

COUNCIL ON GOVERNMENTAL RELATIONS

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TO: COGR Membership
FROM: COGR Staff
SUBJECT: Fall 2011 Update

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House Bill Would Lower the NIH Salary Cap

On October 11 a group of 72 organizations and individual institutions, including COGR, sent a letter to House and Senate Appropriations Committee Chairs urging them to oppose a provision in the House draft FY12 Labor-HHS-Education funding bill that would reduce the cap on extramural salaries at the National Institutes of Health. The House proposal would lower the cap from Executive Level I (\$199,700) to Executive Level III (\$165,300). The letter is posted to the COGR web site.

The letter expresses concern that lowering the salary cap would reduce institutions’ ability to attract and retain the best investigators. Citing the interests of the nation’s long-term health and

research competitiveness, the letter says it is essential that policymakers not create disincentives for research careers and that they adopt “policies to ensure that America retains the most talented, productive, and diverse group of biomedical and behavioral researchers.”

A-21 Task Force Update

COGR continues to pay close attention to developments from the A-21 Task Force. We are in regular correspondence with the members from the Task Force and have responded to their data and other requests over the past two months. They received over 150 response letters and they accumulated hundreds of recommendations from those letters. The Task Force is thoughtfully considering many of the recommendations that COGR and your institutions made and is engaging the broad knowledge-base of the COGR membership to understand cost impacts and other dynamics that would be associated with any changes in policy.

As most of you know, the Office of Management and Budget (OMB) convened an A-21 Task Force under the Office of Science and Technology Policy (OSTP) to explore policy updates that could reduce cost and administrative burden for research universities and institutions. A “Request for Information” (RFI) was issued by the Task Force in June, under the auspices of an NIH RFI (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-091.html>). In late July, COGR and many COGR member institutions responded to the RFI and provided the Task Force with recommendations. The COGR Recommendations covered 45 pages of detailed analysis and specific suggestions designed to address a wide variety of topics. A separate cover letter and the 45-page Recommendation document can be found at www.cogr.edu (see Latest News, July 28, 2011 link on the COGR home page).

The A-21 Task Force implemented an aggressive schedule for reviewing and responding to the RFI responses. The Task Force provided their internal recommendations to senior leadership at OMB and OSTP at the end of August. The timing of releasing the Phase I recommendations has been coordinated with a similar initiative specific to OMB Circular A-87, *Cost Principles for State, Local and Indian Tribal Governments*. The A-21 Task Force will continue working toward a Phase II series of recommendations with a target for completion by the end of the calendar year.

At a September 15th session during the Federal Demonstration Project (FDP) Meetings, the three A-21 Task Force Co-Chairs (Gil Tran-OMB, Sally Rockey-NIH, and Mark Herbst-DOD) provided the FDP membership with a Task Force Update. Unfortunately, the Task Force members were limited on what they could share – before any public report or recommendations can be made available, OMB must complete internal reviews by legal counsel as well as coordinating the timing for public release of the A-21 and the A-87 recommendations. However, the Task Force was able to provide a list of items that they have addressed, and that they will continue to address. The list below is not necessarily based on “priority,” but it appears to represent those items that were most frequently raised in the responses to the RFI and which the Task Force is focusing its resources.

- Effort Reporting
- F&A Rate Negotiation Transparency
- Federal Audit Coordination
- Subrecipient Monitoring
- Utility Cost Adjustment, 1.3%
- Arbitrary Agency F&A Limitations
- Cost Sharing
- Direct Charging of Project Support
- Coordination of Regulations
- Financial Reporting

As the Task Force engages COGR and your institutions for feedback and follow-up to recommendations that we have made, we encourage active and enthusiastic responses. The Task Force is committed to addressing the issues of regulatory and cost burden. If your institution has been contacted by a member of the Task Force, you are welcome to contact COGR staff and we can talk through any questions or concerns you may have in regard to the Task Force inquiry. In addition, we want to be in a mode of reminding the Task Force of our concerns and proposed solutions that we raised in our responses to the original RFI. We remain cautiously optimistic that there will be significant and positive outcomes as this process continues to unfold.

Presentation of the Phase I Recommendations by the A-21 Task Force: COGR Meeting, October 27th

Members from the A-21 Task Force will present the Phase I recommendations, including their perspective on how the recommendations will be implemented and any challenges that they foresee during the implementation phase. And to the extent that they are able to do so, they will share those topics that they hope will be part of the Phase II recommendations.

As of the writing of this COGR Update, the Phase I recommendations are not available. However, we have been informed by the Task Force that they will be able to address the Phase I Recommendations in detail and that this session can be an interactive session with opportunities for questions and answers between COGR members and the Task Force members.

Maintaining Momentum on “Arbitrary Agency Policies”

The November 2010 paper, *Federal Funding Agency Limitations on Cost Reimbursement: A Request for Consistency in the Application of Federal Guidelines*, was one of the formal initiatives by COGR designed to address the broad topic of “Financial Reform”. The paper can be accessed at www.cogr.edu under “Educational Materials/Financial Management” – there are two documents, the first is the policy paper and the second is an appendix. The Appendix includes a sampling of Federal agencies and/or programs where arbitrary agency policy results in financial burden for research institutions.

In the COGR Recommendations to the A-21 Task Force, we reiterated our concern with arbitrary agency policies. Consequently, we included these recommendations to the Task Force:

- The Negotiated F&A Rate should be reimbursed by all Federal funding agencies on all Federally-sponsored research, service and educational programs, unless statutorily prohibited.
- Prohibit arbitrary Federal funding agency restrictions on F&A cost recoveries associated with Bulk Purchase, High-Volume, and/or Significant Dollar Transactions. If arbitrary restrictions persist, develop solutions to update Circular A-21 and the definition of “modified total direct cost.”
- Prohibit Voluntary Committed Cost Sharing on all Federally-sponsored research, service, and educational programs.

