whether all these restrictions are warranted. The other is that the qualifying terms of 740.13(f)(3)(i) include the ITAR requirement that "The employee's permanent abode throughout the period of employment is in the U.S." Many U.S. institutions of higher learning do not use the current ITAR exemption because the use of the term "permanent abode" appears to contradict the terms of the employee's nonimmigrant visa. We urged BIS to clarify that "permanent abode" in this context really was intended to mean "residence" in the U.S. for the period of employment, consistent with informal guidance that the Association of University Export Control Officers received from State.

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

House Subcommittee Holds Hearing on Relationship Between Business and Research Universities

On August 1 the House S&T Subcommittee on Research and Science Education held a hearing on “The Relationship Between Business and Research Universities: Collaborations Fueling American Innovation and Job Creation.” Witnesses included William D. Green, Executive Chairman of Accenture and member of the NAS Committee on Research Universities—the hearing focused in large part on their recent report (see COGR June [Meeting Report](#)); three other industry representatives, from Lockheed Martin, Deere and Dow Chemical; and Jilda Garton, Vice President for Research and General Manager of Georgia Tech Research Company, Georgia Institute of Technology, who was the lone university representative.

Two previous House S&T Subcommittee hearings in June focused on related topics. One, held on June 19 by the Subcommittee on Technology and Innovation, focused on the Bayh-Dole Act (see COGR [June Meeting Report](#)). The other, held on June 27 by the Subcommittee on Research and Science Education, centered on the 150th anniversary of the Morrill Act. At that hearing, Members said that universities not only contribute the academic researchers who work to move basic scientific research forward but also those who comprise the STEM related workforce in the country. Witnesses from research institutions and Members discussed the challenges facing universities, including restricted budgets, rising costs, over-regulation or regulatory burden, and global competition.

At the August 1 hearing, Mr. Green stated that the NAS report recommendations he focuses on are ones calling for more collaboration, reduced time to innovation, and reforming and creating new degrees. The other industry witnesses cited their companies’ collaborations with universities, but also complained about long and complex intellectual property rights negotiations with universities. Dr. Garton noted university efforts to streamline licensing of technology, and that universities are dealing with limited resources and greater regulation and reporting requirements, often with numerous redundancies. Members’ questions focused on the role of community colleges and the importance of federal funding. In response, Mr. Green stated “we need to double down on research we fund federally,” but that we also “need to industrialize the way industry works with universities.” With regard to a question raised about competition for federal funding, he stated that research capabilities are “an untapped asset.” If you fund a “shovel ready” project, you get a pool or building; if you fund a “research ready” project, you can significantly change the entire economy and how the world works. He added that, when the return for a shovel-ready project might be 5(X), a research ready project could be up to 1000(X). Other witnesses noted that over 50 percent of new jobs are in the STEM fields and we are on the cusp of the convergence of technologies that “have been behind the curtain.” The focus should be on the transition period from research to development projects. Bringing in other groups, such as community colleges, may streamline that period.

In response to a Member question as to how the subcommittee could make the difficulties in negotiating IP between universities and industries easier, witnesses stated that they did not see a role for the federal government in this process. Dr. Garton cited UIDP as one group that was working to address that issue. She was specifically asked by the Chairman to provide the Subcommittee with a list of unnecessary and redundant federal regulations. As with the previous two hearings, the overall tone was positive, although there were a number of pointed questions. An archived webcast of the hearing and the previous hearings mentioned above may be viewed at the House S&T Committee website.

White House Event on University Innovation, Entrepreneurship, and Research Commercialization Planned

The COGR Spring 2012 Update discussed the “deep dive” investigation by the Commerce Department of the efforts to promote innovation, entrepreneurship and research commercialization by several of the 137 universities that had pledged specific, expanded efforts to advance regional and national economic growth. The letter to the Commerce Secretary was signed by the university presidents, under the auspices of the Secretary’s National Advisory Council on Innovation and Entrepreneurship (NACIE). AAU, APLU and AASCU also signed the letter. The letter promised to expand activities in several general areas: student innovation and entrepreneurship; faculty innovation and entrepreneurship; actively supporting the university technology transfer function; facilitating university-industry collaboration; and engaging with local and regional economic development efforts. A copy of the letter is on the AAU website (www.aau.edu/ -Policy Issues/Intellectual Property/Technology Transfer).