To maintain momentum on this specific issue, we have called out to your institutions over the past year to provide examples where an agency imposed an arbitrary policy by limiting F&A

reimbursement, including a vague request for cost sharing, or instituting another form of financial restriction that results in a financial burden.

In a letter to OMB dated September 8, 2011, COGR provided 11 recent examples of arbitrary agency policies. The examples spanned a diverse range of research funding agencies (e.g., NSF, NIH, USDA, just to name several) and again highlighted our concern that agencies too frequently engage in these types of practices. OMB was receptive to COGR sharing these examples and responded by stating that this is a topic that is being addressed by the A-21 Task Force. A copy of the September 8, 2011 letter can be found at www.cogr.edu (see Latest News, September 8, 2011 link on the COGR home page).

COGR Co-Authors Recent Policy Paper: Reforming Regulation of Research Universities

In the Summer 2011 issue of the quarterly journal, *Issues in Science and Technology Policy*, COGR staff co-authored with staff from the Association of American Universities (AAU) a paper entitled: *Reforming Regulation of Research Universities*. The paper proposes regulatory reform solutions that will help restore some balance to the current regulatory and financial burdens being faced by all research institutions. Several of the themes addressed in the recommendations to the A-21 Task Force are addressed in the policy paper. A copy of the article can be found at www.cogr.edu (see Latest News, September 1, 2011 link on the COGR home page).

The National Research Council (NRC) “Study on Research Universities” Update

It’s been almost one-year since COGR began reporting on the “Study on Research Universities” – a study to be completed by the NRC to address the top ten actions that research university stakeholders and the nation can take to ensure U.S. global competitiveness. This initiative was started in response to a bipartisan request by Senators Lamar Alexander (R-TN) and Barbara Mikulski (D-MD) and Representatives Bart Gordon (retired) (D-TN) and Ralph Hall (R-TX) for a study focused on the health and competitiveness of our nation’s research universities. COGR, in conjunction with AAU and APLU, provided recommendations to the NRC working committee earlier in the year (see www.cogr.edu, “Latest News”, March 22, 2011 link – item 4).

COGR initially reported that the study would be completed in the Summer – however, completion of the study has been delayed. The working committee met three times, the last time in February, and continues to vet their findings and recommendations. In the context of the work being completed by the A-21 Task Force, it is possible there could be synergy between the NRC and the A-21 Task Force reports. Our understanding is that the NRC is close to finalizing their report and that it should be available by the end of this year or in early 2012. We will keep the membership posted on all developments.

2011 COGR Survey of F&A Rates: Reports Available and Discussion to Follow

One of the Thursday morning sessions at the October 27th COGR Meeting is entitled: “The COGR Survey of F&A Rates, Current Trends, Future Surveys, and an Update on Recent Negotiations.” We have accumulated a robust set of F&A rate data and have begun to assemble the data into various report formats. For the first time, COGR collected comprehensive F&A rate data for all institutional F&A rates. In addition, the COGR survey has transitioned to maintaining historical F&A rate data which provides for more readily available trend analysis.

The Thursday morning session will provide some compilations from the most recent survey, including analysis and perspective on what the trends may suggest. We also will open the discussion to future surveys and what data would be useful to the COGR membership, as well as discussing how/if the results from the COGR survey could be used for advocacy and other public purposes. Distribution of reports and availability of the source data also will be part of discussion as we work to provide the COGR membership with the most useful and accessible resources.

The Thursday morning session also will allow an opportunity to do an Update on Recent Negotiations. As many of you know, one of COGR's recommendations to the A-21 Task Force was to *Formalize an F&A Rate Negotiation Model that is transparent, unambiguous, consistent and collaborative between the Federal government and Research Universities and Institutions*. We understand that the Task Force is considering taking action on this recommendation. We will use the second half of this session to identify practices employed by DCA and ONR that we can share with the A-21 Task Force that would help inform specific actions taken by the Task Force.

The 2011 Survey of F&A Rates includes survey results for over 120 institutions – this represents a 67% completion ratio. As reports are distributed, some may be disappointed that their institution are not included. Our intent is for the survey to have a “real-time” element and to regularly update the master data file and to periodically produce new reports. Consequently, during the session we will discuss the process for including and/or updating your institutional F&A rate data and other relevant information.

Audit Update: 2012 Inspectors General (IG) Workplan Status

The Department of Health and Human Services (HHS), Office of Inspector General (OIG), is responsible for auditing NIH programs. The HHS Office of Inspector General 2012 Workplan is now available at: <http://oig.hhs.gov/reports-and-publications/workplan/index.asp#current>

The 2012 HHS OIG Workplan highlights several initiatives, shown below. These items are described in more detail in Part V: Public Health Reviews and Part VII: Other HHS-Related Reviews, per the Workplan. Several of the initiatives are carry-overs from last year (i.e., the first three and the final items) and the others listed in the Workplan are indicted as “New” initiatives. However, the Workplan will expand and contract as the HHS OIG does ongoing risk assessment. COGR will follow the status, accordingly. The published Workplan includes:

- Colleges' and Universities' Compliance With Cost Principles, page V-9
- Review of Extra Service Compensation Payments Made by Educational Institutions, page V-9
- Recharge Centers at Colleges and Universities, page V-10
- Informed Consent and Privacy Protection Procedures for NIH Grantees Conducting Genetic Research (New), page V-10
- Inappropriate Salary Draws From Multiple Universities (New), page V-11
- Cost Sharing Claimed by Universities (New), page V-11
- Awardee Eligibility for Small Business Innovation Research Awards (New), page V-11
- Classifications of Federal Pass-Through Funding Recipients, page VII-7

COGR staff is scheduled to meet with representatives from the HHS OIG during the week of October 17th. In that meeting, we will raise issues on the timing, scope, and Federal concern as it

relates to each audit initiative, and also inquire about other HHS OIG plans that may not be included in the Workplan.

The National Science Foundation (NSF), Office of Inspector General (OIG), is responsible for auditing NSF programs. The 2012 NSF Annual Audit Plan is not yet available. However, COGR staff is scheduled to meet with representatives from the NSF OIG during the week of October 24th. We hope to get a preview of the NSF OIG's audit plans for 2012 in that meeting. As applicable, COGR will provide additional information to the membership during the COGR Meetings on October 27-28 and in subsequent COGR Updates to the membership.

As always, COGR is interested in audit experiences at your institution so that we can update the general landscape for the membership. Please contact David Kennedy at dkennedy@cogr.edu if your institution has been contacted by an agency to conduct an audit or review. We will keep all correspondences confidential.

HHS OIG Administrative & Clerical Audits

The first audit report pertaining to this initiative was released in August. We are aware of a second “soon-to-be-released” audit report. If your institution has been involved with one of these audits and is in a position to share the status, please contact COGR.

As we reported in the COGR Summer Update (August 26, 2011), the first Administrative & Clerical audit report (i.e., “*College and University Indirect Costs Claimed as Direct Costs*,” HHS Office of Inspector General Workplan, Fiscal Year 2011) was released in August: <http://oig.hhs.gov/oas/reports/region10/11101500.pdf>

The audit focused on a sample of 168 DHHS grants and contracts active in fiscal years 2009 and 2010. Within the sample, the administrative costs were a subset and the institution was able to justify those expenses through a combination of documents including grant applications, budget justifications, project descriptions, copies of invoices, business purpose statements and question and answer sessions with the auditors. The overall process was lengthy and consumed hundreds of staff and auditor hours – significant backup documentation was provided to the auditors. Per the OIG's review of a sample of these expenditures, the OIG concluded that the institution complied with Federal regulations. As stated in the audit report:

These transactions were allowable as direct costs because they were charged to a major project, had unlike circumstances, or were directly related to or necessary to achieve the objectives or goals of the HHS grants or contracts. Accordingly, this report contains no recommendations.

The 2012 HHS OIG Workplan (see above) does not refer to the “*College and University Indirect Costs Claimed as Direct Costs*” audit initiative, so this may suggest that after the remaining audits are completed this work item will be closed. COGR hopes to learn more during its meeting with representatives from the HHS OIG during the week of October 17th.

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.

NIH under the Continuing Resolution (CR). The recent CR passed by Congress funds government agencies through November 18, 2011. On October 7, NIH published Notice Number: NOT-OD-12-004, which states: *Until FY 2012 appropriations are enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). This is consistent with our practice during the CRs of FY 2006 - 2011. Upward adjustments to awarded levels will be considered after our FY 2012 appropriations are enacted but NIH expects institutions to monitor their expenditures carefully during this period.* The NIH Notice is available at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-004.html>

Workplace Flexibility (“Family-Friendly”) Science Policy. In late September, the White House Office of Science and Technology Policy (OSTP) and the National Science Foundation (NSF) announced a series of new NSF policies allowing for new flexibilities related to child and dependent care leave, including flexible award deferral and no-cost extension policies, award supplements to pay for staff to maintain a lab while the PI is on leave, and “virtual” peer review for those who cannot travel. Links to the White House press release, the NSF Notice, and NSF FAQs Related to Dependent Care are shown below. While supportive of family-friendly policies, COGR currently is reviewing the new policies.

<http://www.whitehouse.gov/the-press-office/2011/09/26/white-house-and-national-science-foundation-announce-new-workplace-flexi>

http://www.nsf.gov/publications/pub_summ.jsp?ods_key=balance

<http://www.nsf.gov/pubs/2010/nsf10032/nsf10032.jsp?org=EHR>

NIH and Genomic Arrays. In the Spring 2011 Update (dated May 27, 2011), we included a narrative that addressed Genomic Arrays using “The Costing and the Science” as the context. We have shared this analysis with NIH and COGR’s position remains that this NIH policy should be retracted. We highlighted this specific concern in the response to the A-21 Task Force (Recommendation B2). We continue to correspond with NIH on this topic and we will update the membership on developments.

NSF Cash Payment System. As COGR wrote in the June Meeting Report (June 29, 2011), the National Science Foundation is proposing the roll-out of a new Cash Payment System. Rick Noll, the Branch Chief of the Cash Management Branch, Division of Financial Management, provided a detailed overview during a session at the June Meeting. NSF currently is in the early stages of planning and system development, but it is important to note that NSF is targeting the new system to be implemented during FY2013. NSF will work conscientiously with the grantee community to develop a timeline that will not interfere with the fiscal year end dates of our institutions, which suggests the transition to

the new system will take place in late 2012 / early 2013. NSF will provide regular updates to stakeholders as the timeline is developed, and COGR will follow all developments closely.

NIH Request, Costing on Core Facilities – On Hold, but plans to address in near future. COGR submitted a response letter to NIH concerning the NIH request for comments on “*FAQs to Explain Costing Issues for Core Facilities.*” A copy of the COGR letter can be found on www.cogr.edu (see Latest News, December 8, 2010 link on the COGR home page). Our latest update from NIH on this topic is that any action is on-hold, partly due to reorganization that is taking place at the National Center for Research Resources (NCRR), but that NIH plans to revisit soon. We will keep the membership updated on developments.