Commerce now has invited the presidents to a joint White House/Commerce event to be held at the Commerce Dept. on October 1. The invitation is extended to one person per institution. The event will highlight emerging practices in innovation and entrepreneurship in U.S. higher education. There will be of presentations and discussions around student entrepreneurship, faculty entrepreneurship, technology transfer, industry collaboration and economic development. Participants are asked to complete a list of five “buckets” about their programs and activities in these areas, for use in a report to be released by the Commerce Office of Innovation and Entrepreneurship and NACIE on trends in higher education-related innovation and entrepreneurship.

Patent Reform Developments

- a) **COGR Comments on Proposed Micro Entity Patent Status Rule** - The June Meeting Report discussed proposed rules (77*FedReg*31806) for the new micro-entity patent status provided by the America Invents Act (AIA) issued by the U.S. Patent and Trademark Office (USPTO) on May 30. The discussion noted that the proposed rules clarified that micro-entity status for institutions of higher education is an alternative category to which the micro-entity income and other limitations do not apply. However, we noted a number of other possible concerns with the proposed rules.

On July 27 COGR, jointly with AAU, APLU and AAMC, submitted comments to USPTO on the proposed rules. While we generally supported the proposed rule, we noted two concerns. First, the proposed language indicates that for micro-entity status patent “applicants” must certify that they qualify as a small entity; that their employer from whom they obtain the majority of income is an institution of higher education; and that they have assigned, granted, conveyed or are under an obligation to assign, grant or convey, a license or other ownership interest in the application to an institution of higher education. We pointed out that in the case of university inventions, the university typically is the applicant (with the inventors listed). This creates an anomaly in the proposed rules, since the institution logically cannot make the certifications required. We also noted that under the Supreme Court’s decision in the *Stanford v. Roche* case last year (563 U.S. ____), if inventors have made present assignments, legal title is immediately

vested in the institution when an invention is made (see COGR June 2011 Meeting Report). This further complicates the “applicant” issue.

We noted that one possible fix is for the proposed rule to state that for these purposes, the “applicant” will be considered to mean the inventor(s) listed in the patent application (In the notice, USPTO had invited public comments on whether the term “inventor” should be used in place of “applicant” at any instance in the proposed rules). However, this may be problematic in the case of university-owned inventions with multiple inventors, not all of whom are university employees entitled to claim micro-entity status. An alternative suggestion is for the rules to provide that the certification requirement does not apply if the applicant is an institution of higher education.

The second concern is that university foundations are excluded from claiming the benefits of micro-entity status, since it is available only for institutions of higher education meeting the definition in the 1965 Higher Education Act (20 USC 1001(a)). Our letter noted that this would exclude technology transfer organizations whose primary purpose is to facilitate the commercialization of technologies developed by one or more institutions of higher education. There are about 40 such organizations. The AIA recognizes the special status of such organizations in other provisions, and we urged USPTO to expand the scope to include such organizations for purposes of micro-entity status.

As discussed in the June 2012 Meeting Report, the advantages of micro-entity status may be more apparent than real. Nevertheless we hope USPTO will accept our suggestions. A copy of the comment letter is posted on the COGR website.

- b) **USPTO Publishes Proposed Implementation of “First Inventor to File” and Other Final AIA Implementing Rules** - On July 26 USPTO published proposed rules (77FedReg43742) to implement the conversion of the U.S. patent system from “first to invent” to “first inventor to file,” pursuant to the America Invents Act (AIA). A companion set of proposed examination guidelines for patent examiners also was published (77FedReg43759).

The proposed package of rules is over 30 pages long. We plan to assess the rules in collaboration with the AAU Patent Implementation Task Force. Much of the proposed implementation involves rules of practice before USPTO. However, we have identified a potential major issue for universities. The proposed examination guidelines indicate (p. 43767) that for the one-year grace period for public disclosures in the AIA to apply (102(b)(1)(B)), the subject matter disclosed must be identical. Insubstantial changes or obvious variations to the subject matter disclosed are not covered by the grace period. The effect is that a patent application claiming such an obvious variant of the disclosure will not be defeated as prior art. Thus for subject matter disclosed in a scientific publication, a third party could file for a patent on an obvious variant, despite the one year grace period provided by the AIA. Some see this as a “license to steal” university inventions.