Patent Reform Legislation Enacted

As we reported to the COGR membership, the President signed the patent reform legislation (America Invents Act) on September 16. Attention now shifts to the implementation.

As discussed in the COGR August Update, there are a dozen items where changes in the patent law were effective immediately or within 10 days. Other changes will be phased in over the next 12—18 months. Most of the new review provisions are effective in 12 months (9/16/12). The change to first inventor to file is effective in 18 months (3/16/13). The timelines for various changes, including a very useful chart of the effective dates and other information on the planned implementation, can be found on the Patent and Trademark Office (PTO) website at http://www.uspto.gov/patents/init_events/aia_implementation.jsp.

Many law firms and other groups have issued materials pertaining to implementation of the patent reform legislation. Another very good summary of the timeline for implementation is at <http://www.michaelbest.com/pubs/pubDetailMB.aspx?xpST=PubDetail&pub=2979>. Other helpful summaries of the legislation and implementation may be found at http://www.foley.com/publications/pub_detail.aspx?pubid=8481; http://www.pepperlaw.com/publications_update.aspx?ArticleKey=2190 and <http://view.mc.millercanfield.com/?j=fe6b16757563067d7114&m=fef81278746107&ls=fddf1078706c07757d1d7771&l=fe971072756c077d72&s=fe23157677610d7e721374&jb=ffcf14&ju=fe3817717066057e741271>

One key point is that effective within 10 days (9/26/11) there was a 15% increase (surcharge) in patent filing and related fees. However, PTO has been given authority under the Act to establish a new fee schedule. According to the PTO implementation timeline, this may take up to 18 months. Our understanding is that universities will qualify for the 75% fee reduction for “micro entity” status; however, this will not be effective until the new fees are set (universities currently are eligible for “small entity” filing status).

The America Invents Act gives PTO many new responsibilities, and greater ability to use the fees it collects to support its operations. Unfortunately the continuing resolution (CR) to fund the government in FY’12 does not include the needed special language to give PTO access to the added funding authorized by the Act. The FY12 omnibus appropriations package is expected to reinstate USPTO’s facilitated access to its fees, as provided by the new law and committed to in the report of the House-passed FY12 Commerce-Justice-Science appropriations bill. However, without special language in the CR, current funding will continue for USPTO through November 18. And the prospect of Congress needing one or more short-term CRs before a final FY12

funding package is agreed to has led patent stakeholders to urge House and Senate appropriators to insert the USPTO fee access language into any funding legislation for the agency.

A PTO representative will meet with the COGR Contracts and Intellectual Property Committee at its October meeting to discuss PTO's implementation plans and opportunities for public input. We will report to the membership on the discussion.

Administration Announces Commercialization Initiative and Related Efforts

Also as we reported, at the signing of the America Invents Act, the President called attention to the Administration's University Commercialization Initiative and called attention to other related initiatives. A copy of the White House press release was sent to the COGR membership on September 16. It noted the commitments by 135 university presidents and chancellors made in response to the National Advisory Council on Innovation and Entrepreneurship (NACIE) to work more closely with industry, investors, and agencies to bolster entrepreneurship, encourage university-industry collaboration, and enhance economic development. The White House press release stated that "Today, over 40 universities are answering the President's call to expand their commercialization programs and goals. These institutions include The Georgia Institute of Technology, which has outlined its expanded initiatives, as well as universities like the University of Virginia and Carnegie Mellon University, which are announcing plans today."

In addition, the Commerce Department also issued a press release on September 16 on the NACIE commitments. It noted that NACIE had "worked in close cooperation with AAU and APLU, as well as other key stakeholders to present (the former Commerce Secretary) with a set of recommendations on policies and actions that would enhance university efforts to commercialize federally-funded research. In support of the recommendations, NACIE spearheaded a signature drive that resulted in these university leaders' commitments to push their institutions for results by: upgrading their programmatic efforts to teach entrepreneurs; enabling more innovation by faculty; accelerating technology transfer to the private sector; developing deeper and broader partnerships; and fostering regional economic development."

Other initiatives mentioned at the America Invents Act signing include the proposed NIH National Center for Advancing Translational Sciences (NCATS) and two Coulter Foundation activities: a university commercialization prize competition jointly funded by NSF with AAAS designing and implementing the prize competition in partnership with other agencies and organizations; and four new Coulter Translational Partnership Awards (according to a subsequent Chronicle article, there actually will be six. The Chronicle article also noted that rather than the \$20M endowment mentioned in the White House press release, each institution will receive two-to-one matching grants to create 5-year \$5M programs).

NCATS will collaborate with DARPA and the FDA "to develop a chip to screen for safe and effective drugs far more swiftly and efficiently than current methods, and before they are tested in humans." Over the next five years, the NIH plans to commit up to \$70 million and DARPA will commit a comparable amount to this effort (see <http://www.nih.gov/news/health/sep2011/od-16.htm>). By January 2012, the Administration also will develop a Bioeconomy Blueprint "detailing Administration-wide steps to harness biological research innovations to address national challenges in health, food, energy, and the environment."

President Obama also announced a new, short-term Start-Up Evaluation License Agreement for early-stage biomedical inventions developed by intramural researchers at NIH or FDA that that can be converted to an exclusive Start –Up Commercial License within one year with minimum annual royalties and patent expenses (50%) payable to NIH but with deferments. Companies that are less than 5 years old, have fewer than 50 employees and have less than \$5M in funding since incorporation will be eligible for the licenses, which must be for developing drugs, vaccines or therapeutics from NIH or FDA patented technologies. The fee for the Evaluation License is \$2000. In lieu of a fee for the Commercialization License the company will have an obligation to make a cash payment to NIH at the time of the earliest liquidity event (see <http://www.ott.nih.gov/startup/default.aspx> and <http://www.nih.gov/news/health/sep2011/od-16a.htm>).

Rehearing Requested by Both Sides in Gene Patent Case

We reported in the Summer Update that the Federal Circuit in a divided opinion had upheld the patents held by Myriad Genetics on certain genes (BRCA 1 and 2) linked to breast and ovarian cancers. While the federal district court had invalidated the patents as “products of nature,” and the Justice Department supported that position in a surprise brief, the Federal Circuit majority held that isolating genes from the body created a new chemical entity with a different structure. (The Federal Circuit upheld the district court’s finding that Myriad’s diagnostic patent claims that involved comparing and analyzing the BRCA genes and “normal” gene sequences were abstract ideas ineligible for patents). In the Update we noted that the decision would almost certainly be appealed.

In a somewhat surprising development, both sides filed petitions on August 25 with the Federal Circuit asking for a panel rehearing. The plaintiffs’ (ACLU and others) petition claims that the majority opinion ignored the fact that the altered gene (DNA) fragments with identical chemical structures are found in nature. Myriad’s petition is based on standing: the court had found that only one of the medical researcher plaintiffs had standing as a potential infringer to bring the suit. Just before the Federal Circuit decision in July, Myriad had notified the court that this researcher was leaving his present institution, and according to Myriad’s petition this means there is no longer any controversy since Myriad’s attempts to enforce its patents had involved the (former) institution. Myriad’s petition asks that the Federal Circuit opinion be left intact but that further action on the case be rendered moot. The plaintiff’s petition disputes the Federal Circuit’s finding that only one researcher had standing.

As we noted in the Update, most observers had expected the case to be appealed either to the Federal Circuit *en banc* or directly to the Supreme Court. However, given the closely divided nature of the Federal Circuit decision with three separate opinions, perhaps the rehearing request should not have come as a surprise. We will continue to follow and report on developments.

NIH Holds Web-ex on New Electronic MTA System for COGR Representatives

NIH has developed a new Electronic MTA System, which it is calling the NIH Transfer Agreement Dashboard (TAD). The system initially will be implemented for outbound transfers of NIH materials to the extramural community. Beta testing has been completed. NIH plans to begin a “soft launch” of the system on October 17.

Because the system will engage the extramural community, NIH approached COGR about the possibility of a presentation to the COGR membership. Unfortunately there was a conflict for NIH in the dates of the October meeting. However, NIH and COGR arranged for a web-ex meeting for NIH to explain the plans for and objectives of the system for members of the COGR CIP and RCA committees and/or their representatives.

The web-ex meeting was held on October 6. About 16 representatives from COGR member institutions participated. The TAD will be an enterprise-wide system for NIH. Planning to define the requirements began last November and included interviews with extramural groups including representatives from a number of COGR institutions. Concerns identified included long lead times necessary to process MTAs, lack of status visibility both within outside organizations and NIH, non-availability of data and metrics on MTAs, and the fact the current system is paper-based. The goals of the electronic system are to reduce processing times, provide for on-line intuitive access, provide 24/7 tracking and status information, and enable quick searches to identify lessons learned.

7 NIH institutes will participate in the soft launch phase, 2 of which will begin the launch on October 17. They will send out participation agreements to groups and institutions that they will identify. This initial phase will last approximately 4–6 weeks, after which the soft launch will expand to the other participating NIH institutes.

When a materials transfer is initiated, email notifications will be sent to the office or individuals identified in the participation agreement, and a draft MTA in Word format will be sent out by the institute. The identified individuals or offices will log on (“My MTA Dashboard”) and may edit or redline the draft. Initially the system will accommodate 4 MTA templates: the NIH Simple Letter Agreement (SLA); the Uniform Biological Materials Transfer Agreement (UBMTA), the MTA for the Transfer of Organisms (MTA-TO), and the Human Material Transfer Agreement (hMTA). Other templates may be added later. Once agreement is reached on the content, further email notifications will be sent, and a PDF will be generated for electronic signature by the institution.

Among questions raised by the COGR representatives was whether authorized officials will be included in the process in all cases—this will depend on the offices or officials identified in the participation agreement; whether the system will establish an institutional profile for all MTAs—this will depend on the participation agreement; security concerns—the system will be protected as with other internal NIH systems; the overlap with institutional document management systems—the system will only pass documents between organizations; and the possibility of expansion to incoming transfers to NIH—the system is bidirectional and could accommodate that down the road (but is not currently planned).

NIH is anxious to engage the extramural community before general launch of the system and has scheduled a session with the NIH/CTSA institutions. Outreach to AUTM and the FDP also is planned. We will discuss with NIH the possibility of a session on the new system at the February COGR meeting.

Note that this system will not directly address the concerns about the proliferation of individual institution MTA templates that we previously identified (see COGR October 2010 [Update](#)). However, the standardization and streamlining provided by the new NIH system may have the potential of helping to reduce burden in the long term.

COGR Comments on Proposed Rule for Migration of USML Items to CCL

The August Update noted that on July 15, the Commerce Bureau of Industry and Security (BIS) announced a proposed rule (76FedReg41958) for transferring items currently controlled for export under the U.S. Munitions List (USML) to the Commerce Control List (CCL) pursuant to the President's export control reform initiative. As discussed in the Update, the proposed rule provides a new regulatory construct for transfer of the items. While we generally supported the BIS plans, our preliminary analysis noted some concerns with the potential loss of existing ITAR license exemptions applicable to universities for the transferred items.