The June Meeting Report noted discussions with Congressional staff on possible technical amendments to the AIA that would address the grace period issue. The AIA appears ambiguous on this point, especially as to what may constitute a “disclosure” for

grace period purposes. However, to date there has been no real progress on such technical amendments. The first inventor to file system becomes effective March 16, 2013. We will continue to analyze and discuss this issue and possible other concerns with the proposed rules with the other higher education associations. There also will be a roundtable discussion at USPTO on September 6 in which AAU will participate. Comments are due October 5.

On August 14 USPTO published a series of final implementing rules for the AIA (77FedReg48612). These include changes to implement *inter partes* and post-grant review, the inventor's oath or declaration and supplemental examination provisions, the transitional program for business method patents, and trial rules of practice. We have not yet begun to assess the implications of these rules, which are effective September 16. However, we elected not to comment on these rules when proposed last February (see COGR Spring 2012 [Update](#)).

Federal Circuit Affirms Previous Holding in Myriad Case

On August 16 the Federal Circuit Court of Appeals affirmed its previous holding in the remand of *AMP et al. v. Myriad Genetics, et al. Supreme Court* appeal (Fed. Cir. No. 2010-1406). We have followed this case involving the BRCA genes 1 and 2 and reported on it for some time; most recently in the COGR Fall 2011 [Update](#). In the Spring [Update](#) earlier this year we discussed the Supreme Court decision in the case of *Mayo v. Prometheus* (No. 10-1150). We noted that subsequently the Court remanded the *Myriad* case back to the Federal Circuit for reconsideration in light of the decision in *Prometheus* that patent claims for determining the proper dosage of drugs used for treatment of autoimmune gastrointestinal diseases based on the correlations of metabolite levels in patients' blood were routine conventional applications of laws of nature and hence unpatentable. The sole issue on the *Myriad* remand was the applicability of *Mayo v. Prometheus*.

The Biotechnology Industry Organization (BIO) joined by the Association of University Technology Managers (AUTM) and the Coalition for 21st Century Medicine filed an *amicus* brief in support of Myriad. The brief argued that the patent-eligibility of isolated DNA claims is unchanged by the Supreme Court's decision in *Prometheus*, principally on the grounds that *Prometheus* decision simply does not apply to composition of matter claims. The brief also cited various procedural issues. The brief also discussed the negative consequences of a patent-eligibility ban on Myriad's DNA claims (because this is ultimately more a policy question than a legal one). The *amici* argued that the policy balance "overwhelmingly favors [the Federal Circuit's] earlier determination that isolated genomic DNA and cDNA are patentable subject matter." The brief includes several examples of how "[r]eliable patent protection is critical to the discovery, disclosure and commercialization of new and useful compositions of matter that are isolated or derived from natural sources," and reminded the Federal Circuit that in all these instance and others, patenting "can speed the pace of innovation by encouraging the inventor to disclose the invention and make it available to other researchers." (COGR did not join the brief; we had been asked earlier in the litigation to join a brief in favor of Myriad and declined to do so given the split views in the university community on the issues).

The Department of Justice (DOJ) had filed a supplementary brief in the case supporting the plaintiffs. The crux of the DOJ argument was that "Patents on isolated but otherwise unmodified DNA would significantly impair the public's ability to study and make use of genomic DNA. ...

[A]s is true in many fields, removing the product of nature from its natural surroundings is a prerequisite to any serious study or commercial exploitation of native DNA. If the process of removing the product from its natural environment necessarily results in creation of the patented composition (and thus in infringement of the patent) – as is the case here – the patent on the composition is in practical effect a patent on the product of nature itself.” The problem with this argument is that it raises many questions about the validity of existing patents on DNA molecules, enzymes, fermentation products, and other naturally-sourced substances.

The same three-judge panel that heard the original case last year heard the oral argument on July 20 and again split 2—1 for Myriad. Perhaps of greatest interest in the majority opinion is the discussion of what in the majority’s view the case is not about.