On September 13 COGR and AAU commented jointly on the proposed rule. In our comments we agreed that the proposed rule would increase efficiency and reduce costs, by transferring less military sensitive items from the USML to the more flexible licensing regime of the CCL. We also noted that the proposed creation of a "Commerce Munitions List" through adding a new 600 series to the CCL for the transferred items should make licensing these items more straightforward with the added benefit of making EAR license exemptions such as the Strategic Trade Authorization available.

However, we expressed concern that the construct in the proposed rule did not indicate that existing ITAR license exemptions would continue to apply to the transferred items. We singled out the "bona fide employee" exemption for institutions of higher education (ITAR 125.4(b)(10)) and the university exemption for articles fabricated for research satellites (ITAR 123.16(b)(10)). While not an immediate issue for institutions since the proposed rule itself did not transfer any items except for certain military ground vehicles (and statutory authorization will be necessary to transfer research satellites), we urged BIS to consider including these exemptions in the construct as the reform initiative proceeds.

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

DOE Proposes Changes to Nuclear Export Control Regulations

On September 7 DOE (National Nuclear Security Administration) proposed substantial changes to its regulations (10 CFR 810) on providing assistance to foreign atomic energy activities (76FR55278). This is the first comprehensive update to the Section 810 regulations since 1986. The main thrust of the regulations is to list countries for which a general authorization for foreign atomic energy activities is available, as opposed to the approach in the current regulations which list countries for which specific authorizations are required. Unclassified activities with the listed countries would be generally authorized if they do not involve "sensitive nuclear technology" (nonpublic information important to the design, construction, fabrication, operation, or maintenance of a uranium enrichment or nuclear fuel reprocessing facility or a facility for the production of heavy water).

The regulations clarify controlled activities (810.2(b)). They include transfer of technology to foreign persons related to nuclear reactors, storage, reprocessing and movement of nuclear materials, processing of high level radioactive waste, and transfer of technology for the development, production or use of equipment or material specially designed or prepared for any of the listed activities. All steps in the nuclear fuel cycle are included.

The two proposed changes of greatest relevance to COGR member institutions are the addition of specific provisions in the regulations addressing deemed exports (currently only incompletely addressed) and the addition of specific exemptions for public information and basic scientific research (as defined in the regulations) from the scope of the regulations (810.2(c)).

Our biggest concern is that the definition of “basic scientific research” in the proposed regulations is not consistent with the NSDD 189 definition of fundamental research incorporated into the Commerce EAR regulations and State ITAR regulations. The proposed rule defines basic scientific research as “experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena and observable fact, not primarily directed towards a specific practical aim or objective” (810.3). Rather than the objective EAR and ITAR fundamental research test of whether the results of the research will be published or broadly disseminated within the scientific community, this proposed definition requires a subjective determination of whether the research is intended for the acquisition of new knowledge of the fundamental principles of phenomena and observable facts. This could lead to confusion and uncertainties as to whether research qualifies under the definition. It also appears inconsistent with the statement in the Federal Register notice that the additional material on deemed exports “is intended to address situations comparable to those covered by the deemed export rule (in the EAR)” (p. 55280).

With regard to deemed exports, U.S. persons seeking to employ a foreign national of a non-generally authorized listed country in a position where technology subject to the regulations may be transferred, must request a specific authorization. The content of the application is prescribed (810.11(a)). However, no application is required if the foreign national is a U.S. permanent resident or has protected status, consistent with the EAR. Where an application is required, the application must include a description of the technology, the purpose of the transfer, copies of any confidentiality agreements, extensive background information about the foreign national, and a signed statement of compliance with the regulations by the foreign national (810(c)).

We do not believe that the proposed regulations will have a substantial impact on COGR member institutions, since relatively few appear to conduct research in areas of nuclear technology covered by the proposed rule or operate nuclear reactors. However, we believe COGR (and AAU) should express concerns about the definition of basic scientific research in the proposed rules. We will continue to assess the proposed regulations for the potential impacts. Comments are due November 7.

OFPP Issues Final Policy on Performance of Inherently Governmental Functions

On September 12 the Office of Federal Procurement Policy (OFPP) issued a final policy letter (11-01) on Performance of Inherently Governmental Functions (76FR56227). A proposed policy letter previously was issued on March 31, 2010. COGR did not comment on the proposed policy, since our member institutions did not appear to be heavily impacted (see COGR June 2010 Meeting Report). However, we did indicate that we would report on the final policy changes.

The final policy distinguishes functions that are “inherently governmental” (so intimately related to the public interest as to mandate performance by federal employees such as control of prosecutions, command of military forces and conduct of foreign relations) from those that are “closely associated” that require special management attention if contracted out. It includes a useful chart (pp. 56233-34) that provides examples of each. One example is determining federal

policies, which is inherently governmental. However, the closely associated function of drafting regulations and performing feasibility studies either can be performed by federal employees or contracted out. Another example is selecting individuals for federal employment, which is inherently governmental, but screening resumes is closely associated work that can be contracted out. When such closely associated functions are contracted out, agency management must limit or guide the contractor's exercise of discretion and provide close oversight of work products, etc. The policy letter discusses FFRDCs and UARCs as examples of closely associated functions where it is to the government's advantage to use outside resources. However, because of their high degree of access to the agency and the critical nature of the work they perform to agency missions and operations, care must be taken to avoid conflicts of interest and to assure that they are not allowed to perform inherently governmental functions. The policy letter also includes the concept of "critical functions," which are core to the agency's mission and operations (e.g. designing the next generation of NASA satellites). Agencies must identify these functions and assure they have sufficient internal capability to maintain control over them.

An important aspect of the policy letter is to clarify that all combat and closely associated security operations are inherently governmental. Also added to the illustrative list of inherently governmental functions are final determinations of contractor performance, determination of offerors' price reasonableness, and selection of grant and cooperative agreement recipients.

As we previously noted, COGR member institutions may occasionally perform "closely associated" types of services, such as managing FFRDCs or UARCs or as subcontractors to firms that perform such services. However, except in such limited instances, we continue to believe that situations where our members will encounter this policy will be relatively rare. The rules for FFRDCs and UARCs are well-established. In any event, the guidance is directed to federal agencies. The 2009 Defense Authorization Act (P.L. 110-417) required OFPP to create a single definition for inherently governmental functions and provide related guidance and criteria. Policy letter 11-01 was effective October 1, 2011.

COGR Publishes Revised *Tutorial on Technology Transfer*

COGR has updated the *Tutorial on Technology Transfer in U.S. Colleges and Universities*, initially published in September 2000. Five copies of the printed version of the updated *Tutorial* were sent to COGR Primary Representatives on October 14.

The *Tutorial* focuses on technology transfer through the transfer of intellectual property rights (patents, copyrights, trademarks) from universities to the for-profit sector for commercialization. The *Tutorial* begins with a discussion of the role of universities and technology transfer in the economy. It describes the Bayh-Dole Act as providing the platform for technology transfer, since the majority of university research in the sciences is funded by the federal government. It describes the different forms of intellectual property and the need for institutions to formulate policies and procedures to manage their intellectual property assets. A detailed discussion of the technology transfer process follows, focused primarily on patents but also including discussion of software, multimedia and web-based products. Brief discussions follow of licensing trademarks and other research products. The *Tutorial* concludes with a discussion of the need to manage conflicts of interest and a section on export controls.

Material that has been updated in particular includes a discussion of the implications of the recent Supreme Court decision in *Stanford v. Roche*, a discussion of "socially responsible"

invention licensing and “open source” software licensing, and the new PHS financial disclosure requirements. The section on export controls is entirely new. In addition, many new references have been incorporated. At the time of publication the America Invents Act still was pending in the Congress; however, it is footnoted in the *Tutorial*.

Additional copies of the printed version may be purchased for \$5.00 each. The *Tutorial* also will be available on the restricted members-only portion of the COGR website.

OHRP/OSTP Proposed Changes to Human Subjects Protections

With the help of COGR members across the country, we are in the final stages of preparing a response to the Department of Health and Human Services’ (HHS) Office for Human Research Protections (OHRP) and the Office of Science and Technology Policy (OSTP) Advanced Notice of Proposed Rulemaking (ANPRM) and request for comments concerning *Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators*. With the extension of the deadline for submission of comments to October 26, 2011, we have been able to consult broadly and prepare responses to the seventy-four questions posed in the ANPRM. We will post COGR’s draft response to the Members’ Only section of the website (look under Latest News on the homepage at www.cogr.edu) no later than Tuesday, October 18, 2011. We have prepared a letter that summarizes our observations on the seven substantive areas discussed in the ANPRM. A 30+ page appendix responding to each question will be attached to the letter.

We encourage members to consider submitting a comment to OHRP (original ANPRM, *Federal Register* July 26, 2011 76FR44512; deadline extension notice, *Federal Register*, September 1, 2011 76FR54408). You can endorse COGR’s response, offer different recommendations, and/or focus your response on particular areas or aspects of the issues and questions raised in the ANPRM. We have approached the ANPRM mindful of the fundamental goal of the regulations – protecting human research subjects from harm. We have challenged changes that do not serve that purpose but may increase the administrative burden to investigators and/or the institution.

It is often said and always sincere – we really welcome your observations, comments and corrections to the draft that will be posted early next week (cblum@cogr.edu). Because the materials will be drafts, some parts of the letter and appendix may change based on members’ observations, thus, we are limiting the distribution to the membership. As with all comments prepared by COGR, we seek to represent the broad perspective of our membership while bringing our Washington-based expertise to the questions.

OHRP/FDA Draft Guidance on Exculpatory Language in Informed Consent

OHRP and the Food and Drug Administration (FDA) have announced the availability of draft *Guidance on Exculpatory Language in Informed Consent* and solicit comments no later than November 7, 2011. The notice, published in the Federal Register on September 7, 2011 (76FR55390) includes a link to the draft Guidance at <http://www.hhs.gov/ohrp/newsroom/rfc/index.html>.

In addition to examples of language that OHRP and the FDA consider acceptable and language considered exculpatory, the draft Guidance offers a discussion of how to identify exculpatory language as well. OHRP/FDA have determined that language becomes exculpatory when a

waiver of a subjects' rights is combined with or includes language that has the general effect of freeing an individual or entity from responsibility for malpractice, guilt etc. Much of the Guidance addresses the waiver of a subject's rights to biospecimens. This discussion of biospecimens is enlightening particularly in the context of the discussion of the use of biospecimens in the ANPRM.

COGR will be preparing a comment on the draft Guidance if necessary and we welcome your observations and suggestions (cblum@cogr.edu).