“Before reviewing the applicability of the Supreme Court’s *Mayo* holding to the claims of the Myriad patents, however, it is important to state what this appeal is not about. It is not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion. Nor is it about whether the University of Utah, the owner of the instant patents, or Myriad, the exclusive licensee, has acted improperly in its licensing or enforcement policies with respect to the patents. The question is also not whether is it desirable for one company to hold a patent or license covering a test that may save people’s lives, or for other companies to be excluded from the market encompassed by such a patent—that is the basic right provided by a patent, *i.e.*, to exclude others from practicing the patented subject matter. It is also not whether the claims at issue are novel or nonobvious or too broad. Those questions are not before us. It is solely whether the claims to isolated BRCA DNA, to methods for comparing DNA sequences, and to a process for screening potential cancer therapeutics meet the threshold test for patent-eligible subject matter under 35 U.S.C. § 101 in light of various Supreme Court holdings, particularly including *Mayo*. The issue is patent eligibility, not patentability.”

While the dissent claimed that isolating the DNA molecules was “akin to snapping a leaf from a tree,” the majority opinion states that “...no one could contemplate that snapping a leaf from a tree would be worthy of a patent, whereas isolating genes to provide useful diagnostic tools and medicines is surely what the patent laws are intended to encourage and protect. Snapping a leaf from a tree is a physical separation, easily done by anyone. Creating a new chemical entity is the work of human transformation, requiring skill, knowledge, and effort.” The opinion noted that finding the isolated DNA molecules ineligible for patents would upend “the settled expectations of the inventing and investing communities,” as well as long-established USPTO practices. “...Disapproving of patents on medical methods and novel biological molecules are policy questions best left to Congress.” The opinion dismissed the DOJ “preemption” argument.

The majority opinion also reaffirmed its prior holding that method claims directed to growing transformed cells and determining growth rates were patent eligible, whereas method claims directed to analyzing and comparing DNA sequences were ineligible in view of *Prometheus*. It is not clear what the plaintiff’s next steps will be. They could request a rehearing by the full Federal Circuit *en banc* or appeal again to the Supreme Court.

Legislation Aimed at Patent Trolls Introduced in House

On August 8 Rep. DeFazio (D-Oregon) introduced a bill “Saving High-tech Innovators from Egregious Legal Disputes” (SHIELD) (H.R. 6245). The bill would amend U.S. patent law to provide for the recovery of computer hardware and software patent litigation costs in cases where the court finds the claimant did not have a reasonable likelihood of succeeding. The bill was cosponsored by Rep. Chaffetz (R-Utah). According to the press release, the SHIELD Act aims to put the financial burden on so-called “patent trolls” that buy patents solely to sue the tech startups that created the products. It provides that where a court determines that a party alleging infringement of a computer hardware or software patent did not have a reasonable likelihood of succeeding, full costs including attorney’s fees may be awarded to the prevailing party.

Previously a software company had approached the AAU Patent Reform Working Group with a proposal for a legislative mandate along similar lines. Also Chief Justice Rader of the Federal Circuit and others have proposed an “E Discovery Model Order” (http://www.cafc.uscourts.gov/images/stories/the-court/Ediscovery_Model_Order.pdf)

to identify “core information” in e-discovery. The notion is that in patent litigation, parties seeding discovery beyond core information would have to bear the costs of that discovery. COGR and the other higher ed. associations have taken no position on the legislation or other initiatives in this area. Nevertheless, we are aware that there is significant concern about Non Practicing Entities who simply buy patents with the principal intent to sue (“Patent Trolls”). Our main concern has been to convey to policymakers that while universities typically do not practice their patents, they are not trolls within the meaning of the term. In a well-known 2006 decision, the Supreme Court noted this distinction (*eBay Inc. v. MercExchange*, 547 U.S. 388).

NIH Plans to Expand Use of Transfer Agreement Dashboard for MTAs

The COGR June 2012 meeting featured a Thursday morning session on Materials Transfer Agreements (MTAs), including an update and demonstration of the new NIH electronic MTA system (Transfer Agreement Dashboard (TAD)). NIH had formally announced this system on December 15, 2011 (<https://techtransferagreements.nih.gov>). The aim is to streamline the transfer of NIH-developed research materials to the biomedical research community by facilitating the completion and tracking of MTAs (see COGR 2011 Holiday Update).

The TAD provides easy-to-use web forms and automatically routes agreements to the appropriate users for negotiation and signature. In addition, TAD seeks to save time through the use of pre-loaded MTA templates and electronic signatures, eliminating the need to scan or print documents. Over the next few months, NIH plans to begin using the TAD to manage MTAs for transfers with external organizations. NIH is encouraging universities and non-profit organizations to register for TAD now to eliminate delays. To register for free, please contact the TAD Support Team at NIHTADSupport@mail.nih.gov or visit the TAD Web site, at <http://techtransferagreements.nih.gov>.

COGR Data Collection on PHS/NIH FCOI Implementation

We know that you’ve been busy this summer preparing for the implementation of the Public Health Service/National Institutes of Health (PHS/NIH) regulations on the *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is*

Sought and Responsible Prospective Contractors [42CFR Part 50; 45CFR Part 94] a.k.a. the financial conflicts of interest regulations (FCOI). The disclosure forms are done; the training is complete; the review processes have been outlined; you survived August 24, 2012; and you're ready to acknowledge your long laboring on the implementation during the long Labor Day weekend coming up.

When you return, we're asking you to (briefly) look back and plan for the future and engage in some data collection and preservation. As we proposed early in the year, COGR would like to prepare for the planned evaluation of the regulations promised by PHS/NIH in its notice of the final rule (published August 25, 2011, 76FR53256).

We have posted to the COGR website (www.cogr.edu under the Educational Materials/Conflicts of Interest) **detailed descriptions of data elements** we propose to request in August 2013. The data areas are outlined below. We are asking you to help prepare a response to any request for comments **by preserving and collecting data** on your implementation of the new regulations with the addition of some baseline FY 2011-12 data collection as well. Early in 2013, we will ask you to submit data for the 2011/12 baseline year; in September/October, 2013, we'll ask you to submit the data elements for the 2012/13. We plan on using a web-based form/format that will ask for some broad institutional data, e.g., total external funding, public or private, medical school, etc., and then data specifically linked to your implementation of the PHS/NIH FCOI regulations. We are aware of the Association of American Medical Colleges (AAMC) Conflicts of Interest Metrics project and believe that the information requested is similar enough not to create an additional burden. Our purpose is to prepare for a more formal regulatory review; AAMC will provide a more in-depth analysis of the implementation.

We hope you'll be willing to engage in this data collection and preservation effort. We are always challenged by Federal agencies to document the time and costs associated with a specific regulation when we argue for changes, reductions or elimination of regulations to manage the costs and burden of compliance. We want to be prepared for the evaluation of these regulations with data that demonstrates those costs and burdens.

Take a look at the data elements here and online. The first set is for the baseline year, 2011/12; the second set (asking similar questions) is for the implementation year 2012/13. We welcome your comments and suggestions NOW (to cblum@cogr.edu) to ensure that the collection of the data minimizes the burden to you and makes sense. As we develop the web-based survey, we'll ask for volunteers to help us get it right but we need you to be preserving information now for the future.

The data includes:

- Initial investment in time and resources to implement the new 2012 regulations
- Total number of disclosures with reportable relationships or interests and the total number of such disclosures from PHS/NIH supported investigators
- Time to complete and to review disclosures and the number of FCOI identified
- Total number and time to review travel disclosures by PHS/NIH investigators and the number resulting in FCOI
- Time to prepare and monitor management plans
- Time to conduct retrospective review and number of mitigation plans prepared

- Time to meet public accessibility requirement including, if possible, the number of “hits” to the website, if applicable
- Time to train investigators

NIH Updates on FCOI

On August 24, 2012, NIH provided guidance on “one-time” reporting requirements for non-competing continuation and multi-year funded awards (NOT-OD-12-143). Because the annual progress reports for FY 2012 non-competing and multi-year awards have been completed before the August 24, 2012 implementation date, NIH is not requiring the submission of financial conflicts of interest (FCOI) reports for those awards issued on or after August 24, 2012 **until requested by NIH staff**. When requested, the grantee organization will be required to submit an FCOI report, if appropriate, with the next report due with the next annual progress report. NIH has developed tables outlining the reporting requirements, in general, and a separate table for these one-time reporting requirements. The tables are available at on the NIH FCOI website at: <http://grants.nih.gov/grants/policy/coi/>.

The FCOI Frequently Asked Questions (FAQs) were updated as well on August 24, 2012. Many of the new FAQs address reporting and are complimented by the tables outlining the reporting requirements noted above. Applicants and administrators will want to review the FAQs and tables.

NIH Special Review of \$1.0 Million Investigators

In May, NIH piloted a Special Council Review process of applications from investigators who received \$1.5 million or more in total project costs to determine if additional funds should be provided to well-supported investigators.