CDC and APHIS Propose Amendments to Select Agent Regulations

On October 3, 2011, the HHS Centers for Disease Control and Prevention (CDC) and the US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) published the biennial request for comment on the list of select agents and toxins regulated jointly by CDC and APHIS as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In addition to the biennial review of agents and toxins, CDC/APHIS propose amendments to the regulations in response to the recommendations of the Federal Experts Security Advisory Panel (FESAP) established by Presidential Executive Order 13546. The CDC and APHIS *Federal Register* notices were published on October 3, 2011 at 76FR61206 and 76FR61228, respectively. The FESAP report, *Recommendations Concerning the Select Agent Program* (November 2, 2010, Revised December 20, 2010 and January 10, 2011, Foreword added June 13, 2011) is available on the HHS Public Health Emergency website at: <http://www.phe.gov/Preparedness/legal/boards/fesap/Pages/default.aspx>. Finally, the President's July 2, 2010 Executive Order 13546, *Optimizing the Security of Biological Select Agents and Toxins in the United States*, which established FESAP is available in the July 8, 2010 *Federal Register* (75FR39439).

As we reported in the COGR June 2011 Meeting Report, FESAP was charged to provide recommendations related to the security of biological select agents and toxins (BSAT) to the Secretaries of HHS and Agriculture and the Attorney General. EO 13546 requires the FESAP recommendations to be considered in the next round of revisions to the select agent regulations. Among the recommendations FESAP offered was the tiering of select agents to provide for greater security measures for those that cause the most risk; removal of a agents/toxins from the list; changes in the security risk assessment to better vet foreign nationals, etc.; guidance to better define "pre-access suitability" and develop systems for periodic reassessment of reliability; tools for continuous physical facilities evaluation; and regulatory standards for Tier 1 agents physical and cyber security.

CDC/APHIS have taken up that challenge proposing to designate a subset of BSAT that present the greatest risk of deliberate misuse. The belief is that tiering of the BSAT will allow the application of greater security measures for those BSAT. In the past, the research community has called for a review of the BSAT list and encouraged a more risk-based approach to the management of BSAT. This call for comments – due December 2, 2011 – is the opportunity to help describe and define how the BSAT program can best achieve a risk-based system of management that continues to protect the public health and safety. In addition to proposing a new, tiered approach, CDC/APHIS propose some additions and deletions from the respective agency list of BSAT.

COGR will be preparing a comment on the CDC/APHIS request and will return to those members of the community that assisted us in commenting on the original regulations. In a search for more assistance on this task, we encourage members to volunteer themselves or members of the campus staff to assist us in the preparation of this comment (cblum@cogr.edu).

NIH Offers FAQs on Financial Conflicts of Interest

The National Institutes of Health (NIH) has posted responses to Frequently Asked Questions (FAQ) concerning the implementation of the Public Health Service (PHS) financial conflicts of interest (FCOI) regulations – formally titled Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors (42 CFR Part 50 and 45 CFR Part 94). The FAQs are available on the NIH FCOI website at: <http://grants.nih.gov/grants/policy/coi/>. Links to the final policy and additional materials are available from the website as well.

This FCOI policy will be the topic of two discussions at the October COGR meeting. On Thursday morning, October 27, 2011 from 10:00 to 11:45 AM, we will discuss some of the new and significantly changed requirements in the final rule to help identify practices under consideration by the membership. We will review some of the information provided in the FAQ. The goal of this morning session is to frame several questions to be posed to Sally Rockey and her NIH colleagues – Joe Ellis, Diane Dean and Kathy Hancock – in the afternoon, general discussion of the rule.

NSF IG Issues Audit of Oversight of Grantee Institutions' Conflicts of Interest

The National Science Foundation's Office of Inspector General (OIG) has issued its *Audit of NSF's Oversight of Grantee Institutions' Conflicts of Interest* (September 30, 2011 – OIG 11-2-009). The audit is available at: <http://www.nsf.gov/oig/11-2-009-COI.pdf>. The audit was initiated in response to a March 2009 request by the Ranking Member of the Senate Committee on Finance. He asked the OIG to determine the number and nature of financial conflicts reported by institutions to NSF, and the extent to which NSF oversees and manages financial conflicts of interest of institutions, primary investigators, and other senior investigators.

Because NSF's COI policy requires reporting of conflicts that institutions cannot manage, it comes as little surprise that the OIG determined that "NSF did not receive any reported unmanageable conflicts from its grantee institutions within the three-year scope of our audit, April 1, 2007 through March 31, 2010." Two reports had been made to NSF subsequent to the period of the review.

Because there were no conflict reports to review, the OIG expanded the audit to sample institutional policies to determine compliance with the NSF policy. The OIG found that the sampled institutions' policy were, generally, in compliance with the NSF policy. There were areas that did not meet the NSF policy and reviewing the OIG audit report identifies those areas.

The OIG recommends that NSF develop a procedures to ensure conflicts are managed, reduced or eliminated as required by the policy. Specifically, the OIG recommends: a process to ensure that institutions have conflicts policies and procedures consistent with NSF's Policy and that the institutions are implementing them appropriately; a procedure to oversee unmanageable conflicts; and a procedure requiring a) the institutions to notify NSF of those situations when an

institution is considering allowing research to proceed without imposing conditions or restrictions when a conflict exists and b) NSF to assess the volume of related conflicts to determine if further action is needed by NSF.

NSF's response as reported by the OIG: "In its written response to the draft of this report, NSF concurred that additional oversight, while not required by the current COI Policy, might be beneficial. Accordingly, NSF will take steps to determine how best to ensure institutions have COI policies and procedures in place that are consistent with NSF's Policy. NSF will also develop an appropriate plan of action to ensure that sufficient oversight of unmanageable conflicts takes place and that it is informed of instances where institutions may allow research to continue without the imposition of conditions or restrictions."