Following the pilot, NIH announced a **Special Council Review of Research Applications from PD/PIs with More than \$1.0 Million Direct Costs in Annual NIH Support** (NOT-OD-12-140, August 20, 2012). In tended to assist NIH in effectively managing its resources, the Special Council Review will provide an additional consideration to Research project Grant (RPG) applications. The principal changes from the pilot program are a lowering of the dollar amount from \$1.5 million to \$1.0 million but a refinement from total costs to direct costs. This approach levels the review, in effect, by eliminating the variable facilities & administration rates (indirect cost rates) from the determination and focusing on the direct cost component. There are award mechanisms excluded from the review. A complete list of the programs affected and excluded is included in the notice.

The Council will receive a list of applications that meet the special review criteria along with a justification to fund or not fund from the appropriate institute or center. The special review will focus on unique opportunities to advance research that is highly promising and distinct from other funded projects from the investigator. Review of renewal applications will take into consideration the value of continuing a productive project and the contribution of the project to the investigators research program and collaboration.

NIH Human Subjects Research Review Guidance

On August 2, 2012, the National Institutes of Health (NIH) has issued two new notices concerning human subjects research. The **Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval** (NOT-OD-12-129) describes the types of changes to research activities involving human subjects that will now require NIH approval. Relying on the current requirement for prior approval in a change in scope to a funded project, changes in human subjects related activities are considered a change in scope.

Changes that result in an increased risk to human subjects are the principal categories that will require prior approval. The risk-based changes include: 1) changes in design that change the protocol designation – from non-human subject research to research involving human subjects, changes resulting in a designation of non-exempt from exempt or no clinical trial to clinical trial; 2) including a new population covered by additional protections, e.g. prisoners, children, etc.; 3) changes that result in an overall increase in risk; and 4) new information that indicates a higher risk level. The notice describes the process for submitting prior approval requests which, effectively, outline the submission a new/revised human subjects application section with related sections, e.g., inclusion of women, targeted enrollment, etc., as applicable.

Some of the descriptions are not entirely clear, e.g., overall increase in “physical, psychological, financial, legal or other risks,” nor is the role of the customary role of the institutional review board (IRB) in managing changes in protocols as a part of the IRB’s responsibilities.

The second August 2nd notice clarifies the requirements for **Prior NIH Approval of Human Subjects Research in Active Awards Initially Submitted without Definitive Plans for Human Subjects Involvement (Delayed Onset Awards)** [NOT-OD-12-130]. Delay Onset Awards are awards for which the actual human subjects research activities could not or were not described in detail at the time of award. Three general categories include: single wards that required initial pre-clinical research; clinical network or consortia in which new protocols are added during the life of the award; and those award mechanisms that provide support for small projects selected by the awardee institution. In the first case, project grants with pre-clinical research, the awardee must submit a complete human subjects section for prior approval, in the latter cases, the process for approval of new protocols or small pilot projects is defined by the funding institute or center (IC) and awardees are directed to contact the IC for direction.

NIH Post-Award Submission Pilots

In three notices published on August 24, 2012, NIH announced a pilot projects for the electronic submission of a series of post-award activities – relinquishing statements (NOT-OD-12-132), change in grantee organization (NOT-OD-12-134) and change in grantee organization successor-in-interest (NOT-OD-12-133). These documents are limited to awards that are currently submitted electronically, a link to a list of activity codes is provided in the notices. These submissions will continue to be accepted directly to the awarding institute or center but NIH is encouraging organizations to consider using the new system for electronic submission. A Commons Change of Institution users guide is posted to eRA Commons (http://era.nih.gov/files/ccoi_userguide.pdf).

Dual-Use Research of Concern

During the June COGR meeting, we discussed the US Government Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC) and anticipated the late summer release of a companion proposed policy for Institutional Oversight of DURC. The proposed policy has not been posted to date. We wanted to remind you of the educational tools available on the National Science Advisory Board for Biosecurity (NSABB) website at: http://oba.od.nih.gov/biosecurity/biosecurity_educational.html. These documents outline the Federal government's current thinking on a variety of related topics including appropriate codes of conduct, investigator and institutional responsibilities and the effective communication of DURC research results. Reviewing these documents may assist in a thoughtful and thorough review of any proposed institutional policy. We will notify the membership as soon as the policy is available for comment.